Oregon OSHA
Text of Changes for Proposed Adoption of Federal OSHA Changes to Hazard Communication

9/23/2024

Proposed Rule Changes

Text removed is in [~~brackets with line through~~].
Text added is in **bold and underline.**

437-002-0005 Adoption by Reference

In addition to, and not in lieu of, any other safety and health codes contained in OAR Chapter 437, the Department adopts by reference the following federal regulations printed as part of the Code of Federal Regulations, 29 CFR 1910, in the Federal Register:

(1) 29 CFR 1910.1, Purpose and scope; published 6/27/74, Federal Register, vol. 39, no. 125, p. 23503.

(2) 29 CFR 1910.2, Definitions; published 6/27/74, Federal Register, vol. 39, no. 125, p. 23503.

(3) 29 CFR 1910.3, Petitions for the issuance, amendment, or repeal of a standard; published 6/27/74, Federal Register, vol. 39, no. 125, p. 23503.

(4) 29 CFR 1910.4, Amendments to this part; published 6/27/74, Federal Register, vol. 39, no. 125, p. 23503.

(5) 29 CFR 1910.5, Applicability of standards, published 2/18/20, FR vol. 85, no. 32, p. 8726-8746.

(6) 29 CFR 1910.6, Incorporation by reference; published [~~5/14/19, FR vol. 84, no. 93, p. 21416~~] **5/20/24, FR vol.89, no. 98, pp. 44144-44461**.

(7) 29 CFR 1910.7, Definition and requirements for a Nationally Recognized Testing Laboratory, published 2/18/20, FR vol. 85, no. 32, p. 8726-8746.

(8) 29 CFR 1910.9, Compliance duties owed to each employee; published 12/12/08, Federal Register, vol. 73, no. 240, pp. 75568-75589.

These standards are on file at the Oregon Occupational Safety and Health Division, Oregon Department of Consumer and Business Services, and the United States Government Printing Office.

Stat. Auth.: ORS 654.025(2) and 656.726(4).
Stat. Implemented: ORS 654.001 through 654.295.

Hist: APD Admin. Order 17-1988, f. 11/10/88, ef. 11/10/88.
OR-OSHA Admin. Order 4-1997, f. 4/2/97, ef. 4/2/97.
OR-OSHA Admin. Order 8-1999, f. 8/6/99, ef. 8/6/99.
OR-OSHA Admin. Order 4-2005, f. 12/14/05, ef. 12/14/05.
OR-OSHA Admin. Order 4-2007, f. 8/15/07, ef. 8/15/07.
OR-OSHA Admin. Order 7-2008, f. 5/30/08, ef. 5/30/08.
OR-OSHA Admin. Order 5-2009, f. 5/29/09, ef. 5/29/09.
OR-OSHA Admin. Order 1-2010, f. 2/19/10, ef. 2/19/10.
OR-OSHA Admin. Order 2-2010, f. 2/25/10, ef. 2/25/10.
OR-OSHA Admin. Order 4-2011, f. 12/8/11, ef. 12/8/11.
OR-OSHA Admin. Order 5-2012, f. 9/25/12, ef. 9/25/12.
OR-OSHA Admin. Order 7-2012, f. 12/14/12, ef. 12/14/12.
OR-OSHA Admin. Order 7-2013, f. 12/12/13, ef. 12/12/13.
OR-OSHA Admin. Order 4-2016, f. 9/7/16, ef. 9/7/16.
OR-OSHA Admin. Order 2-2017, f. 5/16/17, ef. 11/1/17.
OR-OSHA Admin. Order 3-2019, f. 10/29/19, ef. 10/29/19
OR-OSHA Admin. Order X-XXXX, f. XX/XX/XX, ef. XX/XX/XX

1910.6 Incorporation by Reference

(a)

(1) **Certain material is incorporated by reference into this part with the approval of the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, the Occupational Safety and Health Administration (OSHA) must publish a document in the Federal Register and the material must be available to the public.**

~~[(1)]~~ **(i)** The standards of agencies of the U.S. Government, and organizations which are not agencies of the U.S. Government which are incorporated by reference in this part, have the same force and effect as other standards in this part. Only the mandatory provisions (i.e., provisions containing the word “shall” or other mandatory language) of standards incorporated by reference are adopted as standards under the Occupational Safety and Health Act.

[~~(2)~~] **(ii)** Any changes in the standards incorporated by reference in this part and an official historic file of such changes are available for inspection in the Docket Office at the national office of [~~the Occupational Safety and Health Administration~~]**OSHA**, U.S. Department of Labor, Washington, DC [~~20910~~]**20210**; telephone: 202–693–2350 (TTY number: 877–889– 5627).

[~~(3) The standards listed in this section are incorporated by reference into this part with the approval of the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, OSHA must publish a document in the Federal Register and the material must be available to the public.~~

~~(4) Copies of standards listed in this section and issued by private standards organizations are available for purchase from the issuing organizations at the addresses or through the other contact information listed below for these private standards organizations. In addition, these standards are available for inspection~~]

(2) All approved incorporation by reference (IBR) material is available for inspection at OSHA and at the National Archives and Records Administration (NARA).

(i) Contact OSHA at any Regional Office of the Occupational Safety and Health Administration (OSHA), or at the OSHA Docket Office, U.S. Department of Labor, 200 Constitution Avenue NW[~~.~~], Room N–3508, Washington, DC 20210; telephone: 202–693–2350 (TTY number: 877–889–5627).[~~They are also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of these standards at NARA, telephone: 202-741-6030, or go to www.archives.gov/federal-register/cfr/ibr-locations.html.~~]

(ii) For information on the availability of these standards at NARA, visit www.archives.gov/federal-register/cfr/ibr-locations or email fr.inspection@nara.gov.

(3) The IBR material may be obtained from the sources in the following paragraphs of this section or from one or more private resellers listed in

this paragraph (a)(3). For material that is no longer commercially available, contact OSHA (see paragraph (a)(2)(i) of this section).

(i) Accuris Standards Store, 321 Inverness Drive, South Englewood, CO 80112; phone: (800) 332–6077; website: https://store.accuristech.com.

(ii) American National Standards Institute (see paragraph (e) for contact information).

(iii) GlobalSpec, 257 Fuller Road, Suite NFE 1100, Albany, NY 12203– 3621; phone: (800) 261–2052; website: https://standards.globalspec.com.

(iv) Nimonik Document Center, 401 Roland Way, Suite 224, Oakland, CA 94624; phone (650)591–7600; email: info@document-center.com; website: www.document-center.com.

(v) Techstreet, phone: (855) 999–9870; email: store@techstreet.com; website: www.techstreet.com.

(b)The following material is available for purchase from the American Conference of Governmental Industrial Hygienists (ACGIH), 1014 Broadway, Cincinnati, OH 45202:

(1) "Industrial Ventilation: A Manual of Recommended Practice" (22nd ed., 1995), incorporation by reference (IBR) approved for 1910.124(b)(4)(iii).

(2) Threshold Limit Values and Biological Exposure Indices for 1986-87 (1986), IBR approved for 1910.120, PEL definition.

(c) The following material is available for purchase from the American Society of Agricultural Engineers (ASAE), 2950 Niles Road, Post Office Box 229, St. Joseph, MI 49085:

(1) ASAE Emblem for Identifying Slow Moving Vehicles, ASAE S276.2 (1968), IBR approved for 1910.145(d)(10).

(2) (Reserved)

(d) The following material is available for purchase from the Agriculture Ammonia Institute-Rubber Manufacturers (AAI-RMA) Association, 1400 K St. NW, Washington DC 20005:

(1) AAI-RMA Specifications for Anhydrous Ammonia Hose, IBR approved for 1910.111(b)(8)(i).

(2) (Reserved)

(e)[~~Except as noted, copies of the standards listed below in this paragraph are available for purchase from the~~] American National Standards Institute (ANSI), 25 West 43rd Street, [~~4th~~]**Fourth** Floor, New York, NY 10036[~~; telephone:~~]**– 7417; phone: (**212[-]**)** 642[~~-4900; fax: 212-398-0023; Web site: http://www.ansi.org.~~]**–4980; email: info@ansi.org; website: www.ansi.org.**

(1) (Reserved)

(2) (Reserved)

(3) ANSI A11.1-65 (R 70) Practice for Industrial Lighting, IBR approved for 1910.219(c)(5)(iii); 1910.261 (a)(3)(i), (c)(10), and (k)(21); and 1910.265(c)(2).

(4) ANSI A11.1-65 Practice for Industrial Lighting, IBR approved for 1910.262(c)(6) and 1910.265(d)(2)(i)(a).

(5) (Reserved)

(6) ANSI A13.1-56 Scheme for the Identification of Piping Systems, IBR approved for 1910.253(d)(4)(ii); 1910.261(a)(3)(iii); 1910.262(c)(7).

(7) ANSI A14.1-68 Safety Code for Portable Wood Ladders, Supplemented by ANSI A14.1a-77, IBR approved for 1910.261 (a)(3)(iv) and (c)(3)(i).

(8) ANSI A14.2-56 Safety Code for Portable Metal Ladders, Supplemented by ANSI A14.2a-77, IBR approved for 1910.261 (a)(3)(v) and (c)(3)(i).

(9) ANSI A14.3-56 Safety Code for Fixed Ladders, IBR approved for **1910.68(b)(4); and** 1910.261 (a)(3)(vi) and (c)(3)(i).

(10) ANSI A17.1-65 Safety Code for Elevators, Dumbwaiters and Moving Walks, Including Supplements, A17.1a (1967); A17.1b (1968); A17.1c (1969); A17.1d (1970), IBR approved for 1910.261 (a)(3)(vii), (g)(11)(i), and (l)(4)(11) ANSI A17.2-60 Practice for the Inspection of Elevators, Including Supplements, A17.2a (1965), A17.2b (1967), IBR approved for 1910.261(a)(3)(viii).

(12) ANSI A90.1-69 Safety Standard for Manlifts, IBR approved for 1910.68(b)(3).

(13) ANSI A92.2-69 Standard for Vehicle Mounted Elevating and Rotating Work Platforms, IBR approved for 1910.67 (b)(1), (2), (c)(3), and (4) and 1910.268(s)(1)(v).

(14) ANSI A120.1-70 Safety Code for Powered Platforms for Exterior Building Maintenance, IBR approved for 1910.66 App. D (b) through (d).

(15) ANSI B7.1-70 Safety Code for the Use, Care and Protection of Abrasive Wheels, IBR approved for 1910.215(b)(12) and 1910.218(j).

(16) ANSI B15.1-53 (R 58) Safety Code for Mechanical Power Transmission Apparatus, IBR approved for 1910.68(b)(4) and 1910.261 (a)(3)(ix), (b)(1), (e)(3), (e)(9), (f)(4), (j)(5)(iv), (k)(12), and (l)(3).

(17) ANSI B20.1-57 Safety Code for Conveyors, Cableways, and Related Equipment, IBR approved for 1910.218(j)(3); 1910.261 (a)(3)(x), (b)(1), (c)(15)(iv), (f)(4), and (j)(2); 1910.265(c)(18)(i).

(18) ANSI B30.2-43 (R 52) Safety Code for Cranes, Derricks, and Hoists, IBR approved for 1910.261 (a)(3)(xi), (c)(2)(vi), and (c)(8)(i) and (iv).

(19) ANSI B30.2.0-67 Safety Code for Overhead and Gantry Cranes, IBR approved for 1910.179(b)(2); 1910.261 (a)(3)(xii), (c)(2)(v), and (c)(8)(i) and (iv).

(20) ANSI B30.5-68 Safety Code for Crawler, Locomotive, and Truck Cranes, IBR approved for 1910.180(b)(2) and 1910.261(a)(3)(xiii).

(21) ANSI B30.6-69 Safety Code for Derricks, IBR approved for 1910.181(b)(2) and 1910.268(j)(4)(iv)(E) and (H).

(22) ANSI B31.1-55 Code for Pressure Piping, IBR approved for 1910.261(g)(18)(iii).

(23) ANSI B31.1-67, IBR approved for 1910.253(d)(1)(i)(A).

(24) ANSI B31.1a-63 Addenda to ANSI B31.1 (1955), IBR approved for 1910.261(g)(18)(iii).

(25) ANSI B31.1-67 and Addenda B31.1 (1969) Code for Pressure Piping, IBR approved for 1910.103(b)(1)(iii)(b); 1910.104(b)(5)(ii); 1910.218 (d)(4) and (e)(1)(iv); and 1910.261 (a)(3)(xiv) and (g)(18)(iii).

(26) ANSI B31.2-68 Fuel Gas Piping, IBR approved for 1910.261(g)(18)(iii).

(27) ANSI B31.3-66 Petroleum Refinery Piping, IBR approved for 1910.103(b)(3)(v)(b).

(28) ANSI B31.5-66 Addenda B31.5a (1968) Refrigeration Piping, IB approved for 1910.103(b)(3)(v)(b) and 1910.111(b)(7)(iii).

(29) ANSI B56.1-69 Safety Standard for Powered Industrial Trucks, IBR approved for 1910.178(a)(2) and (3) and 1910.261 (a)(3)(xv), (b)(6), (m)(2), and (m)(5)(iii).

(30) ANSI B57.1-65 Compressed Gas Cylinder Valve Outlet and Inlet Connections, IBR approved for 1910.253(b)(1)(iii).

(31) (Reserved)

(32) ANSI B175.1-1991, Safety Requirements for Gasoline-Powered Chain Saws 1910.266(e)(2)(i).

(33) (Reserved)

(34) ANSI C33.2-56 Safety Standard for Transformer-Type Arc Welding Machines, IBR approved for 1910.254(b)(1).

(35) (Reserved)

(36) ANSI H23.1-70 Seamless Copper Water Tube Specification, IBR approved for 1910.110(b)(8)(ii) and (13)(ii)(b)(1).

(37) ANSI H38.7-69 Specification for Aluminum Alloy Seamless Pipe and Seamless Extruded Tube, IBR approved for 1910.110(b)(8)(i).

(38) ANSI J6.4-71 Standard Specification for Rubber Insulating Blankets, IBR approved for 1910.268 (f)(1) and (n)(11)(v).

(39) ANSI J6.6-71 Standard Specification for Rubber Insulating Gloves, IBR approved for 1910.268 (f)(1) and (n)(11)(iv).

(40) ANSI K13.1-67 Identification of Gas Mask Canisters, IBR approved for 1910.261 (a)(3)(xvi) and (h)(2)(iii).

(41) ANSI K61.1-60 Safety Requirements for the Storage and Handling of Anhydrous Ammonia, IBR approved for 1910.111(b)(11)(i).

(42) ANSI K61.1-66 Safety Requirements for the Storage and Handling of Anhydrous Ammonia, IBR approved for 1910.111(b)(11)(i).

(43) ANSI O1.1-54 (R 61) Safety Code for Woodworking Machinery, IBR approved for 1910.261 (a)(3)(xvii), (e)(7), and (i)(2).

(44) ANSI S1.4-71 (R 76) Specification for Sound Level Meters, IBR approved for 1910.95 Appendixes D and I.

(45) ANSI S1.11-71 (R 76) Specification for Octave, Half-Octave and Third-Octave Band Filter Sets, IBR approved for 1910.95 Appendix D.

(46) ANSI S3.6-69 Specifications for Audiometers, IBR approved for 1910.95(h)(2) and (5)(ii) and Appendix D.

(47) ANSI Z4.1-68 Requirements for Sanitation in Places of Employment, IBR approved for 1910.261 (a)(3)(xviii) and (g)(15)(vi).

(48) (Reserved)

(49) ANSI Z9.1-51 Safety Code for Ventilation and Operation of Open Surface Tanks, IBR approved for 1910.261(a)(3)(xix), (g)(18)(v), and (h)(2)(i).

(50) ANSI Z9.1-71 Practices for Ventilation and Operation of Open-Surface Tanks, IBR approved for 1910.124(b)(4)(iv).

(51) ANSI Z9.2-60 Fundamentals Governing the Design and Operation of Local Exhaust Systems, IBR approved for 1910.94(a)(4)(i) introductory text, (a)(6) introductory text, (b)(3)(ix), (b)(4)(i) and (ii), (c)(3)(i) introductory text, (c)(5)(iii)(b), and (c)(7)(iv)(a); 1910.261(a)(3)(xx), (g)(1)(i) and (iii), and (h)(2)(ii).

(52) ANSI Z9.2-79 Fundamentals Governing the Design and Operation of Local Exhaust Systems, IBR approved for 1910.124(b)(4)(i).

(53) ANSI Z12.12-68 Standard for the Prevention of Sulfur Fires and Explosions, IBR Approved for 1910.261 (a)(3)(xxi), (d)(1)(i), (f)(2)(iv), and (g)(1)(i).

(54) ANSI Z12.20-62 (R 69) Code for the Prevention of Dust Explosions in Woodworking and Wood Flour Manufacturing Plants, IBR approved for 1910.265(c)(20)(i).

(55) ANSI Z21.30-64 Requirements for Gas Appliances and Gas Piping Installations, IBR approved for 1910.265(c)(15).

(56) ANSI Z24.22-57 Method of Measurement of Real-Ear Attenuation of Ear Protectors at Threshold, IBR approved for 1910.261(a)(3)(xxii).

(57) ANSI Z33.1-61 Installation of Blower and Exhaust Systems for Dust, Stock, and Vapor Removal or Conveying, IBR approved for 1910.94(a)(4)(i); 1910.261 (a)(3)(xxiii) and (f)(5); and 1910.265(c)(20)(i).

(58) ANSI Z33.1-66 Installation of Blower and Exhaust Systems for Dust, Stock, and Vapor Removal or Conveying, IBR approved for 1910.94(a)(2)(ii).

(59) ANSI Z35.1-1968, Specifications for Accident Prevention Signs; IBR approved for [~~Sec.~~]1910.261(c). Copies available for purchase from the IHS Standards Store, 15 Inverness Way East, Englewood, CO 80112; telephone: 1-877-413-5184; Web site: www.global.ihs.com.

(60) ANSI Z41-1999, American National Standard for Personal Protection[~~--~~]**-**Protective Footwear; IBR approved for 1910.136(b)(1)(ii). Copies of ANSI Z41-1999 are available for purchase only from the National Safety Council, P.O. Box 558, Itasca, IL 60143-0558; telephone: 1-800-621-7619; fax: 708-285-0797; Web site: http://www.nsc.org.

(61) ANSI Z41-1991, American National Standard for Personal Protection [~~--~~]**-**Protective Footwear; IBR approved for 1910.136(b)(1)(iii). Copies of ANSI Z41-1991 are available for purchase only from the National Safety Council, P.O. Box 558, Itasca, IL 60143-0558; telephone: 1-800-621-7619; fax: 708-285-0797; Web site: http://www.nsc.org.

(62) (Reserved)

(63) (Reserved)

(64) ANSI [~~2~~]**Z**49.1-67 Safety in Welding and Cutting, IBR Approved for 1910.252(c)(1)(iv)(A) and (B).

(65) USAS Z53.1-1967 (also referred to as ANSI Z53.1-1967), Safety Color Code for Marking Physical Hazards, ANSI approved October 9, 1967; IBR approved for [~~Sec.~~]1910.97(a) and 1910.145(d). Copies available for purchase from the IHS Standards Store, 15 Inverness Way East, Englewood, CO 80112; telephone: 1-877-413-5184; Web site: www.global.ihs.com.

(66) ANSI Z535.1-2006 (R2011), Safety Colors, reaffirmed July 19, 2011; IBR approved for 1910.97(a) and 1910.145(d). Copies available for purchase from the:

(i) American National Standards Institute's e-Standards Store, 25 W 43rd Street, 4th Floor, New York, NY 10036; telephone: 212-642-4980; Web site: http://webstore.ansi.org;[~~.~~]

(ii) IHS Standards Store, 15 Inverness Way East, Englewood, CO 80112; telephone: 877-413-5184; Web site: www.global.ihs.com; or

(iii) TechStreet Store, 3916 Ranchero Dr., Ann Arbor, MI 48108; telephone: 877-699-9277; Web site: www.techstreet.com.

(67) ANSI Z535.2-2011, Environmental and Facility Safety Signs, published September 15, 2011; IBR approved for 1910.261(c). Copies available for purchase from the:

(i) American National Standards Institute's e-Standards Store, 25 W 43rd Street, 4th Floor, New York, NY 10036; telephone: 212-642-4980; Web site: http://webstore.ansi.org/;

(ii) IHS Standards Store, 15 Inverness Way East, Englewood, CO 80112; telephone: 877-413-5184; Web site: www.global.ihs.com; or

(iii) TechStreet Store, 3916 Ranchero Dr., Ann Arbor, MI 48108; telephone: 877-699-9277; Web site: www.techstreet.com.

(68) ANSI [~~2~~]**Z**54.1-63[~~,~~] Safety Standard for Non-Medical X-Ray and Sealed Gamma Ray Sources, IBR for 1910.252 (d)(1)(vii) and (2)(ii).

(69) ANSI/ISEA Z87.1-2010, Occupational and Educational Personal Eye and Face Protection Devices, Approved April 13, 2010; IBR approved for 1910.133(b). *In Oregon, OAR 437-002-0134 applies.* Copies are available for purchase from:

(i) American National Standards Institute's e-Standards Store, 25 W 43rd Street, 4th Floor, New York, NY 10036; telephone: (212) 642-4980; Web site: http://webstore.ansi.org/;

(ii) IHS Standards Store, 15 Inverness Way East, Englewood, CO 80112; telephone: (877) 413-5184; Web site: http://global.ihs.com; or

(iii) TechStreet Store, 3916 Ranchero Dr., Ann Arbor, MI 48108; telephone: (877) 699-9277; Web site: http://techstreet.com.

(70) ANSI Z87.1-2003, Occupational and Educational Eye and Face Personal Protection Devices Approved June 19, 2003; IBR approved for 1910.133(b). *In Oregon, OAR 437-002-0134 applies.* Copies available for purchase from the:

(i) American National Standards Institute's e-Standards Store, 25 W 43rd Street, 4th Floor, New York, NY 10036; telephone: (212) 642-4980; Web site: http://webstore.ansi.org/;

(ii) IHS Standards Store, 15 Inverness Way East, Englewood, CO 80112; telephone: (877) 413-5184; Web site: http://global.ihs.com; or

(iii) TechStreet Store, 3916 Ranchero Dr., Ann Arbor, MI 48108; telephone: (877) 699-9277; Web site: http://techstreet.com.

(71) ANSI Z87.1-1989 (R-1998), Practice for Occupational and Educational Eye and Face Protection, Reaffirmation approved January 4, 1999; IBR approved for 1910.133(b). *In Oregon, OAR 437-002-0134 applies.* Copies are available for purchase from:

(i) American National Standards Institute's e-Standards Store, 25 W 43rd Street, 4th Floor, New York, NY 10036; telephone: (212) 642-4980; Web site: http://webstore.ansi.org/;

(ii) IHS Standards Store, 15 Inverness Way East, Englewood, CO 80112; telephone: (877) 413-5184; Web site: http://global.ihs.com; or

(iii) TechStreet Store, 3916 Ranchero Dr., Ann Arbor, MI 48108; telephone: (877) 699-9277; Web site: http://techstreet.com.

(72) ANSI Z88.2-1969, Practices for Respiratory Protection; IBR approved for 1910.94(c)(6)(iii)(a), 1910.134(c); and 1910.261(a)(3)(xxvi), (b)(2), (f)(5), (g)(15)(v), (h)(2)(iii), (h)(2)(iv), and (i)(4).

(73) American National Standards Institute (ANSI) Z89.1-2009, American National Standard for Industrial Head Protection, approved January 26, 2009; IBR approved for [~~Sec.~~]1910.135(b)(1)(i). Copies of ANSI Z89.1-2009 are available for purchase only from the International Safety Equipment Association, 1901 North Moore Street, Arlington, VA 22209-1762; telephone: 703-525-1695; fax: 703-528-2148; Web site: www.safetyequipment.org.

(74) American National Standards Institute (ANSI) Z89.1-2003, American National Standard for Industrial Head Protection; IBR approved for 1910.135(b)(1)(ii). Copies of ANSI Z89.1-2003 are available for purchase only from the International Safety Equipment Association, 1901 North Moore Street, Arlington, VA 22209-1762; telephone: 703-525-1695; fax: 703-528-2148; Web site: www.safetyequipment.org.

(75) American National Standards Institute (ANSI) Z89.1-1997, American National Standard for Personnel Protection[--] - Protective Headwear for Industrial Workers[--] - Requirements; IBR approved for 1910.135(b)(1)(iii). Copies of ANSI Z89.1-1997 are available for purchase only from the International Safety Equipment Association, 1901 North Moore Street, Arlington, VA 22209-1762; telephone: 703-525-1695; fax: 703-528-2148; Web site: www.safetyequipment.org.

(76) ANSI Z41.1-1967 Men's Safety Toe Footwear; IBR approved for 1910.261(i)(4).

(77) ANSI Z87.1-1968 Practice of Occupational and Educational Eye and Face Protection; IBR approved for 1910.261(a)(3)(xxv), (d)(1)(ii), (f)(5), (g)(1), (g)(15)(v), (g)(18)(ii), and (i)(4).

(78) ANSI Z89.1-1969 Safety Requirements for Industrial Head Protection; IBR approved for 1910.261(a)(3)(xxvii), (b)(2), (g)(15)(v), and (i)(4).

(79) ANSI Z89.2-1971 Safety Requirements for Industrial Protective Helmets for Electrical Workers, Class B; IBR approved for 1910.268(i)(1).

(f) The following material is available for purchase from the American Petroleum Institute (API), 1220 L Street NW, Washington[~~,~~] DC 20005:

(1) (Reserved)

(2) API 12B (May 1958) Specification for Bolted Production Tanks, 11th Ed., With Supplement No. 1, Mar. 1962, IBR approved for 1910.106(b)(1)(i)(a)(3).

(3) API 12D (Aug. 1957) Specification for Large Welded Production Tanks, 7th Ed., IBR approved for 1910.106(b)(1)(i)(a)(3).

(4) API 12F (Mar. 1961) Specification for Small Welded Production Tanks, 5th Ed., IBR approved for 1910.106(b)(1)(i)(a)(3).

(5) API 620, Fourth Ed. (1970) Including Appendix R, Recommended Rules for Design and Construction of Large Welded Low Pressure Storage Tanks, IBR approved for 1910.103(c)(1)(i)(a); 1910.106(b)(1)(iv)(b)(1); and 1910.111(d)(1)(ii) and (iii).

(6) API 650 (1966) Welded Steel Tanks for Oil Storage, 3rd Ed., IBR approved for 1910.106(b)(1)(iii)(a)(2).

(7) API 1104 (1968) Standard for Welding Pipelines and Related Facilities, IBR approved for 1910.252(d)(1)(v).

(8) API 2000 (1968) Venting Atmospheric and Low Pressure Storage Tanks, IBR approved for 1910.[~~261~~]**106**(b)(2)(iv)(b)(1).

(9) API 2201 (1963) Welding or Hot Tapping on Equipment Containing Flammables, IBR approved for 1910.252(d)(1)(vi).

(g) The following material is available for purchase from the American Society of Mechanical Engineers (ASME), United Engineering Center, 345 East 47th Street, New York, NY 10017:

(1) ASME Boiler and Pressure Vessel Code, Sec. VIII, 1949, 1950, 1952, 1956, 1959, and 1962 Ed., IBR approved for 1910.110 (b)(10)([~~ii~~]**iii**) (Table H**-**26), (d)(2) (Table H-31); (e)(3)([~~1~~]**i**) (Table H-32), (h)(2) (Table H-34); and 1910.111(b)(2)(vi);

(2) ASME Code for Pressure Vessels, 1968 Ed., IBR approved for 1910.106(i)(3)(i); 1910.110(g)(2)(iii)(b)(2); and 1910.217(b)(12);

(3) ASME Boiler and Pressure Vessel Code, Sec. VIII, 1968, IBR approved for 1910.103; 1910.104(b)(4)(ii); 1910.106 (b)(1)(iv)(b)(2) and (i)(3)(ii); 1910.107; 1910.110(b)(11)(i)(b) and (iii)(a)(1); 1910.111(b)(2)(i), (ii), and (iv); and 1910.169(a)(2)(i) and (ii);

(4) ASME Boiler and Pressure Vessel Code, Sec. VIII, Paragraph UG-84, 1968, IBR approved for 1910.104 (b)(4)(ii) and (b)(5)(iii);

(5) ASME Boiler and Pressure Vessel Code, Sec. VIII, Unfired Pressure Vessels, Including Addenda (1969), IBR approved for 1910.261; 1910.262; 1910.263(i)(24)(ii);

(6) Code for Unfired Pressure Vessels for Petroleum Liquids and Gases of the API and the ASME, 1951 Ed., IBR approved for 1910.110(b)(3)(iii); and

(7) ASME B56.6-1992 (with addenda), Safety Standard for Rough Terrain Forklift Trucks, IBR approved for 1910.266(f)(4).

(h)[~~ Copies of the standards listed below in this paragraph (h) are available for purchase from ~~] ASTM International, 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428–2959; [~~Telephone: ~~]**phone: (**610[-]**)** 832-9585; [~~Fax: 610-832-9555; Email: seviceastm.org~~]**email: sevice@astm.org**; [~~Web site: http://~~]**website:** www.astm.org. [~~Copies of historical standards or standards that~~]**(27)** ASTM [~~does not have may be purchased from Information Handling Services, Global Engineering Documents, 15 Inverness Way East, Englewood, CO 80112; Telephone:~~]**D4359–90, Standard Test Method for Determining Whether a Material is a Liquid or a Solid, approved July** 1[~~-800-854-7179; Email: global@ihs.com; Web sites: http://global.ihs.com or http://www.store.ihs.com~~]**, 2019; IBR approved for § 1910.1200.**

(1) ASTM A 47-68, Malleable Iron Castings, IBR approved for 1910.111.

(2) ASTM A 53-69, Welded and Seamless Steel Pipe, IBR approved for 1910.110 and 1910.111.

(3) ASTM A 126-66, Gray Iron Casting for Valves, Flanges and Pipe Fitting, IBR approved for 1910.111.

(4) ASTM A 391-65 (ANSI G61.1-1968), Alloy Steel Chain, IBR approved for 1910.184.

(5) ASTM A 395-68, Ductile Iron for Use at Elevated Temperatures, IBR approved for 1910.111.

(6) ASTM B 88-66A, Seamless Copper Water Tube, IBR approved for 1910.252.

(7) ASTM B 88-69, Seamless Copper Water Tube, IBR approved for 1910.110.

(8) (Reserved)

(9) ASTM B 210-68, Aluminum-Alloy Drawn Seamless Tubes, IBR approved for 1910.110.

(10) ASTM B 241-69, Standard Specifications for Aluminum-Alloy Seamless Pipe and Seamless Extruded Tube, IBR approved for 1910.110.

(11) ASTM D 5-65, Test for Penetration by Bituminous Materials, IBR approved for 1910.106.

(12) ASTM D 56-70, Test for Flash Point by Tag Closed Tester, IBR approved for 1910.106.

(13) ASTM D 56-05, Standard Test Method for Flash Point by Tag Closed Cup Tester, Approved May 1, 2005, IBR approved for Appendix B to 1910.1200.

(14) ASTM D 86-62, Test for Distillation of Petroleum Products, IBR approved for 1910.106 and 1910.119.

(15) ASTM D 86-07a, Standard Test Method for Distillation of Petroleum Products at Atmospheric Pressure, Approved April 1, 2007, IBR approved for Appendix B to 1910.1200.

(16) ASTM D 88-56, Test for Saybolt Viscosity, IBR approved for 1910.106.

(17) ASTM D 93-71, Test for Flash Point by Pensky Martens, IBR approved for 1910.106.

(18) ASTM D 93-08, Standard Test Methods for Flash Point by Pensky-Martens Closed Cup Tester, Approved Oct. 15, 2008, IBR approved for Appendix B to 1910.1200.

(19) ASTM D 240-02 (Reapproved 2007), Standard Test Method for Heat of Combustion of Liquid Hydrocarbon Fuels by Bomb Calorimeter, Approved May 1, 2007, IBR approved for Appendix B to 1910.1200.

(20) ASTM D 323-68, Standard Test Method of Test for Vapor Pressure of Petroleum Products (Reid Method), IBR approved for 1910.106.

(21) ASTM D 445-65, Test for Viscosity of Transparent and Opaque Liquids, IBR approved for 1910.106.

(22) ASTM D 1078-05, Standard Test Method for Distillation Range of Volatile Organic Liquids, Approved May 15, 2005, IBR approved for Appendix B to 1910.1200.

(23) ASTM D 1692-68, Test for Flammability of Plastic Sheeting and Cellular Plastics, IBR approved for 1910.103.

(24) ASTM D 2161-66, Conversion Tables for SUS, IBR approved for 1910.106.

(25) ASTM D 3278-96 (Reapproved 2004) E1, Standard Test Methods for Flash Point of Liquids by Small Scale Closed-Cup Apparatus, Approved November 1, 2004, IBR approved for Appendix B to 1910.1200.

(26) ASTM D 3828-07a, Standard Test Methods for Flash Point by Small Scale Closed Cup Tester, Approved July 15, 2007, IBR approved for Appendix B to 1910.1200

(27) **ASTM D 4359–90, Standard Test Method for Determining Whether a Material is a Liquid or a Solid, Approved 2019, IBR approved for 1910.1200.**

~~[(27)~~]**(28)** ASTM F-2412-2005, Standard Test Methods for Foot Protection, IBR approved for 1910.136.

[(~~28~~)] **(29)** ASTM F-2413-2005, Standard Specification for Performance Requirements for Protective Footwear, IBR approved for 1910.136.

(i) The following material is available at the American Thoracic Society (ATS), 25 Broadway, 18th Floor New York, NY 10004; website: www.atsjournals.org/.

(1) Spirometric Reference Values from a Sample of the General U.S. Population. Hankinson JL, Odencrantz JR, Fedan KB. American Journal of Respiratory and Critical Care Medicine, 159:179-187, 1999, IBR approved for 1910.1043(h).

(2) (Reserved)

(j) The following material is available for purchase from the American Welding Society (AWS), 550 NW**,** LeJeune Road, [~~PO~~]**P.O.** Box 351040, Miami[~~,~~] FL 33135:

(1) (Reserved)

(2) (Reserved)

(3) AWS B3.0-41 Standard Qualification Procedure, IBR approved for 1910.67(c)(5)(i).

(4) AWS D1.0-1966 Code for Welding in Building Construction, IBR approved for 1910.27(b)(6).

(5) AWS D2.0-69 Specifications for Welding Highway and Railway Bridges, IBR approved for 1910.67(c)(5)(iv).

(6) AWS D8.4-61 Recommended Practices for Automotive Welding Design, IBR approved for 1910.67(c)(5)(ii).

(7) AWS D10.9-69 Standard Qualification of Welding Procedures and Welders for Piping and Tubing, IBR approved for 1910.67(c)(5)(iii).

(k) The following material is available for purchase from the Department of Commerce:

(1) (Reserved)

(2) Publication "Model Performance Criteria for Structural Fire Fighters' Helmets," IBR approved for 1910.156(e)(5)(i).

(l) The following material is available for purchase from the Compressed Gas Association (CGA), 1235 Jefferson Davis Highway, Arlington, VA 22202:

(1) CGA C-6 (1968) Standards for Visual Inspection of Compressed Gas Cylinders, IBR approved for 1910.101(a).

(2) CGA C-8 (1962) Standard for Requalification of ICC-3HT Cylinders, IBR approved for 1910.101(a).

(3) *Note: For acetylene in Oregon, OAR 437-002-2102(1) applies, which adopted the CGA Pamphlet G-1-2009.* **CGA G-1-2009 Acetylene, Twelfth Edition, IBR approved for 1910.102(a).** Copies of CGA Pamphlet G-1-2009 are available for purchase from the: Compressed Gas Association, Inc., 4221 Walney Road, 5th Floor, Chantilly, VA 20151; telephone: [~~708-~~]~~(~~**(703)** 788-2700; fax: **(**703[-]**)** 961-1831;[~~e-mail~~]**email**: cga@cganet.com . A copy of CGA Pamphlet G-1-2009 is available for viewing at Oregon OSHA's Resource Center, 350 Winter Street NE, Salem, OR 97301.

(4) CGA G-7.1 (1966) Commodity Specification, IBR approved for 1910.134(d)(1).

(5) CGA G-8.1 (1964) Standard for the Installation of Nitrous Oxide Systems at Consumer Sites, IBR approved for 1910.105.

(6) CGA P-1 (1965) Safe Handling of Compressed Gases, IBR approved for 1910.101(b).

(7) CGA P-3 (1963) Specifications, Properties, and Recommendations for Packaging, Transportation, Storage and Use of Ammonium Nitrate, IBR approved for 1910.109(i)(1)(ii)(b).

(8) CGA S-1.1 (1963) and 1965 Addenda. Safety Release Device Standards – Cylinders for Compressed Gases, IBR approved for 1910.101(c); 1910.103(c)(1)(iv)(a)(2).

(9) CGA S-1.2 (1963) Safety Release Device Standards, Cargo and Portable Tanks for Compressed Gases, IBR approved for 1910.101(c); 1910.103(c)(1)(iv)(a)(2).

(10) CGA S-1.3 (1959) Safety Release Device Standards – Compressed Gas Storage Containers, IBR approved for 1910.103(c)(1)(iv)(a)(2); 1910.104(b)(6)(iii); and 1910.111(d)(4)(ii)(b).

(11) CGA 1957 Standard Hose Connection Standard, IBR approved for 1910.253(e)(4)(v) and (5)(iii).

(12) CGA and RMA (Rubber Manufacturer's Association) Specification for Rubber Welding Hose (1958), IBR approved for 1910.253(e)(5)(i).

(13) CGA 1958 Regulator Connection Standard, IBR approved for 1910.253(e)(4)(iv) and (6).

(m) The following material is available for purchase from the Crane Manufacturer's Association of [~~American~~]**America**, Inc. (CMAA), 1 Thomas Circle NW, Washington[~~,~~] DC 20005:

(1) CMAA Specification 1B61, Specifications for Electric Overhead Traveling Cranes, IBR approved for 1910.179(b)(6)(i).

(2) (Reserved)

(n) [~~The following material is available for purchase from the General Services Administration:~~]**German Institute for Standardization (DIN) (Beuth Verlag GmbH) Am DIN-Platz Burggrafenstraße 6 10787 Berlin, Germany; phone: +49 30 58885 70070; website: https://din.de/en/about-standards/buy-standard.**

(1) [~~GSA Pub. GG-B-0067b, Air Compressed for Breathing Purposes, or Interim Federal Specifications, Apr. 1965, IBR approved for 1910.134(d)(4).~~] **DIN 51794:2003–05—Determining the ignition temperature of petroleum products, May 2003, IBR approved for appendix B to 1910.1200.**

(2) (Reserved)

(o) [~~The following material is available for purchase from the Department of Health and Human Services:~~] **The following material is available for purchase from the Fertilizer Institute, 1015 18th Street NW, Washington, DC 20036:**

(1) **[**~~Publication No. 76-120 (1975), List of Personal Hearing Protectors and Attenuation Data, IBR approved for 1910.95 App. B.~~] **Standard M-1 (1953, 1955, 1957, 1960, 1961, 1963, 1965, 1966, 1967, 1968), Superseded by ANSI K61.1-1972, IBR approved for 1910.111(b)(1) (i) and (iii).**

(2) (Reserved)

(p) [~~The following material is available for purchase from the Institute of Makers of Explosives (IME), 420 Lexington Avenue, New York, NY 10017:~~]**The following material is available for purchase from the General Services Administration:**

(1) [~~IME Pamphlet No. 17, 1960, Safety in the Handling and Use of Explosives, IBR approved for 1910.261(a)(4)(iii) and (c)(14)(ii).~~]**GSA Pub. GG-B-0067b, Air Compressed for Breathing Purposes, or Interim Federal Specifications, Apr. 1965, IBR approved for 1910.134(d)(4).**

(2) (Reserved)

(q) [~~The following material is available from the International Labour Organization (ILO), 4 route des Morillons, CH–1211 Genève 22, Switzerland; telephone: +41 (0)~~]

~~22 799 6111; fax: +41 (0) 22 798 8685; website: www.ilo.org/.~~]**International Electrotechnical Commission (IEC), IEC Secretariat, 3 rue de Varembé, PO Box 131, CH-1211 Geneva 20, Switzerland; phone: +41 22 919 02 11; email: sales@iec.ch; website: https://www.iec.ch.**

(1) [~~Guidelines for the Use of the ILO International Classification of Radiographs of Pneumoconioses, Revised Edition 2011, Occupational safety and health series; 22 Rev.2011), IBR approved for 1910.1001.~~]**IEC 60079-20-1, Explosive atmospheres—Part 20-1: Material characteristics for gas and vapor classification—Test methods and data, Edition 1.0, 2010-01; IBR approved for appendix B to 1910.1200.**

(2) (Reserved)

(r) **The following material is available for purchase from the: International Code Council, Chicago District Office, 4051 W. Flossmoor Rd., Country Club Hills, IL 60478; telephone: 708-799-2300, x3-3801; facsimile: 001-708-799-4981; e-mail: order@iccsafe.org.**

(1) [~~The following materials are available for purchase from the International Standards Organization (ISO) through ANSI, 25 West 43rd Street, Fourth Floor, New York, NY 10036-7417; Telephone: 212-642-4980; Fax: 212-302-1286; Email: info@ansi.org; Web site: http://www.ansi.org~~]**IFC-2009, International Fire Code, copyright 2009, IBR approved for §§1910.34, 1910.35, 1910.36, and 1910.37.**

(2) [~~Documents not available in the ANSI store may be purchased from:~~]**(Reserved)**

[~~(i) Document Center Inc., 111 Industrial Road, Suite 9, Belmont, 94002; Telephone: 650-591-7600; Fax: 650-591-7617; Email: info@document-center.com; Web site: www.document-center.com.~~

~~(ii) DECO--Document Engineering Co., Inc., 15210 Stagg Street, Van Nuys, CA 91405; Telephone: 800-645-7732 or 818-782-1010; Fax: 818-782-2374; Email: doceng@doceng.com; Web site: www.doceng.com.~~

~~(iii) Global Engineering Documents, 15 Inverness Way East, Englewood, CO 80112; Telephone: 1-800-854-7179 or 303-397-7956; Fax: 303-397-2740; Email: global@ihs.com; Web sites: http://global.ihs.com or http://www.store.ihs.com;~~

~~(iv) ILI Infodisk, Inc., 610 Winters Avenue, Paramus, NJ 07652; Telephone: 201-986-1131; Fax: 201-986-7886; Email: sales@iliinfo.com; Web site: www.ili-info.com.~~

~~(v) Techstreet, a business of Thomson Reuters, 3916 Ranchero Drive, Ann Arbor, MI 48108; Telephone: 800-699-9277 or 734-780-8000; Fax: 734-780-2046; Email: techstreet.service@thomsonreuters.com; Web site: www.Techstreet.com.~~

~~(3) ISO 10156:1996 (E), Gases and Gas Mixtures--Determination of Fire Potential and Oxidizing Ability for the Selection of Cylinder Valve Outlets, Second Edition, Feb. 15, 1996, IBR approved for Appendix B to 1910.1200.~~

~~(4) ISO 10156-2:2005 (E), Gas cylinders--Gases and Gas Mixtures--Part 2: Determination of Oxidizing Ability of Toxic and Corrosive Gases and Gas Mixtures, First Edition, Aug. 1, 2005, IBR approved for Appendix B to 1910.1200.~~

~~(5) ISO 13943:2000 (E/F), Fire Safety--Vocabulary, First Edition, April, 15, 2000, IBR approved for Appendix B to 1910.1200.~~]

(s) [~~The following material is available for purchase from the National Electrical Manufacturer's Association (NEMA):~~]**<u>The following material is available for purchase from the Department of Health and Human Services:</u>**

(1) [~~NEMA EW-1 (1962) Requirements for Electric Arc Welding Apparatus, IBR approved for 1910.254(b)(1).~~]**<u>Publication No. 76-120 (1975), List of Personal Hearing Protectors and Attenuation Data, IBR approved for 1910.95 App. B.</u>**

(2) (Reserved)

(t) [~~The following material is available for purchase from the National Fire Protection Association (NFPA), 1 Batterymarch Park, Quincy, MA 02269; Telephone: 800-344-3555 or 617-770-3000; Fax: 1-800-593-6372 or 1-508-895-8301; Email: custserv@nfpa.org; Web site: http://www.nfpa.org.~~]**<u>The following material is available for purchase from the Institute of Makers of Explosives (IME), 420 Lexington Avenue, New York, NY 10017:</u>**

(1) [~~NFPA 30 (1969) Flammable and Combustible Liquids Code, IBR approved for 1910.178(f)(1).~~]**<u>IME Pamphlet No. 17, 1960, Safety in the Handling and Use of Explosives, IBR approved for 1910.261 (a)(4)(iii) and (c)(14)(ii).</u>**

(2) [~~NFPA 32-1970 Standard for Dry Cleaning Plants, IBR approved for 1910.106(j)(6)(i).~~] **(Reserved)**

~~[(3) NFPA 33-1969 Standard for Spray Finishing Using Flammable and Combustible Material, IBR approved for 1910.94(c)(2).~~

~~(4) NFPA 34-1966 Standard for Dip Tanks Containing Flammable or Combustible Liquids, IBR approved for 1910.124(b)(4)(iv).~~

~~(5) NFPA 34-1995 Standard for Dip Tanks Containing Flammable or Combustible Liquids, IBR approved for 1910.124(b)(4)(ii).~~

~~(6) NFPA 35-1970 Standard for the Manufacture of Organic Coatings, IBR approved for 1910.106(j)(6)(ii).~~

~~(7) NFPA 36-1967 Standard for Solvent Extraction Plants, IBR approved for 1910.106(j)(6)(iii).~~

~~(8) NFPA 37-1970 Standard for the Installation and Use of Stationary Combustion Engines and Gas Turbines, IBR approved for 1910.106(j)(6)(iv) and 1910.110(b)(20)(iv)(c) and (e)(11).~~

~~(9) NFPA 51B-1962 Standard for Fire Protection in Use of Cutting and Welding Processes, IBR approved for 1910.252(a)(1) introductory text.~~

~~(10) NFPA 54-1969 Standard for the Installation of Gas Appliances and Gas Piping, IBR approved for 1910.110(b)(20)(iv)(a).~~

~~(11) NFPA 54A-1969 Standard for the Installation of Gas Piping and Gas Equipment on Industrial Premises and Certain Other Premises, IBR approved for 1910.110(b)(20)(iv)(b).~~

~~(12) NFPA 58-1969 Standard for the Storage and Handling of Liquefied Petroleum Gases (ANSI Z106.1-1970), IBR approved for 1910.110(b)(3)(iv) and (i)(3)(i) and (ii); and 1910.178(f)(2).~~

~~(13) NFPA 59-1968 Standard for the Storage and Handling of Liquefied Petroleum Gases at Utility Gas Plants, IBR approved for 1910.110(b)(3)(iv) and (i)(2)(iv).~~

~~(14) NFPA 62-1967 Standard for the Prevention of Dust Explosions in the Production, Packaging, and Handling of Pulverized Sugar and Cocoa, IBR approved for 1910.263(k)(2)(i).~~

~~(15) NFPA 68-1954 Guide for Explosion Venting, IBR approved for 1910.94(a)(2)(iii).~~

~~(16) (Reserved)~~

~~(17) NFPA 78-1968 Lightning Protection Code, IBR approved for 1910.109(i)(6)(ii).~~

~~(18) NFPA 80-1968 Standard for Fire Doors and Windows, IBR approved for 1910.106(d)(4)(i).~~

~~(19) NFPA 80-1970 Standard for the Installation of Fire Doors and Windows, IBR approved for 1910.253(f)(6)(i)(I).~~

~~(20) NFPA 86A-1969 Standard for Oven and Furnaces Design, Location and Equipment, IBR approved for 1910.107(j)(1) and (l)(3) and 1910.108(b)(2) and (d)(2).~~

~~(21) NFPA 91-1961 Standard for the Installation of Blower and Exhaust Systems for Dust, Stock, and Vapor Removal or Conveying (ANSI Z33.1-61), IBR approved for 1910.107(d)(1).~~

~~(22) NFPA 91-1969 Standards for Blower and Exhaust Systems, IBR approved for 1910.108(b)(1).~~

~~(23) NFPA 96-1970 Standard for the Installation of Equipment for the Removal of Smoke and Grease Laden Vapors from Commercial Cooking Equipment, IBR approved for 1910.110(b)(20)(iv)(d).~~

~~(24) NFPA 101-1970 Code for Life Safety From Fire in Buildings and Structures, IBR approved for 1910.261(a)(4)(ii).~~

~~(25) NFPA 101-2009, Life Safety Code, 2009 edition, IBR approved for 1910.34, 1910.35, 1910.36, and 1910.37.~~

~~(26) NFPA 203M-1970 Manual on Roof Coverings, IBR approved for 1910.109(i)(1)(iii)(c).~~

~~(27) NFPA 251-1969 Standard Methods of Fire Tests of Building Construction and Materials, IBR approved for 1910.106(d)(3)(ii) introductory text and (d)(4)(i).~~

~~(28) NFPA 302-1968 Fire Protection Standard for Motor-Craft (Pleasure and Commercial), IBR approved for 1910.265(d)(2)(iv) introductory text.~~

~~(29) NFPA 385-1966 Recommended Regulatory Standard for Tank Vehicles for Flammable and Combustible Liquids, IBR approved for 1910.106(g)(1)(i)(e)(1).~~

~~(30) NFPA 496-1967 Standard for Purged Enclosures for Electrical Equipment in Hazardous Locations, IBR approved for 1910.103(c)(1)(ix)(e)(1).~~

~~(31) NFPA 505-1969 Standard for Type Designations, Areas of Use, Maintenance, and Operation of Powered Industrial Trucks, IBR approved for 1910.110(e)(2)(iv).~~

~~(32) NFPA 566-1965 Standard for the Installation of Bulk Oxygen Systems at Consumer Sites, IBR approved for 1910.253(b)(4)(iv) and (c)(2)(v).~~

~~(33) NFPA 656-1959 Code for the Prevention of Dust Ignition in Spice Grinding Plants, IBR approved for 1910.263(k)(2)(i).~~

~~(34) NFPA 1971-1975 Protective Clothing for Structural Fire Fighting, IBR approved for 1910.156(e)(3)(ii) introductory text.~~

~~(35) NFPA 51A (2001) Standard for Acetylene Cylinder Charging Plants, IBR approved for 1910.102(b) and (c). Copies of NFPA 51A-2001 are available for purchase from the: National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169-7471; telephone: 1-800-344-35557; e-mail: custserv@nfpa.org.~~

~~(36) NFPA 51A (2006) Standard for Acetylene Cylinder Charging Plants, IBR approved for 1910.102(b) and (c). Copies of NFPA 51A-2006 are available for purchase from the: National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169-7471; telephone: 1-800-344-35557; e-mail: custserv@nfpa.org.~~

~~(37) NFPA 30B, Code for the Manufacture and Storage of Aerosol Products, 2007 Edition, Approved August 17, 2006, IBR approved for Appendix B to 1910.1200.~~]

(u) [~~The following material is available for purchase from the National Food Plant Institute, 1700 K St NW, Washington, DC 20006:~~]**The following material is available from the International Labour Organization (ILO), 4 route des Morillons, CH-1211 Genève 22, Switzerland; telephone: +41 (0) 22 799 6111; fax: +41 (0) 22 798 8685; website: www.ilo.org/.**

(1) [~~Definition and Test Procedures for Ammonium Nitrate Fertilizer (Nov. 1964), IBR approved for 1910.109 Table H-22, footnote 3.~~]**Guidelines for the Use of the ILO International Classification of Radiographs of Pneumoconioses, Revised Edition 2011, Occupational safety and health series; 22 (Rev.2011), IBR approved for 1910.1001.**

(2) (Reserved)

(v) [~~The following material is available for purchase from the National Institute for Occupational Safety and Health (NIOSH):~~]**International Organization for Standardization (ISO), ISO Central Secretariat, Chemin de Blandonnet 8 CP 401—1214 Vernier, Geneva, Switzerland; phone: +41 22 749 01 11; email: central@iso.org; website: www.iso.org/store.html.**

(1) [~~Registry of Toxic Effects of Chemical Substances, 1978, IBR approved for 1910.1020(c)(13)(i) and Appendix B.~~]**ISO 817:2014(E), Refrigerants—Designation and safety classification, Third edition, 2014–04–15; IBR approved for appendix B to § 1910.1200.**

(2) [~~Development of Criteria for Fire Fighters Gloves; Vol. II, Part II; Test Methods, 1976, IBR approved for 1910.156(e)(4)(i) introductory text.~~]**ISO 10156:1996 (E), Gases and Gas Mixtures—Determination of Fire Potential and Oxidizing Ability for the Selection of Cylinder Valve Outlets, Second Edition, Feb. 15, 1996; IBR approved for appendix B to § 1910.1200.**

(3) [~~NIOSH Recommendations for Occupational Safety and Health Standards (Sept. 1987), IBR approved for 1910.120 PEL definition.~~] **ISO 10156:2017(E), Gas Cylinders—Gases and gas mixtures— Determination of fire potential and oxidizing ability for the selection of cylinder valve outlets, Fourth edition, 2017–07; IBR approved for appendix B to § 1910.1200.**

(4) ISO 10156–2:2005 (E), Gas cylinders—Gases and Gas Mixtures—Part 2: Determination of Oxidizing Ability of Toxic and Corrosive Gases and Gas Mixtures, First Edition, Aug. 1, 2005; IBR approved for appendix B to subpart Z.

(5) ISO 13943:2000 (E/F); Fire Safety—Vocabulary, First Edition, April, 15, 2000, IBR approved for appendix B to § 1910.1200.

(w) [~~The following material is available for purchase from the Public Health Service:~~] **The following material is available for purchase from the National Electrical Manufacturer's Association (NEMA):**

(1) [~~U.S. Pharmacopeia, IBR approved for 1910.134(d)(1).~~] **NEMA EW-1 (1962) Requirements for Electric Arc Welding Apparatus, IBR approved for §§1910.254(b)(1).**

(2) [~~Publication No. 934 (1962), Food Service Sanitation Ordinance and Code, Part V of the Food Service Sanitation Manual, IBR approved for 1910.142(i)(1).~~] **(Reserved)**

(x)[~~The following material is available for purchase from the Society of Automotive Engineers (SAE), 485 Lexington Avenue, New York, NY 10017:~~] **The following material is available for purchase from the National Fire Protection Association (NFPA), 1 Batterymarch Park, Quincy, MA 02269; Telephone: 800-344-3555 or 617-770-3000; Fax: 1-800-593-6372 or 1-508-895-8301; Email: custserv@nfpa.org; Web site: http://www.nfpa.org.**

(1) [~~SAE J185, June 1988, Recommended Practice for Access Systems for OffRoad Machines, IBR approved for 1910.266(f)(5)(i).~~]**NFPA 30 (1969) Flammable and Combustible Liquids Code, IBR approved for 1910.178(f)(1).**

(2) [~~SAE J231, January 1981, Minimum Performance Criteria for Falling Object Protective Structure (FOPS), IBR approved for 1910.266(f)(3)(ii).~~] **NFPA 32-1970 Standard for Dry Cleaning Plants, IBR approved for 1910.106(j)(6)(i).**

(3) [~~SAE J386, June 1985, Operator Restraint Systems for Off-Road Work Machines, IBR approved for 1910.266(d)(3)(iv).~~] **NFPA 33-1969 Standard for Spray Finishing Using Flammable and Combustible Material, IBR approved for 1910.94(c)(2).**

(4) [~~SAE J397, April 1988, Deflection Limiting Volume – ROPS/FOPS Laboratory Evaluation, IBR approved for 1910.266(f)(3)(iv).~~] **NFPA 34-1966 Standard for Dip Tanks Containing Flammable or Combustible Liquids, IBR approved for 1910.124(b)(4)(iv).**

(5) [~~SAE 765 (1961) SAE Recommended Practice: Crane Loading Stability Test Code, IBR approved for 1910.180(c)(1)(iii) and (e)(2)(iii)(a).~~] **NFPA 34-1995 Standard for Dip Tanks Containing Flammable or Combustible Liquids, IBR approved for 1910.124(b)(4)(ii).**

(6) [~~SAE J1040, April 1988, Performance Criteria for Rollover Protective Structures (ROPS) for Construction, Earthmoving, Forestry and Mining Machines, IBR approved for 1910.266(f)(3)(ii).~~] **NFPA 35-1970 Standard for the Manufacture of Organic Coatings, IBR approved for 1910.106(j)(6)(ii).**

(7) NFPA 36-1967 Standard for Solvent Extraction Plants, IBR approved for 1910.106(j)(6)(iii).

(8) NFPA 37-1970 Standard for the Installation and Use of Stationary Combustion Engines and Gas Turbines, IBR approved for 1910.106(j)(6)(iv) and 1910.110 (b)(20)(iv)(c) and (e)(11).

(9) NFPA 51B-1962 Standard for Fire Protection in Use of Cutting and Welding Processes, IBR approved for 1910.252(a)(1) introductory text.

(10) NFPA 54-1969 Standard for the Installation of Gas Appliances and Gas Piping, IBR approved for 1910.110(b)(20)(iv)(a).

(11) NFPA 54A-1969 Standard for the Installation of Gas Piping and Gas Equipment on Industrial Premises and Certain Other Premises, IBR approved for 1910.110(b)(20)(iv)(b).

(12) NFPA 58-1969 Standard for the Storage and Handling of Liquefied Petroleum Gases (ANSI Z106.1-1970), IBR approved for 1910.110 (b)(3)(iv) and (i)(3)(i) and (ii); and 1910.178(f)(2).

(13) NFPA 59-1968 Standard for the Storage and Handling of Liquefied Petroleum Gases at Utility Gas Plants, IBR approved for 1910.110 (b)(3)(iv) and (i)(2)(iv) (14) NFPA 62-1967 Standard for the Prevention of Dust Explosions in the Production, Packaging, and Handling of Pulverized Sugar and Cocoa, IBR approved for 1910.263(k)(2)(i).

(15) NFPA 68-1954 Guide for Explosion Venting, IBR approved for 1910.94(a)(2)(iii).

(16) (Reserved)

(17) NFPA 78-1968 Lightning Protection Code, IBR approved for 1910.109(i)(6)(ii).

(18) NFPA 80-1968 Standard for Fire Doors and Windows, IBR approved for 1910.106(d)(4)(i).

(19) NFPA 80-1970 Standard for the Installation of Fire Doors and Windows, IBR approved for 1910.253(f)(6)(i)(I).

(20) NFPA 86A-1969 Standard for Oven and Furnaces Design, Location and Equipment, IBR approved for 1910.107 (j)(1) and (l)(3) and 1910.108 (b)(2) and (d)(2).

(21) NFPA 91-1961 Standard for the Installation of Blower and Exhaust Systems for Dust, Stock, and Vapor Removal or Conveying (ANSI Z33.1-61), IBR approved for 1910.107(d)(1).

(22) NFPA 91-1969 Standards for Blower and Exhaust Systems, IBR approved for 1910.108(b)(1).

(23) NFPA 96-1970 Standard for the Installation of Equipment for the Removal of Smoke and Grease Laden Vapors from Commercial Cooking Equipment, IBR approved for 1910.110(b)(20)(iv)(d).

(24) NFPA 101-1970 Code for Life Safety From Fire in Buildings and Structures, IBR approved for 1910.261(a)(4)(ii).

(25) NFPA 101-2009, Life Safety Code, 2009 edition, IBR approved for 1910.34, 1910.35, 1910.36, and 1910.37.

(26) NFPA 203M-1970 Manual on Roof Coverings, IBR approved for 1910.109(i)(1)(iii)(c).

(27) NFPA 251-1969 Standard Methods of Fire Tests of Building Construction and Materials, IBR approved for 1910.106 (d)(3)(ii) introductory text and (d)(4)(i).

(28) NFPA 302-1968 Fire Protection Standard for Motor-Craft (Pleasure and Commercial), IBR approved for 1910.265(d)(2)(iv) introductory text.

(29) NFPA 385-1966 Recommended Regulatory Standard for Tank Vehicles for Flammable and Combustible Liquids, IBR approved for 1910.106(g)(1)(i)(e)(1).

(30) NFPA 496-1967 Standard for Purged Enclosures for Electrical Equipment in Hazardous Locations, IBR approved for 1910.103(c)(1)(ix)(e)(1).

(31) NFPA 505-1969 Standard for Type Designations, Areas of Use, Maintenance, and Operation of Powered Industrial Trucks, IBR approved for 1910.110(e)(2)(iv).

(32) NFPA 566-1965 Standard for the Installation of Bulk Oxygen Systems at Consumer Sites, IBR approved for 1910.253 (b)(4)(iv) and (c)(2)(v).

(33) NFPA 656-1959 Code for the Prevention of Dust Ignition in Spice Grinding Plants, IBR approved for 1910.263(k)(2)(i).

(34) NFPA 1971-1975 Protective Clothing for Structural Fire Fighting, IBR approved for 1910.156(e)(3)(ii) introductory text.

(35) NFPA 51A (2001) Standard for Acetylene Cylinder Charging Plants, IBR approved for 1910.102(b) and (c). Copies of NFPA 51A-2001 are available for purchase from the: National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169-7471; telephone: 1-800-344-35557; e-mail: custserv@nfpa.org.

(36) NFPA 51A (2006) Standard for Acetylene Cylinder Charging Plants, IBR approved for 1910.102(b) and (c). Copies of NFPA 51A-2006 are available for purchase from the: National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169-7471; telephone: 1-800-344-35557; e-mail: custserv@nfpa.org.

(37) NFPA 30B, Code for the Manufacture and Storage of Aerosol Products, 2007 Edition, Approved August 17, 2006, IBR approved for Appendix B to 1910.1200.

(y) [~~The following material is available for purchase from the Fertilizer Institute, 1015 18th Street NW, Washington, DC 20036:~~] **The following material is available for purchase from the National Food Plant Institute, 1700 K St. NW., Washington, DC 20006:**

(1) [~~Standard M-1 (1953, 1955, 1957, 1960, 1961, 1963, 1965, 1966, 1967, 1968), Superseded by ANSI K61.1-1972, IBR approved for 1910.111(b)(1)(i) and (iii).~~] **Definition and Test Procedures for Ammonium Nitrate Fertilizer (Nov. 1964), IBR approved for 1910.109 Table H-22, ftn. 3.**

(2) (Reserved)

(z) [~~The following material is available for purchase from Underwriters Laboratories (UL), 207 East Ohio Street, Chicago, IL 60611:~~]**The following material is available for purchase from the National Institute for Occupational Safety and Health (NIOSH):**

(1) [~~UL 58-61 Steel Underground Tanks for Flammable and Combustible Liquids, 5th Ed., IBR approved for 1910.106(b)(1)(iii)(a)(1).~~]**Registry of Toxic Effects of Chemical Substances, 1978, IBR approved for 1910.20(c)(13)(i) and Appendix B.**

(2) [~~UL 80-63 Steel Inside Tanks for Oil-Burner Fuel, IBR approved for 1910.106(b)(1)(iii)(a)(1).~~] **Development of Criteria for Fire Fighters Gloves; Vol. II, part II; Test Methods, 1976, IBR approved for 1910.156(e)(4)(i) introductory text.**

(3) [~~UL 142-68 Steel Aboveground Tanks for Flammable and Combustible Liquids, IBR approved for 1910.106(b)(1)(iii)(a)(1).~~] **NIOSH Recommendations for Occupational Safety and Health Standards (Sept. 1987), IBR approved for 1910.120 PEL definition.**

(aa) [~~The following material is available for purchase from the: International Code Council, Chicago District Office, 4051 W. Flossmoor Rd., Country Club Hills, IL 60478; telephone: 708-799-2300, x3-3801; facsimile: 001-708-799-4981; email: order@iccsafe.org.~~] **The following material is available for purchase from the Public Health Service:**

(1) [~~IFC-2009, International Fire Code, copyright 2009, IBR approved for 1910.34, 1910.35, 1910.36, and 1910.37.~~]**U.S. Pharmacopeia, IBR approved for 1910.134(d)(1).**

(2) ~~[(Reserved)]~~ **Publication No. 934 (1962), Food Service Sanitation Ordinance and Code, part V of the Food Service Sanitation Manual, IBR approved for 1910.142(i)(1).**

(bb) **The following material is available for purchase from the Society of Automotive Engineers (SAE), 485 Lexington Avenue, New York, NY 10017:**

(1) [~~The following document is available for purchase from United Nations Publications, Customer Service, c/o National Book Network, 15200 NBN Way, PO Box 190, Blue Ridge Summit, PA 17214; telephone: 1-888-254-4286; fax: 1-800-338-4550; email: unpublications@nbnbooks.com. Other distributors of United Nations Publications include:~~] **SAE J185, June 1988, Recommended Practice for Access Systems for Off-Road Machines, IBR approved for 1910.266(f)(5)(i).**

[~~(i) Bernan, 15200 NBN Way, Blue Ridge Summit, PA 17214; telephone: 1-800-865-3457; fax: 1-800-865-3450; email: customercare@bernan; Web site: http://www.bernan.com; and~~

~~(ii) Renouf Publishing Co. Ltd., 812 Proctor Avenue, Ogdensburg, NY13669-2205; telephone: 1-888-551-7470; Fax: 1-888-551-7471; email: orders@renoufbooks.com; Web site: http://www.renoufbooks.com~~]

(2) [~~UN ST/SG/AC.10/Rev.4, The UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, Fourth Revised Edition, 2003, IBR approved for Appendix B to 1910.1200.~~]**SAE J231, January 1981,**

Minimum Performance Criteria for Falling Object Protective Structure (FOPS), IBR approved for 1910.266(f)(3)(ii).

(3) SAE J386, June 1985, Operator Restraint Systems for Off-Road Work Machines, IBR approved for 1910.266(d)(3)(iv).

(4) SAE J397, April 1988, Deflection Limiting Volume-ROPS/FOPS Laboratory Evaluation, IBR approved for 1910.266(f)(3)(iv).

(5) SAE 765 (1961) SAE Recommended Practice: Crane Loading Stability Test Code, IBR approved for 1910.180 (c)(1)(iii) and (e)(2)(iii)(a).

(6) SAE J1040, April 1988, Performance Criteria for Rollover Protective Structures (ROPS) for Construction, Earthmoving, Forestry and Mining Machines, IBR approved for 1910.266(f)(3)(ii).

(cc) The following material is available for purchase from Underwriters Laboratories (UL), 207 East Ohio Street, Chicago, IL 60611:

(1) UL 58-61 Steel Underground Tanks for Flammable and Combustible Liquids, 5th Ed., IBR approved for 1910.106(b)(1)(iii)(a)(1).

(2) UL 80-63 Steel Inside Tanks for Oil-Burner Fuel, IBR approved for 1910.106(b)(1)(iii)(a)(1).

(3) UL 142-68 Steel Above Ground Tanks for Flammable and Combustible Liquids, IBR approved for 1910.106(b)(1)(iii)(a)(1).

(dd) United Nations (UN), United Nations Publications, P.O. Box 960 Herndon, VA 20172; phone: (703) 661-1571;; email: order@un.org; website: https://shop.un.org/.

(1) ADR 2019, European Agreement Concerning the International Carriage of Dangerous Goods by Road; Annex A: General provisions and provisions concerning dangerous substances and articles; (Volumes I and II) including December 2018 corrigendum to Volume II, applicable January 1, 2019; IBR approved for § 1910.1200.

(2) ST/SG/AC.10/Rev.4 (“UN ST/SG/ AC.10/Rev.4”), The UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, Fourth Revised Edition, 2003; IBR approved for Appendix B to 1910.1200.

(3) ST/SG/AC.10/11/Rev.6 (“UN ST/SG/AC.10/11/Rev.6”), Recommendations on the Transport of Dangerous Goods: Manual of

Tests and Criteria, sixth revised edition, copyright 2015; IBR approved for appendix B to § 1910.1200.

[39 FR 23502, June 27, 1974, as amended at 49 FR 5321, Feb. 10, 1984; 61 FR 9227, March 7, 1996; 64 FR 13908, March 23, 1999; 70 FR 53929, Sept. 13, 2005; 72 FR 7190, Feb. 14, 2007; 72 FR 71068, Dec. 14, 2007; 74 FR 40447, August 11, 2009; 74 FR 46355, Sept. 9, 2009; 76 FR 33606, June 8, 2011; 76 FR 75786, Dec. 5, 2011; 77 FR 17764, March 26, 2012; 77 FR 37598, June 22, 2012; 78 FR 35565-35566, June 13, 2013; 78 FR 66641, November 6, 2013; 81 FR 16090, March 25, 2016; 81 FR 82981, Nov. 18, 2016; 84 FR 21416, May 14, 2019; **89 FR 44144-44461, May 20, 2024**]

Stat. Auth.: ORS 654.025(2) and 656.726(4).
Stat. Implemented: ORS 654.001 through 654.295.

Hist: APD Admin. Order 17-1988, f. 11/10/88, ef. 11/10/88.
OR-OSHA Admin. Order 4-1997, f. 4/2/97, ef. 4/2/97.
OR-OSHA Admin. Order 8-1999, f. 8/6/99, ef. 8/6/99.
OR-OSHA Admin. Order 4-2005, f. 12/14/05, ef. 12/14/05.
OR-OSHA Admin. Order 4-2007, f. 8/15/07, ef. 8/15/07.
OR-OSHA Admin. Order 7-2008, f. 5/30/08, ef. 5/30/08.
OR-OSHA Admin. Order 1-2010, f. 2/19/10, ef. 2/19/10.
OR-OSHA Admin. Order 2-2010, f. 2/25/10, ef. 2/25/10.
OR-OSHA Admin. Order 4-2011, f. 12/8/11, ef. 12/8/11.
OR-OSHA Admin. Order 5-2012, f. 9/25/12, ef. 9/25/12.
OR-OSHA Admin. Order 7-2012, f. 12/14/12, ef. 12/14/12.
OR-OSHA Admin. Order 7-2013, f. 12/12/13, ef. 12/12/13.
OR-OSHA Admin. Order 4-2016, f. 9/7/16, ef. 9/7/16.
OR-OSHA Admin. Order 2-2017, f. 5/16/17, ef. 11/1/17.
OR-OSHA Admin. Order 3-2019, f. 10/29/19, ef. 10/29/19
OR-OSHA Admin. Order X-XXXX, f. XX/XX/XX, ef. XX/XX/XX

437-002-0360 Adoption by Reference

In addition to, and not in lieu of, any other safety and health codes contained in OAR Chapter 437, the Department adopts by reference the following federal regulations printed as part of the Code of Federal Regulations, 29 CFR 1910, in the Federal Register:
(1) (Reserved) 29 CFR 1910.1000 Air contaminants.

Note: 29 CFR 1910.1000 was repealed on 11/15/93 by OR OSHA. In Oregon, OAR 437-002-0382 applies.

(2) 29 CFR 1910.1001 Asbestos, published 5/14/19, FR vol. 84, no. 93, p. 21416.

(3) 29 CFR 1910.1002 Coal tar pitch volatiles, interpretation of term, published 1/21/83, Federal Register, vol. 43, p. 2768.

(4) 29 CFR 1910.1003 13 Carcinogens, published 3/26/12, FR vol. 77, no. 58, p. 17574.

(5) 29 CFR 1910.1004 See §1910.1003, 13 Carcinogens.

(6) Reserved for 29 CFR 1910.1005.

(7) 29 CFR 1910.1006 See §1910.1003, 13 Carcinogens.

(8) 29 CFR 1910.1007 See §1910.1003, 13 Carcinogens.

(9) 29 CFR 1910.1008 See §1910.1003, 13 Carcinogens.

(10) 29 CFR 1910.1009 See §1910.1003, 13 Carcinogens.

(11) 29 CFR 1910.1010 See §1910.1003, 13 Carcinogens.

(12) 29 CFR 1910.1011 See §1910.1003, 13 Carcinogens.

(13) 29 CFR 1910.1012 See §1910.1003, 13 Carcinogens.

(14) 29 CFR 1910.1013 See §1910.1003, 13 Carcinogens.

(15) 29 CFR 1910.1014 See §1910.1003, 13 Carcinogens.

(16) 29 CFR 1910.1015 See §1910.1003, 13 Carcinogens.

(17) 29 CFR 1910.1016 See §1910.1003, 13 Carcinogens.

(18) 29 CFR 1910.1017 Vinyl chloride, published 5/14/19, FR vol. 84, no. 93, p. 21416.

(19) 29 CFR 1910.1018 Inorganic arsenic, published 5/14/19, FR vol. 84, no. 93, p. 21416.

(20) 29 CFR 1910.1020 Access to Employee Exposure and Medical Records, published 6/8/11, Federal Register, vol. 76, no. 110, p. 33590.

Appendix A: Sample Authorization Letter.

Appendix B: Availability of NIOSH RTECS.

(21) 29 CFR 1910.1025 Lead, published 5/14/19, FR vol. 84, no. 93, p. 21416.

(22) 29 CFR 1910.1026 Chromium (VI), published 5/14/19, FR vol. 84, no. 93, p. 21416.

(23) 29 CFR 1910.1027 Cadmium, published 2/18/20, FR vol. 85, no. 32, p. 8726-8746.

(24) 29 CFR 1910.1028 Benzene, and Appendices A, B, C, D, and E, published 5/14/19, FR vol. 84, no. 93, p. 21416.

(25) 29 CFR 1910.1029 Coke oven emissions, published 5/14/19, FR vol. 84, no. 93, p. 21416.

(26) 29 CFR 1910.1030 Bloodborne pathogens, published 5/14/19, FR vol. 84, no. 93, p. 21416.

(27) 29 CFR 1910.1043 Cotton dust, published 5/14/19, FR vol. 84, no. 93, p. 21416.

(28) 29 CFR 1910.1044 1,2 dibromo-3 chloropropane, published 5/14/19, FR vol. 84, no. 93, p. 21416.

(29) 29 CFR 1910.1045 Acrylonitrile, published 5/14/19, FR vol. 84, no. 93, p. 21416.

(30) 29 CFR 1910.1047 Ethylene oxide, published 5/14/19, FR vol. 84, no. 93, p. 21416.

(31) 29 CFR 1910.1048 Formaldehyde, and Appendices A, B, C, D and E, published 5/14/19, FR vol. 84, no. 93, p. 21416.

(32) 29 CFR 1910.1050 Methylenedianiline (MDA), published 5/14/19, FR vol. 84, no. 93, p. 21416.

(33) 29 CFR 1910.1051 1,3-Butadiene, published 5/14/19, FR vol. 84, no. 93, p. 21416.

(34) 29 CFR 1910.1052 Methylene Chloride, published 5/14/19, FR vol. 84, no. 93, p. 21416.

Note: 29 CFR 1910.1101 Asbestos, was repealed by Federal Register, vol. 57, no. 110, issued 6/8/92, p. 24330.

(35) 29 CFR 1910.1096 Ionizing radiation, published 6/20/96, FR vol. 61, no. 46, p. 31427.

(36) 29 CFR 1910.1200 Hazard communication, published [~~2/8/13, FR vol. 78, no. 27, p. 9311~~]**5/20/24, FR vol. 89, no. 98, p. 44144-44461.**

(37) 29 CFR 1910.1201 Retention of DOT Markings, Placards and Labels, published 7/19/94, Federal Register, vol. 59, p. 36700.

(38) 29 CFR 1910.1450 Occupational Exposure to Hazardous Chemicals in Laboratories, published 1/22/13, FR vol. 78, no. 14, p. 4324.

(39) 29 CFR 1910.1499 Removed. Published 3/7/96, Federal Register, vol. 61, no. 46, p. 9245.

(40) 29 CFR 1910.1500 Removed. Published 3/7/96, Federal Register, vol. 61, no. 46, p. 9245.

These standards are available at the Oregon Occupational Safety and Health Division, Oregon Department of Consumer and Business Services, and the United States Government Printing Office.

Statutory/Other Authority: ORS 654.025(2) & 656.726(4)
Statutes/Other Implemented: ORS 654.001 - 654.295

History:
OSHA X-20XX, f. XX/XX/XXXX, ef. XX/XX/XXXX
OSHA 1-2024, amend filed 09/11/2024, effective 09/11/2024
OSHA 3-2019, amend filed 10/29/2019, effective 10/29/2019
OSHA 4-2013, f. & cert. ef. 7-19-13
OSHA 3-2013, f. & cert. ef. 7-18-13
OSHA 5-2012, f. & cert. ef. 9-25-12
OSHA 1-2012, f. & cert .ef. 4-10-12
OSHA 5-2011, f. 12-8-11, cert. ef. 7-1-12
OSHA 4-2011, f. & cert. ef. 12-8-11
OSHA 3-2010, f. 6-10-10, cert. ef. 6-15-10
OSHA 5-2009, f. & cert. ef. 5-29-09
OSHA 10-2006, f. & cert. ef. 11-30-06
OSHA 6-2006, f. & cert. ef. 8-30-06
OSHA 4-2006, f. & cert. ef. 7-24-06
OSHA 1-2005, f. & cert. ef. 4-12-05
OSHA 12-2001, f. & cert. ef. 10-26-01
OSHA 10-2001, f. 9-14-01, cert. ef. 10-18-01
OSHA 6-2001, f. & cert. ef. 5-15-01
OSHA 2-1999, f. & cert. ef. 4-30-99
OSHA 1-1999, f. & cert. ef. 3-22-99
OSHA 3-1998, f. & cert. ef. 7-7-98
OSHA 1-1998, f. & cert. ef. 2-13-98
OSHA 8-1997, f. & cert. ef. 11-14-97
OSHA 6-1997, f. & cert. ef. 5-2-97
OSHA 4-1997, f. & cert. ef. 4-2-97
OSHA 6-1996, f. & cert. ef. 11-29-96

OSHA 4-1996, f. & cert. ef. 9-13-96
OSHA 8-1995, f. & cert. ef. 8-25-95
OSHA 5-1995, f. & cert. ef. 4-6-95
OSHA 4-1995, f. & cert. ef. 3-29-95
OSHA 1-1995, f. & cert. ef. 1-19-95
OSHA 4-1994, f. & cert. ef. 8-4-94
OSHA 17-1993, f. & cert. ef. 11-15-93
OSHA 12-1993, f. 8-20-93, cert. ef. 11-1-93
OSHA 6-1993(Temp), f. & cert. ef. 5-17-93
OSHA 1-1993, f. & cert. ef. 1-22-93
OSHA 15-1992, f. & cert. ef. 12-30-92
OSHA 14-1992, f. & cert. ef. 12-7-92
OSHA 12-1992, f. & cert. ef. 10-13-92
OSHA 11-1992, f. & cert. ef. 10-9-92
OSHA 9-1992(Temp), f. & cert. ef. 9-24-92
OSHA 6-1992, f. & cert. ef. 5-18-92
OSHA 5-1992, f. 4-24-92, cert. ef. 7-1-92
OSHA 4-1992, f. & cert. ef. 4-16-92
OSHA 1-1992, f. & cert. ef. 1-22-92
OSHA 15-1991, f. & cert. ef. 12-13-91
OSHA 13-1991, f. & cert. ef. 10-10-91
OSHA 7-1991, f. & cert. ef. 4-25-91
OSHA 21-1990, f. & ef. 9-18-90
OSHA 20-1990, f. & ef. 9-18-90
OSHA 19-1990, f. & ef. 8-31-90
OSHA 14-1990, f. 6-28-90, ef. 8-1-90
OSHA 13-1990(Temp), f. 6-28-90, ef. 8-1-90
OSHA 11-1990, f. 6-7-90, ef. 7-1-90
OSHA 9-1990, f. 5-8-90, ef. 8-8-90
OSHA 7-1990, f. & ef. 3-2-90
OSHA 6-1990, f. & ef. 3-2-90
OSHA 3-1990(Temp), f. & ef. 1-19-90
OSHA 1-1990(Temp), f. & ef. 1-11-90
APD 13-1989, f. & ef. 7-17-89
APD 11-1989, f. 7-14-89, ef. 8-14-89
APD 9-1989, f. & ef. 7-7-89
APD 6-1989(Temp), f. 4-20-89, ef. 5-1-89
APD 4-1989(Temp), f. 3-31-89, ef. 5-1-89
APD 18-1988, f. & ef. 11-17-88
APD 14-1988, f. & ef. 9-12-88
APD 13-1988, f. 8-2-88 & ef. 8-2-88

§1910.1200 Hazard Communication.

(a) Purpose.

(1) The purpose of this section is to ensure that the hazards of all chemicals produced or imported are classified, and that information concerning the classified hazards is transmitted to employers and employees. The requirements of this section are intended to be consistent with the provisions of the United Nations Globally Harmonized System of Classification and Labeling of Chemicals (GHS), **primarily** Revision [~~3~~] **7**. The transmittal of information is to be accomplished by means of comprehensive hazard communication programs, which are to include container labeling and other forms of warning, safety data sheets and employee training.

(2) This occupational safety and health standard is intended to address comprehensively the issue of classifying the potential hazards of chemicals, and communicating information concerning hazards and appropriate protective measures to employees, and to preempt any legislative or regulatory enactments of a state, or political subdivision of a state, pertaining to this subject. Classifying the potential hazards of chemicals and communicating information concerning hazards and appropriate protective measures to employees, may include, for example, but is not limited to, provisions for: developing and maintaining a written hazard communication program for the workplace, including lists of hazardous chemicals present; labeling of containers of chemicals in the workplace, as well as of containers of chemicals being shipped to other workplaces; preparation and distribution of safety data sheets to employees and downstream employers; and development and implementation of employee training programs regarding hazards of chemicals and protective measures. Under section 18 of the Act, no state or political subdivision of a state may adopt or enforce any requirement relating to the issue addressed by this Federal standard, except pursuant to a Federally-approved state plan.

(b) Scope and application.

(1) This section requires chemical manufacturers or importers to classify the hazards of chemicals which they produce or import, and all employers to provide information to their employees about the hazardous chemicals to which they are exposed, by means of a hazard communication program, labels and other forms of warning, safety data sheets, and information and training. In addition, this section requires distributors to transmit the required information to employers. (Employers who do not produce or import chemicals need only focus on those parts of this rule that deal with establishing a workplace program and communicating information to their workers.)

(2) This section applies to any chemical which is known to be present in the workplace in such a manner that employees may be exposed under normal conditions of use or in a foreseeable emergency.

(3) This section applies to laboratories only as follows:

> **(i)** Employers shall ensure that labels on incoming containers of hazardous chemicals are not removed or defaced;
>
> **(ii)** Employers shall maintain any safety data sheets that are received with incoming shipments of hazardous chemicals, and ensure that they are readily accessible during each workshift to laboratory employees when they are in their work areas;
>
> **(iii)** Employers shall ensure that laboratory employees are provided information and training in accordance with paragraph (h) of this section, except for the location and availability of the written hazard communication program under paragraph (h)(2)(iii) of this section; and,
>
> **(iv)** Laboratory employers that ship hazardous chemicals are considered to be either a chemical manufacturer or a distributor under this rule, and thus must ensure that any containers of hazardous chemicals leaving the laboratory are labeled in accordance with paragraph (f) of this section, and that a safety data sheet is provided to distributors and other employers in accordance with paragraphs (g)(6) and (g)(7) of this section.

(4) In work operations where employees only handle chemicals in sealed containers which are not opened under normal conditions of use (such as are found in marine cargo handling, warehousing, or retail sales), this section applies to these operations only as follows:

> (i) Employers shall ensure that labels on incoming containers of hazardous chemicals are not removed or defaced;
>
> (ii) Employers shall maintain copies of any safety data sheets that are received with incoming shipments of the sealed containers of hazardous chemicals, shall obtain a safety data sheet as soon as possible for sealed containers of hazardous chemicals received without a safety data sheet if an employee requests the safety data sheet, and shall ensure that the safety data sheets are readily accessible during each work shift to employees when they are in their work area(s); and,
>
> (iii) Employers shall ensure that employees are provided with information and training in accordance with paragraph (h) of this section (except for the location and availability of the written hazard communication program under paragraph (h)(2)(iii) of this section), to the extent necessary to

protect them in the event of a spill or leak of a hazardous chemical from a sealed container.

(5) This section does not require labeling of the following chemicals:

(i) Any pesticide as such term is defined in the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq.), when subject to the labeling requirements of that Act and labeling regulations issued under that Act by the Environmental Protection Agency;

(ii) Any chemical substance or mixture as such terms are defined in the Toxic Substances Control Act (15 U.S.C. 2601 et seq.), when subject to the labeling requirements of that Act and labeling regulations issued under that Act by the Environmental Protection Agency;

(iii) Any food, food additive, color additive, drug, cosmetic, or medical or veterinary device or product, including materials intended for use as ingredients in such products (e.g. flavors and fragrances), as such terms are defined in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) or the Virus-Serum-Toxin Act of 1913 (21 U.S.C. 151 et seq.), and regulations issued under those Acts, when they are subject to the labeling requirements under those Acts by either the Food and Drug Administration or the Department of Agriculture;

(iv) Any distilled spirits (beverage alcohols), wine, or malt beverage intended for nonindustrial use, as such terms are defined in the Federal Alcohol Administration Act (27 U.S.C. 201 et seq.) and regulations issued under that Act, when subject to the labeling requirements of that Act and labeling regulations issued under that Act by the Bureau of Alcohol, Tobacco, Firearms and Explosives;

(v) Any consumer product or hazardous substance as those terms are defined in the Consumer Product Safety Act (15 U.S.C. 2051 et seq.) and Federal Hazardous Substances Act (15 U.S.C. 1261 et seq.) respectively, when subject to a consumer product safety standard or labeling requirement of those Acts, or regulations issued under those Acts by the Consumer Product Safety Commission; and,

(vi) Agricultural or vegetable seed treated with pesticides and labeled in accordance with the Federal Seed Act (7 U.S.C. 1551 et seq.) and the labeling regulations issued under that Act by the Department of Agriculture.

(6) This section does not apply to:

(i) Any hazardous waste as such term is defined by the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery

Act of 1976, as amended (42 U.S.C. 6901 et seq.), when subject to regulations issued under that Act by the Environmental Protection Agency;

(ii) Any hazardous substance as such term is defined by the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) (42 U.S.C. 9601 et seq.) when the hazardous substance is the focus of remedial or removal action being conducted under CERCLA in accordance with Environmental Protection Agency regulations.

(iii) Tobacco or tobacco products;

(iv) Wood or wood products, including lumber which will not be processed, where the chemical manufacturer or importer can establish that the only hazard they pose to employees is the potential for flammability or combustibility (wood or wood products which have been treated with a hazardous chemical covered by this standard, and wood which may be subsequently sawed or cut, generating dust, are not exempted);

(v) Articles (as that term is defined in paragraph (c) of this section);

(vi) Food or alcoholic beverages which are sold, used, or prepared in a retail establishment (such as a grocery store, restaurant, or drinking place), and foods intended for personal consumption by employees while in the workplace;

(vii) Any drug, as that term is defined in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), when it is in solid, final form for direct administration to the patient (e.g., tablets or pills); drugs which are packaged by the chemical manufacturer for sale to consumers in a retail establishment (e.g., over-the-counter drugs); and drugs intended for personal consumption by employees while in the workplace (e.g., first aid supplies);

(viii) Cosmetics which are packaged for sale to consumers in a retail establishment, and cosmetics intended for personal consumption by employees while in the workplace;

(ix) Any consumer product or hazardous substance, as those terms are defined in the Consumer Product Safety Act (15 U.S.C. 2051 et seq.) and Federal Hazardous Substances Act (15 U.S.C. 1261 et seq.) respectively, where the employer can show that it is used in the workplace for the purpose intended by the chemical manufacturer or importer of the product, and the use results in a duration and frequency of exposure which is not greater than the range of exposures that could reasonably be experienced by consumers when used for the purpose intended;

(x) Nuisance particulates where the chemical manufacturer or importer can establish that they do not pose any physical **hazard,** [~~or~~] health hazard**, or other hazards** covered under this section;

(xi) Ionizing and nonionizing radiation; and,

(xii) Biological hazards.

(c) [~~Definitions.~~]Article means a manufactured item other than a fluid or particle:

(i) [~~w~~]**W**hich is formed to a specific shape or design during manufacture;

(ii) [~~w~~]**W**hich has end use function(s) dependent in whole or in part upon its shape or design during end use; and

(iii) [~~w~~]**W**hich under normal conditions of use does not release more than very small quantities, e.g., minute or trace amounts of a hazardous chemical (as determined under paragraph (d) of this section), and does not pose a physical hazard or health risk to employees.

Assistant Secretary means the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, or designee.

Bulk shipment means any hazardous chemical transported where the mode of transportation comprises the immediate container (i.e. contained in tanker truck, rail car, or intermodal container).

Chemical means any substance, or mixture of substances.

Chemical manufacturer means an employer with a workplace where chemical(s) are produced for use or distribution.

Chemical name means the scientific designation of a chemical in accordance with the nomenclature system developed by the International Union of Pure and Applied Chemistry (IUPAC) or the Chemical Abstracts Service (CAS) rules of nomenclature, or a name that will clearly identify the chemical for the purpose of conducting a hazard classification.

Classification means to identify the relevant data regarding the hazards of a chemical; review those data to ascertain the hazards associated with the chemical; and decide whether the chemical will be classified as hazardous according to the definition of hazardous chemical in this section. In addition, classification for health and physical hazards includes the determination of the degree of hazard, where appropriate, by comparing the data with the criteria for health and physical hazards.

Combustible dust means finely divided solid particulates of a substance or mixture that pose a flash-fire hazard or explosion hazard when dispersed in air or other oxidizing media.

Commercial account means an arrangement whereby a retail distributor sells hazardous chemicals to an employer, generally in large quantities over time and/or at costs that are below the regular retail price.

Common name means any designation or identification such as code name, code number, trade name, brand name or generic name used to identify a chemical other than by its chemical name.

Container means any bag, barrel, bottle, box, can, cylinder, drum, reaction vessel, storage tank, or the like that contains a hazardous chemical. For purposes of this section, pipes or piping systems, and engines, fuel tanks, or other operating systems in a vehicle, are not considered to be containers.

Designated representative means any individual or organization to whom an employee gives written authorization to exercise such employee's rights under this section. A recognized or certified collective bargaining agent shall be treated automatically as a designated representative without regard to written employee authorization.

Director means the Director, National Institute for Occupational Safety and Health, U.S. Department of Health and Human Services, or designee.

Distributor means a business, other than a chemical manufacturer or importer, which supplies hazardous chemicals to other distributors or to employers.

Employee means a worker who may be exposed to hazardous chemicals under normal operating conditions or in foreseeable emergencies. Workers such as office workers or bank tellers who encounter hazardous chemicals only in non-routine, isolated instances are not covered.

Employer means a person engaged in a business where chemicals are either used, distributed, or are produced for use or distribution, including a contractor or subcontractor.

Exposure or exposed means that an employee is subjected in the course of employment to a **hazardous** chemical [~~that is a physical or health hazard~~], and includes potential (e.g., accidental or possible) exposure. "Subjected" in terms of health hazards includes any route of entry (e.g., inhalation, ingestion, skin contact or absorption.)

Foreseeable emergency means any potential occurrence such as, but not limited to, equipment failure, rupture of containers, or failure of control equipment which could result in an uncontrolled release of a hazardous chemical into the workplace.

Gas means a substance which (i) At 122ºF (50°C) has a vapor pressure greater than 43.51 PSI (300 kPa) (absolute); or (ii) Is completely gaseous at 68ºF (20°C) at a standard pressure of 14.69 PSI (101.3 kPa).

Hazard category means the division of criteria within each hazard class, e.g., oral acute toxicity and flammable liquids include four hazard categories. These categories compare hazard severity within a hazard class and should not be taken as a comparison of hazard categories more generally.

Hazard class means the nature of the physical or health hazards, e.g., flammable solid, carcinogen, oral acute toxicity.

Hazard not otherwise classified (HNOC) means an adverse physical or health effect identified through evaluation of scientific evidence during the classification process that does not meet the specified criteria for the physical and health hazard classes addressed in this section. This does not extend coverage to adverse physical and health effects for which there is a hazard class addressed in this section, but the effect either falls below the cut-off value/concentration limit of the hazard class or is under a GHS hazard category that has not been adopted by OSHA (e.g., acute toxicity Category 5).

Hazard statement means a statement assigned to a hazard class and category that describes the nature of the hazard(s) of a chemical, including, where appropriate, the degree of hazard.

Hazardous chemical means any chemical which is classified as a physical hazard or a health hazard, a simple asphyxiant, combustible dust, [~~pyrophoric gas,~~] or hazard not otherwise classified.

Health hazard means a chemical which is classified as posing one of the following hazardous effects: acute toxicity (any route of exposure); skin corrosion or irritation; serious eye damage or eye irritation; respiratory or skin sensitization; germ cell mutagenicity; carcinogenicity; reproductive toxicity; specific target organ toxicity (single or repeated exposure); or aspiration hazard. The criteria for determining whether a chemical is classified as a health hazard are detailed in Appendix A to §1910.1200 -- Health Hazard Criteria.

Immediate outer package means the first package enclosing the container of hazardous chemical.

Immediate use means that the hazardous chemical will be under the control of and used only by the person who transfers it from a labeled container and only within the work shift in which it is transferred.

Importer means the first business with employees within the Customs Territory of the United States which receives hazardous chemicals produced in other countries for the purpose of supplying them to distributors or employers within the United States.

Label means an appropriate group of written, printed or graphic information elements concerning a hazardous chemical that is affixed to, printed on, or attached to the immediate container of a hazardous chemical, or to the outside packaging.

Label elements means the specified pictogram, hazard statement, signal word and precautionary statement for each hazard class and category.

Liquid means a substance or mixture which at 122ºF (50°C) has a vapor pressure of not more than 43.51 PSI (300 kPa (3 bar)), which is not completely gaseous at 68ºF (20°C) and at a standard pressure of 101.3 kPa, and which has a melting point or initial melting point of 68ºF (20°C) or less at a standard pressure of 14.69 PSI (101.3 kPa). Either ASTM D4359-90 (R2019) (incorporated by reference, see § 1910.6); or the test for determining fluidity (penetrometer test) prescribed in section 2.3.4 of ADR 2019 (incorporated by reference, see § 1910.6) can establish whether a viscous substance or mixture is a liquid if a specific melting point cannot be determined.

Mixture means a combination or a solution composed of two or more substances in which they do not react.

Physical hazard means a chemical that is classified as posing one of the following hazardous effects: explosive; flammable (gases, [~~aerosols~~,] liquids, or solids); **aerosols;** oxidizer **(gases, liquids, or solids**)[~~(liquid, solid or gas)~~]; self-reactive; pyrophoric (liquid or solid); self-heating; organic peroxide; corrosive to metal; gas under pressure; [~~or~~] in contact with water emits flammable gas**; or desensitized explosive**. [~~See Appendix B to §1910.1200 -- Physical Hazard Criteria.~~] **The criteria for determining whether a chemical is classified as a physical hazard are detailed in Appendix B to this section.**

Physician or other licensed health care professional (PLHCP) means an individual whose legally permitted scope of practice (i.e., license, registration, or certification) allows the individual to independently provide or be delegated the responsibility to provide some or all of the health care services referenced in paragraph (i) of this section.

Pictogram means a composition that may include a symbol plus other graphic elements, such as a border, background pattern, or color, that is intended to convey specific information about the hazards of a chemical. Eight pictograms are designated under this standard for application to a hazard category.

Precautionary statement means a phrase that describes recommended measures that should be taken to minimize or prevent adverse effects resulting from exposure to a hazardous chemical, or improper storage or handling.

Product identifier means the name or number used for a hazardous chemical on a label or in the SDS. It provides a unique means by which the user can identify the chemical. The product identifier used shall permit cross-references to be made among the list of hazardous chemicals required in the written hazard communication program, the label and the SDS.

Produce means to manufacture, process, formulate, blend, extract, generate, emit, or repackage.

[~~**Pyrophoric gas** means a chemical in a gaseous state that will ignite spontaneously in air at a temperature of 130 degrees F (54.4 degrees C) or below.~~]

Released for shipment means a chemical that has been packaged and labeled in the manner in which it will be distributed or sold.

Responsible party means someone who can provide additional information on the hazardous chemical and appropriate emergency procedures, if necessary.

Safety data sheet (SDS) means written or printed material concerning a hazardous chemical that is prepared in accordance with paragraph (g) of this section.

Signal word means a word used to indicate the relative level of severity of hazard and alert the reader to a potential hazard on the label. The signal words used in this section are “danger” and “warning.” “Danger” is used for the more severe hazards, while “warning” is used for the less severe.

Simple asphyxiant means a substance or mixture that displaces oxygen in the ambient atmosphere, and can thus cause oxygen deprivation in those who are exposed, leading to unconsciousness and death.

Solid means a substance or mixture which does not meet the definitions of liquid or gas.

Specific chemical identity means the chemical name, Chemical Abstracts Service (CAS) Registry Number, or any other information that reveals the precise chemical designation of the substance.

Substance means chemical elements and their compounds in the natural state or obtained by any production process, including any additive necessary to preserve the stability of the product and any impurities deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.

Trade secret means any confidential formula, pattern, process, device, information or compilation of information that is used in an employer's business, and that gives the employer an opportunity to obtain an advantage over competitors who do not know or use it. Appendix E to §1910.1200—Definition of Trade Secret, sets out the criteria to be used in evaluating trade secrets.

Use means to package, handle, react, emit, extract, generate as a byproduct, or transfer.

Work area means a room or defined space in a workplace where hazardous chemicals are produced or used, and where employees are present.

Workplace means an establishment, job site, or project, at one geographical location containing one or more work areas.

(d) [~~Hazard classification.~~]

(1)

(i) Chemical manufacturers and importers shall evaluate chemicals produced in their workplaces or imported by them to classify the chemicals in accordance with this section. For each chemical, the chemical manufacturer or importer shall determine the hazard classes, and where appropriate, the category of each class that apply to the chemical being classified. **The hazard classification shall include any hazards associated with the chemical's intrinsic properties including**:

(A) a change in the chemical's physical form and;

(B) chemical reaction products associated with known or reasonably anticipated uses or applications.

(ii) Employers are not required to classify chemicals unless they choose not to rely on the classification performed by the chemical manufacturer or importer for the chemical to satisfy this [~~requirement~~] **paragraph (d)(1)**.

(2) Chemical manufacturers, importers or employers classifying chemicals shall identify and consider the full range of available scientific literature and other evidence concerning the potential hazards. There is no requirement to test the chemical to determine how to classify its hazards. Appendix A to §1910.1200 shall be consulted for classification of health hazards, and Appendix B to §1910.1200 shall be consulted for the classification of physical hazards.

(3) Mixtures.

(i) Chemical manufacturers, importers, or employers evaluating chemicals shall follow the procedures described in Appendices A and B to §1910.1200 to classify the hazards of the chemicals, including determinations regarding when mixtures of the classified chemicals are covered by this section.

(ii) When classifying mixtures they produce or import, chemical manufacturers and importers of mixtures may rely on the information provided on the current safety data sheets of the individual ingredients except where the chemical manufacturer or importer knows, or in the exercise of reasonable diligence should know, that the safety data sheet misstates or omits information required by this section.

(e) Written hazard communication program.

(1) Employers shall develop, implement, and maintain at each workplace, a written hazard communication program which at least describes how the criteria specified in paragraphs (f), (g), and (h) of this section for labels and other forms of warning, safety data sheets, and employee information and training will be met, and which also includes the following:

(i) A list of the hazardous chemicals known to be present using a product identifier that is referenced on the appropriate safety data sheet (the list may be compiled for the workplace as a whole or for individual work areas); and,

(ii) The methods the employer will use to inform employees of the hazards of non-routine tasks (for example, the cleaning of reactor vessels), and the hazards associated with chemicals contained in unlabeled pipes in their work areas.

(2) Multi-employer workplaces. Employers who produce, use, or store hazardous chemicals at a workplace in such a way that the employees of other employer(s) may be exposed (for example, employees of a construction contractor working on-site) shall additionally ensure that the hazard communication programs developed and implemented under this paragraph (e) include the following:

(i) The methods the employer will use to provide the other employer(s) on-site access to safety data sheets for each hazardous chemical the other employer(s)' employees may be exposed to while working;

(ii) The methods the employer will use to inform the other employer(s) of any precautionary measures that need to be taken to protect employees during the workplace's normal operating conditions and in foreseeable emergencies; and,

(iii) The methods the employer will use to inform the other employer(s) of the labeling system used in the workplace.

(3) The employer may rely on an existing hazard communication program to comply with these requirements, provided that it meets the criteria established in this paragraph (e).

(4) The employer shall make the written hazard communication program available, upon request, to employees, their designated representatives, the

Assistant Secretary and the Director, in accordance with the requirements of [~~29 CFR~~] § 1910.1020(e).

(5) Where employees must travel between workplaces during a workshift, i.e., their work is carried out at more than one geographical location, the written hazard communication program may be kept at the primary workplace facility.

(f) Labels and other forms of warning.

(1) Labels on shipped containers. The chemical manufacturer, importer, or distributor shall ensure that each container of hazardous chemicals leaving the workplace is labeled, tagged or marked. Hazards not otherwise classified **and hazards identified and classified under (d)(1)(ii)** do not have to be addressed on the container. Where the chemical manufacturer**,** [~~or~~] importer**, or distributor** is required to label, tag or mark the following shall be provided:

(i) Product identifier;

(ii) Signal word;

(iii) Hazard statement(s);

(iv) Pictogram(s);

(v) Precautionary statement(s); [~~and~~]

(vi) Name, **U.S.** address, and **U.S.** telephone number of the chemical manufacturer, importer, or other responsible party.

(2) The chemical manufacturer, importer, or distributor shall ensure that the information provided under paragraphs (f)(1)(i) through (v) of this section is in accordance with Appendix C, Allocation of Label Elements, for each hazard class and associated hazard category for the hazardous chemical, prominently displayed, and in English (other languages may also be included if appropriate).

(3) The chemical manufacturer, importer, or distributor shall ensure that the information provided under paragraphs (f)(1)(ii) through (iv) of this section is located together on the label, tag, or mark.

(4) Solid materials.

(i) For solid metal (such as a steel beam or a metal casting), solid wood, or plastic items that are not exempted as articles due to their downstream use, or shipments of whole grain, the required label may be transmitted to the customer at the time of the initial shipment, and need not be included with subsequent shipments to the same employer unless the information on the label changes;

(ii) The label may be transmitted with the initial shipment itself, or with the safety data sheet that is to be provided prior to or at the time of the first shipment; and,

(iii) This exception to requiring labels on every container of hazardous chemicals is only for the solid material itself, and does not apply to hazardous chemicals used in conjunction with, or known to be present with, the material and to which employees handling the items in transit may be exposed (for example, cutting fluids or pesticides in grains).

(5) Transportation.

(i) Chemical manufacturers, importers, or distributors shall ensure that each container of hazardous chemicals leaving the workplace is labeled, tagged, or marked in accordance with this section in a manner which does not conflict with the requirements of the Hazardous Materials Transportation Act (49 U.S.C. [~~1801~~] **5101** et seq.) and regulations issued under that Act by the Department of Transportation **(49 CFR subtitle B)**.

(ii) The label for bulk shipments of hazardous chemicals must be on the immediate container, transmitted with the shipping papers or the bills of lading, or, with the agreement of the receiving entity, transmitted by technological or electronic means so that it is immediately available to workers in printed form on the receiving end of shipment.

(iii) Where a pictogram required by the Department of Transportation under title 49 of the Code of Federal Regulations appears on a shipped container, the pictogram specified in appendix C.4 to this section for the same hazard is not required on the label.

(6) Workplace labeling. Except as provided in paragraphs (f)(7) and (f)(8) of this section, the employer shall ensure that each container of hazardous chemicals in the workplace is labeled, tagged or marked with either:

(i) The information specified under paragraphs (f)(1)(i) through (v) of this section for labels on shipped containers; or,

(ii) Product identifier and words, pictures, symbols, or combination thereof, which provide at least general information regarding the hazards of the chemicals, and which, in conjunction with the other information immediately available to employees under the hazard communication program, will provide employees with the specific information regarding the physical and health hazards of the hazardous chemical.

(7) The employer may use signs, placards, process sheets, batch tickets, operating procedures, or other such written materials in lieu of affixing labels to individual stationary process containers, as long as the alternative method identifies the containers to which it is applicable and conveys the information required by paragraph (f)(6) of this section to be on a label. The employer shall ensure the written materials are readily accessible to the employees in their work area throughout each work shift.

(8) The employer is not required to label portable containers into which hazardous chemicals are transferred from labeled containers, and which are intended only for the immediate use of the employee who performs the transfer. For purposes of this section, drugs which are dispensed by a pharmacy to a health care provider for direct administration to a patient are exempted from labeling.

(9) The employer shall not remove or deface existing labels on incoming containers of hazardous chemicals, unless the container is immediately marked with the required information.

(10) The employer shall ensure that workplace labels or other forms of warning are legible, in English, and prominently displayed on the container, or readily available in the work area throughout each work shift. Employers having employees who speak other languages may add the information in their language to the material presented, as long as the information is presented in English as well.

(11) **Label Updates.**

(i) Chemical manufacturers, importers, distributors, or employers who become newly aware of any significant information regarding the hazards of a chemical shall revise the labels for the chemical within six months of becoming aware of the new information, and shall ensure that labels on containers of hazardous chemicals shipped after that time contain the new information. [~~If the chemical is not currently produced or imported, the chemical manufacturer, importer, distributor, or employer shall add the information to the label before the chemical is shipped or introduced into the workplace again.~~] **For chemicals that have been released for shipment and are awaiting future distribution, chemical manufacturers, importers, distributors, or employers have the option not to relabel those containers; however, if they do not relabel the containers, they must either provide the updated label for each individual container with each shipment or, with the agreement of the receiving entity, transmit the labels by electronic or other technological means.**

(ii) If the chemical is not currently produced or imported, the chemical manufacturer, importer, distributor, or employer shall add the information to the label before the chemical is shipped or introduced into the workplace again.

(12) Small container labelling.

(i) This paragraph applies where the chemical manufacturer, importer, or distributor can demonstrate that it is not feasible to use pullout labels, fold-back labels, or tags containing the full label information required by paragraph (f)(1) of this section.

(ii) For a container less than or equal to 100 ml capacity, the chemical manufacturer, importer, or distributor must include, at a minimum, the following information on the label of the container:

(A) Product identifier;

(B) Pictogram(s);

(C) Signal word;

(D) Chemical manufacturer’s name and phone number; and

(E) A statement that the full label information for the hazardous chemical is provided on the immediate outer package.

(iii) For a container less than or equal to 3 ml capacity, where the chemical manufacturer, importer, or distributor can demonstrate that any label interferes with the normal use of the container, no label is required, but the container must bear, at a minimum, the product identifier.

(iv) For all small containers covered by paragraph (f)(12)(ii) or (iii) of this section, the immediate outer package must include:

(A) The full label information required by paragraph (f)(1) of this section for each hazardous chemical in the immediate outer package. The label must not be removed or defaced, as required by paragraph (f)(9) of this section.

(B) A statement that the small container(s) inside must be stored in the immediate outer package bearing the complete label when not in use.

(g) Safety data sheets.

(1) Chemical manufacturers and importers shall obtain or develop a safety data sheet for each hazardous chemical they produce or import. Employers shall have a safety data sheet in the workplace for each hazardous chemical which they use.

(2) The chemical manufacturer or importer [~~preparing the safety data sheet~~] shall ensure that [~~it~~]**the safety data sheet** is in English (although the employer may maintain copies in other languages as well), and includes at least the following section numbers and headings, and associated information under each heading, in the order listed ~~[(See Appendix D to §1910.1200--Safety Data Sheets~~]**(see appendix D to this section**, for the specific content of each section of the safety data sheet):

(i) Section 1, Identification;

(ii) Section 2, Hazard(s) identification;

(iii) Section 3, Composition/information on ingredients;

(iv) Section 4, First-aid measures;

(v) Section 5, Fire-fighting measures;

(vi) Section 6, Accidental release measures;

(vii) Section 7, Handling and storage;

(viii) Section 8, Exposure controls/personal protection;

(ix) Section 9, Physical and chemical properties;

(x) Section 10, Stability and reactivity;

(xi) Section 11, Toxicological information.

(xii) Section 12, Ecological information;

(xiii) Section 13, Disposal considerations;

(xiv) Section 14, Transport information;

(xv) Section 15, Regulatory information; and

(xvi) Section 16, Other information, including date of preparation or last revision.

Note 1 to paragraph (g)(2): To be consistent with the GHS, an SDS must also include the headings in paragraphs (g)(2)(xii) through (g)(2)(xv) **of this section** in order.

Note 2 to paragraph (g)(2): OSHA will not be enforcing information requirements in sections 12 through 15, as these areas are not under its jurisdiction.

(3) If no relevant information is found for any sub-heading within a section on the safety data sheet, the chemical manufacturer, importer or employer preparing the safety data sheet shall mark it to indicate that no applicable information was found.

(4) Where complex mixtures have similar hazards and contents (i.e. the chemical ingredients are essentially the same, but the specific composition varies from mixture to mixture), the chemical manufacturer, importer or employer may prepare one safety data sheet to apply to all of these similar mixtures.

(5) The chemical manufacturer, importer or employer preparing the safety data sheet shall ensure that the information provided accurately reflects the scientific evidence used in making the hazard classification. If the chemical manufacturer, importer or employer preparing the safety data sheet becomes newly aware of any significant information regarding the hazards of a chemical, or ways to protect against the hazards, this new information shall be added to the safety data sheet within three months. If the chemical is not currently being produced or imported the chemical manufacturer or importer shall add the information to the safety data sheet before the chemical is introduced into the workplace again.

(6)

(i) Chemical manufacturers or importers shall ensure that distributors and employers are provided an appropriate safety data sheet with their initial shipment, and with the first shipment after a safety data sheet is updated;

(ii) The chemical manufacturer or importer shall either provide safety data sheets with the shipped containers or send them to the distributor or employer prior to or at the time of the shipment;

(iii) If the safety data sheet is not provided with a shipment that has been labeled as a hazardous chemical, the distributor or employer shall obtain one from the chemical manufacturer or importer as soon as possible; and,

(iv) The chemical manufacturer or importer shall also provide distributors or employers with a safety data sheet upon request.

(7)

(i) Distributors shall ensure that safety data sheets, and updated information, are provided to other distributors and employers with their initial shipment and with the first shipment after a safety data sheet is updated;

(ii) The distributor shall either provide safety data sheets with the shipped containers, or send them to the other distributor or employer prior to or at the time of the shipment;

(iii) Retail distributors selling hazardous chemicals to employers having a commercial account shall provide a safety data sheet to such employers upon request, and shall post a sign or otherwise inform them that a safety data sheet is available;

(iv) Wholesale distributors selling hazardous chemicals to employers over-the-counter may also provide safety data sheets upon the request of the employer at the time of the over-the-counter purchase, and shall post a sign or otherwise inform such employers that a safety data sheet is available;

(v) If an employer without a commercial account purchases a hazardous chemical from a retail distributor not required to have safety data sheets on file (i.e., the retail distributor does not have commercial accounts and does not use the materials), the retail distributor shall provide the employer, upon request, with the name, address, and telephone number of the chemical manufacturer, importer, or distributor from which a safety data sheet can be obtained;

(vi) Wholesale distributors shall also provide safety data sheets to employers or other distributors upon request; and,

(vii) Chemical manufacturers, importers, and distributors need not provide safety data sheets to retail distributors that have informed them that the retail distributor does not sell the product to commercial accounts or open the sealed container to use it in their own workplaces.

(8) The employer shall maintain in the workplace copies of the required safety data sheets for each hazardous chemical, and shall ensure that they are readily accessible during each work shift to employees when they are in their work area(s). (Electronic access and other alternatives to maintaining paper copies of the safety data sheets are permitted as long as no barriers to immediate employee access in each workplace are created by such options.)

(9) Where employees must travel between workplaces during a workshift, i.e., their work is carried out at more than one geographical location, the safety data sheets may be kept at the primary workplace facility. In this situation, the employer shall ensure that employees can immediately obtain the required information in an emergency.

(10) Safety data sheets may be kept in any form, including **as** operating procedures, and may be [~~designed~~]**stored in such a way** to cover groups of hazardous chemicals in a work area where it may be more appropriate to address the hazards of a process rather than individual hazardous chemicals. However, the employer shall ensure that in all cases the required information is provided for each hazardous chemical, and is readily accessible during each work shift to employees when they are in their work area(s).

(11) Safety data sheets shall also be made readily available, upon request, to designated representatives, the Assistant Secretary, and the Director, in accordance with the requirements of 29 CFR 1910.1020(e).

(h) Employee information and training.

(1) Employers shall provide employees with effective information and training on hazardous chemicals in their work area at the time of their initial assignment, and whenever a new chemical hazard the employees have not previously been trained about is introduced into their work area. Information and training may be designed to cover categories of hazards (e.g., flammability, carcinogenicity) or specific chemicals. Chemical-specific information must always be available through labels and safety data sheets.

(2) Information. Employees shall be informed of:

(i) The requirements of this section;

(ii) Any operations in their work area where hazardous chemicals are present; and,

(iii) The location and availability of the written hazard communication program, including the required list(s) of hazardous chemicals, and safety data sheets required by this section.

(3) Training. Employee training shall include at least:

(i) Methods and observations that may be used to detect the presence or release of a hazardous chemical in the work area (such as monitoring conducted by the employer, continuous monitoring devices, visual appearance or odor of hazardous chemicals when being released, etc.);

(ii) The physical, health, simple asphyxiation, combustible dust, and pyrophoric gas hazards, as well as hazards not otherwise classified, of the chemicals in the work area;

(iii) The measures employees can take to protect themselves from these hazards, including specific procedures the employer has implemented to protect employees from exposure to hazardous chemicals, such as appropriate work practices, emergency procedures, and personal protective equipment to be used; and,

(iv) The details of the hazard communication program developed by the employer, including an explanation of the labels received on shipped containers and the workplace labeling system used by their employer; the safety data sheet, including the order of information and how employees can obtain and use the appropriate hazard information.

(i) Trade secrets.

(1) The chemical manufacturer, importer, or employer may withhold the specific chemical identity, including the chemical name, other specific identification of a hazardous chemical, [~~or~~]**and/or** the exact percentage (concentration) **or concentration range** of the substance in a mixture, from **section 3 of** the safety data sheet, provided that:

(i) The claim that the information withheld is a trade secret can be supported;

(ii) Information contained in the safety data sheet concerning the properties and effects of the hazardous chemical is disclosed;

(iii) The safety data sheet indicates that the specific chemical identity and/or [~~percentage~~] **concentration or concentration range** of composition is being withheld as a trade secret; [~~and,~~]

(iv) [~~The specific chemical identity and percentage is made available to health professionals, employees, and designated representatives in accordance with the applicable provisions of this paragraph (i).~~] **If the concentration or concentration range is being claimed as a trade secret then the safety data sheet provides the ingredient's concentration as one of the prescribed ranges below in paragraphs (i)(1)(iv)(A) through (M) of this section.**

(A) from 0.1% to 1%;

(B) from 0.5% to 1.5%;

(C) from 1% to 5%;

(D) from 3% to 7%;

(E) from 5% to 10%;

(F) from 7% to 13%;

(G) from 10% to 30%;

(H) from 15% to 40%;

(I) from 30% to 60%;

(J) from 45% to 70%;

(K) from 60% to 80%;

(L) from 65% to 85%; and

(M) from 80% to 100%.

(v) The prescribed concentration range used must be the narrowest range possible. If the exact concentration range falls between 0.1% and 30% and does not fit entirely into one of the prescribed concentration ranges of paragraphs (i)(1)(iv)(A) to (G) of this section, a single range created by the combination of two applicable consecutive ranges between paragraphs (i)(1)(iv)(A) and (G) of this section may be disclosed instead, provided that the combined concentration range does not include any range that falls entirely outside the exact concentration range in which the ingredient is present.

(vi) Manufacturers may provide a range narrower than those prescribed in (i)(1)(v).

(vii) The specific chemical identity and exact concentration or concentration range is made available to health professionals, employees, and designated representatives in accordance with the applicable provisions of this paragraph (i) of this section.

(2) Where a treating [~~physician or nurse~~] **PLHCP** determines that a medical emergency exists and the specific chemical identity and/or specific [~~percentage of composition~~] **concentration or concentration range** of a hazardous chemical is necessary for emergency or first-aid treatment, the chemical manufacturer, importer, or employer shall immediately disclose the specific chemical identity or percentage composition of a trade secret chemical to that treating [~~physician or nurse~~] **PLHCP**, regardless of the existence of a written statement of need or a confidentiality agreement. The chemical manufacturer, importer, or employer may require a written statement of need and confidentiality agreement, in accordance with the provisions of paragraphs (i)(3) and (4) of this section, as soon as circumstances permit.

(3) In non-emergency situations, a chemical manufacturer, importer, or employer shall, upon request, disclose a specific chemical identity or [~~percentage composition~~] **exact concentration or concentration range**, otherwise permitted to be withheld under paragraph (i)(1) of this section, to a health professional (**e.g.,** ~~physician~~ **PLHCP**, industrial hygienist, toxicologist, **or** epidemiologist[~~, or occupational health nurse~~]) providing medical or other occupational health services to exposed employee(s), and to employees or designated representatives, if:

(i) The request is in writing;

(ii) The request describes with reasonable detail one or more of the following occupational health needs for the information:

(A) To assess the hazards of the chemicals to which employees will be exposed;

(B) To conduct or assess sampling of the workplace atmosphere to determine employee exposure levels;

(C) To conduct pre-assignment or periodic medical surveillance of exposed employees;

(D) To provide medical treatment to exposed employees;

(E) To select or assess appropriate personal protective equipment for exposed employees;

(F) To design or assess engineering controls or other protective measures for exposed employees; and,

To conduct studies to determine the health effects of exposure.

(iii) The request explains in detail why the disclosure of the specific chemical identity or percentage composition is essential and that, in lieu thereof, the disclosure of the following information to the health professional, employee, or designated representative, would not satisfy the purposes described in paragraph (i)(3)(ii) of this section:

(A) The properties and effects of the chemical;

(B) Measures for controlling workers' exposure to the chemical;

(C) Methods of monitoring and analyzing worker exposure to the chemical; and,

(D) Methods of diagnosing and treating harmful exposures to the chemical;

(iv) The request includes a description of the procedures to be used to maintain the confidentiality of the disclosed information; and,

(v) The health professional, and the employer or contractor of the services of the health professional (i.e. downstream employer, labor organization, or individual employee), employee, or designated representative, agree in a written confidentiality agreement that the health professional, employee, or designated representative, will not use the trade secret information for any purpose other than the health need(s) asserted and agree not to release the information under any circumstances other than to OSHA, as provided in paragraph (i)(6) of this section, except as authorized by the terms of the agreement or by the chemical manufacturer, importer, or employer.

(4) The confidentiality agreement authorized by paragraph (i)(3)(iv) of this section:

(i) May restrict the use of the information to the health purposes indicated in the written statement of need;

(ii) May provide for appropriate legal remedies in the event of a breach of the agreement, including stipulation of a reasonable pre-estimate of likely damages; and,

(iii) May not include requirements for the posting of a penalty bond.

(5) Nothing in this standard is meant to preclude the parties from pursuing non-contractual remedies to the extent permitted by law.

(6) If the health professional, employee, or designated representative receiving the trade secret information decides that there is a need to disclose it to OSHA, the chemical manufacturer, importer, or employer who provided the information shall be informed by the health professional, employee, or designated representative prior to, or at the same time as, such disclosure.

(7) If the chemical manufacturer, importer, or employer denies a written request for disclosure of a specific chemical identity or percentage composition, the denial must:

(i) Be provided to the health professional, employee, or designated representative, within thirty days of the request;

(ii) Be in writing;

(iii) Include evidence to support the claim that the specific chemical identity or percent of composition is a trade secret;

(iv) State the specific reasons why the request is being denied; and,

(v) Explain in detail how alternative information may satisfy the specific medical or occupational health need without revealing the trade secret.

(8) The health professional, employee, or designated representative whose request for information is denied under paragraph (i)(3) of this section may refer the request and the written denial of the request to OSHA for consideration.

(9) When a health professional, employee, or designated representative refers the denial to OSHA under paragraph (i)(8) of this section, OSHA shall consider the evidence to determine if:

(i) The chemical manufacturer, importer, or employer has supported the claim that the specific chemical identity or percentage composition is a trade secret;

(ii) The health professional, employee, or designated representative has supported the claim that there is a medical or occupational health need for the information; and,

(iii) The health professional, employee or designated representative has demonstrated adequate means to protect the confidentiality.

(10)

(i) If OSHA determines that the specific chemical identity or percentage composition requested under paragraph (i)(3) of this section is not a "bona fide" trade secret, or that it is a trade secret, but the requesting health professional, employee, or designated representative has a legitimate medical or occupational health need for the information, has executed a written confidentiality agreement, and has shown adequate means to protect the confidentiality of the information, the chemical manufacturer, importer, or employer will be subject to citation by OSHA.

(ii) If a chemical manufacturer, importer, or employer demonstrates to OSHA that the execution of a confidentiality agreement would not provide sufficient protection against the potential harm from the unauthorized disclosure of a trade secret, the Assistant Secretary may issue such orders or impose such additional limitations or conditions upon the disclosure of the requested chemical information as may be appropriate to assure that the occupational health services are provided without an undue risk of harm to the chemical manufacturer, importer, or employer.

(11) If a citation for a failure to release trade secret information is contested by the chemical manufacturer, importer, or employer, the matter will be adjudicated before the Occupational Safety and Health Review Commission in accordance with the Act's enforcement scheme and the applicable Commission rules of procedure. In accordance with the Commission rules, when a chemical manufacturer, importer, or employer continues to withhold the information during the contest, the Administrative Law Judge may review the citation and supporting documentation "in camera" or issue appropriate orders to protect the confidentiality of such matters.

(12) Notwithstanding the existence of a trade secret claim, a chemical manufacturer, importer, or employer shall, upon request, disclose to the Assistant Secretary any information which this section requires the chemical manufacturer, importer, or employer to make available. Where there is a trade secret claim, such claim shall be made no later than at the time the information is provided to the Assistant Secretary so that suitable determinations of trade secret status can be made and the necessary protections can be implemented.

(13) Nothing in this paragraph shall be construed as requiring the disclosure under any circumstances of process information which is a trade secret.

(j) [~~Effective~~] [~~d~~]Dates.

(1) ~~Employers shall train employees regarding the new label elements and safety data sheets format by December 1, 2013~~ **Effective date. This section shall become effective July 19, 2024.**

(2) **Substances.** [~~Chemical manufacturers, importers, distributors, and employers shall be in compliance with all modified provisions of this section no later than June 1, 2015, except:~~]

(i) [~~After December 1, 2015, the distributor shall not ship containers labeled by the chemical manufacturer or importer unless the label has been modified to comply with paragraph (f)(1) of this section.~~] **Manufacturers, importers, and distributors, evaluating substances shall be in compliance with all modified provisions of this section no later than January 19, 2026.**

(ii) [~~All employers shall, as necessary, update any alternative workplace labeling used under paragraph (f)(6) of this section, update the hazard communication program required by paragraph (h)(1), and provide any additional employee training in accordance with paragraph (h)(3) for newly identified physical or health hazards no later than June 1, 2016.~~] **For substances, all employers shall, as necessary, update any alternative workplace labeling used under paragraph (f)(6) of this section, update the hazard communication program required by paragraph (h)(1) of this section, and provide any additional employee training in accordance with paragraph (h)(3) of this section for newly identified**

physical hazard, or health hazards or other hazards covered under this section no later than July 20, 2026.

(3) Mixtures. [~~Chemical manufacturers, importers, distributors, and employers may comply with either §1910.1200 revised as of October 1, 2011, or the current version of this standard, or both during the transition period.~~]

(i) Chemical manufacturers, importers, and distributors evaluating mixtures shall be in compliance with all modified provisions of this section no later than July 19, 2027.

(ii) For mixtures, all employers shall, as necessary, update any alternative workplace labeling used under paragraph (f)(6) of this section, update the hazard communication program required by paragraph (h)(1) of this section, and provide any additional employee training in accordance with paragraph (h)(3) of this section for newly identified physical hazards, health hazards, or other hazards covered under this section no later than January 19, 2028.

(4) Compliance. Between May 20, 2024 and the dates specified in paragraphs (j)(2) and (3) of this section, as applicable, chemical manufacturers, importers, distributors, and employers may comply with either this section or § 1910.1200 revised as of July 1, 2023, or both during the transition period.

(Approved by the Office of Management and Budget under control number 1218-0072)

Stat. Auth: ORS 654.025(2) and 656.726(4).
Stats. Implemented: ORS 654.001 through 654.295.
Hist: OR-OSHA Admin. Order 12-1993, f. 8/20/93, ef. 11/1/93.
OR-OSHA Admin. Order 4-1994, f. 8/4/94, ef. 8/4/94.
OR-OSHA Admin. Order 5-1995, f. 4/6/95, ef. 4/6/95.
OR-OSHA Admin. Order 4-1997, f. 4/2/97, ef. 4/2/97.
OR-OSHA Admin. Order 5-2012, f. 9/25/12, ef. 9/25/12.
OR-OSHA Admin. Order 4-2013, f. 7/19/13, ef. 7/19/13.

Appendix A to §1910.1200 – Health Hazard Criteria (Mandatory)

A.0 GENERAL CLASSIFICATION CONSIDERATIONS

A.0.1 Classification

A.0.1.1 The term “hazard classification” is used to indicate that only the intrinsic hazardous properties of chemicals are considered. Hazard classification incorporates three steps:

(a) Identification of relevant data regarding the hazards of a chemical;

(b) Subsequent review of those data to ascertain the hazards associated with the chemical;

(c) Determination of whether the chemical will be classified as hazardous and the degree of hazard.

A.0.1.2 For many hazard classes, the criteria are semi-quantitative or qualitative and expert judgment is required to interpret the data for classification purposes.

A.0.1.3 Where impurities, additives or individual constituents of a substance or mixture have been identified and are themselves classified, they should be taken into account during classification if they exceed the cut-off value/concentration limit for a given hazard class.

A.0.2 Available data, test methods and test data quality

A.0.2.1 There is no requirement for testing chemicals.

A.0.2.2 The criteria for determining health hazards are test method neutral, i.e., they do not specify particular test methods, as long as the methods are scientifically validated.

A.0.2.3 The term “scientifically validated” refers to the process by which the reliability and the relevance of a procedure are established for a particular purpose. Any test that determines hazardous properties, which is conducted according to recognized scientific principles, can be used for purposes of a hazard determination for health hazards. Test conditions need to be standardized so that the results are reproducible with a given substance, and the standardized test yields “valid” data for defining the hazard class of concern.

A.0.2.4 Existing test data are acceptable for classifying chemicals, although expert judgment also may be needed for classification purposes.

A.0.2.5 The effect of a chemical on biological systems is influenced, by the physico-chemical properties of the substance and/or ingredients of the mixture and the way in which ingredient substances are biologically available. A chemical need not be classified when it can be shown by conclusive experimental data from scientifically validated test methods that the chemical is not biologically available.

A.0.2.6 For classification purposes, epidemiological data and experience on the effects of chemicals on humans (e.g., occupational data, data from accident databases) shall be taken into account in the evaluation of human health hazards of a chemical.

A.0.3 Classification based on weight of evidence

A.0.3.1 For some hazard classes, classification results directly when the data satisfy the criteria. For others, classification of a chemical shall be determined on the basis of the total weight of evidence using expert judgment. This means that all available information bearing on the classification of hazard shall be considered together, including the results of valid *in vitro* tests, relevant animal data, and human experience such as epidemiological and clinical studies and well-documented case reports and observations.

A.0.3.2 The quality and consistency of the data shall be considered. Information on chemicals related to the material being classified shall be considered as appropriate, as well as site of action and mechanism or mode of action study results. Both positive and negative results shall be considered together in a single weight-of-evidence determination.

A.0.3.3 Positive effects which are consistent with the criteria for classification, whether seen in humans or animals, shall normally justify classification. Where evidence is available from both humans and animals and there is a conflict between the findings, the quality and reliability of the evidence from both sources shall be evaluated in order to resolve the question of classification. Reliable, good quality human data shall generally have precedence over other data. However, even well-designed and conducted epidemiological studies may lack a sufficient number of subjects to detect relatively rare but still significant effects, or to assess potentially confounding factors. Therefore, positive results from well-conducted animal studies are not necessarily negated by the lack of positive human experience but require an assessment of the robustness, quality and statistical power of both the human and animal data.

A.0.3.4 Route of exposure, mechanistic information, and metabolism studies are pertinent to determining the relevance of an effect in humans. When such information raises doubt about relevance in humans, a lower classification may be warranted. When there is scientific evidence demonstrating that the mechanism or mode of action is not relevant to humans, the chemical should not be classified.

A.0.3.5 Both positive and negative results are considered together in the weight of evidence determination. However, a single positive study performed according to good scientific principles and with statistically and biologically significant positive results may justify classification.

A.0.4 Considerations for the classification of mixtures

A.0.4.1 [~~For most hazard classes~~] **Except as provided in A.0.4.2**, the [~~recommended~~] process of classification of mixtures is based on the following sequence:

(a) Where test data are available for the complete mixture, the classification of the mixture will always be based on those data;

(b) Where test data are not available for the mixture itself, the bridging principles designated in each health hazard chapter of this appendix shall be considered for classification of the mixture;

(c) If test data are not available for the mixture itself, and the available information is not sufficient to allow application of the above-mentioned bridging principles, then the method(s) described in each chapter for estimating the hazards based on the information known will be applied to classify the mixture (e.g., application of cut-off values/concentration limits).

A.0.4.2 An exception to the above order or precedence is made for Carcinogenicity, Germ Cell Mutagenicity, and Reproductive Toxicity. For these three hazard classes, mixtures shall be classified based upon information on the ingredient substances, unless on a case-by-case basis, justification can be provided for classifying based upon the mixture as a whole. See [~~chapters~~] A.5, A.6, and A.7 **of this section** for further information on case-by-case bases.

A.0.4.3 Use of cut-off values/concentration limits:

A.0.4.3.1 When classifying an untested mixture based on the hazards of its ingredients, cut-off values/concentration limits for the classified ingredients of the mixture are used for several hazard classes. While the adopted cut-off values/concentration limits adequately identify the hazard for most mixtures, there may be some that contain hazardous ingredients at lower concentrations than the specified cut-off values/concentration limits that still pose an identifiable hazard. There may also be cases where the cut-off value/concentration limit is considerably lower than the established non-hazardous level for an ingredient.

A.0.4.3.2 If the classifier has information that the hazard of an ingredient will be evident (i.e., it presents a health risk) below the specified cut-off value/concentration limit, the mixture containing that ingredient shall be classified accordingly.

A.0.4.3.3 In exceptional cases, conclusive data may demonstrate that the hazard of an ingredient will not be evident (i.e., it does not present a health risk) when present at a level above the specified cut-off value/concentration limit(s). In these cases the mixture may be classified according to those data. The data must exclude the possibility that the ingredient will behave in the mixture in a manner that would increase the hazard over that of the pure substance. Furthermore, the mixture must not contain ingredients that would affect that determination.

A.0.4.4 Synergistic or antagonistic effects:

When performing an assessment in accordance with these requirements, the evaluator must take into account all available information about the potential occurrence of synergistic effects among the ingredients of the mixture. Lowering classification of a mixture to a less hazardous category on the basis of antagonistic effects may be done only if the determination is supported by sufficient data.

A.0.5 Bridging principles for the classification of mixtures where test data are not available for the complete mixture

A.0.5.1 Where the mixture itself has not been tested to determine its toxicity, but there are sufficient data on both the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data shall be used in accordance with the following bridging principles, subject to any specific provisions for mixtures for each hazard class. These principles ensure that the classification process uses the available data to the greatest extent possible in characterizing the hazards of the mixture.

A.0.5.1.1 Dilution[~~:~~]

For mixtures classified in accordance with A.1 through A.10 of this Appendix, if a tested mixture is diluted with a diluent that has an equivalent or lower toxicity classification than the least toxic original ingredient, and which is not expected to affect the toxicity of other ingredients, then:

(a) The new diluted mixture shall be classified as equivalent to the original tested mixture; or

(b) For classification of acute toxicity in accordance with A.1 of this Appendix, paragraph A.1.3.6 (the additivity formula) shall be applied.

A.0.5.1.2 Batching[~~:~~]

For mixtures classified in accordance with A.1 through A.10 of this Appendix, the toxicity of a tested production batch of a mixture can be assumed to be substantially equivalent to that of another untested production batch of the same mixture, when produced by or under the control of the same *chemical manufacturer*, unless there is reason to believe there is significant variation such that the toxicity of the untested batch has changed. If the latter occurs, a new classification is necessary.

A.0.5.1.3 Concentration of mixtures[~~:~~]

For mixtures classified in accordance with A.1, A.2, A.3, **A.4,** A.8, A.9, or A.10 of this Appendix, if a tested mixture is classified in Category 1, and the concentration of the ingredients of the tested mixture that are in Category 1 is increased, the resulting untested mixture shall be classified in Category 1.

A.0.5.1.4 Interpolation within one [~~toxicity~~] hazard category[~~:~~]

For mixtures classified in accordance with A.1, A.2, A.3, **A.4**, A.8, A.9, or A.10 of this Appendix, for three mixtures (A, B and C) with identical ingredients, where mixtures A and B have been tested and are in the same [~~toxicity~~] **hazard** category, and where untested mixture C has the same toxicologically active ingredients as mixtures A and B but has concentrations of toxicologically active ingredients intermediate to the concentrations in mixtures A and B, then mixture C is assumed to be in the same [~~toxicity~~] **hazard** category as A and B.

A.0.5.1.5 Substantially similar mixtures

For mixtures classified in accordance with A.1 through A.10 of this Appendix, given the following set of conditions:

(a) Where there are two mixtures:

(i) A + B;

(ii) C + B;

(b) The concentration of ingredient B is essentially the same in both mixtures;

(c) The concentration of ingredient A in mixture (i) equals that of ingredient C in mixture (ii);

(d) And data on toxicity for A and C are available and substantially equivalent; i.e., they are in the same hazard category and are not expected to affect the toxicity of B; then

If mixture (i) or (ii) is already classified based on test data, the other mixture can be assigned the same hazard category.

A.0.5.1.6 Aerosols

For mixtures classified in accordance with A.1, A.2, A.3, A.4, A.8, or A.9 of this Appendix, an aerosol form of a mixture shall be classified in the same hazard category as the tested, non-aerosolized form of the mixture, provided the added propellant does not affect the toxicity of the mixture when spraying.

A.1 ACUTE TOXICITY

A.1.1 Definition

Acute toxicity refers to [~~those~~] **serious** adverse **health** effects **(i.e., lethality)** occurring [~~following~~] **after a single or short-term** oral**,** ~~or~~ dermal**, or inhalation** [~~administration of a single dose of a substance, or multiple doses given within 24 hours, or an inhalation~~] exposure [~~of 4 hours~~]**to a substance or mixture**.

A.1.2 Classification criteria for substances

A.1.2.1 Substances can be allocated to one of four [~~toxicity~~] **hazard** categories based on acute toxicity by the oral, dermal or inhalation route according to the numeric cut-off criteria as shown in Table A.1.1. Acute toxicity values are expressed as (approximate) LD$_{50}$ (oral, dermal) or LC$_{50}$ (inhalation) values or as acute toxicity estimates (ATE). **While some *in vivo* methods determine LD50/LC50 values directly, other newer *in vivo* methods (e.g., using fewer animals) consider other indicators of acute toxicity, such as significant clinical signs of toxicity, which are used by reference to assign the hazard category.** See the footnotes following Table A.1.1 for further explanation on the application of these values.

Table A.1.1: Acute toxicity [~~hazard categories and acute~~] estimate (ATE) values ~~defining the respective categories~~] and criteria for acute toxicity hazard categories

Exposure route		Category 1	Category 2	Category 3	Category 4
Oral (mg/kg bodyweight)		**ATE** ≤ 5	>5 **ATE** [~~and~~] ≤ 50	>50 **ATE** [~~and~~] ≤ 300	>300 **ATE** [~~and~~] ≤ 2000
see:	*Note (a)* *Note (b)*				

Dermal (mg/kg bodyweight)	*see:*	*Note (a)* *Note (b)*	**ATE** ≤ 5	>50 **ATE** [~~and~~] ≤ 200	>200 **ATE** [~~and~~] ≤ 1000	>1000 **ATE** [~~and~~] ≤ 2000
Inhalation - Gases (ppmV)	*see:*	*Note (a)* *Note (b)* *Note (c)*	**ATE** ≤ 100	>100 **ATE** [~~and~~] ≤ 500	>500 **ATE** [~~and~~] ≤ 2500	>2500 **ATE** [~~and~~] ≤ 20000
Inhalation - Vapors (mg/l)	*see:*	*Note (a)* *Note (b)* *Note (c)* *Note (d)*	**ATE** ≤ 0.5	>0.5 **ATE** [~~and~~] ≤ 2.0	>2.0 **ATE** [~~and~~] ≤ 10.0	>10.0 **ATE** [~~and~~] ≤ 20.0
Inhalation – **Dusts and Mists** (mg/l)	*see:*	*Note (a)* *Note (b)* *Note (c)*	**ATE** ≤ 0.05	>0.05 **ATE** [~~and~~] ≤ 0.5	>0.5 **ATE** [~~and~~] ≤ 1.0	>1.0 **ATE** [~~and~~] ≤ 5.0

Note: Gas concentrations are expressed in parts per million per volume (ppmV).

Notes to Table A.1.1:

(a) The acute toxicity estimate (ATE) for the classification of a substance is derived using the LD_{50}/LC_{50} *where available;*

(b) The acute toxicity estimate (ATE) for the classification of a substance or ingredient in a mixture is derived using:

(i) the LD_{50}/LC_{50} *where available. Otherwise,*

(ii) the appropriate conversion value from Table 1.2 that relates to the results of a range test, or

(iii) the appropriate conversion value from Table 1.2 that relates to a classification category;

(c) Inhalation cut-off values in the table are based on 4 hour testing exposures. Conversion of existing inhalation toxicity data which has been generated according to 1 hour exposure is achieved by dividing by a factor of 2 for gases and vapors and 4 for dusts and mists;

(d) For some substances the test atmosphere will be a vapor which consists of a combination of liquid and gaseous phases. For other substances the test atmosphere may consist of a vapor which is nearly all the gaseous phase. In these latter cases, classification is based on ppmV as follows: Category 1 (100 ppmV), Category 2 (500 ppmV), Category 3 (2500 ppmV), Category 4 (20000 ppmV).

The terms "dust", "mist" and "vapor" are defined as follows:

> *(i) Dust: solid particles of a substance or mixture suspended in a gas (usually air);*
>
> *(ii) Mist: liquid droplets of a substance or mixture suspended in a gas (usually air);*
>
> *(iii) Vapor: the gaseous form of a substance or mixture released from its liquid or solid state.*

A.1.2.3 The preferred test species for evaluation of acute toxicity by the oral and inhalation routes is the rat, while the rat or rabbit are preferred for evaluation of acute dermal toxicity. Test data already generated for the classification of chemicals under existing systems should be accepted when reclassifying these chemicals under the harmonized system. When experimental data for acute toxicity are available in several animal species, scientific judgment should be used in selecting the most appropriate LD_{50} value from among scientifically validated tests. **In cases where data from human experience (i.e., occupational data, data from accident databases, epidemiology studies, clinical reports) is also available, it should be considered in a weight of evidence approach consistent with the principles described in A.0.3.**

A.1.2.4 In addition to classification for inhalation toxicity, if data are available that indicates that the mechanism of toxicity was corrosivity of the substance or mixture, the classifier must consider if the chemical is *corrosive to the respiratory tract*. Corrosion of the respiratory tract is defined as destruction of the respiratory tract tissue after a single, limited period of exposure analogous to skin corrosion; this includes destruction of the mucosa. The corrosivity evaluation could be based on expert judgment using such evidence as: human and animal experience, existing (*in vitro*) data, Ph values, information from similar substances or any other pertinent data.

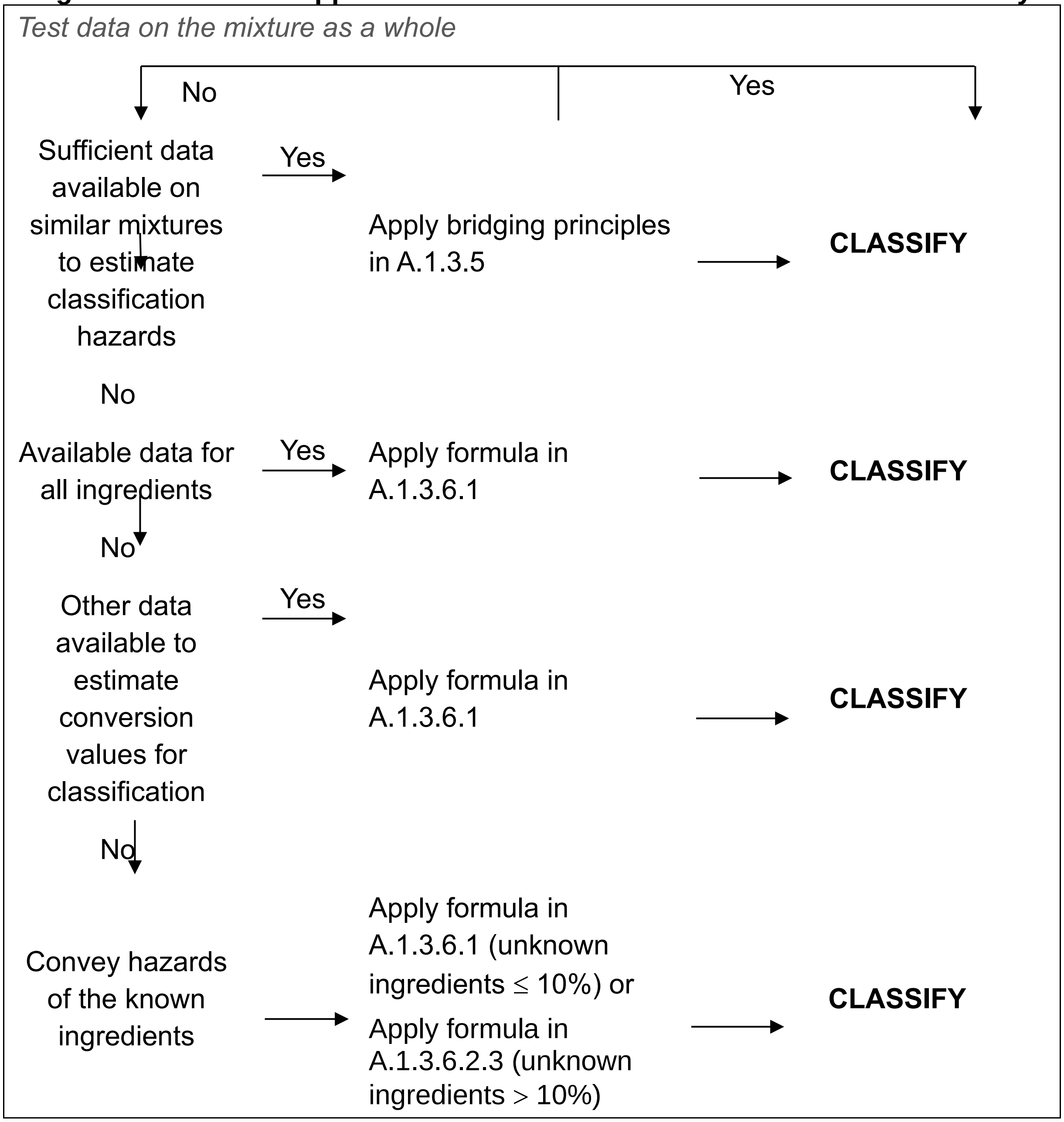
A.1.2.4.1 If the classifier determines the chemical is corrosive to the respiratory tract and data are available that indicate that the effect leads to lethality, then in addition to the appropriate acute toxicity pictogram and hazard statement, the chemical must be labelled with the hazard statement "corrosive to the respiratory tract" and the corrosive pictogram.

A.1.2.4.2 If the classifier determines the chemical is corrosive to the respiratory tract and the effect does not lead to lethality, then the chemical must be addressed in the Specific Target Organ Toxicity hazard classes (see A.8). If data is insufficient for classification under STOT, but the classifier determines, based on skin or eye data, that the chemical may be corrosive to the respiratory tract, then the hazard must be addressed using data for classification in the skin corrosion/irritation hazard class (see A.2) or Serious Eye Damage/Eye irritation hazard class (see A.3).

A.1.3 Classification criteria for mixtures

A.1.3.1 The approach to classification of mixtures for acute toxicity is tiered, and is dependent upon the amount of information available for the mixture itself and for its ingredients. The flow chart of Figure A.1.1 indicates the process that must be followed:

Figure A.1.1: Tiered approach to classification of mixtures for acute toxicity



A.1.3.2 Classification of mixtures for acute toxicity may be carried out for each route of exposure, but is only required for one route of exposure as long as this route is followed (estimated or tested) for all ingredients and there is no relevant evidence to suggest acute toxicity by multiple routes. When there is relevant evidence of acute toxicity by multiple routes of exposure, classification is to be conducted for all appropriate routes of exposure. All available information shall be considered. The pictogram and signal word used shall reflect the most severe hazard category; and all relevant hazard statements shall be used.

A.1.3.3 For purposes of classifying the hazards of mixtures in the tiered approach:

(a) The "relevant ingredients" of a mixture are those which are present in concentrations ≥ 1% (weight/weight for solids, liquids, dusts, mists and vapors and volume/volume for gases). If there is reason to suspect that an ingredient present at a concentration < 1% will affect classification of the mixture for acute toxicity, that ingredient shall also be considered relevant. Consideration of ingredients present at a concentration < 1% is particularly important when classifying untested mixtures which contain ingredients that are classified in Category 1 and Category 2;

(b) Where a classified mixture is used as an ingredient of another mixture, the actual or derived acute toxicity estimate (ATE) for that mixture is used when calculating the classification of the new mixture using the formulas in A.1.3.6.1 and A.1.3.6.2.4.

(c) If the converted acute toxicity point estimates for all ingredients of a mixture are within the same category, then the mixture should be classified in that category.

(d) When only range data (or acute toxicity hazard category information) are available for ingredients in a mixture, they may be converted to point estimates in accordance with Table A.1.2 when calculating the classification of the new mixture using the formulas in A.1.3.6.1 and A.1.3.6.2.4.

A.1.3.4 Classification of mixtures where acute toxicity test data are available for the complete mixture

Where the mixture itself has been tested to determine its acute toxicity, it is classified according to the same criteria as those used for substances, presented in Table A.1.1. If test data for the mixture are not available, the procedures presented below must be followed.

A.1.3.5 Classification of mixtures where acute toxicity test data are not available for the complete mixture: bridging principles

Where the mixture itself has not been tested to determine its acute toxicity, but there are sufficient data on both the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data will be used in accordance with the following bridging principles as found in paragraph A.0.5 of this Appendix: Dilution, Batching, Concentration of mixtures, Interpolation within one [~~toxicity~~] **hazard** category, Substantially similar mixtures, and Aerosols.

A.1.3.6 Classification of mixtures based on ingredients of the mixture (additivity formula)

A.1.3.6.1 Data available for all ingredients

The acute toxicity estimate (ATE) of ingredients is considered as follows:

(a) Include ingredients with a known acute toxicity, which fall into any of the acute toxicity categories, or have an oral or dermal LD_{50} greater than 2000 but less than or equal to 5000 mg/kg body weight (or the equivalent dose for inhalation);

(b) Ignore ingredients that are presumed not acutely toxic (e.g., water, sugar);

(c) Ignore ingredients if the data available are from a limit dose test (at the upper threshold for Category 4 for the appropriate route of exposure as provided in Table A.1.1) and do not show acute toxicity.

Ingredients that fall within the scope of this paragraph are considered to be ingredients with a known acute toxicity estimate (ATE). See note (b) to Table A.1.1 and paragraph A.1.3.3 for appropriate application of available data to the equation below, and paragraph A.1.3.6.2.4.

The ATE of the mixture is determined by calculation from the ATE values for all relevant ingredients according to the following formula below for oral, dermal or inhalation toxicity:

$$\frac{100}{ATEmix} = \sum_{n} \frac{Ci}{ATE_i}$$

where:
Ci = concentration of ingredient i
n ingredients and i is running from 1 to n
ATEi = acute toxicity estimate of ingredient i.

A.1.3.6.2 Data are not available for one or more ingredients of the mixture

A.1.3.6.2.1 Where an ATE is not available for an individual ingredient of the mixture, but available information provides a derived conversion value, the formula in A.1.3.6.1 may be applied. This information may include evaluation of:

(a) Extrapolation between oral, dermal and inhalation acute toxicity estimates. Such an evaluation requires appropriate pharmacodynamic and pharmacokinetic data;

(b) Evidence from human exposure that indicates toxic effects but does not provide lethal dose data;

(c) Evidence from any other toxicity tests/assays available on the substance that indicates toxic acute effects but does not necessarily provide lethal dose data; or

(d) Data from closely analogous substances using structure/activity relationships.

A.1.3.6.2.2 This approach requires substantial supplemental technical information, and a highly trained and experienced expert, to reliably estimate acute toxicity. If sufficient information is not available to reliably estimate acute toxicity, proceed to the provisions of A.1.3.6.2.[~~3~~]**4**.

A.1.3.6.2.3 In the event that an ingredient with unknown acute toxicity is used in a mixture at a concentration ≥ 1%, and the mixture has not been classified based on testing of the mixture as a whole, the mixture cannot be attributed a definitive acute toxicity estimate. In this situation the mixture is classified based on the known ingredients only.

[~~(~~]Note: A statement that × percent of the mixture consists of ingredient(s) of unknown ***acute (oral/dermal/inhalation)*** *toxicity is required on the label and safety data sheet in such cases; see [~~A~~]**a**ppendix C to this section, Allocation of Label Elements and [~~A~~]**a**ppendix D to this section, Safety Data Sheets.[~~)~~]*

~~[Where an ingredient with unknown acute toxicity is used in a mixture at a concentration ≥ 1%, and the mixture is not classified based on testing of the mixture as a whole, a statement that X% of the mixture consists of ingredient(s) of unknown acute toxicity is required on the label and safety data sheet in such cases; see~~

~~Appendix C to this section, Allocation of Label Elements and Appendix D to this section, Safety Data Sheets.)~~]

A.1.3.6.2.4 If the total concentration of the relevant ingredient(s) with unknown acute toxicity is ≤ 10% then the formula presented in A.1.3.6.1 must be used. If the total concentration of the relevant ingredient(s) with unknown acute toxicity is > 10%, the formula presented in A.1.3.6.1 is corrected to adjust for the percentage of the unknown ingredient(s) as follows:

$$\frac{100-\left(\sum C_{\mathrm{unknown}}\ \mathrm{if} > 10\%\right)}{ATE_{\mathrm{mix}}} = \sum_{n} \frac{Ci}{ATE_{i}}$$

Table A.1.2: Conversion from experimentally obtained acute toxicity range values (or acute toxicity hazard categories) to acute toxicity point estimates for use in the formulas for the classification of mixtures

Exposure routes	Classification category or experimentally obtained acute toxicity range estimate	Converted Acute Toxicity point estimate
Oral (mg/kg bodyweight)	**0** < Category 1 ≤ 5	0.5
	5 < Category 2 ≤ 50	5
	50 < Category 3 ≤ 300	100
	300 < Category 4 ≤ 2000	500
Dermal (mg/kg bodyweight)	**0** < Category 1 ≤ 50	5
	50 < Category 2 ≤ 200	50
	200 < Category 3 ≤ 1000	300
	1000 < Category 4 ≤ 2000	1100
Gases (ppmV)	**0** < Category 1 ≤ 100	10
	100 < Category 2 ≤ 500	100
	500 < Category 3 ≤ 2500	700
	2500 < Category 4 ≤ 20000	4500
Vapors (mg/l)	**0** < Category 1 ≤ 0.5	0.05
	0.5 < Category 2 ≤ 2.0	0.5
	2.0 < Category 3 ≤ 10.0	3
	10.0 < Category 4 ≤ 20.0	11
Dust/mist (mg/l)	**0** < Category 1 ≤ 0.05	0.005
	0.05 < Category 2 ≤ 0.5	0.05
	0.5 < Category 3 ≤ 1.0	0.5
	1.0 < Category 4 ≤ 5.0	1.5

Note: Gas concentrations are expressed in parts per million per volume (ppmV).

A.2 SKIN CORROSION/IRRITATION

A.2.1 Definitions and general considerations

A.2.1.1 *Skin corrosion* [~~is~~] **refers to** the production of irreversible damage to the skin; namely, visible necrosis through the epidermis and into the dermis, **occurring after initial exposure to a substance or mixture.** [~~following the application of a test substance for up to 4 hours. Corrosive reactions are typified by ulcers, bleeding, bloody scabs, and, by the end of observation at 14 days, by discoloration due to blanching of the skin, complete areas of alopecia, and scars. Histopathology should be considered to evaluate questionable lesions~~.]

Skin irritation [~~is~~] **refers to** the production of reversible damage to the skin [~~following the application of a test substance for up to 4 hours.~~] **occurring after initial exposure to a substance or mixture.**

A.2.1.2 [~~Skin corrosion/irritation shall be classified using a tiered approach as detailed in figure A.2.1. Emphasis shall be placed upon existing human data (See A.0.2.6), followed by other sources of information. Classification results directly when the data satisfy the criteria in this section. In case the criteria cannot be directly applied, classification of a substance or a mixture is made on the basis of the total weight of evidence (See A.0.3.1). This means that all available information bearing on the determination of skin corrosion/irritation is considered together, including the results of appropriate scientifically validated in-vitro tests, relevant animal data, and human data such as epidemiological and clinical studies and well-documented case reports and observations.~~] **To classify, all available and relevant information on skin corrosion/irritation is collected and its quality in terms of adequacy and reliability is assessed. Wherever possible classification should be based on data generated using internationally validated and accepted methods, such as OECD Test Guidelines (TG) or equivalent methods. Sections A.2.2.1 to A.2.2.6 provide classification criteria for the different types of information that may be available.**

A.2.1.3 A *tiered approach* (see A.2.2.7) organizes the available information into levels/tiers and provides for decision-making in a structured and sequential manner. Classification results directly when the information consistently satisfies the criteria. However, where the available information gives inconsistent and/or conflicting results within a tier, classification of a substance or a mixture is made on the basis of the weight of evidence within that tier. In some cases when information from different tiers gives inconsistent and/or conflicting results (see A.2.2.7.3) or where data individually are insufficient to conclude on the classification, an overall weight of evidence approach is used (see A.0.3).

A.2.2 Classification criteria for substances [~~using animal test data~~]:

Substances shall be allocated to one of the following categories within this hazard class:

(a) Category 1 (skin corrosion)

This category may be further divided into up to three sub-categories (1A, 1B, and 1C), which can be used by those authorities requiring more than one designation for corrosivity.

Corrosive substances should be classified in Category 1 where sub-categorization is not required by a competent authority or where data are not sufficient for sub-categorization.

When data are sufficient, substances may be classified in one of the three sub-categories 1A, 1B, or 1C.

(b) Category 2 (skin irritation)

A.2.2.1 [~~Corrosion:~~]Classification based on standard human data

Existing reliable and good quality human data on skin corrosion/irritation should be given high weight for classification. Existing human data could be derived from single or repeated exposure(s), for example in occupational, consumer, transport or emergency response scenarios and epidemiological and clinical studies in well-documented case reports and observations (see A.0.2.6 and A.0.3). Although human data from accident or poison center databases can provide evidence for classification, absence of incidents is not itself evidence for no classification, as exposures are generally unknown or uncertain.

[~~Table A.2.1: Skin corrosion category and sub-categories~~

~~Category 1: Corrosive~~	~~Corrosive sub-categories~~	~~Corrosive in ≥ 1 of 3 animals~~	
		~~Exposure~~	~~Observation~~
	~~1A~~	~~≤ 3 min~~	~~≤ 1 h~~
	~~1B~~	~~> 3 min ≤ 1 h~~	~~≤ 14 days~~
	~~1C~~	~~> 1 h ≤ 4 h~~	~~≤ 14 days~~]

A.2.2.2 [~~Irritation~~] Classification based on standard animal test data

[~~A.2.2.2.1 A single irritant category (Category 2) is presented in the Table A.2.2. The major criterion for the irritant category is that at least 2 tested animals have a mean score of ≥ 2.3 ≤ 4.0.~~] **OECD TG 404 is the currently available internationally validated and accepted animal test for classification as skin corrosive or irritant (See Table A.2.1 and A.2.2) and is the standard animal test. The current version of OECD TG 404 uses a maximum of 3 animals. Results from animal studies conducted under previous versions of OECD TG 404 that used more than 3 animals are also considered standard animal tests.**

A.2.2.2.1 Skin corrosion

A.2.2.2.1.1 A substance is corrosive to the skin when it produces destruction of skin tissue, namely, visible necrosis through the epidermis and into the dermis, in at least one tested animal after initial exposure up to a 4-hour duration.

A.2.2.2.1.2 Three sub-categories of Category 1 are provided in Table A.2.1, all of which shall be regulated as Category 1.

[~~Table A.2.2 Skin irritation category~~

	Criteria
~~**Irritant**~~ ~~**(Category 2)**~~	~~(1)~~ ~~Mean value of ≥ 2.3 ≤ 4.0 for erythema/eschar or for edema in at least 2 of 3 tested animals from gradings at 24, 48 and 72 hours after patch removal or, if reactions are delayed, from grades on 3 consecutive days after the onset of skin reactions; or~~ ~~(2)~~ ~~Inflammation that persists to the end of the observation period normally 14 days in at least 2 animals, particularly taking into account alopecia (limited area), hyperkeratosis, hyperplasia, and scaling; or~~ ~~(3)~~ ~~In some cases where there is pronounced variability of response among animals, with very definite positive effects related to chemical exposure in a single animal but less than the criteria above.~~]

Table A.2.1: Skin corrosion category and sub-categories [a]

	Criteria
Category 1	**Destruction of skin tissue, namely, visible necrosis through the epidermis and into the dermis, in at least one tested animal after exposure ≤ 4 h**
Sub-category 1A	**Corrosive responses in at least one animal following exposure ≤ 3 min during an observation period ≤ 1 h**

Sub-category 1B	**Corrosive responses in at least one animal following exposure > 3 min and ≤ 1 h and observations ≤ 14 days**
Sub-category 1C	**Corrosive responses in at least one animal after exposures > 1 h and ≤ 4 h and observations ≤ 14 days**

[a] ***The use of human data is discussed in A.2.2.1***

A.2.2.2.2 [~~Animal irritant responses within a test can be quite variable, as they are with corrosion. A separate irritant criterion accommodates cases when there is a significant irritant response but less than the mean score criterion for a positive test. For example, a substance might be designated as an irritant if at least 1 of 3 tested animals shows a very elevated mean score throughout the study, including lesions persisting at the end of an observation period of normally 14 days. Other responses could also fulfil this criterion. However, it should be ascertained that the responses are the result of chemical exposure. Addition of this criterion increases the sensitivity of the classification system.~~] **Skin Irritation**

A.2.2.2.2.1 A substance is irritant to skin when it produces reversible damage to the skin following its application for up to 4 hours.

A.2.2.2.2.2 A single irritant category (Category 2) is presented in the Table A.2.2. A substance is irritant to skin, when after the first application, it produces reversible damage to the skin following its application for up to 4 hours. A irritation category (Category 2) is provided that:

(a) recognizes that some test substances may lead to effects which persist throughout the length of the test; and

(b) acknowledges that animal responses in a test may be variable.

A.2.2.2.2.3 Reversibility of skin lesions is another consideration in evaluating irritant responses. When inflammation persists to the end of the observation period in 2two or more test animals, taking into consideration alopecia (limited area), hyperkeratosis, hyperplasia and scaling, then a chemical should be considered to be an irritant.

A.2.2.2.2.4. Animal irritant responses within a test can be quite variable, as they are with corrosion. A separate irritant criterion accommodates cases when there is a significant irritant response but less than the mean score criterion for a positive test. For example, a substance should be designated as an irritant if at least 1 of 3 tested animals shows a very elevated mean score according to test method used throughout the study, including lesions persisting at the end of an observation period of normally 14 days. Other responses should also fulfil this criterion. However, it should be ascertained that the

responses are the result of chemical exposure. Addition of this criterion increases the sensitivity of the classification system.

Table A.2.2 Skin irritation category [a]

	Criteria
Irritant (Category 2)	**(1) Mean score of ≥ 2.3 ≤ 4.0 for erythema/eschar o for edema in at least 2 of 3 tested animals from gradings at 24, 48 and 72 hours after patch removal or, if reactions are delayed, from grades on 3 consecutive days after the onset of skin reactions; or** **(2) Inflammation that persists to the end of the observation period normally 14 days in at least 2 animals, particularly taking into account alopecia (limited area), hyperkeratosis, hyperplasia, and scaling; or** **(3) In some cases where there is pronounced variability of response among animals, with very definite positive effects related to chemical exposure in a single animal but less than the criteria above.**

[a] ***Grading criteria are understood as described in OECD Test Guideline 404***

~~[A.2.2.2.3. Reversibility of skin lesions is another consideration in evaluating irritant responses. When inflammation persists to the end of the observation period in 2 or more test animals, taking into consideration alopecia (limited area), hyperkeratosis, hyperplasia and scaling, then a chemical should be considered to be an irritant]~~

A.2.2.3 *Classification based on in vitro/ex vivo data*

A.2.2.3.1 The currently available individual in *vitro/ex vivo* test methods address either skin irritation or skin corrosion, but do not address both endpoints in one single test. Therefore, classification based solely on *in vitro/ex vivo* test results may require data from more than one method.

A.2.2.3.2 Wherever possible classification should be based on data generated using internationally validated and accepted *in vitro/ex vivo* test methods, and the classification criteria provided in these test methods needs to be applied. *In vitro/ex vivo* data can only be used for classification when the tested substance is within the applicability domain of the test methods used. Additional limitations described in the published literature should also be taken into consideration.

A.2.2.3.3 *Skin corrosion*

A.2.2.3.3.1 Where tests have been undertaken in accordance with OECD Test Guidelines (TGs) 430, 431, or 435, a substance is classified for skin corrosion in category 1 (and, where possible and required into subcategories 1A, 1B, or 1C) based on the criteria in Table A.2.6.

A.2.2.3.3.2 Some *in vitro/ex vivo* methods do not allow differentiation between sub-categories 1B and 1C. Where existing in vitro/ex vivo data cannot distinguish between the sub-categories, additional information has to be taken into account to differentiate between these two sub-categories. Where no or insufficient additional information is available, category 1 is applied.

A.2.2.3.3.3 A substance identified as not corrosive should be considered for classification as skin irritant.

A.2.2.3.4 *Skin irritation*

A.2.2.3.4.1 Where a conclusion of corrosivity can be excluded and where tests have been undertaken in accordance with OECD Test Guideline 439, a substance is classified for skin irritation in category 2 based on the criteria in Table A.2.7

A.2.2.3.4.2 A negative result in an internationally accepted and validated *in vitro/ex vivo* test for skin irritation, e.g., OECD TG 439, can be used to conclude as not classified for skin irritation.

A.2.2.4 *Classification based on other, existing skin data in animals*

Other existing skin data in animals may be used for classification, but there may be limitations regarding the conclusions that can be drawn if a substance is highly toxic via the dermal route, an *in vivo* skin corrosion/irritation study may not have been conducted since the amount of test substance to be applied would considerably exceed the toxic dose and, consequently, would result in the death of the animals. When observations of skin corrosion/irritation in acute toxicity studies are made, these data may be used for classification, provided that the dilutions used and species tested are relevant. Solid substances (powders) may become corrosive or irritant when moistened or in contact with moist skin or mucous membranes. This is generally indicated in the standardized test methods.

A.2.2.5 *Classification based on chemical properties*

Skin effects may be indicated by pH extremes such as ≤ 2 and ≥ 11.5 especially when associated with significant acid/alkaline reserve (buffering capacity). Generally, such substances are expected to produce significant effects on the skin. In the absence of any other information, a substance is considered corrosive (Skin Category 1) if it has a pH ≤ 2 or a pH ≥ 11.5. However, if consideration of acid/alkaline reserve suggests the substance may not be corrosive despite the low or high pH, this needs to be confirmed by other data, preferably from an appropriate validated *in vitro/ ex vivo* test. Buffering capacity and pH can be determined by test methods including OECD TG 122.

A.2.2.6 *Classification based on non-test methods*

A.2.2.6.1 Classification, including non-classification, can be based on non-test methods, with due consideration of reliability and applicability, on a case-by-case basis. Such methods include computer models predicting qualitative structure-activity relationships (structural alerts, SAR); quantitative structure-activity relationships (QSARs); computer expert systems; and read-across using analogue and category approaches.

A.2.2.6.2 Read-across using analogue or category approaches requires sufficiently reliable test data on similar substance(s) and justification of the similarity of the tested substance(s) with the substance(s) to be classified. Where adequate justification of the read-across approach is provided, it has in general higher weight than (Q)SARs.

A.2.2.6.3 Classification based on (Q)SARs requires sufficient data and validation of the model. The validity of the computer models and the prediction should be assessed using internationally recognized principles for the validation of (Q)SARs. With respect to reliability, lack of alerts in a SAR or expert system is not sufficient evidence for no classification.

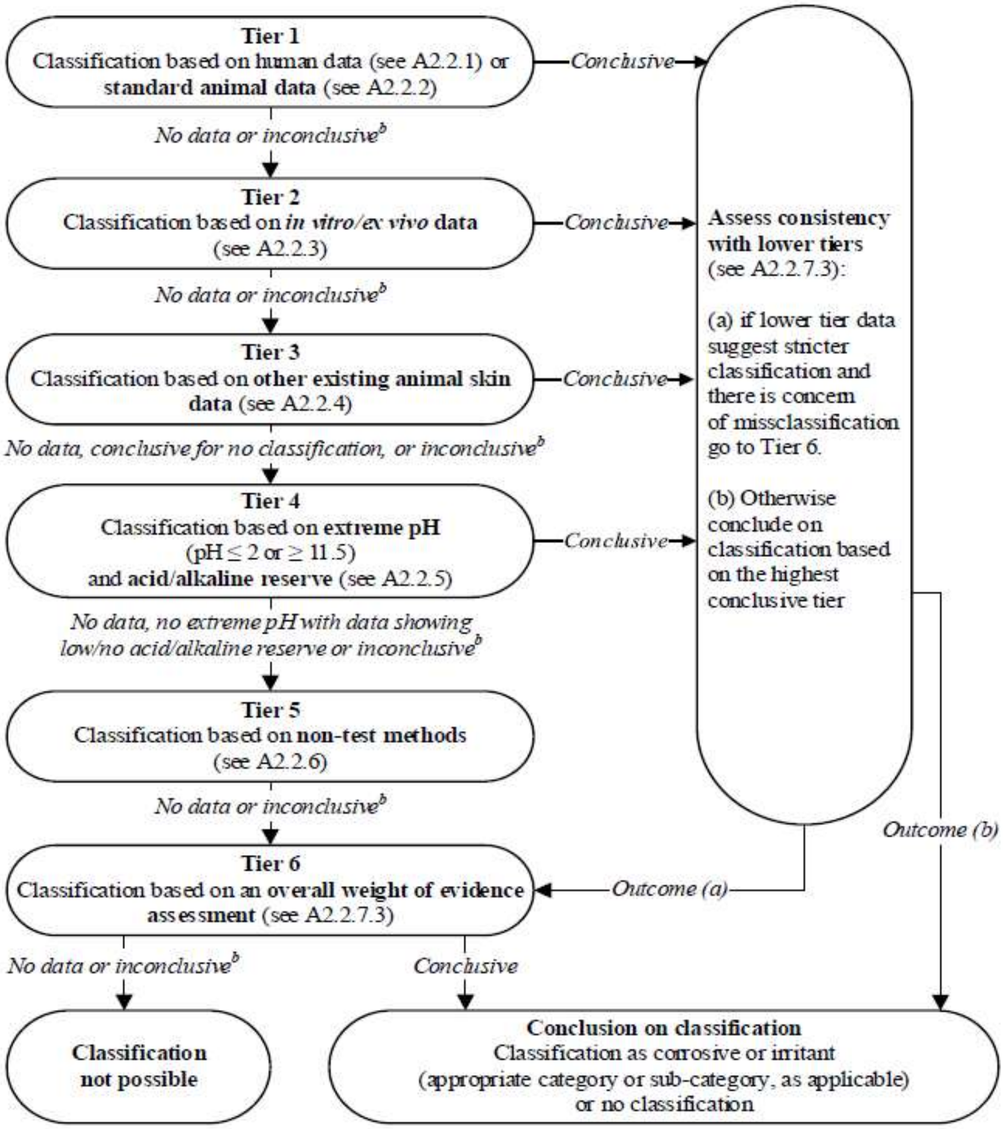
A.2.2.7 Classification in a tiered approach

A.2.2.7.1 A tiered approach to the evaluation of initial information should be considered, where applicable (Figure A.2.1), recognizing that not all elements may be relevant. However, all available and relevant information of sufficient quality needs to be examined for consistency with respect to the resulting classification.

A.2.2.7.2 In the tiered approach (Figure A.2.1), existing human and animal data form the highest tier, followed by in vitro/ex vivo data, other existing skin data in animals, and then other sources of information. Where information from data within the same tier is inconsistent and/or conflicting, the conclusion from that tier is determined by a weight of evidence approach.

A.2.2.7.3 Where information from several tiers is inconsistent and/or conflicting with respect to the resulting classification, information of sufficient quality from a higher tier is generally given a higher weight than information from a lower tier. However, when information from a lower tier would result in a stricter classification than information from a higher tier and there is concern for misclassification, then classification is determined by an overall weight of evidence approach. The same would apply in the case where there is human data indicating irritation but positive results from an *in vitro/ex vivo* test for corrosion.

<u>Figure A.2.1: Application of the tiered approach for skin corrosion and irritation</u>



<u>(a) Before applying the approach, the explanatory text in A.2.2.7 should be consulted. Only adequate and reliable data of sufficient quality should be included in applying the tiered approach.</u>

<u>(b) Information may be inconclusive for various reasons, *e.g.:*</u>

<u>- The available data may be of insufficient quality, or otherwise insufficient/inadequate for the purpose of</u>

classification, e.g., due to quality issues related to experimental design and/or reporting.

- The available data may be insufficient to conclude on the classification, e.g., they might be adequate to demonstrate irritancy, but inadequate to demonstrate absence of corrosivity.

- The method used to generate the available data may not be suitable for concluding on no classification (see A.2.2. for details). Specifically, *in vitro/ex vivo* and non-test methods need to be validated explicitly for this purpose.

A.2.3 Classification [~~C~~]criteria [~~for Substances Using Other Data Elements~~] for mixtures

A.2.3.1 [~~Existing human and animal data including information from single or repeated exposure should be the first line of analysis, as they give information directly relevant to effects on the skin. If a substance is highly toxic by the dermal route, a skin corrosion/irritation study may not be practicable since the amount of test substance to be applied would considerably exceed the toxic dose and, consequently, would result in the death of the animals. When observations are made of skin corrosion/irritation in acute toxicity studies and are observed up through the limit dose, these data may be used for classification provided that the dilutions used and species tested are equivalent.~~ ~~*In vitro*~~ ~~alternatives that have been scientifically validated shall be used to make classification decisions. Solid substances (powders) may become corrosive or irritant when moistened or in contact with moist skin or mucous membranes. Likewise, pH extremes like ≤ 2 and ≥ 11.5 may indicate skin effects, especially when associated with significant buffering capacity. Generally, such substances are expected to produce significant effects on the skin. In the absence of any other information, a substance is considered corrosive (Skin Category 1) if it has a pH ≤ 2 or a pH ≥ 11.5. However, if consideration of alkali/acid reserve suggests the substance or mixture may not be corrosive despite the low or high pH value, then further evaluation may be necessary. In some cases enough information may be available from structurally related compounds to make classification decisions.~~]
Classification of mixtures when data are available for the complete mixture

[~~A.2.3.2 A~~ ~~*tiered approach*~~ ~~to the evaluation of initial information shall be used (Figure A.2.1) recognizing that all elements may not be relevant in certain cases.~~]

A.2.3.1.1 In general, the mixture shall be classified using the criteria for substances, taking into account the tiered approach to evaluate data for this hazard class (as illustrated in Figure A.2.1) and A.2.3.1.2 and A.2.3.1.3.

If classification is not possible using the tiered approach, then the approach described in A.2.3.2, or, if that is not applicable A.2.2.3.3 should be followed.

A.2.3.1.2 *In vitro/ex vivo* data generated from validated test methods may not have been validated using mixtures; although these methods are considered broadly applicable to mixtures, they can only be used for classification of mixtures when all ingredients of the mixture fall within the applicability domain of the test methods used. Specific limitations regarding applicability domains are described in the respective test methods, and should be taken into consideration as well as any further information on the limitations from the published literature. Where there is reason to assume or evidence indicating that the applicability domain of a particular test method is limited, data interpretation should be exercised with caution, or the results should be considered not applicable.

A.2.3.1.3 In the absence of any other information, a mixture is considered corrosive (Skin Category 1) if it has a pH ≤ 2 or a pH ≥ 11.5. However, if consideration of acid/alkaline reserve suggests the mixture may not be corrosive despite the low or high pH value, this needs to be confirmed by other data, preferably from an appropriate validated *in vitro/ex vivo* test.

A.2.3.2 Classification of mixtures when data are not available for the complete mixture: bridging principles

A.2.3.2.1 Where the mixture itself has not been tested to determine its skin corrosion/irritation potential, but there are sufficient data on both the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data will be used in accordance with the following bridging principles, as found in paragraph A.0.5 of this Appendix: Dilution, Batching, Concentration of mixtures, Interpolation within one hazard category, Substantially similar mixtures, and Aerosols.

A.2.3.3 [~~The tiered approach explains how to organize information on a substance and to make a weight-of-evidence decision about hazard assessment and hazard classification.~~] **Classification of mixtures**

when data are available for all ingredients or only for some ingredients of the mixture

A.2.3.3.1 In order to make use of all available data for purposes of classifying the skin corrosion/irritation hazards of mixtures, the following assumption has been made and is applied where appropriate in the tiered approach:

The “relevant ingredients” of a mixture are those which are present in concentrations ≥1% (weight/weight for solids, liquids, dusts, mists and vapors and volume/volume for gases.). If the classifier has reason to suspect that an ingredient present at a concentration <1% will affect classification of the mixture for skin corrosion/irritation, that ingredient shall also be considered relevant.

A.2.3.3.2 In general, the approach to classification of mixtures as corrosive or irritant to the skin when data are available on the ingredients, but not on the mixture as a whole, is based on the theory of additivity, such that each corrosive or irritant ingredient contributes to the overall corrosive or irritant properties of the mixture in proportion to its potency and concentration. A weighting factor of 10 is used for corrosive ingredients when they are present at a concentration below the concentration limit for classification with Category 1, but are at a concentration that will contribute to the classification of the mixture as an irritant. The mixture is classified as corrosive or irritant when the sum of the concentrations of such ingredients exceeds a cut-off value/concentration limit.

A.2.3.3.3
Table A.2.3 below provides the cut-off value/concentration limits to be used to determine if the mixture is considered to be corrosive or irritant to the skin.

[~~A.2.3.4 All the above information that is available on a substance shall be evaluated. Although information might be gained from the evaluation of single parameters within a tier, there is merit in considering the totality of existing information and making an overall weight of evidence determination. This is especially true when there is information available on some but not all parameters. Emphasis shall be placed upon existing human experience and data, followed by animal experience and testing data, followed by other sources of information, but case-by-case determinations are necessary.~~]

A.2.3.3.4 Particular care shall be taken when classifying certain types of chemicals such as acids and bases, inorganic salts,

aldehydes, phenols, and surfactants. The approach explained in A.2.3.3.1 and A.2.3.3.2 might not work given that many of such substances are corrosive or irritant at concentrations < 1%. For mixtures containing strong acids or bases the pH should be used as classification criteria since pH will be a better indicator of corrosion than the concentration limits in Table A.2.3. A mixture containing corrosive or irritant ingredients that cannot be classified based on the additivity approach shown in Table A.2.3, due to chemical characteristics that make this approach unworkable, should be classified as skin corrosion Category 1 if it contains ≥ 1% of a corrosive ingredient and as skin irritation Category 2 when it contains ≥ 3% of an irritant ingredient. Classification of mixtures with ingredients for which the approach in Table A.2.3 does not apply is summarized in Table A.2.4 below.

A.2.3.3.5 On occasion, reliable data may show that the skin corrosion/irritation of an ingredient will not be evident when present at a level above the generic cut-off values/ concentration limits mentioned in Tables A.2.3 and A.2.4. In these cases the mixture could be classified according to those data (*See Use of cut-off values/concentration limits*, paragraph A.0.4.3 of this Appendix).

A.2.3.3.6 If there are data showing that (an) ingredient(s) may be corrosive or irritant to skin at a concentration of < 1% (corrosive) or < 3% (irritant), the mixture shall be classified accordingly (See *Use of cutoff values /concentration limits*, paragraph A.0.4.3 of this Appendix).

Table A.2.3: Concentration of ingredients of a mixture classified as skin Category 1 or 2 that would trigger classification of the mixture as hazardous to skin (Category 1 or 2)

Sum of ingredients classified as:	**Concentration triggering classification of a mixture as:**	
	Skin corrosive	**Skin irritant**
	Category 1	**Category 2**
Skin Category 1	≥ 5%	≥ 1% but < 5%
Skin Category 2		≥ 10%
(10 × Skin Category 1) + Skin Category 2		≥ 10%

Note : Where the sub-categories of skin Category 1 (corrosive) are used, the sum of all ingredients of a mixture classified as sub-category

1A, 1B or 1C respectively, must each be ≥5% in order to classify the mixture as either skin sum category 1A, 1B or 1C. Where the sum of 1A ingredients is < 5% but the sum of 1A+1B ingredients is ≥5%, the mixture must be classified as sub-category 1B. Similarly, where the sum of 1A + 1B ingredients is < 5% but the sum of 1A + 1B + 1C ingredients is ≥ 5% the mixture must be classified as sub-category 1C. Where at least one relevant ingredient in a mixture is classified as a Category 1 categorization, the mixture must be classified as Category 1 without sub-categorization if the sum of all ingredients corrosive to skin is ≥5%.

Table A.2.4: Concentration of ingredients of a mixture [~~for which~~] when the additivity approach does not apply, that would trigger classification of the mixture as hazardous to skin

		Mixture classified as:
Ingredient:	**Concentration:**	**Skin**
Acid with pH ≤ 2	≥ 1%	Category 1
Base with pH ≥ 11.5	≥ 1%	Category 1
Other corrosive (Category 1) ingredient[~~s for which additivity does not apply~~]	≥ 1%	Category 1
Other irritant (Category 2) ingredient[~~s for which additivity does not apply~~], including acids and bases	≥ 3%	Category 2

[~~Figure A.2.1: Tiered evaluation of skin corrosion and irritation potential~~

~~Step~~	~~Parameter~~	~~Finding~~	~~Conclusion~~
~~1a~~	~~Existing human or animal data~~[1] ~~Not corrosive or no data~~	~~Skin corrosive~~	~~Category 1~~[2]
~~1b~~	~~Existing human or animal data~~[1] ~~Not an irritant or no data~~	~~Skin irritant~~	~~Category 2~~[2]
~~1c~~	~~Existing human or animal data~~[1] ~~No/Insufficient data~~	~~Not a skin corrosive or skin irritant~~	~~Not classified~~
~~2:~~	~~Other, existing skin data in animals~~[3] ~~No/Insufficient data~~	~~Skin corrosive~~ ~~Skin irritant~~	~~Category 1~~[2] ~~Category 2~~[2]
~~3:~~	~~Existing skin corrosive *ex vivo / in vitro* data~~[4] ~~Not corrosive or no data~~ ~~Existing skin irritation *ex vivo / in vitro* data~~[4] ~~No/Insufficient data~~	~~Positive: Skin corrosive~~ ~~Positive: Skin irritant~~ ~~Negative: Not a skin irritant~~[5]	~~Category 1~~[2] ~~Category 2~~[2] ~~Not classified~~
~~4:~~	~~pH-Based assessment (with consideration of buffering capacity of the chemical, or no buffering capacity data)~~[5] ~~Not a pH extreme, No pH data or extreme pH with low/no buffering capacity~~	~~pH ≤ 2 or ≥ 11.5~~	~~Category 1~~[2]

~~**5:**~~	~~Validated Structure/Activity Relationship (SAR) models~~	→	~~Skin corrosive~~ ~~Skin irritant~~	~~Category 1[2]~~ ~~Category 2[2]~~
	↓ ~~No/Insufficient data~~ ↓			
~~**6:**~~	~~Consideration of the total Weight of Evidence[6]~~	→	~~Skin corrosive~~ ~~Skin irritant~~	~~Category 1[2]~~ ~~Category 2[2]~~
	↓ ~~No concern based on consideration of the sum of available data~~ ↓			
~~**7:**~~	~~**Not Classified**~~	→		~~Not classified~~]

[~~Notes to Figure A.2.1:~~

[1] ~~*Evidence of existing human or animal data may be derived from single or repeated exposure(s) in occupational, consumer, transportation, or emergency response scenarios; from ethically-conducted human clinical studies; or from purposely-generated data from animal studies conducted according to scientifically validated test methods (at present, there is no internationally accepted test method for human skin irritation testing).*~~

[2] ~~*Classify in the appropriate harmonized category, as shown in Tables A.2.1 and A.2.2.*~~

[3] ~~*Pre-existing animal data (e.g. from an acute dermal toxicity test or a sensitisation test) should be carefully reviewed to determine if sufficient skin corrosion/irritation evidence is available through other, similar information. For example, classification/categorization may be done on the basis of whether a chemical has or has not produced any skin irritation in an acute dermal toxicity test in animals at the limit dose, or produces very toxic effects in an acute dermal toxicity test in animals. In the latter case, the chemical would be classified as being very hazardous by the dermal route for acute toxicity, and it would be moot whether the chemical is also irritating or corrosive on the skin. It should be kept in mind in evaluating acute dermal toxicity information that the reporting of dermal lesions may be incomplete, testing and observations may be made on a species other than the rabbit, and species may differ in sensitivity in their responses.*~~

[4] ~~*Evidence from studies using scientifically validated protocols with isolated human/animal tissues or other, non-tissue-based, though scientifically validated, protocols should be assessed. Examples of scientifically validated test methods for skin corrosion include OECD TG 430 (Transcutaneous Electrical Resistance Test (TER)), 431 (Human Skin Model Test), and 435 (Membrane Barrier Test*~~

~~*Method). OECD TG 439 (Reconstructed Human Epidermis Test Method) is a scientifically validated in vitro test method for skin irritation.*~~

~~[5] *Measurement of pH alone may be adequate, but assessment of acid or alkali reserve (buffering capacity) would be preferable. Presently, there is no scientifically validated and internationally accepted method for assessing this parameter.*~~

~~[6] *All information that is available on a chemical should be considered and an overall determination made on the total weight of evidence. This is especially true when there is conflict in information available on some parameters. Professional judgment should be exercised in making such a determination.*~~*]*

[~~A.2.4 Classification criteria for mixtures:~~]

[~~A.2.4.1 Classification of mixtures when data are available for the complete mixture~~

~~A.2.4.1.1 The mixture shall be classified using the criteria for substances (See A.2.3).~~]

[~~A.2.4.2 Classification of mixtures when data are not available for the complete mixture: bridging principles~~]

[~~A.2.4.2.1 Where the mixture itself has not been tested to determine its skin corrosion/irritation, but there are sufficient data on both the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data will be used in accordance with the following bridging principles, as found in paragraph A.0.5 of this Appendix: Dilution, Batching, Concentration of mixtures, Interpolation within one toxicity category, Substantially similar mixtures, and Aerosols.~~]

~~[A.2.4.3 Classification of mixtures when data are available for all ingredients or only for some ingredients of the mixture]~~

~~[A.2.4.3.1 For purposes of classifying the skin corrosion/irritation hazards of mixtures in the tiered approach:~~

~~The “relevant ingredients” of a mixture are those which are present in concentrations ≥1% (weight/weight for solids, liquids, dusts, mists and vapors and volume/volume for gases.) If the classifier has reason to suspect that an ingredient present at a concentration <1% will affect classification of the mixture for skin corrosion/irritation, that ingredient shall also be considered relevant.]~~

[~~A.2.4.3.2 In general, the approach to classification of mixtures as irritant or corrosive to skin when data are available on the ingredients, but not on the mixture as a whole, is based on the theory of additivity, such that each corrosive or irritant ingredient contributes to the overall irritant or corrosive properties of the mixture in proportion to its potency and concentration. A weighting factor of 10 is used for corrosive ingredients when they are present at a concentration below the concentration limit for classification with Category 1, but are at a concentration that will contribute to the classification of the mixture as an irritant. The mixture is classified as corrosive or irritant when the sum of the concentrations of such ingredients exceeds a cut-off value/concentration limit.~~]

[~~A.2.4.3.3 Table A.2.3 below provides the cut-off value/concentration limits to be used to determine if the mixture is considered to be an irritant or a corrosive to the skin.~~]

[~~A.2.4.3.4 Particular care shall be taken when classifying certain types of chemicals such as acids and bases, inorganic salts, aldehydes, phenols, and surfactants. The approach explained in A.2.4.3.1 and A.2.4.3.2 might not work given that many of such substances are corrosive or irritant at concentrations < 1%. For mixtures containing strong acids or bases the pH should be used as classification criteria since pH will be a better indicator of corrosion than the concentration limits of Table A.2.3. A mixture containing corrosive or irritant ingredients that cannot be classified based on the additivity approach shown in Table A.2.3, due to chemical characteristics that make this approach unworkable, should be classified as Skin Category 1 if it contains ≥ 1% of a corrosive ingredient and as Skin Category 2 when it contains ≥ 3% of an irritant ingredient. Classification of mixtures with ingredients for which the approach in Table A.2.3 does not apply is summarized in Table A.2.4 below.~~]

[~~A.2.4.3.5 On occasion, reliable data may show that the skin corrosion/irritation of an ingredient will not be evident when present at a level above the generic concentration cut-off values mentioned in Tables A.2.3 and A.2.4. In these cases the mixture could be classified according to those data (See *Use of cut-off values/concentration limits*, paragraph A.0.4.3 of this Appendix).~~]

[~~A.2.4.3.6 If there are data showing that (an) ingredient(s) may be corrosive or irritant at a concentration of < 1% (corrosive) or < 3% (irritant), the mixture shall be classified accordingly (See *Use of cut-off values /concentration limits*, paragraph A.0.4.3 of this Appendix).~~]

~~Table A.2.3: Concentration of ingredients of a mixture classified as skin Category 1 or 2~~
~~that would trigger classification of the mixture as hazardous to skin (Category 1 or 2)~~

~~Sum of ingredients classified as:~~	**~~Concentration triggering classification of a mixture as:~~**	
	~~Skin corrosive~~	**~~Skin irritant~~**
	~~Category 1~~	**~~Category 2~~**

~~Skin Category 1~~	~~≥ 5%~~	~~≥ 1% but < 5%~~
~~Skin Category 2~~		~~≥ 10%~~
~~(10 × Skin Category 1) +~~ ~~Skin Category 2~~		~~≥ 10%~~

~~[Table A.2.4: Concentration of ingredients of a mixture [for which]~~ <u>when</u> ~~the additivity approach does not apply, that would trigger classification of the mixture as hazardous to skin~~

~~**Ingredient:**~~	~~**Concentration:**~~	~~**Mixture classified as:**~~ ~~**Skin**~~
~~Acid with pH ≤ 2~~	~~≥ 1%~~	~~Category 1~~
~~Base with pH ≥ 11.5~~	~~≥ 1%~~	~~Category 1~~
~~Other corrosive (Category 1) ingredient[s for which additivity does not apply]~~	~~≥ 1%~~	~~Category 1~~
~~Other irritant (Category 2) ingredient[s for which additivity does not apply], including acids and bases~~	~~≥ 3%~~	~~Category 2~~]

A.3 SERIOUS EYE DAMAGE /EYE IRRITATION

A.3.1 Definitions and general considerations

A.3.1.1 *<u>Serious eye damage</u>* [~~is~~] **<u>refers to</u>** the production of tissue damage in the eye, or serious physical decay of vision, [~~following application of a test substance to the anterior surface of the eye~~], which is not fully reversible**<u>, occurring after exposure of the eye to a substance or mixture</u>** [~~within 21 days of application~~].

<u>Eye irritation</u> [~~is~~] **<u>refers to</u>**-the production of changes in the eye [~~following the application of test substance to the anterior surface of the eye~~], which are fully reversible [~~within 21 days of application~~]**<u>, occurring after exposure of the eye to a substance or mixture</u>**.

A.3.1.2 Serious eye damage/eye irritation shall be classified using a tiered approach as detailed in [~~f~~]**<u>F</u>**igure A.3.1. Emphasis shall be placed upon existing human data (See A.0.2.6), followed by **<u>existing</u>** animal data, followed by ***<u>in vitro</u>*** **<u>data and then</u>** other sources of information. Classification results directly when the data satisfy the criteria in this section. In case the criteria cannot be directly applied, classification of a substance or a mixture is made on the basis of the total weight of evidence (See A.0.3.1). This means that all available information bearing on the determination of serious eye damage/eye irritation is considered together, including the results of appropriate scientifically validated *in vitro* tests, relevant animal data, and human data such as epidemiological and clinical studies and well-documented case reports and observations.

A.3.2 Classification criteria for substances [~~using animal test data~~]

Substances are allocated to one of the categories within this hazard class, Category 1 (serious eye damage) or Category 2 (eye irritation), as follows:

(a) Category 1 (serious eye damage/irreversible effects on the eye): substances that have the potential to seriously damage the eyes (see Table A.3.1).

(b) Category 2 (eye irritation/reversible effects on the eye): substances that have the potential to induce reversible eye irritation (see Table A.3.2).

A.3.2.1 [~~Irreversible effects on the eye/serious damage to eyes (Category 1)~~] **Classification based on standard animal test data**

A.3.2.1.1 Serious eye damage (Category 1)/Irreversible effects on the eye

A single hazard category is provided in Table A.3.1, for substances that have the potential to seriously damage the eyes. Category 1, irreversible effects on the eye, includes the criteria listed below. These observations include animals with grade 4 cornea lesions and other severe reactions (e.g. destruction of cornea) observed at any time during the test, as well as persistent corneal opacity, discoloration of the cornea by a dye substance, adhesion, pannus, and interference with the function of the iris or other effects that impair sight. In this context, persistent lesions are considered those which are not fully reversible within an observation period of normally 21 days. Category 1 also contains substances fulfilling the criteria of corneal opacity ≥ 3 and/or iritis > 1.5 **observed in at least 2 of 3 tested animals** detected in a Draize eye test with rabbits, because severe lesions like these usually do not reverse within a 21-day observation period.

Table A.3.1: Serious eye damage/Irreversible [~~eye~~] effects on the eye category ^{a}	
[~~A substance is classified as **Serious Eye Damage Category 1 (irreversible effects on the eye)** when it produces:~~]	
~~(a)~~	~~at least in one tested animal, effects on the cornea, iris or conjunctiva that are not expected to reverse or have not fully reversed within an observation period of normally 21 days; and/or~~
~~(b)~~	~~at least in 2 of 3 tested animals, a positive response of:~~

	~~(i)~~	~~corneal opacity ≥ 3; and/or~~
	~~(ii)~~	~~iritis > 1.5;~~
	~~calculated as the mean scores following grading at 24, 48 and 72 hours after instillation of the substance.~~]	

	Criteria
Category 1: **Serious eye damage/Irreversible effects on the eye**	**A substance that produces:** **(a) in at least one animal effects on the cornea, iris or conjunctiva that are not expected to reverse or have not fully reversed within an observation period of normally 21 days;** **and/or** **(b) in at least 2 of 3 tested animals, a positive response of:** **(i) corneal opacity ≥ 3; and/or** **(ii) iritis > 1.5;** **calculated as the mean scores following grading at 24, 48 and 72 hours after instillation of the test material**.

[a] ***Grading criteria are understood as described in OECD Test Guideline 405***

A.3.2.1.2 Eye irritation (Category 2)/Reversible effects on the eye

A single Category 2 is provided in Table A.3.2 for substances that have the potential to induce reversible eye irritation.

When data are available, substances may be classified into Category 2A and Category 2B:

- **(a) For substances inducing eye irritant effects reversing within an observation time of normally 21 days, Category 2A applies.**
- **(b) For substances inducing eye irritant effects reversing within an observation time of 7 days, Category 2B applies.**

When a substance is classified as Category 2, without further categorization, the classification criteria are the same as those for 2A.

A.3.2.1.3 For those substances where there is pronounced variability among animal responses this information must be taken into account in determining the classification.

[~~A.3.2.2 Reversible effects on the eye (Category 2)~~]

[~~A single category is provided in Table A.3.2 for substances that have the potential to induce reversible eye irritation.~~]

Table A.3.2: Reversible effects on the eye [~~effects~~] categories [a]

[~~A substance is classified as~~ ~~**Eye irritant Category 2A (irritating to eyes)**~~ ~~when it produces in at least in 2 of 3 tested animals a positive response of:~~

- (i) ~~corneal opacity ≥ 1; and/or~~
- (ii) ~~iritis ≥ 1; and/or~~
- (iii) ~~conjunctival redness ≥ 2; and/or~~
- (iv) ~~conjunctival edema (chemosis) ≥ 2~~

~~calculated as the mean scores following grading at 24, 48 and 72 hours after instillation of the substance, and which fully reverses within an observation period of normally 21 days.~~

~~An eye irritant is considered~~ ~~**mildly irritating to eyes (Category 2B)**~~ ~~when the effects listed above are fully reversible within 7 days of observation.~~]

	Criteria
	Substances that have the potential to induce reversible eye irritation
Category 2/2A	**Substances that produce in at least 2 of 3 tested animals a positive response of:** **(a) corneal opacity ≥ 1; and/or** **(b) iritis ≥ 1; and/or** **(c) conjunctival redness ≥ 2; and/or** **(d) conjunctival oedema (chemosis) ≥ 2** **calculated as the mean scores following grading at 24, 48 and 72 hours after instillation of the test material, and which fully reverses within an observation period of normally 21 days.**
Category 2B	**Within Category 2A an eye irritant is considered mildly irritating to eyes (Category 2B) when the effects listed above are fully reversible within 7 days of observation.**

[a] ***Grading criteria are understood a described in OECD Test Guideline 405***

A.3.2.2 [~~Reversible effects on the eye (Category 2)~~] **Classification in a tiered approach**

A.3.2.2.1 A tiered approach to the evaluation of initial information shall be used where applicable, recognizing that all elements may not be relevant in certain cases (Figure A.3.1).

A.3.2.2.2 Existing human and animal data should be the first line of analysis, as they give information directly relevant to effects on the eye. Possible skin corrosion shall be evaluated prior to consideration of any testing for serious eye damage/eye irritation in order to avoid testing for local effects on eyes with skin corrosive substances.

A.3.2.2.3 *In vitro* alternatives that have been validated and accepted should be used to make classification decisions.

A.3.2.2.4 Likewise, pH extremes like ≤ 2 and ≥ 11.5, may indicate serious eye damage, especially when associated with significant acid/alkaline reserve (buffering capacity). Generally, such substances are expected to produce significant effects on the eyes. In the absence of any other information, a substance is considered to cause serious eye damage (Category 1) if it has a pH ≤ 2 or ≥ 11.5. However, if consideration of acid/alkaline reserve suggests the substance may not cause serious eye damage despite the low or high pH value, this needs to be confirmed by other data, preferably by data from an appropriate validated *in vitro* test.

A.3.2.2.5 In some cases sufficient information may be available from structurally related substances to make classification decisions.

A.3.2.2.6 The tiered approach provides guidance on how to organize existing information and to make a weight-of-evidence decision about hazard assessment and hazard classification (ideally without conducting new animal tests). Animal testing with corrosive substances should be avoided wherever possible. Although information might be gained from the evaluation of single parameters within a tier, consideration should be given to the totality of existing information and making an overall weight of evidence determination. This is especially true when there is conflict in information available on some parameters.

A.3.2.2.7 The tiered approach explains how to organize existing information and to make a weight-of-evidence decision about hazard assessment and hazard classification. Although information might be gained from the evaluation of single parameters within a tier, consideration should be given to the totality of existing information and making an overall weight of evidence determination. This is especially true when there is conflict in information available.

Figure A.3.1 Tiered Evaluation [~~strategy~~] for serious eye damage and eye irritation (*See* also Figure A.2.1)

Step	Parameter	Finding	Conclusion
1a:	Existing human or animal serious eye damage/eye irritation data [a] → ↓ ↘ Negative data/Insufficient data/No data ↓	Serious eye damage Eye irritant →	**Category 1** **Category 2**[b]
1b:	Existing human or animal data, skin corrosion → ↓ Negative data/Insufficient data/No data ↓	Skin corrosion	**Category 1**
1c:	Existing human or animal serious eye damage/eye irritation data [a] → ↓ No/Insufficient data ↓	Existing data showing that substance does not cause serious eye damage or eye irritation	**Not classified**
2:	Other, existing skin/eye data in animals [c] → ↘ ↓ No/Insufficient data ↓	Yes, other existing data showing that substance may cause serious eye damage Yes, other existing data → showing that substance may cause-eye irritation	**Category 1** [b] **Category 2**[b]
3:	Existing *ex vivo/in vitro eye* data[d] ↘ No/Insufficient data/Negative response ↓	Positive: serious eye damage Positive: eye irritant	Category 1 Category 2[b]
4:	pH-based assessment (with consideration of acid/alkaline reserve of the chemical) [e] ↓ Not pH extreme, no pH data or extreme pH with data showing low/no acid/alkaline reserve ↓	pH ≤ 2 or ≥ 11.5 with high acid/alkaline reserve or no data for acid/alkaline reserve	Category 1
5:	↗ Validated Structure Activity Relationship (SAR) methods ↓ ↘ No/Insufficient data ↓	Severe damage to eyes Eye irritant Skin corrosive	Category 1 Category 2[b] Category 1
6:	Consideration of the total weight of evidence [f] ↓ ↘	Serious eye damage Eye irritant	Category 1 Category 2[b]
	No concern based on consideration of the sum of available data ↓		
7:	**Not classified**		

a Existing human or animal data could be derived from single or repeated exposure(s), for example in occupational, consumer, transport, or emergency response scenarios; or from purposely-generated data from animal studies conducted according to validated and internationally accepted test methods. Although human data from accident or poison center databases can provide evidence for classification, absence of incidents is not itself evidence for no classification as exposures are generally unknown or uncertain;

b Classify in the appropriate category as applicable;

c Existing animal data should be carefully reviewed to determine if sufficient serious eye damage/eye irritation evidence is available through other, similar information. It is recognized that not all skin irritants are eye irritants. Expert judgment should be exercised prior to making such a determination;

d Evidence from studies using validated protocols with isolated human/animal tissues or other non-tissue-based, validated protocols should be assessed. Examples of internationally accepted, validated test methods for identifying eye corrosives and severe irritants (i.e., Serious Eye Damage) include OECD Test Guidelines 437 (Bovine Corneal Opacity and Permeability (BCOP)), 438 (Isolated Chicken Eye (ICE) and 460 (Fluorescein leakage (FL)). Presently there are no validated and internationally accepted in vitro test methods for identifying eye irritation. A positive test result from a validated in vitro test on skin corrosion would lead to the conclusion to classify as causing serious eye damage;

e Measurement of pH alone may be adequate, but assessment of acid/alkaline reserve (buffering capacity) would be preferable. Presently, there is no validated and internationally accepted method for assessing this parameter;

f All information that is available on a substance must be considered and an overall determination made on the total weight of evidence. This is especially true when there is conflict in information available on some parameters. The weight of evidence including information on skin irritation may lead to classification for eye irritation. Negative results from applicable validated in vitro tests are considered in the total weight of evidence evaluation.

[~~A.3.2.3 For those chemicals where there is pronounced variability among animal responses, this information may be taken into account in determining the classification.~~]

A.3.3 Classification criteria for [~~Substances Using Other Data Elements~~] mixtures

A.3.3.1 [~~Existing human and animal data should be the first line of analysis, as they give information directly relevant to effects on the eye. Possible skin corrosion shall be evaluated prior to consideration of serious eye damage/eye irritation in order to avoid testing for local effects on eyes with skin corrosive substances. *In vitro* alternatives that have been scientifically validated and accepted shall be used to make classification decisions. Likewise, pH extremes like ≤ 2 and ≥ 11.5, may indicate serious eye damage, especially when associated with significant buffering capacity. Generally, such substances are expected to produce significant effects on the eyes. In the absence of any other information, a mixture/substance is considered to cause serious eye damage (Eye Category 1) if it has a pH ≤ 2 or ≥ 11.5. However, if consideration of acid/alkaline reserve suggests the substance may not have the potential to cause serious eye damage despite the low or high pH value, then further evaluation may be necessary. In some cases enough information may be available from structurally related compounds to make classification decisions.~~] **Classification of mixtures when data are available for the complete mixture**

A.3.3.1.1 The mixture will be classified using the criteria for substances, and taking into account the tiered approach to evaluate data for this hazard class (as illustrated in Figure A.3.1).

A.3.3.1.2 When considering testing of the mixture, chemical manufacturers shall use a tiered approach as included in the criteria for classification of substances for skin corrosion and serious eye damage and eye irritation to help ensure an accurate classification, as well as to avoid unnecessary animal testing. In the absence of any other information, a mixture is considered to cause serious eye damage (Category 1) if it has a pH ≤ 2 or ≥ 11.5. However, if consideration of acid/alkaline reserve suggests the mixture may not have the potential to cause serious eye damage despite the low or high pH value, then further evaluation may be necessary.

A.3.3.2 [~~A tiered approach to the evaluation of initial information shall be used where applicable, recognizing that all elements may not be relevant in certain cases (Figure A.3.1).~~]**Classification of mixtures when data are not available for the completemixture: bridging principles**

A.3.3.2.1 Where the mixture itself has not been tested to determine its skin corrosivity or potential to cause serious eye

damage or eye irritation, but there are sufficient data on both the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data will be used in accordance with the following bridging principles, as found in paragraph A.0.5 of this Appendix: Dilution, Batching, Concentration of mixtures, Interpolation within one hazard category, Substantially similar mixtures, and Aerosols.

A.3.3.3 [~~The tiered approach explains how to organize existing information on a substance and to make a weight-of-evidence decision, where appropriate, about hazard assessment and hazard classification.~~] **Classification of mixtures when data are available for all ingredients or only for some ingredients of the mixture**

A.3.3.3.1 For purposes of classifying the serious eye damage/ eye irritation hazards of mixtures in the tiered approach:

The "relevant ingredients" of a mixture are those which are present in concentrations ≥1% (weight/weight for solids, liquids, dusts, mists and vapors and volume/volume for gases.) If the classifier has reason to suspect that an ingredient present at a concentration <1% will affect classification of the mixture for serious eye damage/ eye irritation, that ingredient shall also be considered relevant.

A.3.3.3.2 In general, the approach to classification of mixtures as seriously damaging to the eye or eye irritant when data are available on the ingredients, but not on the mixture as a whole, is based on the theory of additivity, such that each skin corrosive or serious eye damage/ eye irritant ingredient contributes to the overall serious eye damage/ eye irritation properties of the mixture in proportion to its potency and concentration. A weighting factor of 10 is used for skin corrosive and serious eye damaging ingredients when they are present at a concentration below the concentration limit for classification with Category 1, but are at a concentration that will contribute to the classification of the mixture as serious eye damaging/ eye irritant. The mixture is classified as seriously damaging to the eye or eye irritant when the sum of the concentrations of such ingredients exceeds a threshold cut-off value/concentration limit.

A.3.3.3.3 Table A.3.3 provides the cut-off value/concentration limits to be used to determine if the mixture must be classified as seriously damaging to the eye or an eye irritant.

A.3.3.3.4 Particular care must be taken when classifying certain types of chemicals such as acids and bases, inorganic salts, aldehydes, phenols, and surfactants. The approach explained in A.3.3.3.1 and A.3.3.3.2 might not work given that many of such substances are seriously damaging to the eye /eye irritating at concentrations <1 %. For mixtures containing strong acids or bases, the pH should be used as classification criteria (See A.3.3.1.2) since pH will be a better indicator of serious eye damage (subject to consideration of acid/alkali reserve) than the concentration limits of Table A.3.3. A mixture containing skin corrosive or serious eye damaging/eye irritating ingredients that cannot be classified based on the additivity approach applied in Table A.3.3 due to chemical characteristics that make this approach unworkable, should be classified as serious eye damage (Category 1) if it contains ≥ 1% of a skin corrosive or serious eye damaging ingredient and as Eye Irritation (Category 2) when it contains ≥ 3% of an eye irritant ingredient. Classification of mixtures with ingredients for which the approach in Table A.3.3 does not apply is summarized in Table A.3.4.

A.3.3.3.5 On occasion, reliable data may show that the irreversible/reversible eye effects of an ingredient will not be evident when present at a level above the generic cut-off values/concentration limits mentioned in Tables A.3.3 and A.3.4. In these cases the mixture couldbe classified according to those data (See also A.0.4.3 Use of cut-off values/concentration limits"). On occasion, when it is expected that the skin corrosion/irritation or the reversible/irreversible eyeeffects of an ingredient will not be evident when present at a level above the generic concentration/cut-off levels mentioned in Tables A.3.3 and A.3.4, testing of the mixture may be considered. In those cases, the tiered weight of evidence approach should be applied as referred to in section A.3.2, Figure A.3.1 and explained in detail in this chapter.

A.3.3.3.6 If there are data showing that (an) ingredient(s) may be corrosive to the skin or seriously damaging to the eye/eye irritating at a concentration of ≤ 1% (corrosive to the skin or seriously damaging to the eye) or ≤ 3% (eye irritant), the mixture shall be classified accordingly (See also paragraph A.0.4.3, Use of cut-off values/concentration limits).

[~~A.3.3.4 All the above information that is available on a substance shall be evaluated. Although information might be gained from the evaluation of single parameters within a tier, consideration should be given to the totality of existing information and making an overall weight of evidence determination.~~

~~This is especially true when there is conflict in information available on some parameters.~~]

Table A.3.3: Concentration of ingredients of a mixture classified as Skin Category 1 and/or Eye Category 1 or 2 that would trigger classification of the mixtures as hazardous to the eye

Sum of ingredients classified as	Concentration triggering classification of a mixture as	
	Serious eye damage	Eye irritation
	Category 1	Category 2/2A
Skin corrosion (Category 1) + Serious eye damage (Category 1)[a]	≥ 3%	≥ 1% but < 3%
Eye irritation (Category 2)		≥ 10% [b]
10 x (Skin corrosion (Category 1) + Serious eye damage (Category 1))[a] + Eye irritation (Category 2)		≥ 10%

Notes:

a) If an ingredient is classified as both skin Category 1 and eye Category 1 its concentration is considered only once in the calculation.

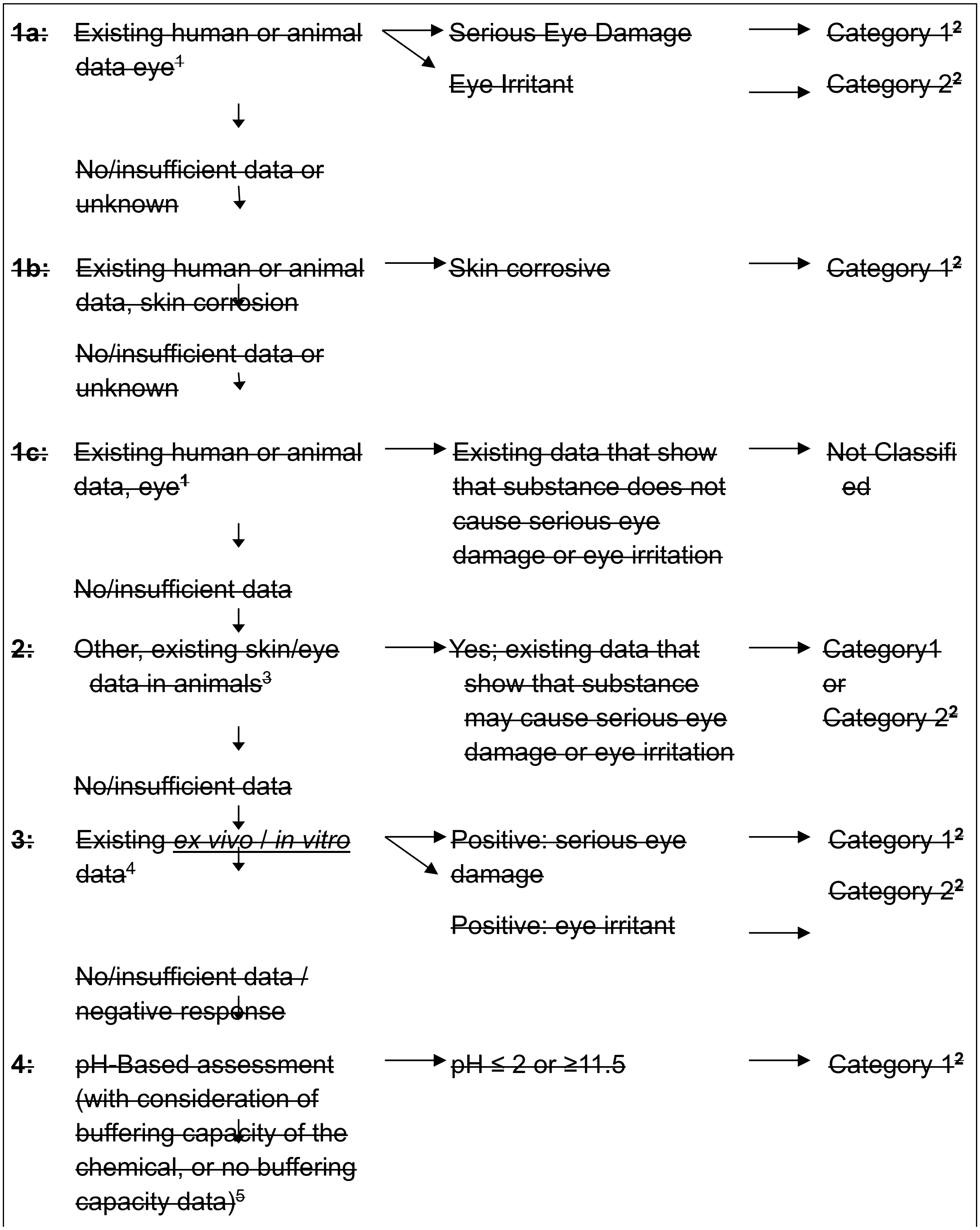
b A mixture may be classified as Eye Irritation Category 2B in cases when all relevant ingredients are classified a Eye Irritation Category 2B.

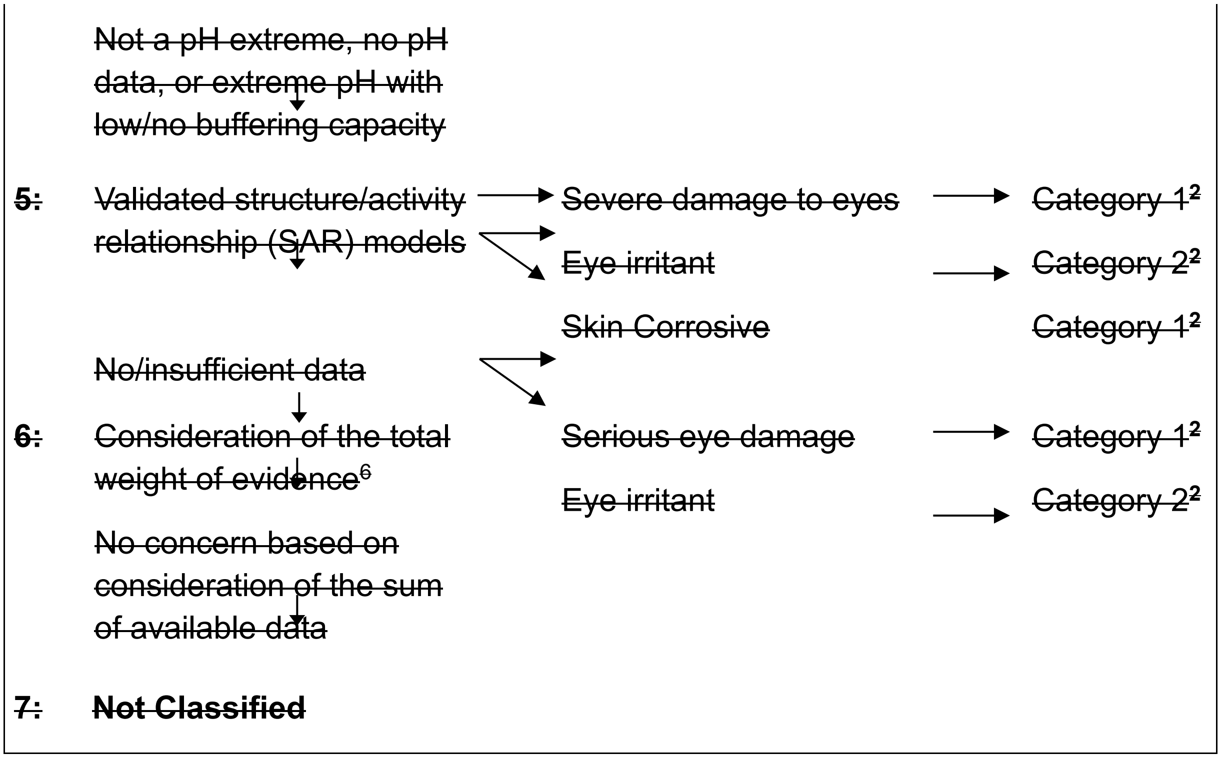
Table A.3.4: Concentration of ingredients of a mixture for which the additivity approach does not apply, that would trigger classification of the mixture as hazardous to the eye

Ingredient	Concentration	Mixture classified as:
Acid with pH < 2	≥ 1%	Serious eye damage (Category 1)
Base with pH ≥ 11.5	≥ 1%	Serious eye damage (Category 1)
Other skin corrosive or serious eye damage (Category 1) ingredients	≥ 1%	Serious eye damage (Category 1)
Other eye irritant (Category 2) ingredients	≥ 3%	Eye irritation (Category 2)

[**~~Figure A.3.1 Evaluation strategy for serious eye damage and eye irritation (See also Figure A.2.1)~~**]

~~Step~~	**~~Parameter~~**	**~~Finding~~**	**~~Conclusion~~**


~~1a:~~
~~Existing human or animal data eye~~[1]
~~Serious Eye Damage~~
~~Category 1~~[2]
~~Eye Irritant~~
~~Category 2~~[2]
~~No/insufficient data or unknown~~
~~1b:~~
~~Existing human or animal data, skin corrosion~~
~~Skin corrosive~~
~~Category 1~~[2]
~~No/insufficient data or unknown~~
~~1c:~~
~~Existing human or animal data, eye~~[1]
~~Existing data that show that substance does not cause serious eye damage or eye irritation~~
~~Not Classified~~
~~No/insufficient data~~
~~2:~~
~~Other, existing skin/eye data in animals~~[3]
~~Yes; existing data that show that substance may cause serious eye damage or eye irritation~~
~~Category1 or Category 2~~[2]
~~No/insufficient data~~
~~3:~~
~~Existing *ex vivo / in vitro* data~~[4]
~~Positive: serious eye damage~~
~~Category 1~~[2]
~~Category 2~~[2]
~~Positive: eye irritant~~
~~No/insufficient data / negative response~~
~~4:~~
~~pH-Based assessment (with consideration of buffering capacity of the chemical, or no buffering capacity data)~~[5]
~~pH ≤ 2 or ≥11.5~~
~~Category 1~~[2]



~~Not a pH extreme, no pH data, or extreme pH with low/no buffering capacity~~

~~5:~~ ~~Validated structure/activity relationship (SAR) models~~ → ~~Severe damage to eyes~~ → ~~Category 1~~[~~2~~]

→ ~~Eye irritant~~ → ~~Category 2~~[~~2~~]

~~Skin Corrosive~~ ~~Category 1~~[~~2~~]

~~No/insufficient data~~

~~6:~~ ~~Consideration of the total weight of evidence~~[6] → ~~Serious eye damage~~ → ~~Category 1~~[~~2~~]

→ ~~Eye irritant~~ → ~~Category 2~~[~~2~~]

~~No concern based on consideration of the sum of available data~~

~~7:~~ ~~**Not Classified**~~

~~Notes to Figure A.3.1:~~

[1] *~~Evidence of existing human or animal data may be derived from single or repeated exposure(s) in occupational, consumer, transportation, or emergency response scenarios; from ethically-conducted human clinical studies; or from purposely-generated data from animal studies conducted according to scientifically validated test methods. At present, there are no internationally accepted test methods for human skin or eye irritation testing.~~*

[2] *~~Classify in the appropriate harmonized category, as shown in Tables A.3.1 and A.3.2.~~*

[3] *~~Pre-existing animal data should be carefully reviewed to determine if sufficient skin or eye corrosion/irritation evidence is available through other, similar information.~~*

[4] *~~Evidence from studies using scientifically validated protocols with isolated human/animal tissues or other, non-tissue-based, though scientifically validated, protocols should be assessed. Examples of, scientifically validated test methods for identifying eye corrosives and severe irritants (i.e., Serious Eye Damage) include OECD TG 437 (Bovine Corneal Opacity and Permeability (BCOP)) and TG 438 (Isolated Chicken Eye). Positive test results from a scientifically validated in vitro test for skin corrosion would likely also lead to a conclusion to classify as causing Serious Eye Damage.~~*

[5] *~~Measurement of pH alone may be adequate, but assessment of acid or alkali reserve (buffering capacity) would be preferable.~~*

[6] *~~All information that is available on a chemical should be considered and an overall determination made on the total weight of evidence. This is especially true when there is conflict in information available on some parameters. The weight of evidence including information on skin irritation could lead to classification of eye irritation. It is recognized that not all skin irritants are eye irritants as well. Professional judgment should be exercised in making such a determination.~~*

[~~A.3.4 Classification criteria for mixtures~~]

[~~A.3.4.1 Classification of mixtures when data are available for the complete mixture~~]

[~~A.3.4.1.1 The mixture will be classified using the criteria for substances~~]

[~~A.3.4.1.2 Unlike other hazard classes, there are alternative tests available for skin corrosivity of certain types of chemicals that can give an accurate result for classification purposes, as well as being simple and relatively inexpensive to perform. When considering testing of the mixture, chemical manufacturers are encouraged to use a tiered~~

~~weight of evidence strategy as included in the criteria for classification of substances for skin corrosion and serious eye damage and eye irritation to help ensure an accurate classification, as well as avoid unnecessary animal testing. In the absence of any other information, a mixture is considered to cause serious eye damage (Eye Category 1) if it has a pH ≤ 2 or ≥ 11.5. However, if consideration of acid/alkaline reserve suggests the substance or mixture may not have the potential to cause serious eye damage despite the low or high pH value, then further evaluation may be necessary.~~]

[~~A.3.4.2 Classification of mixtures when data are not available for the complete mixture: bridging principles~~]

[~~A.3.4.2.1 Where the mixture itself has not been tested to determine its skin corrosivity or potential to cause serious eye damage or eye irritation, but there are sufficient data on both the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data will be used in accordance with the following bridging principles, as found in paragraph A.0.5 of this Appendix: Dilution, Batching, Concentration of mixtures, Interpolation within one toxicity category, Substantially similar mixtures, and Aerosols.~~]

[~~A.3.4.3 Classification of mixtures when data are available for all ingredients or only for some ingredients of the mixture~~]

[~~A.3.4.3.1 For purposes of classifying the eye corrosion/irritation hazards of mixtures in the tiered approach:~~

~~The "relevant ingredients" of a mixture are those which are present in concentrations ≥1% (weight/weight for solids, liquids, dusts, mists and vapors and volume/volume for gases.) If the classifier has reason to suspect that an ingredient present at a concentration <1% will affect classification of the mixture for eye corrosion/irritation, that ingredient shall also be considered relevant.~~]

[~~A.3.4.3.2 In general, the approach to classification of mixtures as seriously damaging to the eye or eye irritant when data are available on the ingredients, but not on the mixture as a whole, is based on the theory of additivity, such that each corrosive or irritant ingredient contributes to the overall irritant or corrosive properties of the mixture in proportion to its potency and concentration. A weighting factor of 10 is used for corrosive ingredients when they are present at a concentration below the concentration limit for classification with Category 1, but are at a concentration that will contribute to the classification of the mixture as an irritant. The mixture is classified as seriously damaging to the eye or eye~~

~~irritant when the sum of the concentrations of such ingredients exceeds a threshold cut-off value/concentration limit.~~]

[~~A.3.4.3.3 Table A.3.3 provides the cut-off value/concentration limits to be used to determine if the mixture should be classified as seriously damaging to the eye or an eye irritant.~~][~~A.3.4.3.4 Particular care must be taken when classifying certain types of chemicals such as acids and bases, inorganic salts, aldehydes, phenols, and surfactants. The approach explained in A.3.4.3.1 and A.3.4.3.2 might not work given that many of such substances are corrosive or irritant at concentrations < 1 %. For mixtures containing strong acids or bases, the pH should be used as classification criteria (See A.3.4.1) since pH will be a better indicator of serious eye damage than the concentration limits of Table A.3.3. A mixture containing corrosive or irritant ingredients that cannot be classified based on the additivity approach applied in Table A.3.3 due to chemical characteristics that make this approach unworkable, should be classified as Eye Category 1 if it contains ≥ 1% of a corrosive ingredient and as Eye Category 2 when it contains ≥ 3% of an irritant ingredient. Classification of mixtures with ingredients for which the approach in Table A.3.3 does not apply is summarized in Table A.3.4.~~]

[~~A.3.4.3.5 On occasion, reliable data may show that the reversible/irreversible eye effects of an ingredient will not be evident when present at a level above the generic cut-off values/concentration limits mentioned in Tables A.3.3 and A.3.4. In these cases the mixture could be classified according to those data (See also A.0.4.3 *Use of cut-off values/concentration limits”*). On occasion, when it is expected that the skin corrosion/irritation or the reversible/irreversible eye effects of an ingredient will not be evident when present at a level above the generic concentration/cut-off levels mentioned in Tables A.3.3 and A.3.4, testing of the mixture may be considered. In those cases, the tiered weight of evidence strategy should be applied as referred to in section A.3.3, Figure A.3.1 and explained in detail in this chapter.~~]

[~~A.3.4.3.6 If there are data showing that (an) ingredient(s) may be corrosive or irritant at a concentration of < 1% (corrosive) or < 3% (irritant), the mixture should be classified accordingly (See also paragraph A.0.4.3, *Use of cut-off values/concentration limits*).~~]

[~~Table A.3.3: Concentration of ingredients of a mixture classified as Skin Category 1 and/or Eye Category 1 or 2 that would trigger classification of the mixtures as hazardous to the eye~~]

[~~Sum of ingredients classified as~~	**~~Concentration triggering classification of a mixture as~~**

	~~Irreversible eye effects~~	**~~Reversible eye effects~~**
	~~Category 1~~	**~~Category 2~~**
~~Eye or Skin Category 1~~	~~≥ 3%~~	~~≥ 1% but < 3%~~
~~Eye Category 2~~		~~≥ 10%~~
~~(10 × Eye Category 1) + Eye Category 2~~		~~≥ 10%~~
~~Skin Category 1 + Eye Category 1~~	~~≥ 3%~~	~~≥ 1% but < 3%~~
~~10 × (Skin Category 1 + Eye Category 1) + Eye Category 2~~		~~≥ 10%~~]

*[**~~Note:~~** ~~A mixture may be classified as Eye Category 2B in cases when all relevant ingredients are classified as Eye Category 2B.~~]*

[~~Table A.3.4: Concentration of ingredients of a mixture for which the additivity approach~~

~~does not apply, that would trigger classification of the mixture as hazardous to the eye~~]

[~~Ingredient~~	**~~Concentration~~**	**~~Mixture classified as:~~ ~~Eye~~**
~~Acid with pH ≤ 2~~	~~≥ 1%~~	~~Category 1~~
~~Base with pH ≥ 11.5~~	~~≥ 1%~~	~~Category 1~~
~~Other corrosive (Category 1) ingredients for which additivity does not apply~~	~~≥ 1%~~	~~Category 1~~
~~Other irritant (Category 2) ingredients for which additivity does not apply, including acids and bases~~	~~≥ 3%~~	~~Category 2~~]

A.4 RESPIRATORY OR SKIN SENSITIZATION

A.4.1 Definitions and general considerations

A.4.1.1 *Respiratory* [*~~sensitizer~~* ~~means a chemical that will lead to hypersensitivity of the airways following inhalation of the chemical~~] **sensitization refers to hypersensitivity of the airways occurring after inhalation of a substance or mixture**.

Skin [*~~sensitizer~~* ~~means a chemical that will lead to an allergic response following skin contact~~] ***sensitization*** **refers to an allergic response occurring after skin contact with a substance or mixture.**

A.4.1.2 For the purpose of this chapter, sensitization includes two phases: the first phase is induction of specialized immunological memory in an individual by exposure to an allergen. The second phase is elicitation, i.e., production of a cell-mediated or antibody-mediated allergic response by exposure of a sensitized individual to an allergen.

A.4.1.3 For respiratory sensitization, the pattern of induction followed by elicitation phases is shared in common with skin sensitization. For skin sensitization, an induction phase is required in which the immune system learns to react; clinical symptoms can then arise when subsequent exposure is sufficient to elicit a visible skin reaction (elicitation phase). As a consequence, predictive tests usually follow this pattern in which there is an induction phase, the response to which is measured by a standardized elicitation phase, typically involving a patch test. The local lymph node assay is the exception, directly measuring the induction response. Evidence of skin sensitization in humans normally is assessed by a diagnostic patch test.

A.4.1.4 Usually, for both skin and respiratory sensitization, lower levels are necessary for elicitation than are required for induction.

A.4.1.5 The hazard class “respiratory or skin sensitization” is differentiated into:

(a) Respiratory sensitization; and

(b) Skin sensitization

A.4.2 Classification criteria for substances

A.4.2.1 Respiratory sensitizers

A.4.2.1.1 Hazard categories

A.4.2.1.1.1 Effects seen in either humans or animals will normally justify classification in a weight of evidence approach for respiratory sensitizers. Substances may be allocated to one of the two sub-categories 1A or 1B using a weight of evidence approach in accordance with the criteria given in Table A.4.1 and on the basis of reliable and good quality evidence from human cases or epidemiological studies and/or observations from appropriate studies in experimental animals.

A.4.2.1.1.2 Where data are not sufficient for sub-categorization, respiratory sensitizers shall be classified in Category 1.

Table A.4.1: Hazard category and sub-categories for respiratory sensitizers

Category 1:	**Respiratory sensitizer**
	A substance is classified as a respiratory sensitizer (a) if there is evidence in humans that the substance can lead to specific respiratory hypersensitivity and/or (b) if there are positive results from an appropriate animal test.[1]
Sub-category 1A:	Substances showing a high frequency of occurrence in humans; or a probability of occurrence of a high sensitization rate in humans based on animal or other tests.[1] Severity of reaction may also be considered.
Sub-category 1B:	Substances showing a low to moderate frequency of occurrence in humans; or a probability of occurrence of a low to moderate sensitization rate in humans based on animal or other tests.[1] Severity of reaction may also be considered.

A.4.2.1.2 Human evidence

A.4.2.1.2.1 Evidence that a substance can lead to specific respiratory hypersensitivity will normally be based on human experience. In this context, hypersensitivity is normally seen as asthma, but other hypersensitivity reactions such as rhinitis/conjunctivitis and alveolitis are also considered. The condition will have the clinical character of an allergic reaction. However, immunological mechanisms do not have to be demonstrated.

A.4.2.1.2.2 When considering the human evidence, it is necessary that in addition to the evidence from the cases, the following be taken into account:

(a) The size of the population exposed;

(b) The extent of exposure.

A.4.2.1.[~~2~~.]3 The evidence referred to above could be:

(a) Clinical history and data from appropriate lung function tests related to exposure to the substance, confirmed by other supportive evidence which may include:

(i) *In vivo* immunological test (e.g., skin prick test);

(ii) *In vitro* immunological test (e.g., serological analysis);

(iii) Studies that may indicate other specific hypersensitivity reactions where immunological mechanisms of action have not been proven, e.g., repeated low-level irritation, pharmacologically mediated effects;

(iv) A chemical structure related to substances known to cause respiratory hypersensitivity;

(b) Data from positive bronchial challenge tests with the substance conducted according to accepted guidelines for the determination of a specific hypersensitivity reaction.

A.4.2.1.2.4 Clinical history should include both medical and occupational history to determine a relationship between exposure to a specific substance and development of respiratory hypersensitivity. Relevant information includes aggravating factors both in the home and workplace, the onset and progress of the disease, family history and medical history of the patient in question. The medical history should also include a note of other allergic or airway disorders from childhood and smoking history.

A.4.2.1.2.5 The results of positive bronchial challenge tests are considered to provide sufficient evidence for classification on their own. It is, however, recognized that in practice many of the examinations listed above will already have been carried out.

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[1] ~~At this writing, recognized and validated animal models for the testing of respiratory hypersensitivity are not available. Under certain circumstances, data from animal studies may provide valuable information in a weight of evidence assessment~~.

[1] **As of May 20, 2024, recognized and validated animal models for the testing of respiratory hypersensitivity are not available. Under certain**

<u>circumstances, data from animal studies may provide valuable information in a weight of evidence assessment.</u>

A.4.2.1.3 Animal studies

A.4.2.1.2.3 Data from appropriate animal studies[2] which may be indicative of the potential of a substance to cause sensitization by inhalation in humans[3] may include:

(a) Measurements of Immunoglobulin E (IgE) and other specific immunological parameters, for example in mice

(b) Specific pulmonary responses in guinea pigs.

A.4.2.2 Skin sensitizers

A.4.2.2.1 Hazard categories

A.4.2.2.1.1 Effects seen in either humans or animals will normally justify classification in a weight of evidence approach for skin sensitizers. Substances may be allocated to one of the two sub-categories 1A or 1B using a weight of evidence approach in accordance with the criteria given in Table A.4.2 and on the basis of reliable and good quality evidence from human cases or epidemiological studies and/or observations from appropriate studies in experimental animals according to the guidance values provided in A.4.2.2.2.1 and A.4.2.2.3.2 for sub-category 1A and in A.4.2.2.2.2 and A.4.2.2.3.3 for sub-category 1B.

A.4.2.2.1.2 Where data are not sufficient for sub-categorization, skin sensitizers shall be classified in Category 1.

Table A.4.2: Hazard category and sub-categories for skin sensitizers

Category 1:	**Skin sensitizer**
	A substance is classified as a skin sensitizer (a) if there is evidence in humans that the substance can lead to sensitization by skin contact in a substantial number of persons, or (b) if there are positive results from an appropriate animal test.
Sub-category 1A:	Substances showing a high frequency of occurrence in humans and/or a high potency in animals can be presumed to have the potential to produce significant sensitization in humans. Severity of reaction may also be considered.

Sub-category 1B:	Substances showing a low to moderate frequency of occurrence in humans and/or a low to moderate potency in animals can be presumed to have the potential to produce sensitization in humans. Severity of reaction may also be considered.

A.4.2.2.2 Human evidence

A.4.2.2.2.1 Human evidence for sub-category 1A may include:

(a) Positive responses at ≤ 500 µg/cm^2 (Human Repeat Insult Patch Test (HRIPT), Human Maximization Test (HMT) – induction threshold);

(b) Diagnostic patch test data where there is a relatively high and substantial incidence of reactions in a defined population in relation to relatively low exposure;

(c) Other epidemiological evidence where there is a relatively high and substantial incidence of allergic contact dermatitis in relation to relatively low exposure.

A.4.2.2.2.2 Human evidence for sub-category 1B may include:

(a) Positive responses at > 500 µg/cm^2 (HRIPT, HMT – induction threshold);

(b) Diagnostic patch test data where there is a relatively low but substantial incidence of reactions in a defined population in relation to relatively high exposure;

---

[2] **At this writing, recognized and validated animal models for the testing of respiratory hypersensitivity are not available. Under certain circumstances, data from animal studies may provide valuable information in a weight of evidence assessment.**

[3] **The mechanisms by which substances induce symptoms of asthma are not yet fully known. For preventive measures, these substances are considered respiratory sensitizers. However, if on the basis of the evidence, it can be demonstrated that these substances induce symptoms of asthma by irritation only in people with bronchial hyperactivity, they should not be considered as respiratory sensitizers.**

(c) Other epidemiological evidence where there is a relatively low but substantial incidence of allergic contact dermatitis in relation to relatively high exposure.

A.4.2.2.3 Animal studies

A.4.2.2.3.1 For Category 1, when an adjuvant type test method for skin sensitization is used, a response of at least 30% of the animals is considered as positive. For a non-adjuvant Guinea pig test method, a response of at least 15% of the animals is considered positive. For Category 1, a stimulation index of three or more is considered a positive response in the local lymph node assay.[4]

A.4.2.2.3.2 Animal test results for sub-category 1A can include data with values indicated in Table A.4.3 below:

Table A.4.3: Animal test results for sub-category 1A

Assay	Criteria
Local lymph node assay	EC3 value ≤ 2%
Guinea pig maximization test	≥ 30% responding at ≤ 0.1% intradermal induction dose <u>or</u> ≥ 60% responding at > 0.1% to ≤ 1% intradermal induction dose
Buehler assay	≥15% responding at ≤ 0.2% topical induction dose <u>or</u> ≥ 60% responding at > 0.2% to ≤ 20% topical induction dose

Note: *EC3 refers to the estimated concentration of test chemical required to induce a stimulation index of 3 in the local lymph node assay.*

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[4] Test methods for skin sensitization are described in OECD Guideline 406 (the Guinea Pig Maximization test and the Buehler guinea pig test) and Guideline 429 (Local Lymph Node Assay). Other methods may be used provided that they are scientifically validated. The Mouse Ear Swelling Test (MEST), appears to be a reliable screening test to detect moderate to strong sensitizers, and can be used, in accordance with professional judgment, as a first stage in the assessment of skin sensitization potential.

A.4.2.2.3.3 Animal test results for sub-category 1B can include data with values indicated in Table A.4.4 below:

Table A.4.4: Animal test results for sub-category 1B

Assay	Criteria
Local lymph node assay	EC3 value > 2%
Guinea pig maximization test	≥ 30% to < 60% responding at > 0.1% to ≤ 1% intradermal induction dose or ≥ 30% responding at > 1% intradermal induction dose
Buehler assay	≥ 15% to < 60% responding at > 0.2% to ≤ 20% topical induction dose or ≥ 15% responding at > 20% topical induction dose

Note: *EC3 refers to the estimated concentration of test chemical required to induce a stimulation index of 3 in the local lymph node assay.*

A.4.2.2.4 Specific considerations

A.4.2.2.4.1 For classification of a substance, evidence shall include one or more of the following using a weight of evidence approach:

(a) Positive data from patch testing, normally obtained in more than one dermatology clinic;

(b) Epidemiological studies showing allergic contact dermatitis caused by the substance. Situations in which a high proportion of those exposed exhibit characteristic symptoms are to be looked at with special concern, even if the number of cases is small;

(c) Positive data from appropriate animal studies;

(d) Positive data from experimental studies in man (See paragraph A.0.2.6 of this Appendix);

(e) Well documented episodes of allergic contact dermatitis, normally obtained in more than one dermatology clinic;

(f) Severity of reaction.

A.4.2.2.4.2 Evidence from animal studies is usually much more reliable than evidence from human exposure. However, in cases where evidence is available from both sources, and there is conflict between the results, the quality and reliability of the evidence from both sources must be assessed in order to resolve the question of classification on a case-by-case basis. Normally, human data are not generated in controlled experiments with volunteers for the purpose of hazard classification but rather as part of risk assessment to confirm lack of effects seen in animal tests. Consequently, positive human data on skin sensitization are usually derived from case-control or other, less defined studies. Evaluation of human data must, therefore, be carried out with caution as the frequency of cases reflect, in addition to the inherent properties of the substances, factors such as the exposure situation, bioavailability, individual predisposition and preventive measures taken. Negative human data should not normally be used to negate positive results from animal studies. For both animal and human data, consideration should be given to the impact of vehicle.

A.4.2.2.4.3 If none of the above-mentioned conditions are met, the substance need not be classified as a skin sensitizer. However, a combination of two or more indicators of skin sensitization, as listed below, may alter the decision. This shall be considered on a case-by-case basis.

(a) Isolated episodes of allergic contact dermatitis;

(b) Epidemiological studies of limited power, e.g., where chance, bias or confounders have not been ruled out fully with reasonable confidence;

(c) Data from animal tests, performed according to existing guidelines, which do not meet the criteria for a positive result described in A.4.2.2.3, but which are sufficiently close to the limit to be considered significant;

(d) Positive data from non-standard methods;

(e) Positive results from close structural analogues.

A.4.2.2.4.4 Immunological contact urticaria

A.4.2.2.4.4.1 Substances meeting the criteria for classification as respiratory sensitizers may, in addition, cause immunological contact urticaria. Consideration shall be given to classifying these substances as skin sensitizers.

A.4.2.2.4.4.2 Substances which cause immunological contact urticaria without meeting the criteria for respiratory sensitizers shall be considered for classification as skin sensitizers.

A.4.2.2.4.4.3 There is no recognized animal model available to identify substances which cause immunological contact urticaria. Therefore, classification will normally be based on human evidence, similar to that for skin sensitization.

A.4.3 Classification criteria for mixtures

A.4.3.1 Classification of mixtures when data are available for the complete mixture

When reliable and good quality evidence, as described in the criteria for substances, from human experience or appropriate studies in experimental animals, is available for the mixture, then the mixture shall be classified by weight of evidence evaluation of these data. Care must be exercised in evaluating data on mixtures that the dose used does not render the results inconclusive.

A.4.3.2 Classification of mixtures when data are not available for the complete mixture: bridging principles

A.4.3.2.1 Where the mixture itself has not been tested to determine its sensitizing properties, but there are sufficient data on both the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data will be used in accordance with the following agreed bridging principles as found in paragraph A.0.5 of this Appendix: Dilution, Batching, Concentration of mixtures, Interpolation, **within one hazard category/subcategory,** Substantially similar mixtures, and Aerosols.

A.4.3.3 Classification of mixtures when data are available for all ingredients or only for some ingredients of the mixture

The mixture shall be classified as a respiratory or skin sensitizer when at least one ingredient has been classified as a respiratory or skin sensitizer and is present at or above the appropriate cut-off value/concentration limit for the specific endpoint as shown in Table A.4.5.

Table A.4.5: Cut-off values/concentration limits of ingredients of a mixture classified as either respiratory sensitizers or skin sensitizers that would trigger classification of the mixture

Ingredient classified as:	Cut-off values/concentration limits triggering classification of a mixture as:		
	Respiratory Sensitizer Category 1		Skin Sensitizer Category 1
	Solid/Liquid	Gas	All physical states
Respiratory Sensitizer Category 1	≥ 0.1%	≥ 0.1%	
Respiratory Sensitizer Sub-category 1A	≥ 0.1%	≥ 0.1%	
Respiratory Sensitizer Sub-category 1B	≥ 1.0%	≥ 0.2%	
Skin Sensitizer Category 1			≥ 0.1%
Skin Sensitizer Sub-category 1A			≥ 0.1%
Skin Sensitizer Sub-category 1B			≥ 1.0%

A.5 GERM CELL MUTAGENICITY

A.5.1 Definitions and general considerations

A.5.1.1 [~~A *mutation* is defined as a permanent change in the amount or structure of the genetic material in a cell. The term *mutation* applies both to heritable genetic changes that may be manifested at the phenotypic level and to the underlying DNA modifications when known (including, for example, specific base pair changes and chromosomal translocations). The term *mutagenic* and *mutagen* will be used for agents giving rise to an increased occurrence of mutations in populations of cells and/or organisms.~~] **Germ cell mutagenicity refers to heritable gene mutations, including heritable structure and numerical chromosome aberrations in germ cells occurring after exposure to a substance or mixture.**

A.5.1.2 [~~The more general terms *genotoxic* and *genotoxicity* apply to agents or processes which alter the structure, information content, or segregation of DNA, including those which cause DNA damage by interfering with normal replication processes, or which in a non-physiological manner (temporarily) alter its replication. Genotoxicity test results are usually taken as indicators for mutagenic effects.~~]**A *mutation* is defined as a permanent change in the amount or structure of the genetic material in a cell. The term *mutation* applies both to heritable genetic changes that may be manifested at the phenotypic level and to the underlying DNA modifications when known (including, for example, specific base pair changes and chromosomal translocations). The term *mutagenic* and *mutagen* will be used for agents giving rise to an increased occurrence of mutations in populations of cells and/or organisms.**

A.5.1.3 [~~This hazard class is primarily concerned with chemicals that may cause mutations in the germ cells of humans that can be transmitted to the progeny. However, mutagenicity/genotoxicity tests *in vitro* and in mammalian somatic cells *in vivo* are also considered in classifying substances and mixtures within this hazard class~~.] **The more general terms *genotoxic* and *genotoxicity* apply to agents or processes which alter the structure, information content, or segregation of DNA, including those which cause DNA damage by interfering with normal replication processes, or which in a non-physiological manner (temporarily) alter its replication. Genotoxicity test results are usually taken as indicators for mutagenic effects.**

A.5.1.4 This hazard class is primarily concerned with chemicals that may cause mutations in the germ cells of humans that can be transmitted to the progeny. However, mutagenicity/genotoxicity tests *in vitro* and in mammalian somatic cells *in vivo* are also considered in classifying substances and mixtures within this hazard class.

A.5.2 Classification criteria for substances

A.5.2.1 The classification system provides for two different categories of germ cell mutagens to accommodate the weight of evidence available. The two-category system is described in the Figure A.5.1.

Figure A.5.1: Hazard categories for germ cell mutagens

CATEGORY 1:	**Substances known to induce heritable mutations or to be regarded as if they induce heritable mutations in the germ cells of humans**
Category 1A:	**Substances known to induce heritable mutations in germ cells of humans** Positive evidence from human epidemiological studies.
Category 1B:	**Substances which should be regarded as if they induce heritable mutations in the germ cells of humans** (a Positive result(s) from *in vivo* heritable germ cell mutagenicity tests in mammals; or (b Positive result(s) from *in vivo* somatic cell mutagenicity tests in mammals, in combination with some evidence that the substance has potential to cause mutations to germ cells. This supporting evidence may, for example, be derived from mutagenicity/genotoxicity tests in germ cells *in vivo*, or by demonstrating the ability of the substance or its metabolite(s) to interact with the genetic material of germ cells; or (c Positive results from tests showing mutagenic effects in the germ cells of humans, without demonstration of transmission to progeny; for example, an increase in the frequency of aneuploidy in sperm cells of exposed people.
CATEGORY 2:	**Substances which cause concern for humans owing to the possibility that they may induce heritable mutations in the germ cells of humans**

	Positive evidence obtained from experiments in mammals and/or in some cases from *in vitro* experiments, obtained from: (a Somatic cell mutagenicity tests *in vitro*, in mammals; or (b Other *in vivo* somatic cell genotoxicity tests which are supported by positive results from *in vitro* mutagenicity assays. *Note: Substances which are positive in in vitro mammalian mutagenicity assays, and which also show chemical structure activity relationship to known germ cell mutagens, should be considered for classification as Category 2 mutagens.*

A.5.2.2 Specific considerations for classification of substances as germ cell mutagens:

A.5.2.2.1 To arrive at a classification, test results are considered from experiments determining mutagenic and/or genotoxic effects in germ and/or somatic cells of exposed animals. Mutagenic and/or genotoxic effects determined in *in vitro* tests shall also be considered.

A.5.2.2.2 The system is hazard based, classifying chemicals on the basis of their intrinsic ability to induce mutations in germ cells. The scheme is, therefore, not meant for the (quantitative) risk assessment of chemical substances.

A.5.2.2.3 Classification for heritable effects in human germ cells is made on the basis of scientifically validated tests. Evaluation of the test results shall be done using expert judgment and all the available evidence shall be weighed for classification.

A.5.2.2.4 The classification of substances shall be based on the total weight of evidence available, using expert judgment. In those instances where a single well-conducted test is used for classification, it shall provide clear and unambiguously positive results. The relevance of the route of exposure used in the study of the substance compared to the route of human exposure should also be taken into account.

A.5.3 Classification criteria for mixtures[5]

A.5.3.1 Classification of mixtures when data are available for all ingredients or only for some ingredients of the mixture

A.5.3.1.1 Classification of mixtures shall be based on the available test data for the individual ingredients of the mixture using cut-off values/concentration limits for the ingredients classified as germ cell mutagens.

A.5.3.1.2 The mixture will be classified as a mutagen when at least one ingredient has been classified as a Category 1A, Category 1B or Category 2 mutagen and is present at or above the appropriate cut-off value/concentration limit as shown in Table A.5.1 below for Category 1 and 2 respectively.

Table A.5.1: Cut-off values/concentration limits of ingredients of a mixture classified as germ cell mutagens that would trigger classification of the mixture

~~**[Table A.5.1: Cut-off values/concentration limits of ingredients of a mixture classified as germ cell mutagens that would trigger classification of the mixture]**~~		
Ingredient classified as:	**Cut-off/concentration limits triggering classification of a mixture as:**	
	Category 1 mutagen	**Category 2 mutagen**
Category 1A/B mutagen	≥ 0.1 %	-
Category 2 mutagen	-	≥ 1.0%

Note: The cut-off values/concentration limits in the table above apply to solids and liquids (w/w units) as well as gases (v/v units).

A.5.3.2 Classification of mixtures when data are available for the mixture itself

The classification may be modified on a case-by-case basis based on the available test data for the mixture as a whole. In such cases, the test results for the mixture as a whole must be shown to be conclusive taking into account dose and other factors such as duration, observations and analysis (e.g. statistical analysis, test sensitivity) of germ cell mutagenicity test systems.

[5] It should be noted that the classification criteria for health hazards usually include a tiered scheme in which test data available on the complete mixture are considered as the first tier in the evaluation, followed by the applicable bridging principles, and lastly, cut-off values/concentration limits or additivity. However, this approach is not used for Germ Cell Mutagenicity. These criteria for Germ Cell Mutagenicity consider the cut-off values/concentration limits as the primary tier and allow the classification to be modified only on a case-by-case evaluation based on available test data for the mixture as a whole.

A.5.3.3 Classification of mixtures when data are not available for the complete mixture: bridging principles

A.5.3.3.1 Where the mixture itself has not been tested to determine its germ cell mutagenicity hazard, but there are sufficient data on both the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data will be used in accordance with the following bridging principles as found in paragraph A.0.5 of this Appendix: Dilution, Batching, and Substantially similar mixtures.

A.5.4 Examples of scientifically validated test methods:

A.5.4.1 Examples of *in vivo* heritable germ cell mutagenicity tests are:

(a) Rodent dominant lethal mutation test (OECD 478)

(b) Mouse heritable translocation assay (OECD 485)

(c) Mouse specific locus test

A.5.4.2 Examples of *in vivo* somatic cell mutagenicity tests are:

(a) Mammalian bone marrow chromosome aberration test (OECD 475)

(b) [~~Mouse spot test (OECD 484)~~

~~(c)~~] Mammalian erythrocyte micronucleus test (OECD 474)

A.5.4.3 Examples of mutagenicity/genotoxicity tests in germ cells are:

(a) Mutagenicity tests:

(i) Mammalian spermatogonial chromosome aberration test (OECD 483)

(ii) Spermatid micronucleus assay

(b) Genotoxicity tests:

  (i) Sister chromatid exchange analysis in spermatogonia

  (ii) Unscheduled DNA synthesis test (UDS) in testicular cells

A.5.4.4 Examples of genotoxicity tests in somatic cells are:

(a) Liver Unscheduled DNA Synthesis (UDS) *in vivo* (OECD 486)

(b) Mammalian bone marrow Sister Chromatid Exchanges (SCE)

A.5.4.5 Examples of *in vitro* mutagenicity tests are:

(a) *In vitro* mammalian chromosome aberration test (OECD 473)

(b) *In vitro* mammalian cell gene mutation test (OECD 476)

(c) Bacterial reverse mutation tests (OECD 471)

A.5.4.6 As new, scientifically validated tests arise, these may also be used in the total weight of evidence to be considered.

A.6 CARCINOGENICITY

A.6.1 Definitions

[*~~Carcinogen~~* ~~means a substance or a mixture of substances which induce cancer or increase its incidence.~~] **Carcinogenicity refers to the induction of cancer or an increase in the incidence of cancer occurring after exposure to a substance or mixture.** Substances and mixtures which have induced benign and malignant tumors in well-performed experimental studies on animals are considered also to be presumed or suspected human carcinogens unless there is strong evidence that the mechanism of tumor formation is not relevant for humans.

Classification of a substance or mixture as posing a carcinogenic hazard is based on its inherent properties and does not provide information on the level of the human cancer risk which the use of the substance or mixture may represent.

A.6.2 Classification criteria for substances[6]

A.6.2.1 For the purpose of classification for carcinogenicity, substances are allocated to one of two categories based on strength of evidence and additional weight of evidence considerations. In certain instances, route-specific classification may be warranted.

Figure A.6.1: Hazard categories for carcinogens

[~~Figure A.6.1: Hazard categories for carcinogens~~]	
CATEGORY 1:	**Known or presumed human carcinogens** **The placing of a substance in Category 1 is done on the basis of epidemiological and/or animal data. An individual substance may be further distinguished:** [~~An individual substance may be further distinguished: The classification of a substance as a Category 1 carcinogen is done on the basis of epidemiological and/or animal data. This classification is further distinguished on the basis of whether the evidence for classification is largely from human data (Category 1A) or from animal data (Category 1B):~~]
Category 1A:	**Known to have carcinogenic potential for humans[~~. Classification in this category~~]; the placing of a substance is largely based on human evidence.**

Category 1B:

Presumed to have carcinogenic potential for humans[~~.~~ ~~Classification in this category~~]; the placing of a substance is largely based on animal evidence.

[~~The classification of a substance in Category 1A and 1B is based on strength of evidence together with weight of evidence considerations (See paragraph A.6.2.5). Such evidence may be derived from:~~

- ~~human studies that establish a causal relationship between human exposure to a substance and the development of cancer (known human carcinogen); or~~
- ~~animal experiments for which there is sufficient evidence to demonstrate animal carcinogenicity (presumed human carcinogen).~~

~~In addition, on a case by case basis, scientific judgment may warrant a decision of presumed human carcinogenicity derived from studies showing limited evidence of carcinogenicity in humans together with limited evidence of carcinogenicity in experimental animals.~~]

Based on strength of evidence together with additional considerations, such evidence may be derived from human studies that establish a causal relationship between human exposure to a substance and the development of cancer (known human carcinogen). Alternatively, evidence may be derived from animal experiments for which there is sufficient evidence to demonstrate animal carcinogenicity (presumed human carcinogen). In addition, on a case by case basis, scientific judgement may warrant a decision of presumed human carcinogenicity derived from studies showing limited evidence of

carcinogenicity in humans together with limited evidence of carcinogenicity in experimental animals.

Classification: Category 1 (A and B) Carcinogen

CATEGORY 2:	**Suspected human carcinogens**
	[~~The classification of a substance in Category 2 is done on the basis of evidence obtained from human and/or animal studies, but which is not sufficiently convincing to place the substance in Category 1A or B. This classification is based on strength of evidence together with weight of evidence considerations (See paragraph A.6.2.5). Such evidence may be from either limited evidence of carcinogenicity in human studies or from limited evidence of carcinogenicity in animal studies.~~]
[~~Other considerations:~~]	[~~Where the weight of evidence for the carcinogenicity of a substance does not meet the above criteria, any positive study conducted in accordance with established scientific principles, and which reports statistically significant findings regarding the carcinogenic potential of the substance, must be noted on the safety data sheet.~~]
	The placing of a substance in Category 2 is done on the basis of evidence obtained from human and/or animal studies, but which is not sufficiently convincing to place the substance in Category 1. Based on strength of evidence together with additional considerations, such evidence may be from either limited evidence of carcinogenicity in human studies or from limited evidence of carcinogenicity in animal studies.
	Classification: Category 2 Carcinogen

A.6.2.2 Classification as a carcinogen is made on the basis of evidence from reliable and acceptable methods, and is intended to be used for substances which have an intrinsic property to produce such toxic effects. The evaluations are to be based on all

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[6] See Non-mandatory Appendix F **of this section,** [~~P~~]**p**art A for further guidance regarding hazard classification for carcinogenicity. This appendix is consistent with the GHS and is provided as guidance excerpted from the International Agency for Research on Cancer (IARC) “Monographs on the Evaluation of Carcinogenic Risks to Humans” (2006).

existing data, peer-reviewed published studies and additional data accepted by regulatory agencies.

A.6.2.3 *Carcinogen classification* is a one-step, criterion-based process that involves two interrelated determinations: evaluations of strength of evidence and consideration of all other relevant information to place substances with human cancer potential into hazard categories.

A.6.2.4 *Strength of evidence* involves the enumeration of tumors in human and animal studies and determination of their level of statistical significance. Sufficient human evidence demonstrates causality between human exposure and the development of cancer, whereas sufficient evidence in animals shows a causal relationship between the agent and an increased incidence of tumors. Limited evidence in humans is demonstrated by a positive association between exposure and cancer, but a causal relationship cannot be stated. Limited evidence in animals is provided when data suggest a carcinogenic effect, but are less than sufficient. (Guidance on consideration of important factors in the classification of carcinogenicity and a more detailed description of the terms “limited” and “sufficient” have been developed by the International Agency for Research on Cancer (IARC) and are provided in non-mandatory Appendix F **of this section**.)

A.6.2.5 *Weight of evidence*: Beyond the determination of the strength of evidence for carcinogenicity, a number of other factors should be considered that influence the overall likelihood that an agent may pose a carcinogenic hazard in humans. The full list of factors that influence this determination is very lengthy, but some of the important ones are considered here.

A.6.2.5.1 These factors can be viewed as either increasing or decreasing the level of concern for human carcinogenicity. The relative emphasis accorded to each factor depends upon the amount and coherence of evidence bearing on each. Generally there is a requirement for more complete information to decrease than to increase the level of concern. Additional considerations should be used in evaluating the tumor findings and the other factors in a case-by-case manner.

A.6.2.5.2 Some important factors which may be taken into consideration, when assessing the overall level of concern are:

(a) Tumor type and background incidence;

(b) Multisite responses;

(c) Progression of lesions to malignancy;

(d) Reduced tumor latency;

Additional factors which may increase or decrease the level of concern include:

(e) Whether responses are in single or both sexes;

(f) Whether responses are in a single species or several species;

(g) Structural similarity or not to a substance(s) for which there is good evidence of carcinogenicity;

(h) Routes of exposure;

(i) Comparison of absorption, distribution, metabolism and excretion between test animals and humans;

(j) The possibility of a confounding effect of excessive toxicity at test doses; and,

(k) Mode of action and its relevance for humans, such as mutagenicity, cytotoxicity with growth stimulation, mitogenesis, immunosuppression.

Mutagenicity: It is recognized that genetic events are central in the overall process of cancer development. Therefore evidence of mutagenic activity *in vivo* may indicate that a substance has a potential for carcinogenic effects.

A.6.2.5.3 A substance that has not been tested for carcinogenicity may in certain instances be classified in Category 1A, Category 1B, or Category 2 based on tumor data from a structural analogue together with substantial support from consideration of other important factors such as formation of common significant metabolites, e.g., for benzidine congener dyes.

A.6.2.5.4 The classification should also take into consideration whether or not the substance is absorbed by a given route(s); or whether there are only local tumors at the site of administration for the tested route(s), and adequate testing by other major route(s) show lack of carcinogenicity.

A.6.2.5.5 It is important that whatever is known of the physico-chemical, toxicokinetic and toxicodynamic properties of the substances, as well as any available relevant information on chemical analogues, i.e., structure activity relationship, is taken into consideration when undertaking classification.

A.6.3 Classification criteria for mixtures[7]

A.6.3.1 The mixture shall be classified as a carcinogen when at least one ingredient has been classified as a Category 1 or Category 2 carcinogen and is present at or above the appropriate cut-off value/concentration limit as shown in Table A.6.1.

Table A.6.1: Cut-off values/concentration limits of ingredients of a mixture classified as carcinogen that would trigger classification of the mixture

Ingredient classified as:	Category 1 carcinogen	Category 2 carcinogen
Category 1 carcinogen	≥ 0.1 %	
Category 2 carcinogen		≥ 0.1% (note 1)

Note: *If a Category 2 carcinogen ingredient is present in the mixture at a concentration between 0.1% and 1%, information is required on the SDS for a product. However, a label warning is optional. If a Category 2 carcinogen ingredient is present in the mixture at a concentration of ≥ 1%, both an SDS and a label is required and the information must be included on each.*

A.6.3.2 Classification of mixtures when data are available for the complete mixture

A mixture may be classified based on the available test data for the mixture as a whole. In such cases, the test results for the mixture as a whole must be shown to be conclusive taking into account dose and other factors such as duration, observations and analysis (e.g., statistical analysis, test sensitivity) of carcinogenicity test systems.

A.6.3.3 Classification of mixtures when data are not available for the complete mixture: bridging principles

Where the mixture itself has not been tested to determine its carcinogenic hazard, but there are sufficient data on both the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data will be used in accordance with the following bridging principles as found in paragraph A.0.5 of this Appendix: Dilution; Batching; and Substantially similar mixtures.

A.6.4 Classification of carcinogenicity[8]

A.6.4.1 Chemical manufacturers, importers and employers evaluating chemicals may treat the following sources as establishing that a substance is a carcinogen or potential carcinogen for hazard communication purposes in lieu of applying the criteria described herein:

A.6.4.1.1 National Toxicology Program (NTP), “Report on Carcinogens” (latest edition);

A.6.4.1.2 International Agency for Research on Cancer (IARC) “Monographs on the Evaluation of Carcinogenic Risks to Humans” (latest editions)

A.6.4.2 Where OSHA has included cancer as a health hazard to be considered by classifiers for a chemical covered by 29 CFR part 1910, Subpart Z, [~~Toxic and Hazardous Substances,~~] chemical manufacturers, importers, and employers shall classify the chemical as a carcinogen.

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[7] It should be noted that the classification criteria for health hazards usually include a tiered scheme in which test data available on the complete mixture are considered as the first tier in the evaluation, followed by the applicable bridging principles, and lastly, cut-off values/concentration limit or additivity. However, this approach is not used for Carcinogenicity. These criteria for Carcinogenicity consider the cut-off values/concentration limits as the primary tier and allow the classification to be modified only on a case-by-case evaluation based on available test data for the mixture as a whole.

[8] See Non-mandatory Appendix F **of this section** for further guidance regarding hazard classification for carcinogenicity and how to relate carcinogenicity classification information from IARC and NTP to GHS.

A.7 REPRODUCTIVE TOXICITY

A.7.1 Definitions and general considerations

A.7.1.1 *Reproductive toxicity* [~~includes~~] **refers to** *adverse effects on sexual function and fertility* in adult males and females, as well as [~~*adverse effects on development of*]~~ **developmental toxicity in** *the offspring* ***occurring after exposure to a substance or mixture.*** Some reproductive toxic effects cannot be clearly assigned to either impairment of sexual function and fertility or to developmental toxicity. Nonetheless, substances and mixtures [~~chemicals~~] with these effects shall be classified as reproductive toxicants.

For classification purposes, the known induction of genetically based inheritable effects in the offspring is addressed in *Germ cell mutagenicity* (See A.5).

A.7.1.2 *Adverse effects on sexual function and fertility* means any effect of chemicals that interferes with reproductive ability or sexual capacity. This includes, but is not limited to, alterations to the female and male reproductive system, adverse effects on onset of puberty, gamete production and transport, reproductive cycle normality, sexual behaviour, fertility, parturition, pregnancy outcomes, premature reproductive senescence, or modifications in other functions that are dependent on the integrity of the reproductive systems.

A.7.1.3 *Adverse effects on development of the offspring* means any effect of chemicals which interferes with normal development of the conceptus either before or after birth, which is induced during pregnancy or results from parental exposure. These effects can be manifested at any point in the life span of the organism. The major manifestations of developmental toxicity include death of the developing organism, structural abnormality, altered growth and functional deficiency.

A.7.1.4 Adverse effects on or via lactation are also included in reproductive toxicity, but for classification purposes, such effects are treated separately (See A.7.2.1).

A.7.2 Classification criteria for substances

A.7.2.1 For the purpose of classification for reproductive toxicity, substances shall be classified in one of two categories in accordance with Figure A.7.1(a). Effects on sexual function and fertility, and on development, shall be considered. In addition, effects on or via lactation shall be classified in a separate hazard category in accordance with Figure A.7.1(b).

Figure A.7.1(a): Hazard categories for reproductive toxicants

CATEGORY 1:	**Known or presumed human reproductive toxicant** ~~[Substance shall be classified in Category 1 for reproductive toxicity when they are known to have produced an adverse effect on sexual function and fertility or on development in humans or when there is evidence from animal studies, possibly supplemented with other information, to provide a strong presumption that the substance has the capacity to interfere with reproduction in humans. The classification of a substance is further distinguished on the basis of whether the evidence for classification is primarily from human data (Category 1A) or from animal data (Category 1B).]~~ **This category includes substances which are known to have produced an adverse effect on sexual function and fertility or on development in humans or for which there is evidence from animal studies, possibly supplemented with other information, to provide a strong presumption that the substance has the capacity to interfere with reproduction in humans. For regulatory purposes, a substance can be further distinguished on the basis of whether the evidence for classification is primarily from human data (Category 1A) or from animal data (Category 1B).**
Category 1A:	**Known human reproductive toxicant** ~~[The classification of a substance in this category is largely based on evidence from humans.]~~ **The placing of the substance in this category is largely based on evidence from humans**.
Category 1B:	**Presumed human reproductive toxicant** ~~[The classification of a substance in this category is largely based on evidence from experimental animals. Data from animal studies shall provide sufficient evidence of an adverse effect on sexual function and fertility or on development in the absence of other toxic effects, or if occurring together with other toxic effects the adverse effect on reproduction is considered not to be a secondary non-specific consequence of other toxic effects. However, when there is mechanistic information that raises doubt about the relevance of the effect for humans, classification in Category 2 may be more appropriate.]~~

	The placing of the substance in this category is largely based on evidence from experimental animals. Data from animal studies should provide clear evidence of an adverse effect on sexual function and fertility or on development in the absence of other toxic effects, or if occurring together with other toxic effects the adverse effect on reproduction is considered not to be a secondary non-specific consequence of other toxic effects. However, when there is mechanistic information that raises doubt about the relevance of the effect for humans, classification in Category 2 may be more appropriate.
CATEGORY 2:	**Suspected human reproductive toxicant** [~~Substances shall be classified in Category 2 for reproductive toxicity when there is some evidence from humans or experimental animals, possibly supplemented with other information, of an adverse effect on sexual function and fertility, or on development, in the absence of other toxic effects, or if occurring together with other toxic effects the adverse effect on reproduction is considered not to be a secondary non-specific consequence of the other toxic effects, and where the evidence is not sufficiently convincing to place the substance in Category 1. For instance, deficiencies in the study may make the quality of evidence less convincing, and in view of this, Category 2 would be the more appropriate classification.~~] **This category includes substances for which there is some evidence from humans or experimental animals, possibly supplemented with other information, of an adverse effect on sexual function and fertility, or on development, in the absence of other toxic effects, or if occurring together with other toxic effects the adverse effect on reproduction is considered not to be a secondary non-specific consequence of the other toxic effects, and where the evidence is not sufficiently convincing to place the substance in Category 1. For instance, deficiencies in the study may make the quality of evidence less convincing, and in view of this Category 2 could be the more appropriate classification.**

Figure A.7.1(b): Hazard category for effects on or via lactation

EFFECTS ON OR VIA LACTATION

Effects on or via lactation **are allocated to** [~~shall be classified in~~] a separate single category. [~~Chemicals that~~] **It is appreciated that for many substances there is no information on the potential to cause adverse effects on the offspring via lactation. However, substances which** are absorbed by women and have been shown to interfere with lactation**,** or [~~that~~]**which** may be present (including metabolites) in breast milk in amounts sufficient to cause concern for the health of a breastfed child, [~~shall~~]**should** be classified to indicate this property [~~hazardous to breastfed babies~~]. [~~This c~~] **C**lassification **for effects via lactation** shall be assigned on the basis of:

(a) absorption, metabolism, distribution and excretion studies that indicate the likelihood the substance would be present in potentially toxic levels in breast milk; and/or
(b) results of one or two generation studies in animals which provide clear evidence of adverse effect in the offspring due to transfer in the milk or adverse effect on the quality of the milk; and/or
(c) human evidence indicating a hazard to babies during the lactation period.

A.7.2.2 Basis of classification

A.7.2.2.1 Classification is made on the basis of the criteria, outlined above, an assessment of the total weight of evidence, and the use of expert judgment. Classification as a reproductive toxicant is intended to be used for substances which have an intrinsic, specific property to produce an adverse effect on reproduction and substances should not be so classified if such an effect is produced solely as a non-specific secondary consequence of other toxic effects.

A.7.2.2.2 In the evaluation of toxic effects on the developing offspring, it is important to consider the possible influence of maternal toxicity.

A.7.2.2.3 For human evidence to provide the primary basis for a Category 1A classification there must be reliable evidence of an adverse effect on reproduction in humans. Evidence used for classification shall be from well conducted epidemiological studies, if available, which include the use of appropriate controls, balanced assessment, and due consideration of bias or confounding factors. Less rigorous data from studies in humans may be sufficient for a Category 1A classification if supplemented with adequate data from studies in experimental animals, but classification in Category 1B may also be considered.

A.7.2.3 Weight of evidence

A.7.2.3.1 Classification as a reproductive toxicant is made on the basis of an assessment of the total weight of evidence using expert judgment. This means that all available information that bears on the determination of reproductive toxicity is considered together. Included is information such as epidemiological studies and case reports in humans and specific reproduction studies along with sub-chronic, chronic and special study results in animals that provide relevant information regarding toxicity to reproductive and related endocrine organs. Evaluation of substances chemically related to the material under study may also be included, particularly when information on the material is scarce. The weight given to the available evidence will be influenced by factors such as the quality of the studies, consistency of results, nature and severity of effects, level of statistical significance for intergroup differences, number of endpoints affected, relevance of route of administration to humans and freedom from bias. Both positive and negative results are considered together in a weight of evidence determination. However, a single, positive study performed according to good scientific principles and with statistically or biologically significant positive results may justify classification (See also A.7.2.2.3).

A.7.2.3.2 Toxicokinetic studies in animals and humans, site of action and mechanism or mode of action study results may provide relevant information, which could reduce or increase concerns about the hazard to human health. If it is conclusively demonstrated that the clearly identified mechanism or mode of action has no relevance for humans or when the toxicokinetic differences are so marked that it is certain that the hazardous property will not be expressed in humans then a chemical which produces an adverse effect on reproduction in experimental animals should not be classified.

A.7.2.3.3 In some reproductive toxicity studies in experimental animals the only effects recorded may be considered of low or minimal toxicological significance and classification may not necessarily be the outcome. These effects include, for example, small changes in semen parameters or in the incidence of spontaneous defects in the fetus, small changes in the proportions of common fetal variants such as are observed in skeletal examinations, or in fetal weights, or small differences in postnatal developmental assessments.

A.7.2.3.4 Data from animal studies shall provide sufficient evidence of specific reproductive toxicity in the absence of other systemic toxic effects. However, if developmental toxicity occurs together with other toxic effects in the dam (mother), the potential influence of the generalized adverse effects should be assessed to the extent possible. The preferred approach is to consider adverse effects in the embryo/fetus first, and then evaluate maternal toxicity, along with any other factors which are likely to have influenced these effects, as part of the weight of evidence. In general, developmental effects that are observed at maternally toxic doses should not be automatically discounted. Discounting developmental effects that are observed at maternally toxic doses can only be done on a case-by-case basis when a causal relationship is established or refuted.

A.7.2.3.5 If appropriate information is available it is important to try to determine whether developmental toxicity is due to a specific maternally mediated mechanism or to a non-specific secondary mechanism, like maternal stress and the disruption of homeostasis. Generally, the presence of maternal toxicity should not be used to negate findings of embryo/fetal effects, unless it can be clearly demonstrated that the effects are secondary non-specific effects. This is especially the case when the effects in the offspring are significant, e.g., irreversible effects such as structural malformations. In some situations it is reasonable to assume that reproductive toxicity is due to a secondary consequence of maternal toxicity and discount the effects, for example if the chemical is so toxic that dams fail to thrive and there is severe inanition; they are incapable of nursing pups; or they are prostrate or dying.

A.7.2.4 Maternal toxicity

A.7.2.4.1 Development of the offspring throughout gestation and during the early postnatal stages can be influenced by toxic effects in the mother either through non-specific mechanisms related to stress and the disruption of maternal homeostasis, or by specific maternally-mediated mechanisms. So, in the interpretation of the developmental outcome to decide classification for developmental effects it is important to consider the possible influence of maternal toxicity. This is a complex issue because of uncertainties surrounding the relationship between maternal toxicity and developmental outcome. Expert judgment and a weight of evidence approach, using all available studies, shall be used to determine the degree of influence to be attributed to maternal toxicity when interpreting the criteria for classification for developmental effects. The adverse effects in the embryo/fetus shall be first considered, and then maternal toxicity, along with any other factors which are likely to have influenced these effects, as weight of evidence, to help reach a conclusion about classification.

A.7.2.4.2 Based on pragmatic observation, it is believed that maternal toxicity may, depending on severity, influence development via non-specific secondary mechanisms, producing effects such as depressed fetal weight, retarded ossification, and possibly resorptions and certain malformations in some strains of certain species. However, the limited numbers of studies which have investigated the relationship between developmental effects and general maternal toxicity have failed to demonstrate a consistent, reproducible relationship across species. Developmental effects which occur even in the presence of maternal toxicity are considered to be evidence of developmental toxicity, unless it can be unequivocally demonstrated on a case by case basis that the developmental effects are secondary to maternal toxicity. Moreover, classification shall be considered where there is a significant toxic effect in the offspring, e.g., irreversible effects such as structural malformations, embryo/fetal lethality, or significant post-natal functional deficiencies.

A.7.2.4.3 Classification shall not automatically be discounted for chemicals that produce developmental toxicity only in association with maternal toxicity, even if a specific maternally-mediated mechanism has been demonstrated. In such a case, classification in Category 2 may be considered more appropriate than Category 1. However, when a chemical is so toxic that maternal death or severe inanition results, or the dams (mothers) are prostrate and incapable of nursing the pups, it is reasonable to assume that developmental toxicity is produced solely as a secondary consequence of maternal toxicity and discount the developmental effects. Classification is not necessarily the outcome in the case of minor developmental changes, e.g., a small reduction in fetal/pup body weight or retardation of ossification when seen in association with maternal toxicity.

A.7.2.4.4 Some of the endpoints used to assess maternal toxicity are provided below. Data on these endpoints, if available, shall be evaluated in light of their statistical or biological significance and dose-response relationship.

(a) Maternal mortality: An increased incidence of mortality among the treated dams over the controls shall be considered evidence of maternal toxicity if the increase occurs in a dose-related manner and can be attributed to the systemic toxicity of the test material. Maternal mortality greater than 10% is considered excessive and the data for that dose level shall not normally be considered to need further evaluation.

(b) Mating index (Number of animals with seminal plugs or sperm/Number of mated × 100)

(c) Fertility index (Number of animals with implants/Number of matings × 100)

(d) Gestation length (If allowed to deliver)

(e) Body weight and body weight change: Consideration of the maternal body weight change and/or adjusted (corrected) maternal body weight shall be included in the evaluation of maternal toxicity whenever such data are available. The calculation of an adjusted (corrected) mean maternal body weight change, which is the difference between the initial and terminal body weight minus the gravid uterine weight (or alternatively, the sum of the weights of the fetuses), may indicate whether the effect is maternal or intrauterine. In rabbits, the body weight gain may not be a useful indicator of maternal toxicity because of normal fluctuations in body weight during pregnancy.

(f) Food and water consumption (if relevant): The observation of a significant decrease in the average food or water consumption in treated dams (mothers) compared to the control group may be useful in evaluating maternal toxicity, particularly when the test material is administered in the diet or drinking water. Changes in food or water consumption must be evaluated in conjunction with maternal body weights when determining if the effects noted are reflective of maternal toxicity or more simply, unpalatability of the test material in feed or water.

(g) Clinical evaluations (including clinical signs, markers, and hematology and clinical chemistry studies): The observation of increased incidence of significant clinical signs of toxicity in treated dams (mothers) relative to the control group is useful in evaluating maternal toxicity. If this is to be used as the basis for the assessment of maternal toxicity, the types, incidence, degree and duration of clinical signs shall be reported in the study. Clinical signs of maternal intoxication include, but are not limited to: coma, prostration, hyperactivity, loss of righting reflex, ataxia, or labored breathing.

(h) Post-mortem data: Increased incidence and/or severity of post-mortem findings may be indicative of maternal toxicity. This can include gross or microscopic pathological findings or organ weight data, including absolute organ weight, organ-to-body weight ratio, or organ-to-brain weight ratio. When supported by findings of adverse histopathological effects in the affected organ(s), the observation of a significant change in the average weight of suspected target organ(s) of treated dams (mothers), compared to those in the control group, may be considered evidence of maternal toxicity.

A.7.2.5 Animal and experimental data

A.7.2.5.1 A number of scientifically validated test methods are available, including methods for developmental toxicity testing (e.g., OECD Test Guideline 414, ICH Guideline S5A, 1993), methods for peri- and post-natal toxicity testing (e.g., ICH S5B, 1995), and methods for one or two-generation toxicity testing (e.g., OECD Test Guidelines 415, 416**, 443**).

A.7.2.5.2 Results obtained from screening tests (e.g., OECD Guidelines 421 - Reproduction/ Developmental Toxicity Screening Test, and 422 - Combined Repeated Dose Toxicity Study with Reproduction/Development Toxicity Screening Test) can also be used to justify classification, although the quality of this evidence is less reliable than that obtained through full studies.

A.7.2.5.3 Adverse effects or changes, seen in short- or long-term repeated dose toxicity studies, which are judged likely to impair reproductive function and which occur in the absence of significant generalized toxicity, may be used as a basis for classification, e.g., histopathological changes in the gonads.

A.7.2.5.4 Evidence from *in vitro* assays, or non-mammalian tests, and from analogous substances using structure-activity relationship (SAR), can contribute to the procedure for classification. In all cases of this nature, expert judgment must be used to assess the adequacy of the data. Inadequate data shall not be used as a primary support for classification.

A.7.2.5.5 It is preferable that animal studies are conducted using appropriate routes of administration which relate to the potential route of human exposure. However, in practice, reproductive toxicity studies are commonly conducted using the oral route, and such studies will normally be suitable for evaluating the hazardous properties of the substance with respect to reproductive toxicity. However, if it can be conclusively demonstrated that the clearly identified mechanism or mode of action has no relevance for humans or when the toxicokinetic differences are so marked that it is certain that the hazardous property will not be expressed in humans then a substance which produces an adverse effect on reproduction in experimental animals should not be classified.

A.7.2.5.6 Studies involving routes of administration such as intravenous or intraperitoneal injection, which may result in exposure of the reproductive organs to unrealistically high levels of the test substance, or elicit local damage to the reproductive organs, e.g., by irritation, must be interpreted with extreme caution and on their own are not normally the basis for classification.

A.7.2.5.7 There is general agreement about the concept of a limit dose, above which the production of an adverse effect may be considered to be outside the criteria which lead to classification. Some test guidelines specify a limit dose, other test guidelines qualify the limit dose with a statement that higher doses may be necessary if anticipated human exposure is sufficiently high that an adequate margin of exposure would not be achieved. Also, due to species differences in toxicokinetics, establishing a specific limit dose may not be adequate for situations where humans are more sensitive than the animal model.

A.7.2.5.8 In principle, adverse effects on reproduction seen only at very high dose levels in animal studies (for example doses that induce prostration, severe inappetence, excessive mortality) do not normally lead to classification, unless other information is available, for example, toxicokinetics information indicating that humans may be more susceptible than animals, to suggest that classification is appropriate.

A.7.2.5.9 However, specification of the actual “limit dose” will depend upon the test method that has been employed to provide the test results.

A.7.3 Classification criteria for mixtures[9]

[9] It should be noted that the classification criteria for health hazards usually include a tiered scheme in which test data available on the complete mixture are considered as the first tier in the evaluation, followed by the applicable bridging principles, and lastly, cut-off values/concentration limits or additivity. However, this approach is not used for Reproductive Toxicity. These criteria for Reproductive Toxicity consider the cut-off values/concentration limits as the primary tier and allow the classification to be modified only on a case-by-case evaluation based on available test data for the mixture as a whole.

A.7.3.1 Classification of mixtures when data are available for all ingredients or only for some ingredients of the mixture

A.7.3.1.1 The mixture shall be classified as a reproductive toxicant when at least one ingredient has been classified as a Category 1 or Category 2 reproductive toxicant and is present at or above the appropriate cut-off value/concentration limit specified in Table A.7.1 for Category 1 and 2, respectively.

A.7.3.1.2 The mixture shall be classified for effects on or via lactation when at least one ingredient has been classified for effects on or via lactation and is present at or above the appropriate cut-off value/concentration limit specified in Table A.7.1 for the additional category for effects on or via lactation.

Table A.7.1: Cut-off values/concentration limits of ingredients of a mixture classified as reproductive toxicants or for effects on or via lactation that trigger classification of the mixture

Ingredients classified as:	**Cut-off values/concentration limits triggering classification of a mixture as:**		
	Category 1 **reproductive toxicant**	**Category 2** **reproductive toxicant**	**Additional category** **for effects on or via lactation**
Category 1 reproductive toxicant	≥ 0.1%		
Category 2 reproductive toxicant		≥ 0.1 %	

Additional category for effects on or via lactation			≥ 0.1 %

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[9] [~~See Non-mandatory Appendix F for further guidance regarding hazard classification for carcinogenicity and how to relate carcinogenicity classification information from IARC and NTP to GHS~~

A.7.3.2 Classification of mixtures when data are available for the complete mixture

Available test data for the mixture as a whole may be used for classification on a case-by-case basis. In such cases, the test results for the mixture as a whole must be shown to be conclusive taking into account dose and other factors such as duration, observations and analysis (e.g., statistical analysis, test sensitivity) of reproduction test systems.

A.7.3.3 Classification of mixtures when data are not available for the complete mixture: bridging principles

A.7.3.3.1 Where the mixture itself has not been tested to determine its reproductive toxicity, but there are sufficient data on both the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data shall be used in accordance with the following bridging principles as found in paragraph A.0.5 of this Appendix: Dilution, Batching, and Substantially similar mixtures.

A.8 SPECIFIC TARGET ORGAN TOXICITY SINGLE EXPOSURE

A.8.1 Definitions and general considerations

A.8.1.1 *Specific target organ toxicity - single exposure, (STOT-SE)* [~~means~~] **refers to** specific, non-lethal [~~target organ toxicity~~] **toxic effects on target organs occurring after** [~~arising from~~] a single exposure to a [~~chemical~~] **substance or mixture**. All significant health effects that can impair function, both reversible and irreversible, immediate and/or delayed and not specifically addressed in A.1 to A.7 and A.10 of this Appendix are included. Specific target organ toxicity following repeated exposure is classified in accordance with *SPECIFIC TARGET ORGAN TOXICITY – REPEATED EXPOSURE* (A.9 of this Appendix) and is therefore not included here.

A.8.1.2 Classification identifies the chemical as being a specific target organ toxicant and, as such, it presents a potential for adverse health effects in people who are exposed to it.

A.8.1.3 The adverse health effects produced by a single exposure include consistent and identifiable toxic effects in humans; or, in experimental animals, toxicologically significant changes which have affected the function or morphology of a tissue/organ, or have produced serious changes to the biochemistry or hematology of the organism, and these changes are relevant for human health. Human data is the primary source of evidence for this hazard class.

A.8.1.4 Assessment shall take into consideration not only significant changes in a single organ or biological system but also generalized changes of a less severe nature involving several organs.

A.8.1.5 Specific target organ toxicity can occur by any route that is relevant for humans, i.e., principally oral, dermal or inhalation.

A.8.1.6 The classification criteria for specific **target** organ [~~systemic~~] toxicity **-** single exposure are organized as criteria for substances Categories 1 and 2 (See A.8.2.1), criteria for substances Category 3 (See A.8.2.2) and criteria for mixtures (See A.8.3). See also Figure A.8.1.

A.8.2 Classification criteria for substances

A.8.2.1 Substances of Category 1 and Category 2

A.8.2.1.1 Substances shall be classified for immediate or delayed effects separately, by the use of expert judgment on the basis of the weight of all evidence available, including the use of recommended guidance values (See A.8.2.1.9). Substances shall then be classified in Category 1 or 2, depending upon the nature and severity of the effect(s) observed, in accordance with Figure A.8.1.

Figure A.8.1: Hazard categories for specific target organ toxicity following single exposure

CATEGORY 1:	**Substances that have produced significant toxicity in humans, or that, on the basis of evidence from studies in experimental animals can be presumed to have the potential to produce significant toxicity in humans following single exposure** ~~Substances are classified in Category 1 for STOT-SE on the basis of:~~ **Placing a substance in Category 1 is done on the basis of:** (a) reliable and good quality evidence from human cases or epidemiological studies; or (b) observations from appropriate studies in experimental animals in which significant and/or severe toxic effects of relevance to human health were produced at generally low exposure concentrations. Guidance dose/concentration values are provided below (See A.8.2.1.9) to be used as part of weight-of-evidence evaluation.

CATEGORY 2:	**Substances that, on the basis of evidence from studies in experimental animals can be presumed to have the potential to be harmful to human health following single exposure** [~~Substances are classified in Category 2 for STOT-SE on the basis of observations from appropriate studies in experimental animals in which significant toxic effects, of relevance to human health, were produced at generally moderate exposure concentrations. Guidance dose/concentration values are provided below (See A.8.2.1.9) in order to help in classification~~.] **Placing a substance in Category 2 is done on the basis of observations from appropriate studies in experimental animals in which significant toxic effects, of relevance to human health, were produced at generally moderate exposure concentrations. Guidance dose/concentration values are provided below (see 3.8.2.1.9) in order to help in classification.** In exceptional cases, human evidence can also be used to place a substance in Category 2 [~~(See A.8.2.1.6)~~] **(see 3.8.2.1.9).**
CATEGORY 3:	**Transient target organ effects** ~~[There are target organ effects for which a substance does not meet the criteria to be classified in Categories 1 or 2 indicated above. These are effects which adversely alter human function for a short duration after exposure and from which humans may recover in a reasonable period without leaving significant alteration of structure or function. This category only includes narcotic effects and respiratory tract irritation. Substances are classified specifically for these effects as discussed in A.8.2.2.]~~ **There are target organ effects for which a substance/mixture may not meet the criteria to be classified in Categories 1 or 2 indicated above. These are effects which adversely alter human function for a short duration after exposure and from which humans may recover in a reasonable period without leaving significant alteration of structure or function. This category only includes**

<table>
<tr><td></td><td>narcotic effects and respiratory tract irritation. Substances/mixtures may be classified specifically for these effects as discussed in 3.8.2.2.</td></tr>
<tr><td colspan="2"><i>~~[Note: The primary target organ/system shall be identified where possible, and where this is not possible, the substance shall be identified as a general toxicant. The data shall be evaluated and, where possible, shall not include secondary effects (e.g., a hepatotoxicant can produce secondary effects in the nervous or gastro-intestinal systems).]~~</i>
<i>NOTE: For these categories the specific target organ/system that has been primarily affected by the classified substance may be identified, or the substance may be identified as a general toxicant. Attempts should be made to determine the primary target organ/system of toxicity and classify for that purpose, e.g. hepatotoxicants, neurotoxicants. One should carefully evaluate the data and, where possible, not include secondary effects, e.g. a hepatotoxicant can produce secondary effects in the nervous or gastro-intestinal systems.</i></td></tr>
</table>

A.8.2.1.2 The relevant route(s) of exposure by which the classified substance produces damage shall be identified.

A.8.2.1.3 Classification is determined by expert judgment, on the basis of the weight of all evidence available including the guidance presented below.

A.8.2.1.4 Weight of evidence of all available data, including human incidents, epidemiology, and studies conducted in experimental animals is used to substantiate specific target organ toxic effects that merit classification.

A.8.2.1.5 The information required to evaluate specific target organ toxicity comes either from single exposure in humans (e.g., exposure at home, in the workplace or environmentally), or from studies conducted in experimental animals. The standard animal studies in rats or mice that provide this information are acute toxicity studies which can include clinical observations and detailed macroscopic and microscopic examination to enable the toxic effects on target tissues/organs to be identified. Results of acute toxicity studies conducted in other species may also provide relevant information.

A.8.2.1.6 In exceptional cases, based on expert judgment, it may be appropriate to place certain substances with human evidence of target organ toxicity in Category 2: (a) when the weight of human evidence is not sufficiently convincing to warrant Category 1 classification, and/or (b) based on the nature and severity of effects. Dose/concentration levels in humans shall not be considered in the classification and any available evidence from animal studies shall be consistent with the Category 2 classification. In other words, if there are also animal data available on the substance that warrant Category 1 classification, the chemical shall be classified as Category 1.

A.8.2.1.7 Effects considered to support classification for Category 1 and 2

A.8.2.1.7.1 Classification is supported by evidence associating single exposure to the substance with a consistent and identifiable toxic effect.

A.8.2.1.7.2 Evidence from human experience/incidents is usually restricted to reports of adverse health consequences, often with uncertainty about exposure conditions, and may not provide the scientific detail that can be obtained from well-conducted studies in experimental animals.

A.8.2.1.7.3 Evidence from appropriate studies in experimental animals can furnish much more detail, in the form of clinical observations, and macroscopic and microscopic pathological examination and this can often reveal hazards that may not be life-threatening but could indicate functional impairment. Consequently, all available evidence, and evidence relevance to human health, must be taken into consideration in the classification process. Relevant toxic effects in humans and/or animals include, but are not limited to:

(a) Morbidity resulting from single exposure;

(b) Significant functional changes, more than transient in nature, in the respiratory system, central or peripheral nervous systems, other organs or other organ systems, including signs of central nervous system depression and effects on special senses (e.g., sight, hearing and sense of smell);

(c) Any consistent and significant adverse change in clinical biochemistry, hematology, or urinalysis parameters;

(d) Significant organ damage that may be noted at necropsy and/or subsequently seen or confirmed at microscopic examination;

(e) Multi-focal or diffuse necrosis, fibrosis or granuloma formation in vital organs with regenerative capacity;

(f) Morphological changes that are potentially reversible but provide clear evidence of marked organ dysfunction; and,

(g) Evidence of appreciable cell death (including cell degeneration and reduced cell number) in vital organs incapable of regeneration.

A.8.2.1.8 Effects considered not to support classification for Category 1 and 2.

Effects may be seen in humans and/or animals that do not justify classification. Such effects include, but are not limited to:

(a) Clinical observations or small changes in bodyweight gain, food consumption or water intake that may have some toxicological importance but that do not, by themselves, indicate "significant" toxicity;

(b) Small changes in clinical biochemistry, hematology or urinalysis parameters and/or transient effects, when such changes or effects are of doubtful or of minimal toxicological importance;

(c) Changes in organ weights with no evidence of organ dysfunction;

(d) Adaptive responses that are not considered toxicologically relevant; and,

(e) Substance-induced species-specific mechanisms of toxicity, i.e., demonstrated with reasonable certainty to be not relevant for human health, shall not justify classification.

A.8.2.1.9 Guidance values to assist with classification based on the results obtained fromstudies conducted in experimental animals for Category 1 and 2.

A.8.2.1.9.1 In order to help reach a decision about whether a substance shall be classified or not, and to what degree it shall be classified (Category 1 vs. Category 2), dose/concentration "guidance values" are provided for consideration of the dose/concentration which has been shown to produce significant health effects. The principal argument for proposing such guidance values is that all chemicals are potentially toxic and there has to be a reasonable dose/concentration above which a degree of toxic effect is acknowledged.

A.8.2.1.9.2 Thus, in animal studies, when significant toxic effects are observed that indicate classification, consideration of the dose/concentration at which these effects were seen, in relation to the suggested guidance values, provides useful information to help assess the need to classify (since the toxic effects are a consequence of the hazardous property(ies) and also the dose/concentration).

A.8.2.1.9.3 The guidance value (C) ranges for single-dose exposure which has produced a significant non-lethal toxic effect are those applicable to acute toxicity testing, as indicated in Table A.8.1.

Table A.8.1: Guidance value ranges for single-dose exposures

		Guidance value ranges for:		
Route of exposure	*Units*	**Category 1**	**Category 2**	**Category 3**
Oral (rat)	mg/kg body weight	$C \leq 300$	$2000 \geq C > 300$	Guidance values do not apply
Dermal (rat or rabbit)	mg/kg body weight	$C \leq 1000$	$2000 \geq C > 1000$	
Inhalation (rat) gas	ppmV/4h	$C \leq 2500$	$20{,}000 \geq C > 2500$	
Inhalation (rat) vapor	mg/1/4h	$C \leq 10$	$20 \geq C > 10$	
Inhalation (rat) dust/mist/fume	mg/l/4h	$C \leq 1.0$	$5.0 \geq C > 1.0$	

A.8.2.1.9.4 The guidance values and ranges mentioned in Table A.8.1 are intended only for guidance purposes, i.e., to be used as part of the weight of evidence approach, and to assist with decisions about classification. They are not intended as strict demarcation values. Guidance values are not provided for Category 3 since this classification is primarily based on human data; animal data may be included in the weight of evidence evaluation.

A.8.2.1.9.5 Thus, it is feasible that a specific profile of toxicity occurs at a dose/concentration below the guidance value, e.g., < 2000 mg/kg body weight by the oral route, however the nature of the effect may result in the decision not to classify. Conversely, a specific profile of toxicity may be seen in animal studies occurring at above a guidance value, e.g., ≥ 2000 mg/kg body weight by the oral route, and in addition there is supplementary information from other sources, e.g., other single dose studies, or human case experience, which supports a conclusion that, in view of the weight of evidence, classification is the prudent action to take.

A.8.2.1.10 Other considerations

A.8.2.1.10.1 When a substance is characterized only by use of animal data the classification process includes reference to dose/concentration guidance values as one of the elements that contribute to the weight of evidence approach.

A.8.2.1.10.2 When well-substantiated human data are available showing a specific target organ toxic effect that can be reliably attributed to single exposure to a substance, the substance shall be classified. Positive human data, regardless of probable dose, predominates over animal data. Thus, if a substance is unclassified because specific target organ toxicity observed was considered not relevant or significant to humans, if subsequent human incident data become available showing a specific target organ toxic effect, the substance shall be classified.

A.8.2.1.10.3 A substance that has not been tested for specific target organ toxicity shall, where appropriate, be classified on the basis of data from a scientifically validated structure activity relationship and expert judgment-based extrapolation from a structural analogue that has previously been classified together with substantial support from consideration of other important factors such as formation of common significant metabolites.

A.8.2.2 Substances of Category 3

A.8.2.2.1 Criteria for respiratory tract irritation

The criteria for classifying substances as Category 3 for respiratory tract irritation are:

(a) Respiratory irritant effects (characterized by localized redness, edema, pruritis and/or pain) that impair function with symptoms such as cough, pain, choking, and breathing difficulties are included. It is recognized that this evaluation is based primarily on human data;

(b) Subjective human observations supported by objective measurements of clear respiratory tract irritation (RTI) (e.g., electrophysiological responses, biomarkers of inflammation in nasal or bronchoalveolar lavage fluids);

(c) The symptoms observed in humans shall also be typical of those that would be produced in the exposed population rather than being an isolated idiosyncratic reaction or response triggered only in individuals with hypersensitive airways. Ambiguous reports simply of “irritation” should be excluded as this term is commonly used to describe a wide range of sensations including those such as smell, unpleasant taste, a tickling sensation, and dryness, which are outside the scope of classification for respiratory tract irritation;

(d) There are currently no scientifically validated animal tests that deal specifically with RTI; however, useful information may be obtained from the single and repeated inhalation toxicity tests. For example, animal studies may provide useful information in terms of clinical signs of toxicity (dyspnoea, rhinitis etc) and histopathology (e.g., hyperemia, edema, minimal inflammation, thickened mucous layer) which are reversible and may be reflective of the characteristic clinical symptoms described above. Such animal studies can be used as part of weight of evidence evaluation; and,

(e) This special classification will occur only when more severe organ effects including the respiratory system are not observed as those effects would require a higher classification.

A.8.2.2.2 Criteria for narcotic effects

The criteria for classifying substances in Category 3 for narcotic effects are:

(a) Central nervous system depression including narcotic effects in humans such as drowsiness, narcosis, reduced alertness, loss of reflexes, lack of coordination, and vertigo are included. These effects can also be manifested as severe headache or nausea, and can lead to reduced judgment, dizziness, irritability, fatigue, impaired memory function, deficits in perception and coordination, reaction time, or sleepiness; and,

(b) Narcotic effects observed in animal studies may include lethargy, lack of coordination righting reflex, narcosis, and ataxia. If these effects are not transient in nature, then they shall be considered for classification as Category 1 or 2.

A.8.3 Classification criteria for mixtures

A.8.3.1 Mixtures are classified using the same criteria as for substances, or alternatively as described below. As with substances, mixtures may be classified for specific target organ toxicity following single exposure, repeated exposure, or both.

A.8.3.2 Classification of mixtures when data are available for the complete mixture

When reliable and good quality evidence from human experience or appropriate studies in experimental animals, as described in the criteria for substances, is available for the mixture, then the mixture shall be classified by weight of evidence evaluation of this data. Care shall be exercised in evaluating data on mixtures, that the dose, duration, observation or analysis, do not render the results inconclusive.

A.8.3.3 Classification of mixtures when data are not available for the complete mixture: bridging principles

A.8.3.3.1 Where the mixture itself has not been tested to determine its specific target organ toxicity, but there are sufficient data on both the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data shall be used in accordance with the following bridging principles as found in paragraph A.0.5 of this Appendix: Dilution, Batching, Concentration of mixtures, Interpolation within one [~~toxicity~~] **hazard** category, Substantially similar mixtures, or Aerosols.

A.8.3.4 Classification of mixtures when data are available for all ingredients or only for some ingredients of the mixture

A.8.3.4.1 Where there is no reliable evidence or test data for the specific mixture itself, and the bridging principles cannot be used to enable classification, then classification of the mixture is based on the classification of the ingredient substances. In this case, the mixture shall be classified as a specific target organ toxicant (specific organ specified), following single exposure, repeated exposure, or both when at least one ingredient has been classified as a Category 1 or Category 2 specific target organ toxicant and is present at or above the appropriate cut-off value/concentration limit specified in Table A.8.2 for Categories 1 and 2, respectively.

Table A.8.2: Cut-off values/concentration limits of ingredients of a mixture classified as a specific target organ toxicant that would trigger classification of the mixture as Category 1 or 2

Ingredient classified as:	**Cut-off values/concentration limits triggering classification of a mixture as:**	
	Category 1	*Category 2*
Category 1 Target organ toxicant	≥ 1.0 %	
Category 2 Target organ toxicant		≥ 1.0 %

A.8.3.4.2 These cut-off values and consequent classifications shall be applied equally and appropriately to both single- and repeated-dose target organ toxicants.

A.8.3.4.3 Mixtures shall be classified for either or both single and repeated dose toxicity independently.

A.8.3.4.4 Care shall be exercised when toxicants affecting more than one organ system are combined that the potentiation or synergistic interactions are considered, because certain substances can cause target organ toxicity at < 1% concentration when other ingredients in the mixture are known to potentiate its toxic effect.

A.8.3.4.5 Care shall be exercised when extrapolating the toxicity of a mixture that contains Category 3 ingredient(s). A cut-off value/concentration limit of 20%, considered as an additive of all Category 3 ingredients for each hazard endpoint, is appropriate; however, this cut-off value/concentration limit may be higher or lower depending on the Category 3 ingredient(s) involved and the fact that some effects such as respiratory tract irritation may not occur below a certain concentration while other effects such as narcotic effects may occur below this 20% value. Expert judgment shall be exercised. Respiratory tract irritation and narcotic effects are to be evaluated separately in accordance with the criteria given in A.8.2.2. When conducting classifications for these hazards, the contribution of each ingredient should be considered additive, unless there is evidence that the effects are not additive.

A.8.3.4.6 In cases where the additivity approach is used for Category 3 ingredients, the "relevant ingredients" of a mixture are those which are present in concentrations ≥1% (w/w for solids, liquids, dusts, mists, and vapours and v/v for gases), unless there is a reason to suspect that an ingredient present at a concentration <1% is still relevant when classifying the mixture for respiratory tract irritation or narcotic effects.

A.9 SPECIFIC TARGET ORGAN TOXICITY-- REPEATED OR PROLONGED EXPOSURE

A.9.1 Definitions and general considerations

A.9.1.1 *Specific target organ toxicity - repeated exposure (STOT-RE)* [~~means~~] **refers to** specific **toxic effects on** target organ**s** [~~toxicity arising from~~] **occurring after** repeated exposure to a substance or mixture. All significant health effects that can impair function, both reversible and irreversible, immediate and/or delayed and not specifically addressed in A.1 to A.7 and A.10 of this Appendix are included. Specific target organ toxicity following a single-event exposure is classified in accordance with *SPECIFIC TARGET ORGAN TOXICITY – SINGLE EXPOSURE* (A.8 of this Appendix) and is therefore not included here.

A.9.1.2 Classification identifies the substance or mixture as being a specific target organ toxicant and, as such, it may present a potential for adverse health effects in people who are exposed to it.

A.9.1.3 These adverse health effects produced by repeated exposure include consistent and identifiable toxic effects in humans, or, in experimental animals, toxicologically significant changes which have affected the function or morphology of a tissue/organ, or have produced serious changes to the biochemistry or hematology of the organism and these changes are relevant for human health. Human data will be the primary source of evidence for this hazard class.

A.9.1.4 Assessment shall take into consideration not only significant changes in a single organ or biological system but also generalized changes of a less severe nature involving several organs.

A.9.1.5 Specific target organ toxicity can occur by any route that is relevant for humans, e.g., principally oral, dermal or inhalation.

A.9.2 Classification criteria for substances

A.9.2.1 Substances shall be classified as STOT - RE by expert judgment on the basis of the weight of all evidence available, including the use of recommended guidance values which take into account the duration of exposure and the dose/concentration which produced the effect(s), (See A.9.2.9). Substances shall be placed in one of two categories, depending upon the nature and severity of the effect(s) observed, in accordance with Figure A.9.1.

Figure A.9.1: Hazard categories for specific target organ toxicity following repeated exposure

<u>CATEGORY 1:</u> Substances that have produced significant toxicity in humans, or that, on the basis of evidence from studies in experimental animals can be presumed to have the potential to produce significant toxicity in humans following repeated or prolonged exposure

Substances are classified in Category 1 for specific target organ toxicity (repeated exposure) on the basis of

(a) reliable and good quality evidence from human cases or epidemiological studies; or,

(b) observations from appropriate studies in experimental animals in which significant and/or severe toxic effects, of relevance to human health, were produced at generally low exposure concentrations. Guidance dose/concentration values are provided below (See A.9.2.9) to be used as part of weight-of-evidence evaluation.

<u>CATEGORY 2</u>: Substances that, on the basis of evidence from studies in experimental animals can be presumed to have the potential to be harmful to human health following repeated or prolonged exposure

Substances are classified in Category 2 for specific target organ toxicity (repeated exposure) on the basis of observations from appropriate studies in experimental animals in which significant toxic effects, of relevance to human health, were produced at generally moderate exposure concentrations. Guidance dose/concentration values are provided below (See A.9.2.9) in order to help in classification.

In exceptional cases human evidence can also be used to place a substance in Category 2 (See A.9.2.6).

Note: *The primary target organ/system shall be identified where possible, or the substance shall be identified as a general toxicant. The data shall be carefully evaluated and, where possible, shall not include secondary effects (e.g., a hepatotoxicant can produce secondary effects in the nervous or gastro-intestinal systems).*

Editorial Note: figure A.9.1 includes a format change as shown above. Content is unchanged.

A.9.2.2 The relevant route of exposure by which the classified substance produces damage shall be identified.

A.9.2.3 Classification is determined by expert judgment, on the basis of the weight of all evidence available including the guidance presented below.

A.9.2.4 Weight of evidence of all data, including human incidents, epidemiology, and studies conducted in experimental animals, is used to substantiate specific target organ toxic effects that merit classification.

A.9.2.5 The information required to evaluate specific target organ toxicity comes either from repeated exposure in humans, e.g., exposure at home, in the workplace or environmentally, or from studies conducted in experimental animals. The standard animal studies in rats or mice that provide this information are 28 day, 90 day or lifetime studies (up to 2 years) that include hematological, clinico-chemical and detailed macroscopic and microscopic examination to enable the toxic effects on target tissues/organs to be identified. Data from repeat dose studies performed in other species may also be used. Other long-term exposure studies, e.g., for carcinogenicity, neurotoxicity or reproductive toxicity, may also provide evidence of specific target organ toxicity that could be used in the assessment of classification.

A.9.2.6 In exceptional cases, based on expert judgment, it may be appropriate to place certain substances with human evidence of specific target organ toxicity in Category 2: (a) when the weight of human evidence is not sufficiently convincing to warrant Category 1 classification, and/or (b) based on the nature and severity of effects. Dose/concentration levels in humans shall not be considered in the classification and any available evidence from animal studies shall be consistent with the Category 2 classification. In other words, if there are also animal data available on the substance that warrant Category 1 classification, the substance shall be classified as Category 1.

A.9.2.7 Effects considered to support classification

A.9.2.7.1 Classification is supported by reliable evidence associating repeated exposure to the substance with a consistent and identifiable toxic effect.

A.9.2.7.2 Evidence from human experience/incidents is usually restricted to reports of adverse health consequences, often with uncertainty about exposure conditions, and may not provide the scientific detail that can be obtained from well-conducted studies in experimental animals.

A.9.2.7.3 Evidence from appropriate studies in experimental animals can furnish much more detail, in the form of clinical observations, hematology, clinical chemistry, macroscopic and microscopic pathological examination and this can often reveal hazards that may not be life-threatening but could indicate functional impairment. Consequently, all available evidence, and relevance to human health, must be taken into consideration in the classification process. Relevant toxic effects in humans and/or animals include, but are not limited to:

(a) Morbidity or death resulting from repeated or long-term exposure. Morbidity or death may result from repeated exposure, even to relatively low doses/concentrations, due to bioaccumulation of the substance or its metabolites, or due to the overwhelming of the de-toxification process by repeated exposure;

(b) Significant functional changes in the central or peripheral nervous systems or other organ systems, including signs of central nervous system depression and effects on special senses (e.g., sight, hearing and sense of smell);

(c) Any consistent and significant adverse change in clinical biochemistry, hematology, or urinalysis parameters;

(d) Significant organ damage that may be noted at necropsy and/or subsequently seen or confirmed at microscopic examination;

(e) Multi-focal or diffuse necrosis, fibrosis or granuloma formation in vital organs with regenerative capacity;

(f) Morphological changes that are potentially reversible but provide clear evidence of marked organ dysfunction (e.g., severe fatty change in the liver); and,

(g) Evidence of appreciable cell death (including cell degeneration and reduced cell number) in vital organs incapable of regeneration.

A.9.2.8 Effects considered not to support classification

Effects may be seen in humans and/or animals that do not justify classification. Such effects include, but are not limited to:

(a) Clinical observations or small changes in bodyweight gain, food consumption or water intake that may have some toxicological importance but that do not, by themselves, indicate "significant" toxicity;

(b) Small changes in clinical biochemistry, hematology or urinalysis parameters and /or transient effects, when such changes or effects are of doubtful or of minimal toxicological importance;

(c) Changes in organ weights with no evidence of organ dysfunction;

(d) Adaptive responses that are not considered toxicologically relevant;

(e) Substance-induced species-specific mechanisms of toxicity, i.e., demonstrated with reasonable certainty to be not relevant for human health, shall not justify classification.

A.9.2.9 Guidance values to assist with classification based on the results obtained from studies conducted in experimental animals

A.9.2.9.1 In studies conducted in experimental animals, reliance on observation of effects alone, without reference to the duration of experimental exposure and dose/concentration, omits a fundamental concept of toxicology, i.e., all substances are potentially toxic, and what determines the toxicity is a function of the dose/concentration and the duration of exposure. In most studies conducted in experimental animals the test guidelines use an upper limit dose value.

A.9.2.9.2 In order to help reach a decision about whether a substance shall be classified or not, and to what degree it shall be classified (Category 1 vs. Category 2), dose/concentration “guidance values” are provided in Table A.9.1 for consideration of the dose/concentration which has been shown to produce significant health effects. The principal argument for proposing such guidance values is that all chemicals are potentially toxic and there has to be a reasonable dose/concentration above which a degree of toxic effect is acknowledged. Also, repeated-dose studies conducted in experimental animals are designed to produce toxicity at the highest dose used in order to optimize the test objective and so most studies will reveal some toxic effect at least at this highest dose. What is therefore to be decided is not only what effects have been produced, but also at what dose/concentration they were produced and how relevant is that for humans.

A.9.2.9.3 Thus, in animal studies, when significant toxic effects are observed that indicate classification, consideration of the duration of experimental exposure and the dose/concentration at which these effects were seen, in relation to the suggested guidance values, provides useful information to help assess the need to classify (since the toxic effects are a consequence of the hazardous property(ies) and also the duration of exposure and the dose/concentration).

A.9.2.9.4 The decision to classify at all can be influenced by reference to the dose/concentration guidance values at or below which a significant toxic effect has been observed.

A.9.2.9.5 The guidance values refer to effects seen in a standard 90-day toxicity study conducted in rats. They can be used as a basis to extrapolate equivalent guidance values for toxicity studies of greater or lesser duration, using dose/exposure time extrapolation similar to Haber’s rule for inhalation, which states essentially that the effective dose is directly proportional to the exposure concentration and the duration of exposure. The assessment should be done on a case-by-case basis; for example, for a 28-day study the guidance values below would be increased by a factor of three.

A.9.2.9.6 Thus for Category 1 classification, significant toxic effects observed in a 90-day repeated-dose study conducted in experimental animals and seen to occur at or below the (suggested) guidance values (C) as indicated in Table A.9.1 would justify classification:

Table A.9.1: Guidance values to assist in Category 1 classification

(applicable to a 90-day study)

Route of exposure	Units	**Guidance values (dose/concentration)**
Oral (rat)	mg/kg body weight/day	$C \leq 10$
Dermal (rat or rabbit)	mg/kg body weight/day	$C \leq 20$
Inhalation (rat) gas	ppmV/6h/day	$C \leq 50$
Inhalation (rat) vapor	mg/liter/6h/day	$C \leq 0.2$
Inhalation (rat) dust/mist/fume	mg/liter/6h/day	$C \leq 0.02$

A.9.2.9.7 For Category 2 classification, significant toxic effects observed in a 90-day repeated-dose study conducted in experimental animals and seen to occur within the (suggested) guidance value ranges as indicated in Table A.9.2 would justify classification:

Table A.9.2: Guidance values to assist in Category 2 classification (applicable to a 90-day study)

Route of exposure	Units	Guidance value range (dose/concentration)
Oral (rat)	mg/kg body weight/day	$10 < C \leq 100$
Dermal (rat or rabbit)	mg/kg body weight/day	$20 < C \leq 200$
Inhalation (rat) gas	ppmV/6h/day	$50 < C \leq 250$
Inhalation (rat) vapor	mg/liter/6h/day	$0.2 < C \leq 1.0$
Inhalation (rat) dust/mist/fume	mg/liter/6h/day	$0.02 < C \leq 0.2$

A.9.2.9.8 The guidance values and ranges mentioned in A.2.9.9.6 and A.2.9.9.7 are intended only for guidance purposes, i.e., to be used as part of the weight of evidence approach, and to assist with decisions about classification. They are not intended as strict demarcation values.

A.9.2.9.9 Thus, it is possible that a specific profile of toxicity occurs in repeat-dose animal studies at a dose/concentration below the guidance value, e.g., < 100 mg/kg body weight/day by the oral route, however the nature of the effect, e.g., nephrotoxicity seen only in male rats of a particular strain known to be susceptible to this effect, may result in the decision not to classify. Conversely, a specific profile of toxicity may be seen in animal studies occurring at above a guidance value, e.g., ≥ 100 mg/kg body weight/day by the oral route, and in addition there is supplementary information from other sources, e.g., other long-term administration studies, or human case experience, which supports a conclusion that, in view of the weight of evidence, classification is prudent.

A.9.2.10 Other considerations

A.9.2.10.1 When a substance is characterized only by use of animal data the classification process includes reference to dose/concentration guidance values as one of the elements that contribute to the weight of evidence approach.

A.9.2.10.2 When well-substantiated human data are available showing a specific target organ toxic effect that can be reliably attributed to repeated or prolonged exposure to a substance, the substance shall be classified. Positive human data, regardless of probable dose, predominates over animal data. Thus, if a substance is unclassified because no specific target organ toxicity was seen at or below the dose/concentration guidance value for animal testing, if subsequent human incident data become available showing a specific target organ toxic effect, the substance shall be classified.

A.9.2.10.3 A substance that has not been tested for specific target organ toxicity may in certain instances, where appropriate, be classified on the basis of data from a scientifically validated structure activity relationship and expert judgment-based extrapolation from a structural analogue that has previously been classified together with substantial support from consideration of other important factors such as formation of common significant metabolites.

A.9.3 Classification criteria for mixtures

A.9.3.1 Mixtures are classified using the same criteria as for substances, or alternatively as described below. As with substances, mixtures may be classified for specific target organ toxicity following single exposure, repeated exposure, or both.

A.9.3.2 Classification of mixtures when data are available for the complete mixture

When reliable and good quality evidence from human experience or appropriate studies in experimental animals, as described in the criteria for substances, is available for the mixture, then the mixture shall be classified by weight of evidence evaluation of these data. Care shall be exercised in evaluating data on mixtures, that the dose, duration, observation or analysis, do not render the results inconclusive.

A.9.3.3 Classification of mixtures when data are not available for the complete mixture: bridging principles

A.9.3.3.1 Where the mixture itself has not been tested to determine its specific target organ toxicity, but there are sufficient data on both the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data shall be used in accordance with the following bridging principles as found in paragraph A.0.5 of this Appendix: Dilution; Batching; Concentration of mixtures; Interpolation within one [~~toxicity~~] **hazard** category; Substantially similar mixtures; and Aerosols.

A.9.3.4 Classification of mixtures when data are available for all ingredients or only for some ingredients of the mixture

A.9.3.4.1 Where there is no reliable evidence or test data for the specific mixture itself, and the bridging principles cannot be used to enable classification, then classification of the mixture is based on the classification of the ingredient substances. In this case, the mixture shall be classified as a specific target organ toxicant (specific organ specified), following single exposure, repeated exposure, or both when at least one ingredient has been classified as a Category 1 or Category 2 specific target organ toxicant and is present at or above the appropriate cut-off value/concentration limit specified in Table A.9.3 for Category 1 and 2 respectively.

Table A.9.3: Cut-off value/concentration limits of ingredients of a mixture classified as a specific target organ toxicant that would trigger classification of the mixture as Category 1 or 2

Ingredient classified as:	**Cut-off values/concentration limits triggering classification of a mixture as:**	
	Category 1	**Category 2**
Category 1 Target organ toxicant	≥ 1.0 %	
Category 2 Target organ toxicant		≥ 1.0 %

A.9.3.4.2 These cut-off values and consequent classifications shall be applied equally and appropriately to both single- and repeated-dose target organ toxicants.

A.9.3.4.3 Mixtures shall be classified for either or both single- and repeated-dose toxicity independently.

A.9.3.4.4 Care shall be exercised when toxicants affecting more than one organ system are combined that the potentiation or synergistic interactions are considered, because certain substances can cause specific target organ toxicity at < 1% concentration when other ingredients in the mixture are known to potentiate its toxic effect.

A.10 ASPIRATION HAZARD

A.10.1 Definitions and general [~~and specific~~] considerations

A.10.1.1 *Aspiration* [~~means the entry of a liquid or solid chemical directly through the oral or nasal cavity, or indirectly from vomiting, into the trachea and lower respiratory system~~] ***hazard* refers to severe acute effects such as chemical pneumonia, pulmonary injury or death occurring after aspiration of a substance or mixture**.

A.10.1.2 [~~Aspiration toxicity includes severe acute effects such as chemical pneumonia, varying degrees of pulmonary injury or death following aspiration.~~] ***Aspiration* means the entry of a liquid or solid chemical directly through the oral or nasal cavity, or indirectly from vomiting, into the trachea and lower respiratory system**

A.10.1.3 Aspiration is initiated at the moment of inspiration, in the time required to take one breath, as the causative material lodges at the crossroad of the upper respiratory and digestive tracts in the laryngopharyngeal region.

A.10.1.4 Aspiration of a substance or mixture can occur as it is vomited following ingestion. This may have consequences for labeling, particularly where, due to acute toxicity, a recommendation may be considered to induce vomiting after ingestion. However, if the substance/mixture also presents an aspiration toxicity hazard, the recommendation to induce vomiting may need to be modified.

A.10.1.5 Specific considerations

A.10.1.5.1 The classification criteria refer to kinematic viscosity. The following provides the conversion between dynamic and kinematic viscosity:

$$\frac{\text{Dynamic viscosity}(\text{mPa}\cdot\text{s})}{\text{Density}(\text{g/cm}^3)} = \text{Kinematic viscosity}(\text{mm}^2/\text{s})$$

A.10.1.5.2 Although the definition of aspiration in A.10.1.1 includes the entry of solids into the respiratory system, classification according to (b) in table A.10.1 for Category 1 is intended to apply to liquid substances and mixtures only.

A.10.1.5.3 Classification of aerosol/mist products

Aerosol and mist products are usually dispensed in containers such as self-pressurized containers, trigger and pump sprayers. Classification for these products shall be considered if their use may form a pool of product in the mouth, which then may be aspirated. If the mist or aerosol from a pressurized container is fine, a pool may not be formed. On the other hand, if a pressurized container dispenses product in a stream, a pool may be formed that may then be aspirated. Usually, the mist produced by trigger and pump sprayers is coarse and therefore, a pool may be formed that then may be aspirated. When the pump mechanism may be removed and contents are available to be swallowed then the classification of the products should be considered.

A.10.2 Classification criteria for substances

Table A.10.1: Criteria for aspiration toxicity

Category	Criteria
Category 1: Chemicals known to cause human aspiration toxicity hazards or to be regarded as if they cause human aspiration toxicity hazard	A substance shall be classified in Category 1: (a) If reliable and good quality human evidence indicates that it causes aspiration toxicity (See note); or (b) If it is a hydrocarbon and has a kinematic viscosity ≤ 20.5 mm^2/s, measured at 40° C.

Note: Examples of substances included in Category 1 are certain hydrocarbons, turpentine and pine oil.

A.10.3 Classification criteria for mixtures

A.10.3.1 Classification when data are available for the complete mixture

A mixture shall be classified in Category 1 based on reliable and good quality human evidence.

A.10.3.2 Classification of mixtures when data are not available for the complete mixture: bridging principles

A.10.3.2.1 Where the mixture itself has not been tested to determine its aspiration toxicity, but there are sufficient data on both the individual ingredients and similar tested mixtures to adequately characterize the hazard of the mixture, these data shall be used in accordance with the following bridging principles as found in paragraph A.0.5 of this Appendix: Dilution; Batching; Concentration of mixtures; Interpolation within one [~~toxicity~~] **hazard** category; and Substantially similar mixtures. For application of the dilution bridging principle, the concentration of aspiration toxicants shall not be less than 10%.

A.10.3.3 Classification of mixtures when data are available for all ingredients or only for some ingredients of the mixture

A.10.3.3.1 [~~A mixture which contains ≥ 10% of an ingredient or ingredients classified in Category 1, and has a kinematic viscosity ≤ 20.5 mm^2/s, measured at 40 °C, shall be classified in Category 1~~] **The "relevant ingredients" of a mixture are those which are present in concentrations ≥ 1%**.

A.10.3.3.2 [~~In the case of a mixture which separates into two or more distinct layers, one of which contains ≥ 10 % of an ingredient or ingredients classified in Category 1 and has a kinematic viscosity ≤ 20.5 mm^2/s, measured at 40 °C, then the entire mixture shall be classified in~~] Category 1.

A.10.3.3.2.1 A mixture is classified as Category 1 when the sum of the concentrations of Category 1 ingredients is ≥ 10%, and the mixture has a kinematic viscosity of ≤ 20.5 mm^2/s, measured at 40°C.

A.10.3.3.2.2 In the case of a mixture which separates into two or more distinct layers, the entire mixture is classified as Category 1 if in any distinct layer the sum of the concentrations of Category 1 ingredients is ≥ 10%, and it has a kinematic viscosity of ≤ 20.5 mm^2/s, measured at 40°C.

Stat. Auth: ORS 654.025(2) and 656.726(4).
Stats. Implemented: ORS 654.001 through 654.295.

Hist: OR-OSHA Admin. Order 12-1993, f. 8/20/93, ef. 11/1/93.
OR-OSHA Admin. Order 4-1994, f. 8/4/94, ef. 8/4/94.
OR-OSHA Admin. Order 4-2013, f. 7/19/13, ef. 7/19/13.

Appendix B to §1910.1200 – Physical Hazard Criteria (Mandatory)

B.1 EXPLOSIVES

B.1.1 Definitions and [~~g~~]General [~~c~~]Considerations

B.1.1.1 An *explosive chemical* is a solid or liquid chemical which is in itself capable by chemical reaction of producing gas at such a temperature and pressure and at such a speed as to cause damage to the surroundings. Pyrotechnic chemicals are included even when they do not evolve gases.

A *pyrotechnic chemical* is a chemical designed to produce an effect by heat, light, sound, gas or smoke or a combination of these as the result of non-detonative self-sustaining exothermic chemical reactions.

An *explosive item* is an item containing one or more explosive chemicals.

A *pyrotechnic item* is an item containing one or more pyrotechnic chemicals.

An *unstable explosive* is an explosive which is thermally unstable and/or too sensitive for normal handling, transport, or use.

An *intentional explosive* is a chemical or item which is manufactured with a view to produce a practical explosive or pyrotechnic effect.

B.1.1.2 The class of explosives comprises:

(a) Explosive chemicals;

(b) Explosive items, except devices containing explosive chemicals in such quantity or of such a character that their inadvertent or accidental ignition or initiation shall not cause any effect external to the device either by projection, fire, smoke, heat or loud noise; and

(c) Chemicals and items not included under (a) and (b) [~~above~~] **of this section** which are manufactured with the view to producing a practical explosive or pyrotechnic effect.

B.1.2 Classification [~~c~~]Criteria

Chemicals and items of this class shall be classified as unstable explosives or shall be assigned to one of the following six divisions depending on the type of hazard they present:

(a) Division 1.1 - Chemicals and items which have a mass explosion hazard (a mass explosion is one which affects almost the entire quantity present virtually instantaneously);

(b) Division 1.2 - Chemicals and items which have a projection hazard but not a mass explosion hazard;

(c) Division 1.3 - Chemicals and items which have a fire hazard and either a minor blast hazard or a minor projection hazard or both, but not a mass explosion hazard:

(i) Combustion of which gives rise to considerable radiant heat; or

(ii) Which burn one after another, producing minor blast or projection effects or both;

(d) Division 1.4 - Chemicals and items which present no significant hazard: chemicals and items which present only a small hazard in the event of ignition or initiation. The effects are largely confined to the package and no projection of fragments of appreciable size or range is to be expected. An external fire shall not cause virtually instantaneous explosion of almost the entire contents of the package;

(e) Division 1.5 - Very insensitive chemicals which have a mass explosion hazard: chemicals which have a mass explosion hazard but are so insensitive that there is very little probability of initiation or of transition from burning to detonation under normal conditions;

(f) Division 1.6 - Extremely insensitive items which do not have a mass explosion hazard: items which **predominantly** contain [~~only~~] extremely insensitive detonating chemicals and which demonstrate a negligible probability of accidental initiation or propagation.

B.1.3 Additional [~~c~~]Classification [~~c~~]Considerations

B.1.3.1 Explosives shall be classified as unstable explosives or shall be assigned to one of the six divisions identified in B.1.2 in accordance with the three step procedure in Part I of [~~the~~]UN ST/SG/AC.10 (incorporated by reference; [~~S~~]**s**ee §1910.6). The first step is to ascertain whether the substance or mixture has explosive effects (Test Series 1). The second step is the acceptance procedure (Test Series 2 to 4) and the third step is the assignment to a hazard division (Test Series 5 to 7). The assessment whether a candidate for “ammonium nitrate emulsion or suspension or gel, intermediate for blasting explosives (ANE)” is insensitive enough for inclusion as an oxidizing liquid ([~~S~~]**s**ee B.13 **of this appendix**) or an oxidizing solid ([~~S~~]**s**ee B.14 **of this appendix**) is determined by Test Series 8 tests of UN ST/SG/AC.10/.

NOTE 1: Classification of solid chemicals shall be based on tests performed on the chemical as presented. If, for example, for the purposes of supply or transport, the same chemical is to be presented in a physical form different from that which was tested and which is considered likely to materially alter its performance in a classification test, classification must be based on testing of the chemical in the new form.

NOTE 2: Some explosive chemicals are wetted with water or alcohols, diluted with other substances or dissolved or suspended in water or other liquid substances to suppress or reduce their explosive properties or sensitivity. These chemicals shall be classified as desensitized explosives (see Chapter B.17).

NOTE 3: Chemicals with a positive result in Test Series 2 in Part I, Section 12 of UN ST/SG/AC.10/11/Rev.6 (incorporated by reference; see §1910.6) which are exempted from classification as explosives (based on a negative result in Test Series 6 in Part I, Section 16 of UN ST/SG/AC.10/11/Rev.6 (incorporated by reference; see §1910.6)), still have explosive properties. The explosive properties of the chemical shall be communicated in Section 2 (Hazard identification) and Section 9 (Physical and chemical properties) of the Safety Data Sheet, as appropriate.

B.1.3.2 Explosive properties are associated with the presence of certain chemical groups in a molecule which can react to produce very rapid increases in temperature or pressure. The screening procedure in B.1.3.1 is aimed at identifying the presence of such reactive groups and the potential for rapid energy release. If the screening procedure identifies the chemical as a potential explosive, the acceptance procedure ([~~S~~]**s**ee section 10.3 of the UN ST/SG/AC.10 (incorporated by reference; [~~S~~]**s**ee §1910.6)) is necessary for classification.

NOTE: Neither a Series 1 type (a) propagation of detonation test nor a Series 2 type (a) test of sensitivity to detonative shock is necessary if the exothermic decomposition energy of organic materials is less than 800 J/g.

B.1.3.3 If a mixture contains any known explosives, the acceptance procedure is necessary for classification.

B.1.3.4 A chemical is not classified as explosive if:

(a) There are no chemical groups associated with explosive properties present in the molecule. Examples of groups which may indicate explosive properties are given in Table A6.1 in Appendix 6 of the UN ST/SG/AC.10 (incorporated by reference; ~~S~~**s**ee §1910.6); or

(b) The substance contains chemical groups associated with explosive properties which include oxygen and the calculated oxygen balance is less than -200.

The oxygen balance is calculated for the chemical reaction:
$C_xH_yO_z + [x + (y/4)-(z/2)] O_2 \rightarrow x. CO_2 + (y/2) H_2O$
using the formula: oxygen balance = -1600 [2x +(y/2) -z]/molecular weight; or

(c) The organic substance or a homogenous mixture of organic substances contains chemical groups associated with explosive properties but the exothermic decomposition energy is less than 500 J/g and the onset of exothermic decomposition is below 500°C (932°F). The exothermic decomposition energy may be determined using a suitable calorimetric technique; or

(d) For mixtures of inorganic oxidizing substances with organic material(s), the concentration of the inorganic oxidizing substance is:

> (i) less than 15%, by mass, if the oxidizing substance is assigned to Category 1 or 2;
>
> (ii) less than 30%, by mass, if the oxidizing substance is assigned to Category 3.

B.2 FLAMMABLE GASES

B.2.1 Definition

Flammable gas means a gas having a flammable range with air at 20°C (68°F) and a standard pressure of 101.3 kPa (14.7 psi).

A pyrophoric gas means a flammable gas that is liable to ignite spontaneously in air at a temperature of 54°C (130°F) or below.

A chemically unstable gas means a flammable gas that is able to react explosively even in the absence of air or oxygen.

B.2.2 Classification [~~c~~]Criteria

[~~A flammable gas shall be classified in one of the two categories for this class in accordance with Table B.2.1:~~]

B.2.2.1 A flammable gas shall be classified in Category 1A, 1B or 2 [~~one of the two categories for this class~~] in accordance with Table B.2.1:

Table B.2.1[~~:~~] Criteria for flammable gases

[~~Category~~	**~~Criteria~~**
~~1~~	~~Gases, which at 20°C (68°F) and a standard pressure of 101.3 kPa (14.7 psi):~~ ~~(a) are ignitable when in a mixture of 13% or less by volume in air; or~~ ~~(b) have a flammable range with air of at least 12 percentage points regardless of the lower flammable limit.~~
~~2~~	~~Gases, other than those of Category 1, which, at 20°C (68°F) and a standard pressure of 101.3 kPa (14.7 psi), have a flammable range while mixed in air.~~]

Category		**Criteria**
1A	**Flammable gas**	**Gases, which at 20°C (68ºF) and a standard pressure of 101.3 kPa (14.7 psi):** **(a) are ignitable when in a mixture of 13% or less by volume in air; or** **(b) have a flammable range with air of at least 12 percentage points regardless of the lower flammability limit,** **unless data show they meet the criteria for Category 1B.**
	Pyrophoric gas	**Flammable gases that ignite spontaneously in air at a temperature of 54ºC (130ºF) or below.**

	Chemically unstable gas	A	Flammable gases which are chemically unstable at 20°C (68ºF) and a standard pressure of 101.3 kPa (14.7 psi).
		B	Flammable gases which are chemically unstable at a temperature greater than 20°C (68ºF) and/or a pressure greater than 101.3 kPa (14.7 psi).
1B	Flammable gas		Gases which meet the flammability criteria for Category 1A, but which are not pyrophoric, nor chemically unstable, and which have at least either: (a) lower flammability limit of more than 6% by volume in air; or (b) a fundamental burning velocity of less than 10 cm/s.
2	Flammable gas		Gases, other than those of Category 1A or 1B, which, at 20°C (68ºF) and a standard pressure of 101.3 kPa (14.7 psi), have a flammable range while mixed in air.

NOTE 1: *Aerosols should not be classified as flammable gases. See B.3.*

NOTE 2: In the absence of data allowing classification into Category 1B, a flammable gas that meets the criteria for Category 1A shall be classified by default in Category 1A.

NOTE 3: Spontaneous ignition for pyrophoric gases is not always immediate, and there may be a delay.

NOTE 4: In the absence of data on its pyrophoricity, a flammable gas mixture shall be classified as a pyrophoric gas if it contains more than 1% (by volume) of pyrophoric component(s).

B.2.3 Additional [~~c~~]Classification [~~c~~]Considerations

~~Flammability shall be determined by tests or by calculation in accordance with ISO 10156 (incorporated by reference; See §1910.6). Where insufficient data are available to use this method, equivalent validated methods may be used.~~

B.2.3.1 Flammability shall be determined by tests or by calculation in accordance with ISO 10156:1996 or ISO 10156:2017 (incorporated by reference; see §1910.6) and, if using fundamental burning velocity for Category 1B, use Annex C: Method of test for burning velocity measurement of flammable gases of ISO 817:2014(E) (incorporated by reference; see §1910.6). Where insufficient data are available to use this method, equivalent validated methods may be used.

B.2.3.2 Pyrophoricity shall be determined at 130°F (54°C) in accordance with either IEC 60079-20-1 or DIN 51794:2003 (incorporated by reference; see §1910.6).

B.2.3.3 The classification procedure for pyrophoric gases need not be applied when experience in production or handling shows that the substance does not ignite spontaneously on coming into contact with air at a temperature of 130°F (54ºC) or below. Flammable gas mixtures, which have not been tested for pyrophoricity and which contain more than one percent pyrophoric components shall be classified as a pyrophoric gas. Expert judgement on the properties and physical hazards of pyrophoric gases and their mixtures should be used in assessing the need for classification of flammable gas mixtures containing one percent or less pyrophoric components. In this case, testing need only be considered if expert judgement indicates a need for additional data to support the classification process.

B.2.3.4 Chemical instability shall be determined in accordance with the method described in Part III of the UN ST/SG/AC.10/11/Rev.6 (incorporated by reference; see §1910.6). If the calculations performed in accordance with ISO 10156:1996 or ISO 10156:2017 (incorporated by reference; see §1910.6) show that a gas mixture is not flammable, no additional testing is required for determining chemical instability for classification purposes.

B.3 [~~FLAMMABLE~~] AEROSOLS AND CHEMICALS UNDER PRESSURE

B.3.1 Aerosols

B.3.1.1 Definition

Aerosol means any non-refillable receptacle containing a gas compressed, liquefied or dissolved under pressure, and fitted with a release device allowing the contents to be ejected as particles in suspension in a gas, or as a foam, paste, powder, liquid or gas.

B.3.1.2 Classification Criteria

B.3.1.2.1 Aerosols are classified in one of three categories, depending on their flammable properties and their heat of combustion. Aerosols shall be considered for classification in Categories 1 or 2 if they contain more than 1% components (by mass) which are classified as flammable in accordance with this Appendix B, i.e.:

Flammable gases (see B.2);
Flammable liquids (see B.6)
Flammable solids (see B.7)
or if their heat of combustion is at least 20 kJ/g.

B.3.1.2.2 An aerosol shall be classified in one of the three categories for this class in accordance with Table B.3.1.

Table B.3.1[~~:~~]- Criteria for aerosols

Category	Criteria
1	Contains ≥85% flammable components and the chemical heat of combustion is ≥ 30 kJ/g; or (a) For spray aerosols, in the ignition distance test, ignition occurs at a distance ≥75 cm (29.5 in), or (b) For foam aerosols, in the aerosol foam flammability test (i) The flame height is ≥20 cm (7.87 in) and the flame duration ≥2 s; or (ii) The flame height is ≥4 cm (1.57 in) and the flame duration ≥7 s
2	Contains >1% flammable components, or the heat of combustion is ≥20 kJ/g; and (a) for spray aerosols, in the ignition distance test, ignition occurs at a distance ≥15 cm (5.9 in), or in the enclosed space ignition test, the (i) Time equivalent is ≤300 s/m^3; or (ii) Deflagration density is ≤300 g/m^3 (b) For foam aerosols, in the aerosol foam flammability test, the flame height is ≥4 cm and the flame duration is ≥2 s and it does not meet the criteria for Category 1
3	(1) The chemical does not meet the criteria for Categories 1 and 2. (2) The chemical contains ≤1% flammable components (by mass) and has a heat of combustion <20 kJ/g.

[~~**NOTE:** Aerosols not submitted to the flammability classification procedures in this Appendix shall be classified as extremely flammable (Category 1).~~]

NOTE 1: Flammable components do not include pyrophoric, self-heating or water-reactive chemicals.

NOTE 2: Aerosols do not fall additionally within the scope of flammable gases, gases under pressure, flammable liquids, or flammable solids. However, depending on their contents, aerosols may fall within the scope of other hazard classes.

NOTE 3: Aerosols containing more than 1% flammable components or with a heat of combustion of at least 20 kJ/g, which are not submitted to the flammability classification procedures in this Appendix shall be classified as Category 1.

[~~B.3.2 Classification criteria~~]

[~~B.3.2.1 Aerosols shall be considered for classification as flammable if they contain any component which is classified as flammable in accordance with this Appendix, i.e.:~~

~~Flammable liquids (See B.6);~~

~~Flammable gases (See B.2);~~

~~Flammable solids (See B.7).~~

> ~~**NOTE 1:** Flammable components do not include pyrophoric, self-heating or water-reactive chemicals.~~
>
> ~~**NOTE 2:** Flammable aerosols do not fall additionally within the scope of flammable gases, flammable liquids, or flammable solids.~~]

[~~B.3.2.2 A flammable aerosol shall be classified in one of the two categories for this class in accordance with Table B.3.1.~~]

[~~Table B.3.1: Criteria for aerosols~~]

[~~Category~~	**~~Criteria~~**
~~1~~	~~Contains ≥ 85% flammable components and the chemical heat of combustion is ≥ 30 kJ/g; or~~ ~~(a) For spray aerosols, in the ignition distance test, ignition occurs at a distance ≥ 75 cm (29.5 in), or~~ ~~(b) For foam aerosols, in the aerosol foam flammability test~~ ~~(i) The flame height is ≥ 20 cm (7.87 in) and the flame duration ≥ 2 s; or~~ ~~(ii) The flame height is ≥ 4 cm (1.57 in) and the flame duration ≥ 7 s~~
~~2~~	~~Contains > 1% flammable components, or the heat of combustion is ≥ 20 kJ/g; and~~ ~~(a) for spray aerosols, in the ignition distance test, ignition occurs at a distance ≥ 15 cm (5.9 in), or~~ ~~in the enclosed space ignition test, the~~ ~~(i) Time equivalent is ≤ 300 s/m^3; or~~ ~~(ii) Deflagration density is ≤ 300 g/m^3~~ ~~(b) For foam aerosols, in the aerosol foam flammability test, the flame height is ≥ 4 cm and the flame duration is ≥ 2 s~~ ~~and it does not meet the criteria for Category 1~~]

[~~**NOTE:** Aerosols not submitted to the flammability classification procedures in this Appendix shall be classified as extremely flammable (Category 1)~~].

B.3.2 Chemicals Under Pressure

B.3.2.1 Definition

Chemicals under pressure are liquids or solids (e.g., pastes or powders), pressurized with a gas at a pressure of 200 kPa (gauge) or more at 20°C in pressure receptacles other than aerosol dispensers and which are not classified as gases under pressure.

NOTE: Chemicals under pressure typically contain 50% or more by mass of liquids or solids whereas mixtures containing more than 50% gases are typically considered as gases under pressure.

B.3.2.2 Classification Criteria

B.3.2.2.1 Chemicals under pressure are classified in one of three categories of this hazard class, in accordance with Table B.3.2, depending on their content of flammable components and their heat of combustion.

B.3.2.2.2 Flammable components are components which are classified as flammable in accordance with the GHS criteria, i.e.:

- **– Flammable gases (see B.2 of this section);**
- **– Flammable liquids (see B.6 of this section);**
- **– Flammable solids (see B.7 of this section).**

Table B.3.2[~~:~~]- Criteria for chemicals under pressure

Category	Criteria
1	Any chemical under pressure that: (a) contains ≥[]85% flammable components (by mass); and (b) has a heat of combustion of ≥[]20 kJ/g.
2	Any chemical under pressure that: (a) contains >[]1% flammable components (by mass); and (b) has a heat of combustion <[]20 kJ/g; or that: (a) contains <[]85% flammable components (by mass); and (b) has a heat of combustion ≥[]20 kJ/g.
3	Any chemical under pressure that: (a) contains ≤[]1% flammable components (by mass); and (b) has a heat of combustion of <[]20 kJ/g.

NOTE 1: The flammable components in a chemical under pressure do not include pyrophoric, self-heating or water reactive, substances and mixtures because such components are not allowed in chemicals under pressure in accordance with the UN Model Regulations.

NOTE 2: Chemicals under pressure do not fall additionally within the scope of section B.3.1 (aerosols), B.2.2 (flammable gases), B.2.5 (gases under pressure),

B.2.6 (flammable liquids) and B.2.7 (flammable solids). Depending on their contents, chemicals under pressure may however fall within the scope of other hazard classes, including their labelling elements.

B.3.3 Additional [~~c~~]**C**lassification [~~c~~]**C**onsiderations

B.3.3.1 To classify a**n** [~~flammable~~]aerosol, data on its flammable components, on its chemical heat of combustion and, if applicable, the results of the aerosol foam flammability test (for foam aerosols) and of the ignition distance test and enclosed space test (for spray aerosols) are necessary.

B.3.3.2 The chemical heat of combustion (ΔHc), in kilojoules per gram (kJ/g), is the product of the theoretical heat of combustion ($\Delta Hcomb$), and a combustion efficiency, usually less than 1.0 (a typical combustion efficiency is 0.95 or 95%).

For a composite [~~aerosol~~] formulation, the chemical heat of combustion is the summation of the weighted heats of combustion for the individual components, as follows:

ΔHc (product) = $\sum_{i}^{n}$ [w(i)[~~%~~] × $\Delta Hc(i)$]

where:

ΔHc **(product)** = **specific** [~~chemical~~] heat of combustion (kJ/g) **of the product**;
$\Delta Hc(i)$ = specific heat of combustion (kJ/g) of component i in the product;

w(i) = mass fraction of component i in the product;
n = total number of components in the product.

[~~The chemical heats of combustion shall be found in literature, calculated or determined by tests (See ASTM D240-02, ISO 13943, Sections 86.1 to 86.3, and NFPA 30B (incorporated by reference; See §1910.6)).~~]

B.3.3.3 [~~The Ignition Distance Test, Enclosed Space Ignition Test and Aerosol Foam Flammability Test shall be performed in accordance with sub-sections 31.4, 31.5 and 31.6 of the of the UN ST/SG/AC.10 (incorporated by reference; See §1910.6~~).] **The chemical heats of combustion shall be found in literature, calculated or determined by tests: (see ASTM D240; Sections 86.1 to 86.3 of ISO 13943; and NFPA 30B (incorporated by reference; see §1910.6)).**

B.3.3.4 The Ignition Distance Test, Enclosed Space Ignition Test and Aerosol Foam Flammability Test shall be performed in accordance with sub-sections 31.4, 31.5 and 31.6 of UN ST/SG/AC.10 (incorporated by reference; see §1910.6).

B.4 OXIDIZING GASES

B.4.1 Definition

Oxidizing gas means any gas which may, generally by providing oxygen, cause or contribute to the combustion of other material more than air does.

NOTE: “Gases which cause or contribute to the combustion of other material more than air does” means pure gases or gas mixtures with an oxidizing power greater than 23.5% (as determined by a method specified in ISO 10156**:1996, ISO 10156:2017 or 10156-2:2005** [~~or 10156-2~~] (incorporated by reference, [~~S~~]**s**ee §1910.6)or an equivalent testing method.)

B.4.2 Classification [~~c~~]Criteria

An oxidizing gas shall be classified in a single category for this class in accordance with Table B.4.1:

Table B.4.1[~~:~~]- Criteria for oxidizing gases

Category	Criteria
1	Any gas which may, generally by providing oxygen, cause or contribute to the combustion of other material more than air does.

B.4.3 Additional [~~c~~]Classification [~~c~~]Considerations

Classification shall be in accordance with tests or calculation methods as described in ISO 10156**:1996, ISO 10156:2017 or 10156- 2:2005** (incorporated by reference; [~~S~~]**s**ee §1910.6) [~~and ISO 10156-2 (incorporated by reference; see §1910.6)~~].

B.5 GASES UNDER PRESSURE

B.5.1 Definition

Gases under pressure are gases which are contained in a receptacle at a pressure of 200 kPa (29 psi) (gauge) or more **at 20°C (68°F)**, or which are liquefied or liquefied and refrigerated.

They comprise compressed gases, liquefied gases, dissolved gases and refrigerated liquefied gases.

B.5.2 Classification [~~c~~]Criteria

Gases under pressure shall be classified in one of four groups in accordance with Table B.5.1:

Table B.5.1[~~:~~]- Criteria for gases under pressure

Group	Criteria
Compressed gas	A gas which when under pressure is entirely gaseous at -50°C (-58°F), including all gases with a critical temperature[1] ≤ -50°C (-58°F).
Liquefied gas	A gas which when under pressure is partially liquid at temperatures above -50°C (-58°F). A distinction is made between: (a) High pressure liquefied gas: a gas with a critical temperature[1] between -50°C (-58°F) and +65°C (149°F); and (b) Low pressure liquefied gas: a gas with a critical temperature[1] above +65°C (149°F).
Refrigerated liquefied gas	A gas which is made partially liquid because of its low temperature.
Dissolved gas	A gas which when under pressure is dissolved in a liquid phase solvent.

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(1) The critical temperature is the temperature above which a pure gas cannot be liquefied, regardless of the degree of compression.

NOTE: Aerosols should not be classified as gases under pressure. See Appendix B.3 of this section

B.6 FLAMMABLE LIQUIDS

B.6.1 Definition

Flammable liquid means a liquid having a flash point of not more than 93°C (199.4°F).

Flash point means the minimum temperature at which a liquid gives off vapor in sufficient concentration to form an ignitable mixture with air near the surface of the liquid, as determined by a method identified in Section B.6.3 **of this appendix**.

B.6.2 Classification [~~c~~]**C**riteria

A flammable liquid shall be classified in one of four categories in accordance with Table B.6.1 **of this appendix**:

Table B.6.1[~~:~~]-** Criteria for [f]Flammable [~~l~~]Liquids**

Category	Criteria
1	Flash point <23°C (73.4°F) and initial boiling point ≤35°C (95°F)
2	Flash point <23°C (73.4°F) and initial boiling point >35°C (95°F)
3	Flash point ≥23°C (73.4°F) and ≤60°C (140°F)
4	Flash point >60°C (140°F) and ≤93°C (199.4°F)

NOTE: Aerosols should not be classified a flammable liquids. See Appendix B.3 of this section.

B.6.3 Additional [~~c~~]**C**lassification [~~c~~]**C**onsiderations

The flash point shall be determined in accordance with ASTM D56-05, ASTM D3278, ASTM D3828, ASTM D93-08 (incorporated by reference; [~~S~~]see §1910.6), **or any other method** specified in [~~GHS Revision 3, Chapter 2.6~~] 29 CFR 1910.106(a)(14). **It may also be determined by any other method specified in GHS Revision 7, Chapter 2.6.**

The initial boiling point shall be determined in accordance with ASTM D86-07a or ASTM D1078 (incorporated by reference; [~~S~~]**s**ee §1910.6)[9].

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[9] **To determine the appropriate flammable liquid storage container size and type, the boiling point shall be determined by § 1910.106(a)(5). In addition, the manufacturer, importer, and distributor shall clearly note in sections 7 and 9 of the SDS if an alternate calculation was used for storage purposes and the classification for storage differs from the classification listed in Section 2 of the SDS.**

B.7 FLAMMABLE SOLIDS

B.71 Definitions

Flammable solid means a solid which is a readily combustible solid, or which may cause or contribute to fire through friction.

Readily combustible solids are powdered, granular, or pasty chemicals which are dangerous if they can be easily ignited by brief contact with an ignition source, such as a burning match, and if the flame spreads rapidly.

B.7.2 Classification [~~c~~]**C**riteria

B.7.2.1 Powdered, granular or pasty chemicals shall be classified as flammable solids when the time of burning of one or more of the test runs, performed in accordance with the test method described in [~~the UN ST/SG/AC.10 (incorporated by reference; See §1910.6)~~], Part III, subsection 33.2.1 **of UN ST/SG/AC.10 (incorporated by reference; see §1910.6)**, is less than 45 s or the rate of burning is more than 2.2 mm/s (0.0866 in/s).

B.7.2.2 Powders of metals or metal alloys shall be classified as flammable solids when they can be ignited and the reaction spreads over the whole length of the sample in 10 min or less.

B.7.2.3 Solids which may cause fire through friction shall be classified in this class by analogy with existing entries (e.g., matches) until definitive criteria are established.

B.7.2.4 A flammable solid shall be classified in one of the two categories for this class using Method N.1 as described in Part III, sub-section 33.2.1 of the UN ST/SG/AC.10 (incorporated by reference; [~~S~~]**s**ee §1910.6), in accordance with Table B.7.1:

Table B.7.1[~~:~~]- Criteria for [~~f~~]Flammable **[~~s~~]S**olids**

Category	Criteria
1	Burning rate test: Chemicals other than metal powders: (a) Wetted zone does not stop fire; and (b) Burning time <[]45 s or burning rate >[]2.2 mm/s Metal powders: burning time ≤[]5 min
2	Burning rate test: Chemicals other than metal powders: (a) Wetted zone stops the fire for at least 4 min; and (b) Burning time <[]45 s or burning rate >[]2.2 mm/s

		Metal powders: burning time >[]5 min and ≤[]10 min

NOTE 1: Classification of solid chemicals shall be based on tests performed on the chemical as presented. If, for example, for the purposes of supply or transport, the same chemical is to be presented in a physical form different from that which was tested and which is considered likely to materially alter its performance in a classification test, classification must be based on testing of the chemical in the new form.

NOTE 2: Aerosols should not be classified as flammable solids. See Appendix B.3.

B.8 SELF-REACTIVE CHEMICALS

B.8.1 Definitions

Self-reactive chemicals are thermally unstable liquid or solid chemicals liable to undergo a strongly exothermic decomposition even without participation of oxygen (air). This definition excludes chemicals classified under this section as explosives, organic peroxides, oxidizing liquids or oxidizing solids.

A self-reactive chemical is regarded as possessing explosive properties when in laboratory testing the formulation is liable to detonate, to deflagrate rapidly or to show a violent effect when heated under confinement.

B.8.2 Classification [~~c~~]Criteria

B.8.2.1 A self-reactive chemical shall be considered for classification in this class unless:

(a) It is classified as an explosive according to B.1 of this appendix;

(b) It is classified as an oxidizing liquid or an oxidizing solid according to B.13 or B.14 of this appendix, except that a mixture of oxidizing substances which contains 5% or more of combustible organic substances shall be classified as a self-reactive chemical according to the procedure defined in B.8.2.2;

(c) It is classified as an organic peroxide according to B.15 of this appendix;

(d) Its heat of decomposition is less than 300 J/g; or

(e) Its self-accelerating decomposition temperature (SADT) is greater than 75°C (167°F) for a 50 kg (110 lb) package.

B.8.2.2 Mixtures of oxidizing substances, meeting the criteria for classification as oxidizing liquids or oxidizing solids, which contain 5% or more of combustible organic substances and which do not meet the criteria mentioned in B.8.2.1 (a), (c), (d) or (e), shall be subjected to the self-reactive chemicals classification procedure in B.8.2.3. Such a mixture showing the properties of a self-reactive chemical type B to F shall be classified as a self-reactive chemical.

B.8.2.3 Self-reactive chemicals shall be classified in one of the seven categories of “types A to G” for this class, according to the following principles:

(a) Any self-reactive chemical which can detonate or deflagrate rapidly, as packaged, will be defined as self-reactive chemical TYPE A;

(b) Any self-reactive chemical possessing explosive properties and which, as packaged, neither detonates nor deflagrates rapidly, but is liable to undergo a thermal explosion in that package will be defined as self-reactive chemical TYPE B;

(c) Any self-reactive chemical possessing explosive properties when the chemical as packaged cannot detonate or deflagrate rapidly or undergo a thermal explosion will be defined as self-reactive chemical TYPE C;

(d) Any self-reactive chemical which in laboratory testing meets the criteria in (d)(i), (ii), or (iii) will be defined as self-reactive chemical TYPE D:

(i) Detonates partially, does not deflagrate rapidly and shows no violent effect when heated under confinement; or

(ii) Does not detonate at all, deflagrates slowly and shows no violent effect when heated under confinement; or

(iii) Does not detonate or deflagrate at all and shows a medium effect when heated under confinement;

(e) Any self-reactive chemical which, in laboratory testing, neither detonates nor deflagrates at all and shows low or no effect when heated under confinement will be defined as self-reactive chemical TYPE E;

(f) Any self-reactive chemical which, in laboratory testing, neither detonates in the cavitated state nor deflagrates at all and shows only a low or no effect when heated under confinement as well as low or no explosive power will be defined as self-reactive chemical TYPE F;

(g) Any self-reactive chemical which, in laboratory testing, neither detonates in the cavitated state nor deflagrates at all and shows no effect when heated under confinement nor any explosive power, provided that it is thermally stable (self-accelerating decomposition temperature is 60°C (140°F) to 75°C (167°F) for a 50 kg (110 lb) package), and, for liquid mixtures, a diluent having a boiling point greater than or equal to 150°C (302°F) is used for desensitization will be defined as self-reactive chemical TYPE G. If the mixture is not thermally stable or a diluent having a boiling point less than 150°C (302°F) is used for desensitization, the mixture shall be defined as self-reactive chemical TYPE F.

B.8.3 Additional [~~c~~]Classification [~~c~~]Considerations

B.8.3.1 For purposes of classification, the properties of self-reactive chemicals shall be determined in accordance with test series A to H as described in Part II of the UN ST/SG/AC.10 (incorporated by reference; [~~S~~]see §1910.6).

B.8.3.2 Self-accelerating decomposition temperature (SADT) shall be determined in accordance with the UN ST/SG/AC.10, Part II, section 28 (incorporated by reference; [~~S~~] **s**ee §1910.6).

B.8.3.3 The classification procedures for self-reactive substances and mixtures need not be applied if:

(a) There are no chemical groups present in the molecule associated with explosive or self-reactive properties; examples of such groups are given in Tables A6.1 and A6.2 in the Appendix 6 of [~~the~~] UN ST/SG/AC.10 (incorporated by reference; [~~S~~]**s**ee §1910.6); or

(b) For a single organic substance or a homogeneous mixture of organic substances, the estimated SADT is greater than 75°C (167°F) or the exothermic decomposition energy is less than 300 J/g. The onset temperature and decomposition energy may be estimated using a suitable calorimetric technique (See 20.3.3.3 in Part II of the UN ST/SG/AC.10 (incorporated by reference; [~~S~~]**s**ee §1910.6)).

B.9 PYROPHORIC LIQUIDS

B.9.1 Definition

Pyrophoric liquid means a liquid which, even in small quantities, is liable to ignite within five minutes after coming into contact with air.

B.9.2 Classification [~~c~~]Criteria

A pyrophoric liquid shall be classified in a single category for this class using test N.3 in Part III, sub-section 33.3.1.5 of [~~the~~] UN ST/SG/AC.10 (incorporated by reference; [~~S~~]**s**ee §1910.6), in accordance with Table B.9.1 **of this appendix**:

Table B.9.1[~~:~~] - Criteria for pyrophoric liquids

Category	Criteria
1	The liquid ignites within 5 min when added to an inert carrier and exposed to air, or it ignites or chars a filter paper on contact with air within 5 min.

B.9.3 Additional [~~c~~]Classification [~~c~~]Considerations

The classification procedure for pyrophoric liquids need not be applied when experience in production or handling shows that the chemical does not ignite spontaneously on coming into contact with air at normal temperatures (i.e., the substance is known to be stable at room temperature for prolonged periods of time (days)).

B.10 PYROPHORIC SOLIDS

B.10.1 Definition

Pyrophoric solid means a solid which, even in small quantities, is liable to ignite within five minutes after coming into contact with air.

B.10.2 Classification [~~c~~]Criteria

A pyrophoric solid shall be classified in a single category for this class using test N.2 in Part III, sub-section 33.3.1.4 of [~~the~~] UN ST/SG/AC.10 (incorporated by reference; [~~S~~]see §1910.6), in accordance with Table B.10.1 **of this appendix**:

Table B.10.1[~~:~~]- Criteria for pyrophoric solids

Category	Criteria
1	The solid ignites within 5 min of coming into contact with air.

NOTE: Classification of solid chemicals shall be based on tests performed on the chemical as presented. If, for example, for the purposes of supply or transport, the same chemical is to be presented in a physical form different from that which was tested and which is considered likely to materially alter its performance in a classification test, classification must be based on testing of the chemical in the new form.

B.10.3 Additional [~~c~~]Classification [~~c~~]Considerations

The classification procedure for pyrophoric solids need not be applied when experience in production or handling shows that the chemical does not ignite spontaneously on coming into contact with air at normal temperatures (i.e., the chemical is known to be stable at room temperature for prolonged periods of time (days)).

B.11 SELF-HEATING CHEMICALS

B.11.1 Definition

A *self-heating chemical* is a solid or liquid chemical, other than a pyrophoric liquid or solid, which, by reaction with air and without energy supply, is liable to self-heat; this chemical differs from a pyrophoric liquid or solid in that it will ignite only when in large amounts (kilograms) and after long periods of time (hours or days).

NOTE: Self-heating of a substance or mixture is a process where the gradual reaction of that substance or mixture with oxygen (in air) generates heat. If the rate of heat production exceeds the rate of heat loss, then the temperature of the substance or mixture will rise which, after an induction time, may lead to self-ignition and combustion.

B.11.2 Classification [~~c~~]Criteria

B.11.2.1 A self-heating chemical shall be classified in one of the two categories for this class if, in tests performed in accordance with test method N.4 in Part III, sub-section 33.3.1.6 of [~~the~~] UN ST/SG/AC.10 (incorporated by reference; [~~S~~]see §1910.6), the result meets the criteria shown in Table B.11.1.

Table B.11.1[:] - Criteria for self-heating chemicals

Category	Criteria
1	A positive result is obtained in a test using a 25 mm sample cube at 140°C (284°F)
2	A negative result is obtained in a test using a 25 mm cube sample at 140°C (284°F), a positive result is obtained in a test using a 100 mm sample cube at 140°C (284°F), and: (a) The unit volume of the chemical is more than 3 m^3; or (b) A positive result is obtained in a test using a 100 mm cube sample at 120°C (248°F) and the unit volume of the chemical is more than 450 liters; or (c) A positive result is obtained in a test using a 100 mm cube sample at 100°C (212°F).

NOTE: Classification of solid chemicals shall be based on tests performed on the chemical as presented. If, for example, for the purposes of supply or transport, the same chemical is to be presented in a physical form different from that which was tested and which is considered likely to materially alter its performance in a classification test, classification must be based on testing of the chemical in the new form.

B.11.2.2 Chemicals with a temperature of spontaneous combustion higher than 50°C (122°F) for a volume of 27 m^3 shall not be classified as self-heating chemicals.

B.11.2.3 Chemicals with a spontaneous ignition temperature higher than 50°C (122°F) for a volume of 450 liters shall not be classified in Category 1 of this class.

B.11.3 Additional classification considerations

B.11.3.1 The classification procedure for self-heating chemicals need not be applied if the results of a screening test can be adequately correlated with the classification test and an appropriate safety margin is applied.

B.11.3.2 Examples of screening tests are:

(a) The Grewer Oven test (VDI guideline 2263, part 1, 1990, Test methods for the Determination of the Safety Characteristics of Dusts) with an onset temperature 80°K above the reference temperature for a volume of 1 *l*;

(b) The Bulk Powder Screening Test (Gibson, N. Harper, D. J. Rogers, R. Evaluation of the fire and explosion risks in drying powders, Plant Operations Progress, 4 (3), 181-189, 1985) with an onset temperature 60°K above the reference temperature for a volume of 1 *l*.

B.12 CHEMICALS WHICH, IN CONTACT WITH WATER, EMIT FLAMMABLE GASES

B.12.1 Definition

Chemicals which, in contact with water, emit flammable gases are solid or liquid chemicals which, by interaction with water, are liable to become spontaneously flammable or to give off flammable gases in dangerous quantities.

B.12.2 Classification [~~c~~]Criteria

B.12.2.1 A chemical which, in contact with water, emits flammable gases shall be classified in one of the three categories for this class, using test N.5 in Part III, sub-section 33.4.1.4 of [~~the~~] UN ST/SG/AC.10 (incorporated by reference; [~~S~~]**s**ee §1910.6), in accordance with Table B.12.1 **of this appendix**:

Table B.12.1[~~:~~]- Criteria for chemicals which, in contact with water, emit flammable gases

Category	Criteria
1	Any chemical which reacts vigorously with water at ambient temperatures and demonstrates generally a tendency for the gas produced to ignite spontaneously, or which reacts readily with water at ambient temperatures such that the rate of evolution of flammable gas is equal to or greater than 10 liters per kilogram of chemical over any one minute.
2	Any chemical which reacts readily with water at ambient temperatures such that the maximum rate of evolution of flammable gas is equal to or greater than 20 liters per kilogram of chemical per hour, and which does not meet the criteria for Category 1.
3	Any chemical which reacts slowly with water at ambient temperatures such that the maximum rate of evolution of flammable gas is [~~equal to or~~] greater than 1 liter per kilogram of chemical per hour, and which does not meet the criteria for Categories 1 and 2.

NOTE: Classification of solid chemicals shall be based on tests performed on the chemical as presented. If, for example, for the purposes of supply or transport, the same chemical is to be presented in a physical form different from that which was tested and which is considered likely to materially alter its performance in a classification test, classification must be based on testing of the chemical in the new form.

B.12.2.2 A chemical is classified as a chemical which, in contact with water, emits flammable gases if spontaneous ignition takes place in any step of the test procedure.

B.12.3 Additional [~~c~~]Classification [~~c~~]Considerations

The classification procedure for this class need not be applied if:

(a) The chemical structure of the chemical does not contain metals or metalloids;

(b) Experience in production or handling shows that the chemical does not react with water, (e.g., the chemical is manufactured with water or washed with water); or

(c) The chemical is known to be soluble in water to form a stable mixture.

B.13 OXIDIZING LIQUIDS

B.13.1 Definition

Oxidizing liquid means a liquid which, while in itself not necessarily combustible, may, generally by yielding oxygen, cause, or contribute to, the combustion of other material.

B.13.2 Classification [~~c~~]Criteria

An oxidizing liquid shall be classified in one of the three categories for this class using test O.2 in Part III, sub-section 34.4.2 of [~~the~~] UN ST/SG/AC.10 (incorporated by reference; [~~S~~]**s**ee §1910.6), in accordance with Table B.13.1:

Table B.13.1[~~:~~]- Criteria for oxidizing liquids

Category	Criteria
1	Any chemical which, in the 1:1 mixture, by mass, of chemical and cellulose tested, spontaneously ignites; or the mean pressure rise time of a 1:1 mixture, by mass, of chemical and cellulose is less than that of a 1:1 mixture, by mass, of 50% perchloric acid and cellulose;
2	Any chemical which, in the 1:1 mixture, by mass, of chemical and cellulose tested, exhibits a mean pressure rise time less than or equal to the mean pressure rise time of a 1:1 mixture, by mass, of 40% aqueous sodium chlorate solution and cellulose; and the criteria for Category 1 are not met;
3	Any chemical which, in the 1:1 mixture, by mass, of chemical and cellulose tested, exhibits a mean pressure rise time less than or equal to the mean pressure rise time of a 1:1 mixture, by mass, of 65% aqueous nitric acid and cellulose; and the criteria for Categories 1 and 2 are not met.

B.13.3 Additional [~~c~~]Classification [~~c~~]Considerations

B.13.3.1 For organic chemicals, the classification procedure for this class shall not be applied if:

(a) The chemical does not contain oxygen, fluorine or chlorine; or

(b) The chemical contains oxygen, fluorine or chlorine and these elements are chemically bonded only to carbon or hydrogen.

B.13.3.2 For inorganic chemicals, the classification procedure for this class shall not be applied if the chemical does not contain oxygen or halogen atoms.

B.13.3.3 In the event of divergence between test results and known experience in the handling and use of chemicals which shows them to be oxidizing, judgments based on known experience shall take precedence over test results.

B.13.3.4 In cases where chemicals generate a pressure rise (too high or too low), caused by chemical reactions not characterizing the oxidizing properties of the chemical, the test described in Part III, sub-section 34.4.2 of [~~the~~] UN ST/SG/AC.10 (incorporated by reference; [~~S~~]see §1910.6) shall be repeated with an inert substance (e.g., diatomite (kieselguhr)) in place of the cellulose in order to clarify the nature of the reaction.

B.14 OXIDIZING SOLIDS

B.14.1 Definition

Oxidizing solid means a solid which, while in itself is not necessarily combustible, may, generally by yielding oxygen, cause, or contribute to, the combustion of other material.

B.14.2 Classification [~~c~~]Criteria

An oxidizing solid shall be classified in one of the three categories for this class using test O.1 in Part III, sub-section 34.4.1 of [~~the~~] UN ST/SG/AC.10 (incorporated by reference; [~~S~~]**s**ee §1910.6), **or test O.3 in Part III, sub-section 34.4.3 of UN ST/SG/AC.10/11 (incorporated by reference, see §1910.6)**,in accordance with Table B.14.1:

Table B.14.1[:]- Criteria for oxidizing solids

[~~Category~~	~~Criteria~~
~~1~~	~~Any chemical which, in the 4:1 or 1:1 sample-to-cellulose ratio (by mass) tested, exhibits a mean burning time less than the mean burning time of a 3:2 mixture, by mass, of potassium bromate and cellulose.~~
~~2~~	~~Any chemical which, in the 4:1 or 1:1 sample-to-cellulose ratio (by mass) tested, exhibits a mean burning time equal to or less than the mean burning time of a 2:3 mixture (by mass) of potassium bromate and cellulose and the criteria for Category 1 are not met.~~
~~3~~	~~Any chemical which, in the 4:1 or 1:1 sample-to-cellulose ratio (by mass) tested, exhibits a mean burning time equal to or less than the mean burning time of a 3:7 mixture (by mass) of potassium bromate and cellulose and the criteria for Categories 1 and 2 are not met.~~]

Category	**Criteria using test O.1**	**Criteria using test O.3**
1	**Any chemical which, in the 4:1 or 1:1 sample-to-cellulose ratio (by mass) tested, exhibits a mean burning time less than the mean burning time of a 3:2 mixture, (by mass), of potassium bromate and cellulose.**	**Any chemical which, in the 4:1 or 1:1 sample-to- cellulose ratio (by mass) tested, exhibits a mean burning rate greater than the mean burning rate of a 3:1 mixture (by mass) of calcium peroxide and cellulose.**
2	**Any chemical which, in the 4:1 or 1:1 sample-to-cellulose ratio (by mass) tested, exhibits a**	**Any chemical which, in the 4:1 or 1:1 sample-to- cellulose ratio (by mass) tested, exhibits a**

	mean burning time equal to or less than the mean burning time of a 2:3 mixture (by mass) of potassium bromate and cellulose and the criteria for Category 1 are not met.	**mean burning rate equal to or greater than the mean burning rate of a 1:1 mixture (by mass) of calcium peroxide and cellulose and the criteria for Category 1 are not met.**
3	**Any chemical which, in the 4:1 or 1:1 sample-to-cellulose ratio (by mass) tested, exhibits a mean burning time equal to or less than the mean burning time of a 3:7 mixture (by mass) of potassium bromate and cellulose and the criteria for Categories 1 and 2 are not met.**	**Any chemical which, in the 4:1 or 1:1 sample- to - cellulose ratio (by mass) tested, exhibits a mean burning rate equal to or greater than the mean burning rate of a 1:2 mixture (by mass) of calcium peroxide and cellulose and the criteria for Categories 1 and 2 are not met.**

NOTE 1: Some oxidizing solids may present explosion hazards under certain conditions (e.g., when stored in large quantities). For example, some types of ammonium nitrate may give rise to an explosion hazard under extreme conditions and the "Resistance to detonation test" (**International Maritime Solid Bulk Cargoes Code**, IMO[~~: Code of Safe Practice for Solid Bulk Cargoes, 2005, Annex 3, Test 5~~] **(IMSBC), Appendix 2, Section 5**) may be used to assess this hazard. When information indicates that an oxidizing solid may present an explosion hazard, it shall be indicated on the Safety Data Sheet.

NOTE 2: Classification of solid chemicals shall be based on tests performed on the chemical as presented. If, for example, for the purposes of supply or transport, the same chemical is to be presented in a physical form different from that which was tested and which is considered likely to materially alter its performance in a classification test, classification must be based on testing of the chemical in the new form.

B.14.3 Additional [~~c~~]Classification [~~c~~]Considerations

B.14.3.1 For organic chemicals, the classification procedure for this class shall not be applied if:

(a) The chemical does not contain oxygen, fluorine or chlorine; or

(b) The chemical contains oxygen, fluorine or chlorine and these elements are chemically bonded only to carbon or hydrogen.

B.14.3.2 For inorganic chemicals, the classification procedure for this class shall not be applied if the chemical does not contain oxygen or halogen atoms.

B.14.3.3 In the event of divergence between test results and known experience in the handling and use of chemicals which shows them to be oxidizing, judgements based on known experience shall take precedence over test results.

B.15 ORGANIC PEROXIDES

B.15.1 Definition

B.15.1.1 *Organic peroxide* means a liquid or solid organic chemical which contains the bivalent -0-0- structure and as such is considered a derivative of hydrogen peroxide, where one or both of the hydrogen atoms have been replaced by organic radicals. The term organic peroxide includes organic peroxide mixtures containing at least one organic peroxide. Organic peroxides are thermally unstable chemicals, which may undergo exothermic self-accelerating decomposition. In addition, they may have one or more of the following properties:

(a) Be liable to explosive decomposition;

(b) Burn rapidly;

(c) Be sensitive to impact or friction;

(d) React dangerously with other substances.

B.15.1.2 An organic peroxide is regarded as possessing explosive properties when in laboratory testing the formulation is liable to detonate, to deflagrate rapidly or to show a violent effect when heated under confinement.

B.15.2 Classification [~~c~~]Criteria

B.15.2.1 Any organic peroxide shall be considered for classification in this class, unless it contains:

(a) Not more than 1.0% available oxygen from the organic peroxides when containing not more than 1.0% hydrogen peroxide; or

(b) Not more than 0.5% available oxygen from the organic peroxides when containing more than 1.0% but not more than 7.0% hydrogen peroxide.

NOTE: The available oxygen content (%) of an organic peroxide mixture is given by the formula:

$$16 \times \sum_{i}^{n} \left(\frac{n_i \times c_i}{m_i} \right)$$

where:

n_i = number of peroxygen groups per molecule of organic peroxide i;
c_i = concentration (mass %) of organic peroxide i;

m_i = molecular mass of organic peroxide i.

B.15.2.2 Organic peroxides shall be classified in one of the seven categories of “Types A to G” for this class, according to the following principles:

(a) Any organic peroxide which, as packaged, can detonate or deflagrate rapidly shall be defined as organic peroxide TYPE A;

(b) Any organic peroxide possessing explosive properties and which, as packaged, neither detonates nor deflagrates rapidly, but is liable to undergo a thermal explosion in that package shall be defined as organic peroxide TYPE B;

(c) Any organic peroxide possessing explosive properties when the chemical as packaged cannot detonate or deflagrate rapidly or undergo a thermal explosion shall be defined as organic peroxide TYPE C;

(d) Any organic peroxide which in laboratory testing meets the criteria in (d)(i), (ii), or (iii) shall be defined as organic peroxide TYPE D:

(i) Detonates partially, does not deflagrate rapidly and shows no violent effect when heated under confinement; or

(ii) Does not detonate at all, deflagrates slowly and shows no violent effect when heated under confinement; or

(iii) Does not detonate or deflagrate at all and shows a medium effect when heated under confinement;

(e) Any organic peroxide which, in laboratory testing, neither detonates nor deflagrates at all and shows low or no effect when heated under confinement shall be defined as organic peroxide TYPE E;

(f) Any organic peroxide which, in laboratory testing, neither detonates in the cavitated state nor deflagrates at all and shows only a low or no effect when heated under confinement as well as low or no explosive power shall be defined as organic peroxide TYPE[-**]** F;

(g) Any organic peroxide which, in laboratory testing, neither detonates in the cavitated state nor deflagrates at all and shows no effect when heated under confinement nor any explosive power, provided that it is thermally stable (self-accelerating decomposition temperature is 60°C (140°F) or higher for a 50 kg (110 lb) package), and, for liquid mixtures, a diluent having a boiling point of not less than 150°C (302°F) is used for desensitization, shall be defined as organic peroxide TYPE G. If the organic peroxide is not thermally stable or a diluent having a boiling point less than 150°C (302°F) is used for desensitization, it shall be defined as organic peroxide TYPE F.

B.15.3 Additional [~~c~~]**C**lassification [~~c~~]**C**onsiderations

B.15.3.1 For purposes of classification, the properties of organic peroxides shall be determined in accordance with test series A to H as described in Part II of [~~the~~] UN ST/SG/AC.10 (incorporated by reference; [~~S~~]**s**ee §1910.6).

B.15.3.2 Self-accelerating decomposition temperature (SADT) shall be determined in accordance with [~~the~~] UN ST/SG/AC.10 (incorporated by reference; [~~S~~]**s**ee §1910.6), Part II, section 28.

B.15.3.3 Mixtures of organic peroxides may be classified as the same type of organic peroxide as that of the most dangerous ingredient. However, as two stable ingredients can form a thermally less stable mixture, the SADT of the mixture shall be determined.

B.16 CORROSIVE TO METALS

B.16.1 Definition

A *chemical which is corrosive to metals* means a chemical which by chemical action will materially damage, or even destroy, metals.

B.16.2 Classification [~~c~~]Criteria

A chemical which is corrosive to metals shall be classified in a single category for this class, using the test in Part III, sub-section 37.4 of [~~the~~] UN ST/SG/AC.10 (incorporated by reference; [~~S~~]see §1910.6), in accordance with Table B.16.1:

Table B.16.1[~~:~~]- Criteria for chemicals corrosive to metal

Category	Criteria
1	Corrosion rate on either steel or aluminium surfaces exceeding 6.25 mm per year at a test temperature of 55°C (131°F) when tested on both materials.

NOTE: Where an initial test on either steel or aluminium indicates the chemical being tested is corrosive the follow-up test on the other metal is not necessary.

B.16.3 Additional [~~c~~]Classification [~~c~~]Considerations

The specimen to be used for the test shall be made of the following materials:

(a) For the purposes of testing steel, steel types S235JR+CR (1.0037 resp.St 37-2), S275J2G3+CR (1.0144 resp.St 44-3), ISO 3574, Unified Numbering System (UNS) G 10200, or SAE 1020;

(b) For the purposes of testing aluminium: non-clad types 7075-T6 or AZ5GU-T6.

B.17 DESENSITIZED EXPLOSIVES

B.17.1 Definitions and General Considerations

Desensitized explosives are solid or liquid explosive chemicals which are phlegmatized[10] to suppress their explosive properties in such a manner that they do not mass explode and do not burn too rapidly and therefore may be exempted from the hazard class “Explosives” (Chapter B.1; see also Note 2 of paragraph B.1.3).[11]

B.17.1.1 The class of desensitized explosives comprises:

(a) Solid desensitized explosives: explosive substances or mixtures which are wetted with water or alcohols or are diluted with other substances, to form a homogeneous solid mixture to suppress their explosive properties.

NOTE: This includes desensitization achieved by formation of hydrates of the substances.

(b) Liquid desensitized explosives: explosive substances or mixtures which are dissolved or suspended in water or other liquid substances, to form a homogeneous liquid mixture to suppress their explosive properties.

B.17.2 Classification Criteria

B.17.2.1 Any explosive which is desensitized shall be considered in this class, unless:

(a) It is intended to produce a practical, explosive or pyrotechnic effect; or

It has a mass explosion hazard according to test series 6(a) or 6(b) or its corrected burning rate according to the burning rate test described in part V, subsection 51.4 of UNST/SG/AC.10/11/Rev.6 (incorporated by reference, see §1910.6) is greater than 1200 kg/min; or

(b) Its exothermic decomposition energy is less than 300 J/g.

[10] Phlegmatized means that a substance (or “phlegmatizer”) has been added to an explosive to enhance its safety in handling and transport. The phlegmatizer renders the explosive insensitive, or less sensitive, to the following actions:
heat, shock, impact, percussion or friction. Typical phlegmatizing agents include, but are not limited to: wax, paper, water, polymers (such as chlorofluoropolymers), alcohol and oils (such as petroleum jelly and paraffin).

[11] *Unstable explosives as defined in Chapter B.1 can also be stabilized by desensitization and consequently may be reclassified as desensitized explosives, provided all criteria of Chapter B.17 are met. In this case, the desensitized explosive should be tested according to Test Series 3 (Part I of UN ST/SG/AC.10/11/Rev. 6 (incorporated by reference, see §1910.6)) because information about its sensitiveness to mechanical stimuli is likely to be important for determining conditions for safe handling and use. The results shall be communicated on the safety data sheet.*

> *NOTE 1: Substances or mixtures which meet the criterion (a) or (b) shall be classified as explosives (see Chapter B.1). Substances or mixtures which meet the criterion (c) may fall within the scope of other physical hazard classes.*

> *NOTE 2: The exothermic decomposition energy may be estimated using a suitable calorimetric technique (see section 20, sub-section 20.3.3.3 in Part II of UN ST/SG/AC.10/11/Rev.6 (incorporated by reference, see §1910.6).*

[~~B.17.2.2 Desensitized explosives shall be classified in one of the four categories of this class depending on the corrected burning rate (Ac) using the test "burning rate test (external fire)" described in Part V, sub-section 51.4 of UN ST/SG/AC.10/11/Rev.6 (incorporated by reference, see §1910.6), according to Table B.17.1:~~

B.17.2.2 Desensitized explosives shall be classified in one of the four categories of this class depending on the corrected burning rate (Ac) using the test "burning rate test (external fire)" described in Part V, sub-section 51.4 of UN ST/SG/AC.10/11/Rev.6 (incorporated by reference, see §1910.6), according to Table B.17.1:

Table B.17.1- Criteria for Desensitized Explosives

Category	Criteria
1	Desensitized explosives with a corrected burning rate (AC) equal to or greater than 300 kg/min but not more than 1200 kg/min
2	Desensitized explosives with a corrected burning rate (AC) equal to or greater than 140 kg/min but less than 300 kg/min
3	Desensitized explosives with a corrected burning rate (AC) equal to or greater than 60 kg/min but less than 140 kg/min
4	Desensitized explosives with a corrected burning rate (AC) less than 60 kg/min

NOTE 1: Desensitized explosives shall be prepared so that they remain homogeneous and do not separate during normal storage and handling, particularly if desensitized by wetting. The manufacturer, importer, or distributor shall provide information in Section 10 of the safety data sheet about the shelf-life and instructions on verifying desensitization. Under certain conditions the content of desensitizing agent (e.g., phlegmatizer, wetting agent or treatment) may decrease during supply and use, and thus, the hazard potential of the desensitized explosive may increase. In addition, Sections 5 and/or 8 of the safety data sheet shall include advice on avoiding increased fire, blast or protection hazards when the chemical is not sufficiently desensitized.

NOTE 2: Explosive properties of desensitized explosives shall be determined using data from Test Series 2 of UN ST/SG/AC.10/11/Rev.6 (incorporated by reference, see §1910.6) and shall be communicated in the safety data sheet. For testing of liquid desensitized explosives, refer to section 32, sub-section 32.3.2 of UN ST/SG/AC.10/11/Rev.6 (incorporated by reference, see §1910.6). Testing of solid desensitized explosives is addressed in section 33, sub-section 33.2.3 of UN ST/SG/AC.10/11/Rev.6 (incorporated by reference, see §1910.6).

NOTE 3: Desensitized explosives do not fall additionally within the scope of chapters B.1 (explosives), B.6 (flammable liquids) and B.7 (flammable solids)

B.17.3 Additional Classification Considerations

B.17.3.1 The classification procedure for desensitized explosives does not apply if:

(a) The substances or mixtures contain no explosives according to the criteria in Chapter B.1; or

(b) The exothermic decomposition energy is less than 300 J/g.

B.17.3.2 The exothermic decomposition energy shall be determined using the explosive already desensitized (i.e., the homogenous solid or liquids mixture formed by the explosive and the substance(s) used to suppress its explosive properties). The exothermic decomposition energy may be estimated using a suitable calorimetric technique (see Section 20, sub-section 20.3.3.3 in Part II of UN ST/SG/AC.10/11/Rev. 6 (incorporated by reference, see §1910.6).

Stat. Auth: ORS 654.025(2) and 656.726(4).
Stats. Implemented: ORS 654.001 through 654.295.

Hist: OR-OSHA Admin. Order 12-1993, f. 8/20/93, ef. 11/1/93.
OR-OSHA Admin. Order 4-1994, f. 8/4/94, ef. 8/4/94.
OR-OSHA Admin. Order 4-2013, f. 7/19/13, ef. 7/19/13.

Appendix C to §1910.1200 – Allocation of Label Elements (Mandatory)

C.1 The label for each hazardous chemical shall include the product identifier used on the safety data sheet.

C.1.1 The labels on shipped containers shall also include the name, address, and telephone number of the chemical manufacturer, importer, or responsible party.

C.2 The label for each hazardous chemical that is classified shall include the signal word, hazard statement(s), pictogram(s), and precautionary statement(s) specified in C.4 for each hazard class and associated hazard category, except as provided for in C.2.1 through C.2.4.

C.2.1 Precedence of hazard information

C.2.1.1 If the signal word “Danger” is included, the signal word “Warning” shall not appear;

C.2.1.2 If the skull and crossbones pictogram is included, the exclamation mark pictogram shall not appear where it is used for acute toxicity;

C.2.1.3 If the corrosive pictogram is included, the exclamation mark pictogram shall not appear where it is used for skin or eye irritation;

C.2.1.4 If the health hazard pictogram is included for respiratory sensitization, the exclamation mark pictogram shall not appear where it is used for skin sensitization or for skin or eye irritation.

C.2.2 Hazard statement text

C.2.2.1 The text of all applicable hazard statements shall appear on the label, except as otherwise specified. The information in italics shall be included as part of the hazard statement as provided. For example: “causes damage to organs *(state all organs affected)* through prolonged or repeated exposure *(state route of exposure if no other routes of exposure cause the hazard)*”. Hazard statements may be combined where appropriate to reduce the information on the label and improve readability, as long as all of the hazards are conveyed as required.

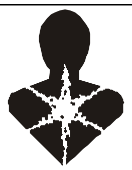
C.2.2.2 If the chemical manufacturer, importer, or responsible party can demonstrate that all or part of the hazard statement is inappropriate to a specific substance or mixture, the corresponding statement may be omitted from the label.

C.2.3 Pictograms

C.2.3.1 Pictograms shall be in the shape of a square set at a point and shall include a black hazard symbol on a white background with a red frame sufficiently wide to be clearly visible. A square red frame set at a point without a hazard symbol is not a pictogram and is not permitted on the label.

C.2.3.2 One of eight standard hazard symbols shall be used in each pictogram. The eight hazard symbols are depicted in Figure C.1. A pictogram using the exclamation mark symbol is presented in Figure C.2, for the purpose of illustration.

Figure C.1 – Hazard Symbols and Classes

Flame	Flame Over Circle	Exclamation Mark	Exploding Bomb
 Flammables Self Reactives Pyrophorics Self-heating Emits Flammable Gas Organic Peroxides **Desensitized Explosives**	 Oxidizers	 Irritant Dermal Sensitizer Acute Toxicity (harmful) Narcotic Effects Respiratory Tract Irritation **HNOC (non-mandatory)**	 Explosives Self Reactives Organic Peroxides
Corrosion	Gas Cylinder	Health Hazard	Skull and Crossbones
 Corrosives		 Carcinogen Respiratory Sensitizer Reproductive Toxicity	

	Gases Under Pressure	Target Organ Toxicity Mutagenicity Aspiration Toxicity	Acute Toxicity (severe)

Figure C.2 – Exclamation Mark Pictogram

C.2.3.3 [~~Where a pictogram required by the Department of Transportation under Title 49 of the Code of Federal Regulations appears on a shipped container, the pictogram specified in C.4 for the same hazard shall not appear.~~] **The exclamation mark pictogram is permitted (but not required) for HNOCs as long as the words "Hazard Not Otherwise Classified" or the letters "HNOC" appear below the pictogram.**

C.2.3.4 Pictograms may only appear once on a label. If multiple hazards require the use of the same pictogram, it may not appear a second time on the label.

C.2.4 Precautionary statement text

C.2.4.1 There are four types of precautionary statements presented, "prevention," "response," "storage," and "disposal." The core part of the precautionary statement is presented in bold print. This is the text, except as otherwise specified, that shall appear on the label. Where additional information is required, it is indicated in plain text.

C.2.4.2 When a backslash or diagonal mark (/) appears in the precautionary statement text, it indicates that a choice has to be made between the separated phrases. In such cases, the chemical manufacturer, importer, or responsible party can choose the most appropriate phrase(s). For example, "Wear protective gloves/protective clothing/eye protection/face protection" could read "wear eye protection".

C.2.4.3 When three full stops (…) appear in the precautionary statement text, they indicate that all applicable conditions are not listed. For example, in "Use explosion-proof electrical/ventilating/lighting/.../equipment", the use of "..." indicates that other equipment may need to be specified. In such cases, the chemical manufacturer, importer, or responsible party can choose the other conditions to be specified.

C.2.4.4 When text *in italics* is used in a precautionary statement, this indicates specific conditions applying to the use or allocation of the precautionary statement. For example, “Use explosion-proof electrical/ventilating/lighting/.../equipment” is only required for flammable solids “*if dust clouds can occur*”. Text in italics is intended to be an explanatory, conditional note and is not intended to appear on the label.

C.2.4.5 Where square brackets ([ ]) appear around text in a precautionary statement, this indicates that the text in square brackets is not appropriate in every case and should be used only in certain circumstances. In these cases, conditions for use explaining when the text should be used are provided. For example, one precautionary statement states: “[In case of inadequate ventilation] wear respiratory protection.” This statement is given with the condition for use “– text in square brackets may be used if additional information is provided with the chemical at the point of use that explains what type of ventilation would be adequate for safe use”. This means that, if additional information is provided with the chemical explaining what type of ventilation would be adequate for safe use, the text in square brackets should be used and the statement would read: “In case of inadequate ventilation wear respiratory protection.” However, if the chemical is supplied without such ventilation information, the text in square brackets should not be used, and the precautionary statement should read: “Wear respiratory protection.”

C.2.4.6 Precautionary statements may be combined or consolidated to save label space and improve readability. For example, “Keep away from heat, sparks and open flame,” “Store in a well-ventilated place” and “Keep cool” can be combined to read “Keep away from heat, sparks and open flame and store in a cool, well-ventilated place.”

C.2.4.7 [~~In most cases, the precautionary statements are independent (e.g., the phrases for explosive hazards do not modify those related to certain health hazards, and products that are classified for both hazard classes shall bear appropriate precautionary statements for both). Where a chemical is classified for a number of hazards, and the precautionary statements are similar, the most stringent shall be included on the label (this will be applicable mainly to preventive measures). An order of precedence may be imposed by the chemical manufacturer, importer or responsible party in situations where phrases concern “Response.” Rapid action may be crucial. For example, if a chemical is carcinogenic and acutely toxic, rapid action may be crucial, and first aid measures for acute toxicity will take precedence over those for long-term effects. In addition, medical attention to delayed health effects may be required in cases of incidental exposure, even if not associated with immediate symptoms of intoxication.~~] **Precautionary statements may**

incorporate minor textual variations from the text prescribed in this Appendix if these variations assist in communicating safety information (e.g., spelling variations, synonyms or other equivalent terms) and the safety advice is not diluted or compromised. Any variations must be used consistently on the label and the safety data sheet.

C.2.4.8 ~~If the chemical manufacturer, importer, or responsible party can demonstrate that a precautionary statement is inappropriate to a specific substance or mixture, the precautionary statement may be omitted from the label.~~ **In most cases, the precautionary statements are independent (e.g., the phrases for explosives hazards do not modify those related to certain health hazards, and products that are classified for both hazard classes shall bear appropriate precautionary statements for both). Where a chemical is classified for a number of hazards, and the precautionary statements are similar, the most stringent shall be included on the label (this will be applicable mainly to preventive measures).**

C.2.4.9 If the chemical manufacturer, importer, or responsible party can demonstrate that a precautionary statement is inappropriate to a specific substance or mixture, the precautionary statement may be omitted from the label.

C.2.4.10 Where a substance or mixture is classified for a number of health hazards, this may trigger multiple precautionary statements relating to medical response, e.g., calling a poison center/doctor/…and getting medical advice/attention.

In general, the following principles should be applied:

> **(a) Where the classification of a substance or mixture triggers several different precautionary statements, a system of prioritization should be applied. If the same medical response statement is triggered multiple times, the label need only include one precautionary statement reflecting the response at the highest level with the greatest urgency, which should always be combined with at least one route of exposure or symptom “IF” statement.**
>
> **(b) Routes of exposure, including “IF exposed or concerned,” may be combined when triggered with a medical response statement. If the response statement is triggered with three or more routes of exposure, “IF exposed or concerned” may be used. However, relevant “IF” statements describing symptoms must be included in full. If a route of exposure is triggered multiple times, it need only be included once.**

(c) This does not apply to “Get medical advice/attention if you feel unwell” or “Get immediate medical advice/attention” when they are combined with an “If” statement and must appear without prioritization.

C.3 Supplementary hazard information

C.3.1 To ensure that non-standardized information does not lead to unnecessarily wide variation or undermine the required information, supplementary information on the label is limited to when it provides further detail and does not contradict or cast doubt on the validity of the standardized hazard information.

C.3.2 Where the chemical manufacturer, importer, or distributor chooses to add supplementary information on the label, the placement of supplemental information shall not impede identification of information required by this section.

C.3.3 Where an ingredient with unknown acute toxicity is used in a mixture at a concentration ≥ 1%, and the mixture is not classified based on testing of the mixture as a whole, a statement that X% of the mixture consists of ingredient(s) of unknown acute toxicity **(oral/dermal/inhalation)** is required on the label **and safety data sheet**.

C.4 REQUIREMENTS FOR SIGNAL WORDS, HAZARD STATEMENTS, PICTOGRAMS, AND PRECAUTIONARY STATEMENTS

C.4.1 ACUTE TOXICITY – ORAL

(Classified in Accordance with Appendix A.1 of this section)

Pictogram

Skull and crossbones

Hazard category	**Signal word**	**Hazard statement**
1	Danger	Fatal if swallowed
2	Danger	Fatal if swallowed
3	**Danger**	**Toxic if swallowed**

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Wash …thoroughly after handling. … Chemical manufacturer, importer, or distributor to specify parts of the body to be washed after handling. **Do not eat, drink or smoke when**	**If swallowed: Immediately call a poison center/doctor/…** … Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice. **Specific treatment (see … on this label)** … Reference to supplemental first aid	**Store locked up.**	**Dispose of contents/container to…** ... in accordance with local/regional/national /international regulations (to be specified). **Chemical manufacturer, importer, or distributor to specify whether disposal requirements apply**

using this product.	instruction. - *if immediate administration of antidote is required*. **Rinse mouth.**		**<u>to contents, container or both</u>**

[~~C.4.1 ACUTE TOXICITY – ORAL (CONTINUED)~~

~~(Classified in Accordance with Appendix A.1)~~

~~Pictogram~~

~~Skull and crossbones~~

~~Hazard category~~	**~~Signal word~~**	**~~Hazard statement~~**
~~3~~	~~Danger~~	~~Toxic if swallowed~~

~~Precautionary statements~~			
~~Prevention~~	**~~Response~~**	**~~Storage~~**	**~~Disposal~~**
~~Wash … thoroughly after handling.~~ ~~… Chemical manufacturer, importer, or distributor to specify parts of the body to be washed after handling.~~ **~~Do not eat, drink or smoke when using this product.~~**	**~~If swallowed: Immediately call a poison center/doctor/…~~** ~~… Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice.~~ **~~Specific treatment (see ... on this label)~~** ~~... Reference to supplemental first aid instruction.~~ ~~- *if immediate administration of antidote is required*.~~ **~~Rinse mouth.~~**	**~~Store locked up.~~**	**~~Dispose of contents/container to...~~** ~~... in accordance with local/regional/national /international regulations (to be specified).~~]

C.4.1 ACUTE TOXICITY – ORAL (CONTINUED)

(Classified in Accordance with Appendix A.1 of this section)

Hazard category	**Signal word**	**Hazard statement**	**Pictogram** Exclamation mark
4	Warning	Harmful if swallowed	

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Wash … thoroughly after handling. … Chemical manufacturer, importer, or distributor to specify parts of the body to be washed after handling. **Do not eat, drink or smoke when using this product.**	**If swallowed: Call a poison center/doctor/…/ if you feel unwell.** … Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice. **Rinse mouth.**		**Dispose of contents/container to...** ... in accordance with local/regional/national /international regulations (to be specified). **Chemical manufacturer, importer, or distributor to specify whether disposal requirements apply to contents, container or both.**

C.4.2 ACUTE TOXICITY – DERMAL

(Classified in Accordance with Appendix A.1 <u>of this section</u>)

Pictogram
Skull and crossbones

Hazard category	**Signal word**	**Hazard statement**
1	Danger	Fatal in contact with skin
2	Danger	Fatal in contact with skin

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Do not get in eyes, on skin, or on clothing. **Wash … thoroughly after handling.** **…** Chemical manufacturer, importer, or distributor to specify parts of the body to be washed after handling. **Do not eat, drink or smoke when using this product.** **Wear protective gloves/protectiv**	**If on skin: Wash with plenty of water/**... … Chemical manufacturer, importer, or distributor may specify a cleansing agent if appropriate, or may recommend an alternative agent in exceptional cases if water is clearly inappropriate. **Immediately call a poison center/doctor/…** … Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice.	**Store locked up.**	**Dispose of contents/container to...** ... in accordance with local/regional/national /international regulations (to be specified). <u>**Chemical manufacturer, importer, or distributor to specify whether disposal requirements apply to contents, container, or both.**</u>

e clothing. Chemical manufacturer, importer, or distributor to specify type of equipment **<u>where appropriate.</u>**	**Specific treatment (see ... on this label)** ... Reference to supplemental first aid instruction. - *if immediate measures such as specific cleansing agent is advised*. **Take off immediately all contaminated clothing and wash it before reuse.**		

C.4.2 ACUTE TOXICITY – DERMAL (CONTINUED)

(Classified in Accordance with Appendix A.1 <u>of this section</u>)

Hazard category	**Signal word**	**Hazard statement**	**Pictogram** Skull and crossbones
3	Danger	Toxic in contact with skin	

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Wear protective gloves/protective clothing. Chemical manufacturer, importer, or distributor to specify type of equipment **<u>where appropriate</u>**	**If on skin: Wash with plenty of water/…** … Chemical manufacturer, importer, or distributor may specify a cleansing agent if appropriate, or may recommend an alternative agent in exceptional cases if water is clearly inappropriate. **Call a poison center/doctor/…/if you feel unwell.** … Chemical manufacturer, importer, or distributor to specify the appropriate source of	**Store locked up.**	**Dispose of contents/container to...** ... in accordance with local/regional/national /international regulations (to be specified). **<u>Chemical manufacturer, importer, or distributor to specify whether disposal requirements apply to contents, container, or both.</u>**

	emergency medical advice. **Specific treatment (see ... on this label)** ... Reference to supplemental first aid instruction. - *if*[~~immediate~~] *measures such as specific cleansing agent is advised.* **Take off immediately all contaminated clothing and wash it before reuse.**		

C.4.2 ACUTE TOXICITY – DERMAL (CONTINUED)

(Classified in Accordance with Appendix A.1 of this section)

Hazard category	**Signal word**	**Hazard statement**	**Pictogram** Exclamation mark
4	Warning	Harmful in contact with skin	

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Wear protective gloves/protective clothing Chemical manufacturer, importer, or distributor to specify type of equipment **where appropriate.**	**If on skin: Wash with plenty of water/...** … Chemical manufacturer, importer, or distributor may specify a cleansing agent if appropriate, or may recommend an alternative agent in exceptional cases if water is clearly inappropriate. **Call a poison center/doctor/…/if you feel unwell.** … Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice.		**Dispose of contents/container to...** ... in accordance with local/regional/national /international regulations (to be specified). **Chemical manufacturer, importer, or distributor to specify whether disposal requirements apply to contents, container or both.**

	Specific treatment (see ... on this label) ... Reference to supplemental first aid instruction. - *if measures such as specific cleansing agent is advised.* **Take off contaminated clothing and wash it before reuse.**		

C.4.3 ACUTE TOXICITY – INHALATION

(Classified in Accordance with Appendix A.1 of this section)

Pictogram

Skull and crossbones

Hazard category	**Signal word**	**Hazard statement**
1	Danger	Fatal if inhaled
2	Danger	Fatal if inhaled

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Do not breathe dust/fume/gas/mist/ vapors/spray. Chemical manufacturer, importer, or distributor to specify applicable conditions. **Use only outdoors or in a well-ventilated area.** **[In case of inadequate ventilation] wear respiratory protection.** Chemical	**If inhaled: Remove person to fresh air and keep comfortable for breathing.** **Immediately call a poison center/doctor/…** …Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice. **Specific treatment is urgent (see ... on this label)** ...Reference to supplemental first aid	**Store in a well-ventilated place. Keep container tightly closed.** - *if **the chemical** [~~product~~] is volatile and may [~~as to~~] generate **a** hazardous atmosphere.* **Store locked up.**	**Dispose of contents/container to...** ... in accordance with local/regional/national /international regulations (to be specified). **Chemical manufacturer, importer, distributor to specify whether disposal requirements apply to contents, container or both.**

manufacturer, importer, or distributor to specify equipment. - *Text in square brackets may be used if additional information is provided with the chemical at the point of use that explains what type of ventilation would be adequate for safe use*.	instruction. - *if immediate administration of antidote is required*.		

Note: If the substance/mixture is determined to be corrosive to the respiratory tract leading to lethality , the corrosivity hazard must also be communicated with the corrosion pictogram and hazard statement "corrosive to the respiratory tract".

C.4.3 ACUTE TOXICITY – INHALATION (CONTINUED)

(Classified in Accordance with Appendix A.1 of this section)

Hazard category	Signal word	Hazard statement	Pictogram
3	Danger	Toxic if inhaled	Skull and crossbones 

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Avoid breathing dust/fume/gas/mist/ vapors/spray. Chemical manufacturer, importer, or distributor to specify applicable conditions. **Use only outdoors or in a well-ventilated area.**	**If inhaled: Remove person to fresh air and keep comfortable for breathing.** **Call a poison center/doctor/...** … Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice. **Specific treatment (see ... on this label)** ... Reference to supplemental first aid instruction. - *if immediate specific measures are required*.	**Store in a well-ventilated place. Keep container tightly closed.** - *if* ***the chemical*** *[~~product~~] is volatile [~~so as to~~]* ***and may*** *generate* ***a*** *hazardous atmosphere.* **Store locked up.**	**Dispose of content/container to…** … in accordance with local/regional/national /international regulations (to be specified). **Chemical manufacturer, importer, or distributor to specify whether disposal requirements apply to contents, container or both.**

C.4.3 ACUTE TOXICITY – INHALATION (CONTINUED)

(Classified in Accordance with Appendix A.1 of this section)

Hazard category	**Signal word**	**Hazard statement**	**Pictogram**
			Exclamation mark 
4	Warning	Harmful if inhaled	

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Avoid breathing dust/fume/gas/mist/ vapors/spray. Chemical manufacturer, importer, or distributor to specify applicable conditions. **Use only outdoors or in a well-ventilated area.**	**If inhaled: Remove person to fresh air and keep comfortable for breathing.** **Call a poison center/doctor/…/if you feel unwell.** … Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice.		

C.4.4 SKIN CORROSION/IRRITATION

(Classified in Accordance with Appendix A.2 of this section)

Hazard category	**Signal word**	**Hazard statement**	**Pictogram** Corrosion
1A to 1C	Danger	Causes severe skin burns and eye damage	

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Do not breathe dusts or mists. - *if inhalable particles of dusts or mists may occur during use.* **Wash …thoroughly after handling.** **…**Chemical manufacturer, importer, or distributor to specify parts of the body to be washed after handling. **Wear protective gloves/protective clothing/eye**	**If swallowed: Rinse mouth. Do NOT induce vomiting.** **If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water[~~/~~] [or shower].** ***- text in square brackets to be included where the chemical manufacturer, importer or distributor considers it appropriate for the specific chemical.*** **Wash contaminated clothing before reuse.** **If inhaled: Remove person to fresh air and keep comfortable for breathing.**	**Store locked up.**	**Dispose of contents/container to...** ... in accordance with local/regional/national /international regulations (to be specified). **Chemical manufacturer, importer, or distributor to specify whether disposal requirements apply to contents, container, or both.**

protection/face protection. Chemical manufacturer, importer, or distributor to specify type of equipment **where appropriate.**	**Immediately call a poison center/doctor/…** … Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice. **Specific treatment (see ... on this label)** ... Reference to supplemental first aid instruction. - *Chemical [~~M~~]**m**anufacturer, importer, or distributor may specify a cleansing agent if appropriate.* **If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.**		
Note: If the classifier determines, based on skin data, that the chemical may be corrosive to the respiratory tract, then the corrosivity hazard must also be communicated with the corrosion pictogram and hazard statement "corrosive to the respiratory tract".			

C.4.4 SKIN CORROSION/IRRITATION (CONTINUED)

(Classified in Accordance with Appendix A.2 of this section)

Pictogram

Exclamation mark

Hazard category	**Signal word**	**Hazard statement**
2	Warning	Causes skin irritation

Precautionary statements

Prevention	**Response**	**Storage**	**Disposal**
Wash … thoroughly after handling. … Chemical manufacturer, importer, or distributor to specify parts of the body to be washed after handling. **Wear protective gloves.** Chemical manufacturer, importer, or distributor to specify type of equipment **where appropriate.**	**If on skin: Wash with plenty of water/**... … Chemical manufacturer, importer, or distributor may specify a cleansing agent if appropriate, or may recommend an alternative agent in exceptional cases if water is clearly inappropriate. **Specific treatment (see ... on this label)** ... Reference to supplemental first aid instruction. - **Chemical** [~~M~~]**m***anufacturers, importer, or distributor may specify a*		

	cleansing agent if appropriate. **If skin irritation occurs: Get medical advice/attention.** **<u>- Chemical manufacturer, importer, or distributor to select medical advice or attention as appropriate.</u>** **Take off contaminated clothing and wash it before reuse.**		

C.4.5 EYE DAMAGE/IRRITATION

(Classified in Accordance with Appendix A.3 of this section)

Hazard category	Signal word	Hazard statement	**Pictogram** Corrosion
1	Danger	Causes serious eye damage	

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Wear eye protection/face protection. Chemical manufacturer, importer, or distributor to specify type of equipment **where appropriate**.	**If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.** **Immediately call a poison center/doctor/…** … Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice.		

Note: If the classifier determines, based on eye data, that the chemical may be corrosive to the respiratory tract, then corrosivity hazard must also be communicated with the corrosion pictogram and hazard statement "corrosive to the respiratory tract".

C.4.5 EYE DAMAGE/IRRITATION (CONTINUED)

(Classified in Accordance with Appendix A.3 of this section)

Pictogram

Exclamation mark

Hazard category	**Signal word**	**Hazard statement**
2A	Warning	Causes serious eye irritation

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Wash … thoroughly after handling. **…** Chemical manufacturer, importer, or distributor to specify parts of the body to be washed after handling. **Wear eye protection/face protection.** Chemical manufacturer, importer, or distributor to specify type of	**If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.** **If eye irritation persists: Get medical advice/attention.** **Chemical manufacturer, importer, or distributor to select medical advice or attention as appropriate.**		

equipment **where appropriate.**			

C.4.5 EYE DAMAGE/IRRITATION (CONTINUED)

(Classified in Accordance with Appendix A.3 of this section)

Pictogram

No Pictogram

Hazard category	**Signal word**	**Hazard statement**
2B	Warning	Causes eye irritation

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Wash … thoroughly after handling. … Chemical manufacturer, importer, or distributor to specify parts of the body to be washed after handling.	**If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.** **If eye irritation persists: Get medical advice/attention.** **Chemical manufacturer, importer, or distributor to select medical advice or attention as appropriate.**		

C.4.6 SENSITIZATION – RESPIRATORY

(Classified in Accordance with Appendix A.4 of this section)

Hazard category	**Signal word**	**Hazard statement**	**Pictogram** Health hazard
1 (including both sub-categories 1A and 1B)	Danger	May cause allergy or asthma symptoms or breathing difficulties if inhaled	

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Avoid breathing dust/fume/gas/mist/ vapors/spray. Chemical manufacturer, importer, or distributor to specify applicable conditions. **[In case of inadequate ventilation] wear respiratory protection.** Chemical manufacturer, importer, or	**If inhaled: [~~If breathing is difficult,~~] [~~r~~]Remove person to fresh air and keep comfortable for breathing.** **If experiencing respiratory symptoms: Call a poison center/doctor/…** … Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice.		**Dispose of contents/container to...** ... in accordance with local/regional/national /international regulations (to be specified). **Chemical manufacturer, importer, or distributor to specify whether disposal requirements apply to contents, container or both.**

distributor to specify equipment - [~~*T*~~]**t***ext in square brackets may be used if additional information is provided with the chemical at the point of use that explains what type of ventilation would be adequate for safe use*.			

C.4.7 SENSITIZATION – SKIN

(Classified in Accordance with Appendix A.4 of this section)

Hazard category	**Signal word**	**Hazard statement**	**Pictogram** Exclamation mark
1 (including both sub-categories 1A and 1B)	Warning	May cause an allergic skin reaction	

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Avoid breathing dust/fume/gas/mist/ vapors/spray. Chemical manufacturer, importer, or distributor to specify applicable conditions. **Contaminated work clothing must not be allowed out of the workplace.** **Wear protective gloves.** Chemical manufacturer, importer, or distributor to	**If on skin: Wash with plenty of water/**... … Chemical manufacturer, importer, or distributor may specify a cleansing agent if appropriate, or may recommend an alternative agent in exceptional cases if water is clearly inappropriate. **If skin irritation or rash occurs: Get medical advice/attention.** **-Chemical manufacturer, importer, or distributor to select medical advice or attention as appropriate.**		**Dispose of contents/container to...** ... in accordance with local/regional/national /international regulations (to be specified). **Chemical manufacturer, importer, or distributor to specify whether disposal requirements apply to contents, container, or both.**

specify type of equipment **where appropriate.**	**Specific treatment (see ... on this label)** ... Reference to supplemental first aid instruction. **-Chemica**l [~~M~~]**m***anufacturer, importer, or distributor may specify a cleansing agent if appropriate.* **Take off contaminated clothing and [~~W~~]wash it [~~contaminated clothing~~] before reuse.**		

C.4.8 GERM CELL MUTAGENICITY

(Classified in Accordance with Appendix A.5 of this section)

Pictogram

Health hazard

Hazard category	**Signal word**	**Hazard statement**
1A and 1B	Danger	May cause genetic defects <...>
2	Warning	Suspected of causing genetic defects <...>
		< > *(state route of exposure if no other routes of exposure cause the hazard)*

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Obtain special instructions before use. **Do not handle until all safety precautions have been read and understood.** **Wear protective gloves/protective clothing/eye protection/face protection.**	**If exposed or concerned: Get medical advice/attention.** **Chemical manufacturer, importer, or distributor to select medical advice or attention as appropriate.**	**Store locked up.**	**Dispose of contents/container to...** ... in accordance with local/regional/national/international regulations (to be specified). **Chemical manufacturer, importer, or distributor to specify whether disposal requirements apply to contents, container or both.**

Chemical manufacturer, importer, or distributor tospecify **the appropriate** [~~type of~~] **personal protective** equipment[~~, as required~~].			

C.4.9 CARCINOGENICITY

(Classified in Accordance with Appendix A.6 of this section)

Pictogram
Health hazard

Hazard category	**Signal word**	**Hazard statement**
1A and 1B	Danger	May cause cancer <...>
2	Warning	Suspected of causing cancer <...> *(state route of exposure if no other routes of exposure cause the hazard)*

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Obtain special instructions before use. **Do not handle until all safety precautions have been read and understood.** **Wear protective gloves/protective clothing/eye protection/face protection.** Chemical manufacturer,	**If exposed or concerned: Get medical advice/attention.** **Chemical manufacturer, importer, or distributor to select medical advice or attention as appropriate.**	**Store locked up.**	**Dispose of contents/container to...** ... in accordance with local/regional/national /international regulations (to be specified). **Chemical manufacturer, importer, or distributor to specify whether disposal requirements apply to contents, container, or both.**

importer, or distributor to specify **the appropriate personal protective** [~~type of~~] equipment[~~, as required~~].			

Note: If a Category 2 carcinogen ingredient is present in the mixture at a concentration between 0.1% and 1%, information is required on the SDS for a product; however, a label warning is optional. If a Category 2 carcinogen ingredient is present in the mixture at a concentration of ≥ 1%, both an SDS and a label is required and the information must be included on each.

C.4.10 [~~TOXIC TO~~] REPRODUCTIVE[~~ON~~] TOXICITY

(Classified in Accordance with Appendix A.7 of this section)

Pictogram

Health hazard

Hazard category	**Signal word**	**Hazard statement**
1A and 1B	Danger	May damage fertility or the unborn child <...> <<...>>
2	Warning	Suspected of damaging fertility or the unborn child <...> <<...>> < > *(state specific effect if known)* << >> *(state route of exposure if no other routes of exposure cause the hazard)*

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Obtain special instructions before use. **Do not handle until all safety precautions have been read and understood.** **Wear protective gloves/protective clothing/eye protection/face protection.**	**If exposed or concerned: Get medical advice/attention.** **Chemical manufacturer, importer, or distributor to select medical advice or attention as appropriate.**	**Store locked up.**	**Dispose of contents/container to...** ... in accordance with local/regional/national /international regulations (to be specified). **Chemical manufacturer, importer, or distributor to specify whether disposal requirements apply**

Chemical manufacturer, importer, or distributor to specify [~~type of~~] **the appropriate personal protective** equipment[~~, as required~~].			**to contents, container, or both.**

C.4.10 TOXIC TO REPRODUCTION (CONTINUED)

(Classified in Accordance with Appendix A.7 <u>of this section</u>)

(EFFECTS ON OR VIA LACTATION)

Pictogram
<u>No Pictogram</u>

Hazard category	**Signal word**	**Hazard statement**
No designated number (See Table A.7.1 in Appendix A.7)	*No signal word*	May cause harm to breast-fed children

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Obtain special instructions before use. **Do not breathe dusts or mists.** - *if inhalable particles of dusts or mists may occur during use.* **Avoid contact during pregnancy <u>and</u> /while nursing.** **Wash … thoroughly after handling.** **…**Chemical manufacturer,	**If exposed or concerned: Get medical advice/attention.** **<u>Chemical manufacturer, importer, or distributor to select medical advice or attention as appropriate.</u>**		

importer, or distributor to specify parts of the body to be washed after handling. **Do not eat, drink or smoke when using this product.**			

C.4.11 SPECIFIC TARGET ORGAN TOXICITY (Single Exposure)
(Classified in Accordance with Appendix A.8 of this section)

Hazard category	Signal word	Hazard statement	**Pictogram** Health hazard
1	Danger	Causes damage to organs <...> <<...>> <...> *(or state all organs affected if known)* <<...>> *(state route of exposure if no other routes of exposure cause the hazard)*	

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Do not breathe dust/fume/gas/mist/ vapors/spray. Chemical manufacturer, importer, or distributor to specify applicable conditions. **Wash …thoroughly after handling.** … Chemical manufacturer, importer, or distributor to specify parts of the body to be	**If exposed or concerned : Call a poison center/doctor/…** … Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice. **Specific treatment (see ... on this label)** ... Reference to supplemental first aid instruction. - *if immediate measures are required*.	**Store locked up.**	**Dispose of contents/container to...** ... in accordance with local/regional/national /international regulations (to be specified). **Chemical manufacturer, importer, or distributor to specify whether disposal requirements apply to contents, container or both.**

washed after handling. **Do not eat, drink or smoke when using this product.**			

Note: If the chemical is determined to be corrosive to the respiratory tract, corrosive to the respiratory tract must be communicated with the hazard statement "corrosive to the respiratory tract, if inhaled" and corrosion pictogram, in lieu of current hazard statement and pictogram.

C.4.11 SPECIFIC TARGET ORGAN TOXICITY (Single Exposure) (CONTINUED)
(Classified in Accordance with Appendix A.8 of this section)

Hazard category	**Signal word**	**Hazard statement**	**Pictogram** Health hazard
2	Warning	May cause damage to organs <...> <<...>> <...> *(or state all organs affected, if known)* <<...>> *(state route of exposure if no other routes of exposure cause the hazard)*	

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Do not breathe dust/fume/gas/mist/ vapors/spray. Chemical manufacturer, importer, or distributor to specify applicable conditions. **Wash … thoroughly after handling.** … Chemical manufacturer, importer, or distributor to specify parts of the body to be	**If exposed or concerned: Call a poison center/doctor/…** … Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice.	**Store locked up.**	**Dispose of contents/container to...** ... in accordance with local/regional/national /international regulations (to be specified). **Chemical manufacturer, importer, or distributor to specify whether disposal requirements apply to contents, container, or both.**

washed after handling. **Do not eat, drink or smoke when using this product.**			

<u>Note: If the substance/mixture is determined to be corrosive to the respiratory tract, corrosivity must be communicated with the hazard statement “corrosive to the respiratory tract, if inhaled” and corrosion pictogram in lieu of current hazard statement and pictogram</u>.

C.4.11 SPECIFIC TARGET ORGAN TOXICITY (Single Exposure) (CONTINUED)

(Classified in Accordance with Appendix A.8 of this section)

Hazard category	**Signal word**	**Hazard statement**	**Pictogram** Exclamation mark
3	Warning	May cause respiratory irritation; or May cause drowsiness or dizziness	

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Avoid breathing dust/fume/gas/mist/ vapors/spray. Chemical manufacturer, importer, or distributor to specify applicable conditions. **Use only outdoors or in a well-ventilated area.**	**If inhaled: Remove person to fresh air and keep comfortable for breathing.** **Call a poison center/doctor/…/if you feel unwell.** … Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice.	**Store in a well-ventilated place. Keep container tightly closed.** **-** *if* ***the chemical*** *~~product~~ is volatile* **and may** [~~so as to~~] *generate a hazardous atmosphere.* **Store locked up.**	**Dispose of contents/container to...** ... in accordance with local/regional/national /international regulations (to be specified). **Chemical manufacturer, importer, or distributor to specify whether disposal requirements apply to contents, container, or both.**

C.4.12 SPECIFIC TARGET ORGAN TOXICITY (Repeated Exposure) (Classified in Accordance with Appendix A.9 of this section)

Hazard category	Signal word	Hazard statement	**Pictogram** Health hazard
1	Danger	Causes damage to organs <...> through prolonged or repeated exposure <...> *(state all organs affected if known)* <<...>> *(state route of exposure if no other routes of exposure cause the hazard)*	

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Do not breathe dust/fume/gas/mist/ vapors/spray. Chemical manufacturer, importer, or distributor to specify applicable conditions. **Wash … thoroughly after handling.** …Chemical manufacturer, importer, or distributor to specify parts of the body to be	**Get medical advice/attention if you feel unwell.** **Chemical manufacturer, importer, or distributor to select medical advice or attention as appropriate.**		**Dispose of contents/container to...** ... in accordance with local/regional/national /international regulations (to be specified). **Chemical manufacturer, importer, or distributor to specify whether disposal requirements apply to contents, container, or both.**

washed after handling. **Do not eat, drink or smoke when using this product.**			

C.4.12 SPECIFIC TARGET ORGAN TOXICITY (Repeated Exposure) (CONTINUED)

(Classified in Accordance with Appendix A.9 of this section)

Hazard category	Signal word	Hazard statement	**Pictogram** Health hazard
2	Warning	May cause damage to organs <...> through prolonged or repeated exposure <<...>> <...> *(state all organs affected, if known)* <<...>> *(state route of exposure if no other routes of exposure cause the hazard)*	

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Do not breathe dust/fume/gas/mist/ vapors/spray. Chemical manufacturer, importer, or distributor to specify applicable conditions.	**Get medical advice/attention if you feel unwell.** **Chemical manufacturer, importer, or distributor to select medical advice or attention as appropriate.**		**Dispose of contents/container to...** ... in accordance with local/regional/national /international regulations (to be specified). **Chemical manufacturer, importer, or distributor to specify whether disposal requirements apply to contents, container, or both.**

C.4.13 ASPIRATION HAZARD
(Classified in Accordance with Appendix A.10 of this section)

Hazard category	Signal word	Hazard statement	**Pictogram** Health hazard
1	Danger	May be fatal if swallowed and enters airways	

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
	If swallowed: Immediately call a poison center/doctor/… … Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice. **Do NOT induce vomiting.**	**Store locked up.**	**Dispose of contents/container to...** ... in accordance with local/regional/national /international regulations (to be specified). **Chemical manufacturer, importer, or distributor to specify whether disposal requirements apply to contents, container or both.**

C.4.14 EXPLOSIVES
(Classified in Accordance with Appendix B.1 of this section)

Hazard category	**Signal word**	**Hazard statement**	**Pictogram** Exploding bomb
Unstable explosive	Danger	Unstable explosive	

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Obtain special instructions before use. ~~**[Do not handle until all safety precautions have been read and understood.]**~~ **Do not subject to grinding/shock/friction/… – if the explosive is mechanically sensitive.** **…Chemical manufacturer, importer, or distributor to specify applicable rough handling.** **Wear protective gloves/protective clothing/eye protection/face**	**In case of fire: Explosion risk. [~~in case of fire~~.]** **Evacuate area.** **DO[~~o~~] NOT fight fire when fire reaches explosives.** **[~~Evacuate area~~.]**	**Store [~~… …~~]**in accordance with **… Chemical manufacturer, importer, or distributor to specify** local/regional/national/international regulations **as applicable.** **[**~~(to be specified).~~]	**Refer to manufacturer, importer, or distributor… for information on disposal, recovery, or recycling.** ~~**[Dispose of contents/container to …**~~ ~~…in accordance with local/regional/national/international regulations (to be specified).~~] **… Manufacturer, importer, or distributor to specify appropriate source of information, in**

protection/<u>hearing protection/….</u> Chemical manufacturer, importer, or distributor to specify [~~type of~~] the **<u>appropriate personal protective</u>** equipment.			**<u>accordance with local/regional/national/ international regulations as applicable.</u>**

C.4.14 EXPLOSIVES (CONTINUED)
(Classified in Accordance with Appendix B.1 of this section)

Pictogram
Exploding bomb

Hazard category	**Signal word**	**Hazard statement**
Division 1.1	Danger	Explosive; mass explosion hazard
Division 1.2	Danger	Explosive; severe projection hazard
Division 1.3	Danger	Explosive; fire, blast or projection hazard

Precautionary statements

Prevention	**Response**	**Storage**	**Disposal**
Keep away from heat[~~/~~], hot surfaces, sparks[~~/~~]open flames[~~/hot surfaces~~] and other ignition sources.- No smoking. ~~[Chemical manufacturer, importer, or distributor to specify applicable ignition source(s).]~~ **Keep wetted with...** ~~[… Chemical manufacturer, importer, or distributor to specify appropriate material.~~ ~~- *if drying out increases explosion hazard, except as needed for manufacturing or operating processes (e.g., nitrocellulose).]*~~	**In case of fire: Explosion risk.** **[~~e~~]Evacuate area.** ~~**[Explosion risk in case of fire.]**~~ **DO[~~o~~] NOT fight fire when fire reaches explosives.**	**Store ...** **[~~...~~]in accordance with…** **… Chemical manufacturer, importer, or distributor to specify** local/regional/national/ international regulations **as applicable** [~~to be specified~~]~~.~~	**Refer to manufacturer, importer, or distributor… for information on disposal, recovery, or recycling.** ~~**[Dispose of contents/container to ...** in accordance with local/ regional/national/ international regulations (to be specified).]~~ **Manufacturer, importer, or distributor to specify appropriate**

for substances and mixtures which are wetted, diluted, dissolved or suspended with a phlegmatizer in order to reduce or suppress their explosive properties (desensitized explosives). **Keep only in original packaging.** **Ground[~~/~~] and /bond container and receiving equipment.** - *if the explosive is electrostatically sensitive.* **Do not subject to grinding/shock/…/friction.** ***-if the explosive is mechanically sensitive.*** ***…Chemical manufacturer, importer, or distributor to specify applicable rough handling.*** **Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/….** Chemical manufacturer, importer, or distributor to specify [~~type of~~] the **appropriate-**			**source of information, in accordance with local/regional/national/ international regulations asapplicable.**

personalprotective equipment.			

Note: Unpackaged explosives or explosives repacked in packaging other than the original or similar packaging shall have the label elements assigned to Division 1.1 unless the hazard is shown to correspond to one of the hazard categories in Appendix B.1 **of this section**, in which case the corresponding symbol, signal word and/or the hazard statement shall be assigned.

C.4.14 EXPLOSIVES (CONTINUED)
(Classified in Accordance with Appendix B.1 of this section)

Hazard category	**Signal word**	**Hazard statement**	**Pictogram** Exploding bomb
Division 1.4	Warning	Fire or projection hazard	

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep away from heat[~~/~~], hot surfaces, sparks[~~/~~]open flames[~~/hot surfaces~~] and other ignition sources.- No smoking. . ~~[Chemical manufacturer, importer, or distributor to specify applicable ignition source(s).]~~ **Keep only in original packaging** **Ground [~~/~~] and / bond container and receiving equipment.** - *if the explosive is electrostatically sensitive.* **Do not subject to grinding/shock/…/frictio**	**In case of fire:** **Explosion risk.** **Evacuate area.** **Do NOT fight fire when fire reaches explosives.** **~~Explosion risk in case of fire.~~** - *except **for** [~~if~~] explosives **of division 1.4 (compatibility group S) in transport packaging** [~~are 1.4S ammunition and components thereof~~]*.	**Store ...** …in accordance with …**Chemical manufacturer, importer, or distributor to specify** local/regional/ national/international regulations [~~(to be specified)~~]. **as applicable.**	**Refer to manufacturer, importer, or distributor… for information on disposal, recovery, or recycling.** **[~~Dispose of contents/container to...~~** ~~… in accordance with local/regional/national /international regulations (to be specified).~~] **… Manufacturer, distributor, or importer to specify appropriate source of information, in accordance with local/regional/national/ international**

n. **-if the explosive is mechanically sensitive** Chemical manufacturer, importer, or distributor to specify applicable rough handling. **Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/….** Chemical manufacturer, importer, or distributor to specify [~~type of~~] the **appropriate personal protective** equipment.	**In case of fire: Evacuate area. Fight fire remotely due to the risk of explosion** **[.~~Do NOT fight fire when fire reaches explosives.~~** **~~Fight fire with normal precautions from a reasonable distance~~]** **for [**~~*if*~~*]* *explosives* ***of division 1.4 (compatibility group S) in transport packaging.*** *[~~are 1.4S ammunition and components thereof~~.]*		**regulations as applicable.**

Note: Unpackaged explosives or explosives repacked in packaging other than the original or similar packaging shall have the label elements assigned to Division 1.1 unless the hazard 1s shown to correspond to one of the hazard categories in Appendix B.1, **of this section,** in which case the corresponding symbol, signal word and/or the hazard statement shall be assigned.[1]

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[1] Except no pictogram is required for explosives that are I .4S small arms ammunition and components thereof. Labels for I .4S small arms ammunition and components shall include appropriate precautionary statements.

C.4.14 EXPLOSIVES (CONTINUED)
(Classified in Accordance with Appendix B.1 of this section)

Pictogram

No pictogram

Hazard category	**Signal word**	**Hazard statement**
Division 1.5	Danger	May mass explode in fire

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep away from heat[~~/~~], hot surfaces, sparks[~~/~~]open flames[~~/hot surfaces~~] and other ignition sources.- No smoking. ~~[Chemical manufacturer, importer, or distributor to specify applicable ignition source(s).~~] **Keep wetted with**... ***-for substances and mixtures which are wetted, diluted, dissolved or suspended with a phlegmatizer in order to reduce or suppress their explosive properties***	**In case of fire: Explosion risk Evacuate area.** **~~[Explosion risk in case of fire~~.]** **DO[~~o~~] NOT fight fire when fire reaches explosives.**	**Store**[~~… …~~]in accordance with… **…Chemical manufacturer, importer, or distributor to specify** local/regional/ national/international regulations **as applicable** [~~(to be specified).~~]	**Refer to manufacturer, importer, or distributor … for information on disposal, recovery, or recycling.** **~~[Dispose of contents/ container to ...~~** ~~… in accordance with local/regional/ national/international regulations (to be specified).~~] **… Manufacturer, distributor, or importer to specify appropriate source of information, in accordance with local/regional/national/ international**

(desensitized explosives). **,,,**Chemical manufacturer, importer, or distributor to specify appropriate material. **[**~~- *if drying out increases explosion hazard, except as needed for manufacturing or operating processes (e.g., nitrocellulose).*~~ **]** **Keep only in original packaging.** **Ground[~~/~~] and bond container and receiving equipment** - *if the explosive is electrostatically sensitive*. **Do not subject to grinding/shock/…/friction**. -***if the explosive is mechanically sensitive.*** **…**Chemical manufacturer, importer, or distributor to specify applicable rough handling. **Wear protective gloves/protective clothing/eye protection/face**			**regulations as applicable**

protection/<u>hearing protection/…</u>. Chemical manufacturer, importer, or distributor to specify [~~type of~~] the **<u>appropriate personal protective</u>** equipment.			

Note: Unpackaged explosives or explosives repacked in packaging other than the original or similar packaging shall have the label elements assigned to Division 1.1 unless the hazard is shown to correspond to one of the hazard categories in Appendix B.1 **<u>of this section,</u>** in which case the corresponding symbol, signal word and/or the hazard statement shall be assigned.

C.4.14 EXPLOSIVES (CONTINUED)
(Classified in Accordance with Appendix B.1 of this section)

Hazard category	Signal word	Hazard statement	Pictogram
Division 1.6	*No signal word*	*No hazard statement*	***No pictogram***

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
None assigned.	None assigned	None assigned	None assigned

Note: Unpackaged explosives or explosives repacked in packaging other than the original or similar packaging shall have the label elements assigned to Division 1.1 unless the hazard is shown to correspond to one of the hazard categories in Appendix B.1 **of this section,** in which case the corresponding symbol, signal word and/or the hazard statement shall be assigned.

C.4.15 FLAMMABLE GASES
(Classified in Accordance with Appendix B.2 of this section)

Pictogram
Flame

Hazard category	**Signal word**	**Hazard statement**
1A	Danger	Extremely flammable gas
1B	**Danger**	**Flammable gas**

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep away from heat[~~/~~], hot surfaces, sparks[~~/~~]open flames[~~/hot surfaces~~] **and other ignition sources.** **No smoking.** [~~Chemical manufacturer, importer, or distributor to specify applicable ignition source(s)~~.]	**Leaking gas fire: Do not extinguish, unless leak can be stopped safely.** **In case of leakage, [~~E~~]eliminate all ignition sources ~~if safe to do so~~.**	**Store in well-ventilated place.**	
NOTE: For flammable gas Category 1A, pyrophoric gas and Category 1A, chemically unstable gas A and B see statements below.			

C.4.15 FLAMMABLE GASES (CONTINUED)
(Classified in Accordance with Appendix B.2 of this section)

Hazard category	Signal word	Hazard statement	Pictogram *Flame*
1A, Pyrophoric gas	Danger	Extremely Flammable gas May ignite spontaneously if exposed to air	

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Do not allow contact with air. *– if emphasis of the hazard statement is deemed necessary.* Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/…. Chemical manufacturer, importer or distributor to	Leaking gas fire: Do not extinguish, unless leak can be stopped safely. In case of leakage, eliminate all ignition sources.	Store in a well-ventilated place.	

specify the appropriate personal protective equipment.			
Note: This table lists only precautionary statements that are assigned due to the flammability and the pyrophoricity of the gas. For the other precautionary statements that are assigned based on chemical instability, see the respective tables for chemically unstable gases A and B.			

C.4.15 FLAMMABLE GASES (CONTINUED)
(Classified in Accordance with Appendix B.2 of this section)

Hazard category	Signal word	Hazard statement	**Pictogram** *Flame*
1A, Chemically unstable gas A	Danger	Extremely flammable gas May react explosively even in the absence of air.	
1A, Chemically unstable gas B	Danger	Extremely flammable gas May react explosively even in the absence of air at elevated pressure and/or temperature.	

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Do not handle until all safety precautions have been read and understood. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.	Leaking gas fire: Do not extinguish, unless leak can be stopped safely. In case of leakage, eliminate all ignition sources.	Store in a well-ventilated place.	

Note: This table lists only the precautionary statements that are assigned due to the flammability and the chemical instability of the gas. For the other precautionary statements that are assigned based on pyrophoricity, see the respective table for pyrophoric gas.

C.4.15 FLAMMABLE GASES (CONTINUED)
(Classified in Accordance with Appendix B.2 of this section)

Hazard category	Signal word	Hazard statement	Pictogram
2	Warning	Flammable gas	*No Pictogram*

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep away from heat[~~/~~], hot surfaces, sparks[~~/~~], open flames[~~/~~]~~hot surfaces~~ and other ignition sources. **No smoking.** [~~Chemical manufacturer, importer, or distributor to specify applicable ignition sources(s).~~]	**Leaking gas fire: Do not extinguish, unless leak can be stopped safely.** **In case of leakage, [~~E~~]eliminate all ignition sources.**	**Store in a well-ventilated place.**	

C.4.16 [~~FLAMMABLE~~] AEROSOLS
(Classified in Accordance with Appendix B.3 of this section)

Pictogram

Flame

Hazard category	**Signal word**	**Hazard statement**
1	Danger	Extremely flammable aerosol **Pressurized container: may burst if heated.**
2	Warning	Flammable aerosol **Pressurized container: may burst if heated.**

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep away from heat[~~/~~], **hot surfaces, sparks[~~/~~], open flames[~~/~~][~~hot surfaces~~] and other ignition sources. -No smoking.** [~~Chemical manufacturer, importer, or distributor to specify applicable ignition sources(s).~~] **Do not spray on an open flame or**		**Protect from sunlight. Do not expose to temperatures exceeding [~~50 ºC~~/]122 ºF (50 ºC).**	

other ignition source. **[~~Pressurized container:~~] Do not pierce or burn, even after use.**			

C.4.16 AEROSOLS
(Classified in Accordance with Appendix B.3.1 of this section)

Pictogram
No symbol

Hazard category	**Signal word**	**Hazard statement**
3	**Warning**	**Pressurized container: may burst if heated.**

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. **Do not pierce or burn, even after use.**		**Protect from sunlight. Do not expose to temperatures exceeding 122ºF (50 ºC)**	

C.4.16 CHEMICAL UNDER PRESSURE
(Classified in Accordance with Appendix B.3.2 of this section)

Hazard category	Signal word	Hazard statement	**Pictogram** ***Gas cylinder and Flame***
1	Danger	Extremely flammable chemical under pressure May burst if heated.	
2	Warning	Flammable chemical under pressure May burst if heated.	

Precautionary statements

Prevention	Response	Storage	Disposal
Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Do not pierce or burn, even after use.	In case of leakage, eliminate all ignition sources. Stop leak if safe to do so.	Protect from sunlight. Store in a well-ventilated place.	

C.4.16 CHEMICAL UNDER PRESSURE
(Classified in Accordance with Appendix B.3 of this section)

Hazard category	**Signal word**	**Hazard statement**	**Pictogram** ***Gas Cylinder***
3	**Warning**	**Pressurized container: may burst if heated.**	

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.	**Stop leak if safe to do so.**	**Protect from sunlight. Store in a well-ventilated place.**	

C.4.17 OXIDIZING GASES
(Classified in Accordance with Appendix B.4 of this section)

Hazard category	Signal word	Hazard statement	Pictogram Flame over circle
1	Danger	May cause or intensify fire; oxidizer	

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep[~~/Store~~] away from clothing[~~/…/~~]and other combustible materials. ~~[…Chemical manufacturer, importer, or distributor to specify other incompatible materials.]~~ **Keep [~~reduction valves~~/]valves and fittings free from oil and grease.**	**In case of fire: Stop leak if safe to do so.**	**Store in well-ventilated place.**	

C.4.18 GASES UNDER PRESSURE
(Classified in Accordance with Appendix B.5 of this section)

Hazard category	**Signal word**	**Hazard statement**
Compressed gas	Warning	Contains gas under pressure; may explode if heated
Liquefied gas	Warning	Contains gas under pressure; may explode if heated
Dissolved gas	Warning	Contains gas under pressure; may explode if heated

Pictogram
Gas cylinder

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
		Protect from sunlight. Store in a well-ventilated place.	

C.4.18 GASES UNDER PRESSURE (CONTINUED)
(Classified in Accordance with Appendix B.5 of this section)

Hazard category	**Signal word**	**Hazard statement**	**Pictogram** Gas cylinder
Refrigerated liquefied gas	Warning	Contains refrigerated gas; may cause cryogenic burns or injury	

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Wear cold insulating gloves[/] **and either face shield[/] or eye protection.**	**Thaw frosted parts with lukewarm water. Do not rub affected area.** **Get immediate medical advice/attention** **Chemical manufacturer, importer, or distributor to select medical advice or attention as appropriate .**	**Store in a well-ventilated place.**	

C.4.19 FLAMMABLE LIQUIDS
(Classified in Accordance with Appendix B.6 of this section)

Pictogram
Flame

Hazard category	**Signal word**	**Hazard statement**
1	Danger	Extremely flammable liquid and vapor
2	Danger	Highly flammable liquid and vapor
3	Warning	Flammable liquid and vapor

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep away from heat[~~/~~],hot surfaces, sparks[/], open flames[~~/hot surfaces~~] and other ignition sources.– No smoking. Chemical manufacturer, importer, or distributor to specify applicable ignition source(s). **Keep container tightly closed. – if the liquid is volatile and may generate an explosive atmosphere.** **Ground / and [~~B~~]bond container and receiving equipment** [~~- *if electrostatically sensitive material is for reloading.*~~] - *if [~~product~~]* ***the liquid*** *is volatile* [~~*so as to*~~] and may *generate[*	**If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water /[~~or shower~~]/[or shower].** ***text in square brackets to be included where the chemical manufacturer, /importer, or distributor considers it appropriate for the specific chemical.***	**Store in a well-ventilated place.** **Keep cool.-** ***for flammable liquids Category 1 and other flammable liquids that are volatile and may generate an explosive atmosphere.***	**Dispose of contents/ container to...** … in accordance with local/regional/ national/international regulations (to be specified). **Chemical manufacturer, or distributor to specify whether disposal requirements apply to contents, container, or both.**

~~*hazardous]*~~ **an explosive** *atmosphere*. **Use explosion-proof [electrical/ventilating/ lighting/.../] equipment.** ***-if the liquid is volatile and may generate an explosive atmosphere*** ***- text in square brackets may be used to specify specific electrical, ventilating, lighting, or other equipment if necessary and as appropriate.*** Chemical manufacturer, importer, or distributor to specify other equipment. **Use [~~only]~~ non-sparking tools.** ***-if the liquid is volatile and may generate an explosive atmosphere and if the minimum ignition energy is very low. (This applies to substances and mixtures where the minimum ignition energy is <0. lmJ, e.g., carbon disulfide).*** **Take action to prevent [~~precautionary measures against]~~ static discharge.** ***-if the liquid is volatile and may generate an explosive atmosphere.*** **Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/,,,**	**In case of fire: Use ... to extinguish *if water increases risk*.** ... Chemical manufacturer, importer, or distributor to specify appropriate media. - [~~*if water increases risk*~~*.]*		

Chemical manufacturer, importer, or distributor to specify **<u>the appropriate personal protective</u>** [~~type of~~] equipment.			

C.4.19 FLAMMABLE LIQUIDS (CONTINUED)
(Classified in Accordance with Appendix B.6 of this section)

Pictogram
No Pictogram

Hazard category	**Signal word**	**Hazard statement**
4	Warning	Combustible liquid

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep away heat, hot surface, sparks, open [~~from~~] flames and [~~hot surfaces~~] other ignition sources. No smoking. **Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/…** Chemical manufacturer, importer, or distributor to specify **the appropriate personal protective** [~~type of~~] equipment.	**In case of fire: Use ... to extinguish.** ***- if water increases risk*** ... Chemical manufacturer, importer, or distributor to specify appropriate media. *[~~- if water increases risk.~~]*	**Store in a well-ventilated place. [~~Keep cool.~~]** ***- for flammable liquids Category 1 and other flammable liquids that are volatile and may generate an explosive atmosphere.***	**Dispose of contents/container to...** in accordance with local/regional/national/international regulations (to be specified). **Chemical manufacturer, importer, or distributor specify whether disposal requirements apply to contents, container or both.**

C.4.20 FLAMMABLE SOLIDS
(Classified in Accordance with Appendix B.7 of this section)

Hazard category	**Signal word**	**Hazard statement**
1	Danger	Flammable solid
2	Warning	Flammable solid

Pictogram
Flame

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep away from heat[/], hot surfaces, sparks[/],open flames[/ ~~hot surfaces]~~ and other ignition sources. - **No smoking.** ~~[Chemical manufacturer, importer, or distributor to specify applicable ignition source(s).]~~ **Ground[~~/~~] and /[~~B~~]bond container and receiving equipment.** - *if* ***the solid is*** *electrostatically sensitive [~~material is for reloading~~]*. **Use explosion-proof [electrical/ventilating/ lighting/... ~~/~~]equipment.** ~~[... Chemical manufacturer, importer, or distributor to specify other equipment.]~~ **-** *if dust clouds can occur*. ***- text in square brackets may be used to specify specific electrical, ventilating, lighting or other***	**In case of fire: Use ... to extinguish** **-if water increases risk.** ... Chemical manufacturer, importer, or distributor to specify appropriate media. [~~- *if water increases risk*.~~]		

equipment if necessary and as appropriate. **Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/…** Chemical manufacturer, importer, or distributor to specify [~~type of~~] **the appropriate personal protective** equipment.			

C.4.21 SELF-REACTIVE SUBSTANCES AND MIXTURES
(Classified in Accordance with Appendix B.8 of this section)

Hazard category	**Signal word**	**Hazard statement**	**Pictogram** Exploding bomb
Type A	Danger	Heating may cause an explosion	

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep away from heat[~~/~~], hot surfaces, sparks[~~/~~],open flames and other ignition sources[~~/hot surfaces~~]. - No smoking. [~~Chemical manufacturer, importer, or distributor to specify applicable ignition source(s).~~] **~~[Keep/Store away from clothing/…/combustible materials.~~** ~~... Chemical manufacturer, importer, or distributor to specify other incompatible materials.]~~ **Keep only in original [~~container~~] packaging.**	**[~~In case of fire: Use ... to extinguish~~]** ~~... Chemical manufacturer, importer, or distributor to specify appropriate media.~~ ~~- *if water increases risk.]*~~ **In case of fire: Explosion risk. Evacuate area. [~~Fight fire remotely due to the risk of explosion]~~ DO NOT fight fire when fire reaches explosives**	**Store in a well-ventilated place. [~~Keep cool.~~]** **- except /or temperature controlled or self-reactive substances and mixtures or organic peroxides because condensation and consequent freezing may take place. Store at temperatures not exceeding [~~…°C/~~]…°F {°C).** . .. Chemical manufacturer, importer, or	**Dispose of contents/ container to...** … in accordance with local/regional/ national/international regulations (to be specified). **Chemical manufacturer, importer, or distributor to specify whether disposal requirements apply to contents, container, or both.**

Keep cool. ***- may be omitted if storage temperatures are listed on the label.*** **Ground and bond container and receiving equipment.** *– if electrostatically sensitive and able to generate an explosive atmosphere.* **Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/….** Chemical manufacturer, importer, or distributorto specify [~~type of~~] **the appropriate personal protective** equipment.		distributor to specify temperature **using applicable temperature scale.** ***- if temperature control is required (see Appendix B.2.3) or if otherwise deemed necessary.*** **Store [~~away from other materials~~] separately**.	

C.4.21 SELF-REACTIVE SUBSTANCES AND MIXTURES (CONTINUED)
(Classified in Accordance with Appendix B.8 of this section)

Hazard category	**Signal word**	**Hazard statement**	**Pictograms** Exploding bomb and flame
Type B	Danger	Heating may cause a fire or explosion	

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep away from heat[~~/~~], hot surfaces, sparks, open flames and other ignition sources~~[/hot surfaces~~]. - No smoking. ~~[Chemical manufacturer, importer, or distributor to specify applicable ignition source(s).~~] **~~Keep/Store away from clothing/.../combustible materials.~~** ~~[... Chemical manufacturer, importer, or distributor to specify other incompatible materials.~~]	**~~[In case of fire: Use ... to extinguish.~~** ~~... Chemical manufacturer, importer, or distributor to specify appropriate media.~~ ~~- *if water increases risk*.~~] **In case of fire: Evacuate area. Fight fire remotely due to the risk of explosion. [Use ... to extinguish].** ***text in square brackets to be includedif water increases risk.*** **... Chemical manufacturer, importer, or distributor to**	**Store in a well-ventilated place. [~~Keep cool.~~]** ***- except for temperature controlled self-reactive substances and mixtures or organic peroxides because condensation and consequent. freezing may take place.*** **Store at temperatures not exceeding [~~...°C/~~]...°F (°C).** **if temperature**	**Dispose of contents/ container to**... …in accordance with local/regional/national/ international regulations (to be specified). **Chemical manufacturer, importer, or distributor to specify whether disposal requirements apply to contents, container, or both.** (

Keep only in original ~~container~~ packaging. **Keep cool.** ***- may be omitted if storage temperatures are listed on the label.*** **Ground and bond container and receiving equipment – *if electrostatically sensitive and able to generate an explosive atmosphere.*** **Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.[~~….~~]…** Chemical manufacturer, importer, or distributor to specify [~~type of~~]**the appropriate personal protective** equipment.	**specify appropriate media. if water increases risk.**	**control is required (*see* Appendix B.2.3) or if otherwise deemed necessary** ... Chemical manufacturer, importer, or distributor to specify temperature **using applicable temperature scale**. **Store [~~away from other materials]~~ separately**.	

C.4.21 SELF-REACTIVE SUBSTANCES AND MIXTURES (CONTINUED)
(Classified in Accordance with Appendix B.8 of this section)

Pictogram
Flame

Hazard category	**Signal word**	**Hazard statement**
Type C	Danger	Heating may cause a fire
Type D	Danger	Heating may cause a fire
Type E	Warning	Heating may cause a fire
Type F	Warning	Heating may cause a fire

Precautionary statements

Prevention	**Response**	**Storage**	**Disposal**
Keep away from heat[~~/~~], hot surfaces, sparks[~~/~~], open flames~~[/hot surfaces~~]. No smoking. ~~[Chemical manufacturer, importer, or distributor to specify applicable ignition source(s).]~~ **~~[Keep/Store away from clothing/…/combustible materials.~~** ~~…Chemical manufacturer, importer, or distributor to specify other incompatible materials.]~~	**In case of fire: Use ... to extinguish - *if water increases risk.*** ... Chemical manufacturer, importer, or distributor to specify appropriate media. ~~[- *if water increases risk.]*~~	**Store in a well-ventilated place. [~~Keep cool~~.] except for temperature *controlled self-reactive substances and mixtures or organic peroxides because condensation and consequent. freezing may take place.*** **Store at temperatures not exceeding**	**Dispose of contents/ container to...** …in accordance with local/regional/national/ international regulations (to be specified). **Chemical manufacturer, importer, or distributor to specify whether disposal requirements apply to contents, container or both.**

Keep only in original packaging ~~container~~. **Keep cool.** ***- may be omitted if storage temperatures are listed on the label.*** **Ground and bond container and receiving equipment.** ***– if electrostatically sensitive and able to generate an explosive atmosphere.*** **Wear protective gloves/protective clothing/ eye protection/face protection/hearing protection/….** Chemical manufacturer, importer, or distributor to specify [~~type of~~] **the appropriate personal protective** equipment.		**[~~…°C~~]/…°F (°C).** ***– if temperature control is required (see Appendix B.2.3) or if otherwise deemed necessary.*** ...Chemical manufacturer, importer, or distributor to specify temperature **using applicable temperature scale**. **Store [~~away from other materials~~] separately.**	

C.4.22 PYROPHORIC LIQUIDS
(Classified in Accordance with Appendix B.9 of this section)

Pictogram
Flame

Hazard category	**Signal word**	**Hazard statement**
1	Danger	Catches fire spontaneously if exposed to air

Precautionary statements

Prevention	**Response**	**Storage**	**Disposal**
Keep away from heat[~~/~~], hot surfaces, sparks[~~/~~]open flames[~~/hot surfaces~~] and other ignition sources. - No smoking. [~~Chemical manufacturer, importer, or distributor to specify applicable ignition sources(s).~~] **Do not allow contact with air.** ***- if emphasis of the hazard statement is deemed necessary.*** **Handle and store contents**	**If on skin: Immerse in cool water[~~/~~] or wrap [~~with~~] in wet bandages** **In case of fire: Use ... to extinguish** - ***if water increases risk.*** ... Chemical manufacturer, importer, or distributor to specify appropriate media. [*~~- if water increases risk.~~*]	~~**[Store contents under ...**~~ ~~... Chemical manufacturer, importer, or distributor to specify appropriate liquid or inert gas.]~~	

under inert gas/…. **…Manufacturer, importer, or distributor to specify appropriate liquid or gas if “inert gas” is not appropriate.** **Keep container tightly closed.** **Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/….** Chemical manufacturer, importer, or distributor tospecify [~~type of~~] **the appropriate persona protective** equipment.			

C.4.23 PYROPHORIC SOLIDS
(Classified in Accordance with Appendix B.10 of this section)

Hazard category	**Signal word**	**Hazard statement**	**Pictogram** Flame
1	Danger	Catches fire spontaneously if exposed to air	

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep away from heat[~~/~~], hot surfaces, sparks[~~/~~]open flames[~~/hot surfaces~~] and other ignition sources. - No smoking. ~~[Chemical manufacturer, importer, or distributor to specify applicable ignition source(s).~~] **Do not allow contact with air. - if emphasis of the hazard statement is deemed necessary.**	**If on skin: Brush off loose particles from skin. Immerse in cool water[~~/~~] or wrap in wet bandages.** **In case of fire: Use ... to extinguish** - *if water increases risk*. ... Chemical manufacturer, importer, or distributor to specify appropriate media. ~~[- *if water increases risk*.~~]	~~**[Store contents under ...**~~ ~~…Chemical manufacturer, importer, or distributor to specify appropriate liquid or inert gas.]~~	

Handle and store contents under inert gas/…. **…Manufacturer, importer, or distributor to specify appropriate liquid or gas if "inert gas" is not appropriate.** **Keep container tightly closed.** **Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.** Chemical manufacturer, importer, or distributor to specify [~~type of~~] **the appropriate personal protective** equipment.			

C.4.24 SELF-HEATING SUBSTANCES AND MIXTURES
(Classified in Accordance with Appendix B.11 **of this section**)

Hazard category	**Signal word**	**Hazard statement**
1	Danger	Self-heating; may catch fire
2	Warning	Self-heating in large quantities; may catch fire

Pictogram
Flame

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep cool. [~~Protect from sunlight.~~] ***- may be omitted if storage temperatures are listed on the label.*** **Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/….** Chemical manufacturer, importer, or distributor to specify [~~type of~~] **the appropriate personal protective** equipment.		**Maintain air gap between stacks[~~/~~]/ or pallets.** **Protect from sunlight.** **Store bulk masses greater than … kg/…lbs at temperatures not exceeding [~~…°C/~~]…°F (°C).** ... Chemical manufacturer, importer, or distributor to specify mass and temperature **using applicable scale**. **Store [~~away from other materials]~~ separately.**	

C.4.25 SUBSTANCES AND MIXTURES WHICH, IN CONTACT WITH WATER, EMIT FLAMMABLE GASES

(Classified in Accordance with Appendix B.12 of this section)

Pictogram
Flame

Hazard category	**Signal word**	**Hazard statement**
1	Danger	In contact with water releases flammable gases, which may ignite spontaneously
2	Danger	In contact with water releases flammable gas

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Do not allow contact with water. ***- if emphasis of the hazard statement is deemed necessary.*** **Handle and store contents under inert gas/… Protect from moisture.** ***- if the substance or mixture reacts readily with moisture in air.*** **… Chemical manufacturer, importer, or distributor to specify appropriate liquid or gas if “inert gas” is not appropriate.**	**If on skin: Brush off loose particles from skin and immerse in cool water[~~/wrap in wet bandages~~].** **In case of fire: Use ... to extinguish** ***- if water increases risk.*** ... Chemical manufacturer, importer, or distributor to specify appropriate media. [~~*- if water increases risk.*~~]	**Store in a dry place.** **Store in a closed container.**	**Dispose of contents/container to...** …in accordance with local/regional/national / international regulations (to be specified). **Chemical manufacturer, importer, or distributor to specify whether disposal requirements apply to contents, container, or both.**

Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/…. Chemical manufacturer, importer, or distributor to specify [~~type of~~] **the appropriate personal protective** equipment.			

C.4.25 SUBSTANCES AND MIXTURES WHICH, IN CONTACT WITH WATER, EMIT FLAMMABLE GASES (CONTINUED)

(Classified in Accordance with Appendix B.12 of this section)

Hazard category	**Signal word**	**Hazard statement**	**Pictogram** Flame
3	Warning	In contact with water releases flammable gas	

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Handle and store contents under inert gas. Protect from moisture. ***- if the substance or mixture reacts readily with moisture in air.*** **… Chemical manufacturer, importer, or distributor to specify appropriate liquid or gas if “inert gas” is not appropriate.** **Wear protective gloves/protective clothing/eye protection/face protection/heari**	**In case of fire: Use ... to extinguish.** ***- if water increases risk.*** ... Chemical manufacturer, importer, or distributor to specify appropriate media. [~~*- if water increases risk*~~].	**Store in a dry place. Store in a closed container.**	**Dispose of contents/container to...** ... in accordance with local/regional/national /international regulations (to be specified). **Chemical manufacturer, importer, or distributor to specify whether disposal requirements apply to contents, container or both.**

ng protection/…. Chemical manufacturer, importer, or distributor to specify [~~type of~~] **the appropriate personal protective** equipment.			

C.4.26 OXIDIZING LIQUIDS
(Classified in Accordance with Appendix B.13 of this section)

Hazard category	**Signal word**	**Hazard statement**	**Pictogram** Flame over circle
1	Danger	May cause fire or explosion; strong oxidizer	

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. **Keep[~~/Store~~] away from clothing and other combustible materials.** ~~**[Take any precaution to avoid mixing with combustibles/...**~~ ~~... Chemical manufacturer, importer, or distributor to specify other incompatible materials.]~~ **Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/….** Chemical manufacturer, importer, or distributor to	**If on clothing: Rinse immediately contaminated clothing and skin with plenty of water before removing clothes.** **In case of major fire and large quantities: Evacuate area. Fight fire remotely due to the risk of explosion.** **In case of fire: Use ... to extinguish.** ***-if water increases risk*.** ... Chemical manufacturer,	**Store separately.**	**Dispose of contents/ container to...** …in accordance with local/regional/national/ international regulations (to be specified). **Chemical manufacturer, importer, or distributor to specify whether disposal requirements apply to contents, container, or both.**

specify [~~type of~~] **the appropriate personal protective** equipment. **Wear fire resistant [~~/~~] or flame [~~resistant/~~]retardant clothing.**	importer, or distributor to specify appropriate media. [~~- *if water increases risk*.~~]		

C.4.26 OXIDIZING LIQUIDS (CONTINUED)
(Classified in Accordance with Appendix B.13 of this section)

Hazard category	Signal word	Hazard statement	**Pictogram** Flame over circle
2	Danger	May intensify fire; oxidizer	
3	Warning	May intensify fire; oxidizer	

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. **Keep[~~/Store~~] away from clothing[~~/…/~~] and other combustible materials.** ~~[…Chemical manufacturer, importer, or distributor to specify other incompatible materials.]~~ ~~**[Take any precaution to avoid mixing with combustibles/...**~~ ~~... Chemical manufacturer, importer, or~~	**In case of fire: Use ... to extinguish.** **- *if water increases risk*.** ... Chemical manufacturer, importer, or distributor to specify appropriate media. [~~- *if water increases risk*.~~]		**Dispose of contents/ container to...** …in accordance with local/regional/national / international regulations (to be specified). **Chemical manufacturer, importer, or distributor to specify whether disposal requirements apply to contents, container, or both.**

~~distributor to specify other incompatible materials.~~] **Wear protective gloves/<u>protective clothing/</u>eye protection/face protection/<u>hearing protection/…</u>.** Chemical manufacturer, importer, or distributor to specify [~~type of~~] **<u>the appropriate personal protective</u>** equipment.			

C.4.27 OXIDIZING SOLIDS
(Classified in Accordance with Appendix B.14 of this section)

Hazard category	Signal word	Hazard statement	**Pictogram** Flame over circle
1	Danger	May cause fire or explosion; strong oxidizer	

Precautionary statements

Prevention	Response	Storage	Disposal
Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. **Keep away from clothing and other combustible materials.** ~~**[Take any precaution to avoid mixing with combustibles/...**~~ ~~…Chemical manufacturer, importer, or distributor to specify other incompatible materials.]~~ **Wear protective gloves/protective clothing/eye protection/face**	**If on clothing: Rinse immediately contaminated clothing and skin with plenty of water before removing clothes.** **In case of major fire and large quantities: Evacuate area. Fight fire remotely due to the risk of explosion.** **In case of fire: Use ... to extinguish.** ***- if water increases risk*.** ... Chemical	**Store separately.**	**Dispose of contents/container to...** …in accordance with local/regional/ national/international regulations (to be specified). **Chemical manufacturer, importer, or distributor to specify whether disposal requirements apply to contents, container, or both.**

protection/hearing protection/…. Chemical manufacturer, importer, or distributor to specify [~~type of~~] **appropriate personal protective** equipment. **Wear fire[~~/flame~~] resistant~~/~~ or flame retardant clothing.**	manufacturer, importer, or distributor to specify appropriate media. [~~- *if water increases risk*~~.]		

C.4.27 OXIDIZING SOLIDS (CONTINUED)

(Classified in Accordance with Appendix B.14 of this section)

Hazard category	Signal word	Hazard statement
2	Danger	May intensify fire; oxidizer
3	Warning	May intensify fire; oxidizer

Pictogram

Flame over circle

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. **Keep[~~/Store~~] away from clothing and other [~~/…/~~] combustible materials.** ~~[… Chemical manufacturer, importer, or distributor to specify incompatible materials.]~~ ~~**[Take any precaution to avoid mixing with combustibles/...**~~ ~~…Chemical manufacturer, importer, or distributor to specify~~	**In case of fire: Use ... to extinguish.** **- *if water increases risk*.** ... Chemical manufacturer, importer, or distributor to specify appropriate media. ~~[- *if water increases risk*.]~~		**Dispose of contents/ container to...** ... in accordance with local/regional/national/ international regulations (to be specified). **Chemical manufacturer, importer, or distributor to specify whether disposal requirements apply to contents, container or both.**

~~other incompatible materials.]~~ **Wear protective gloves/<u>protective clothing/</u>eye protection/face protection<u>/hearing protection/…</u>.** Chemical manufacturer, importer, or distributor to specify ~~type of~~ **<u>the appropriate personal protective</u>** equipment.			

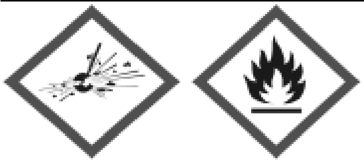
C.4.28 ORGANIC PEROXIDES
(Classified in Accordance with Appendix B.15 of this section)

Hazard category	**Signal word**	**Hazard statement**	**Pictogram** Exploding bomb
Type A	Danger	Heating may cause an explosion	

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep away from heat[~~/~~], hot surfaces, sparks[~~/~~]open flames[~~/hot surfaces~~] and other ignition sources.- No smoking. [~~Chemical manufacturer, importer, or distributor to specify applicable ignition source(s).~~] **[~~Keep/Store away from clothing/…/combustible materials.~~** ~~... Chemical manufacturer, importer, or distributor to specify incompatible materials~~.] **Keep only in original packaging. [~~container~~].** **Keep Cool.** **-*may be omitted if storage temperatures are listed on the label.***	**In case of fire: Explosion risk. Evacuate area. DO NOT fight fire when fire reaches explosives.**	**Store in a well-ventilated place.** ***– except for temperature controlled self-reactive substances and mixtures or organic peroxides because condensation and consequent freezing may take place.*** **Protect from sunlight.** **Store at temperatures not exceeding [~~…°C/~~]…°F (°C). [~~Keep cool.~~]** ***- if temperature***	**Dispose of contents/ container to...** ... in accordance with local/regional/national/ international regulations (to be specified). **Chemical manufacturer, importer, or distributor to specify whether disposal requirements apply to contents, container or both.**

Ground and bond container and receiving equipment. -*if electrostatically sensitive and able to generate an explosive atmosphere.* **Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/….** Chemical manufacturer, importer, or distributor to specify [~~type of~~] the **appropriate personal protective** equipment.		***control is required or if otherwise deemed necessary.*** ... Chemical manufacturer, importer, or distributor to specify temperature **using applicable temperature scale**. ~~**[Protect from sunlight.]**~~ **Store separately ~~[away from other materials]~~.**	

C.4.28 ORGANIC PEROXIDES (CONTINUED)
(Classified in Accordance with Appendix B.15 of this section)

Hazard category	**Signal word**	**Hazard statement**	**Pictograms** Exploding bomb and flame
Type B	Danger	Heating may cause a fire or explosion	

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep away from heat[~~/~~], hot surfaces, sparks[~~/~~]open flames[~~/hot surfaces~~] and other ignition sources.- No smoking. ~~[Chemical manufacturer, importer, or distributor to specify applicable ignition source(s).~~] **~~[Keep /Store away from clothing/.../combustible materials.~~** ~~... Chemical manufacturer, importer, or distributor to specify incompatible materials.~~] **Keep only in original packaging. [~~container~~].** **Keep Cool.**	**In case of fire: Evacuate area. Fight fire remotely due to the risk of explosion. [Use...to extinguish]** ***– text in square brackets to be used if water increases risk.*** **... Chemical manufacturer, importer, distributor to specify appropriate media.**	**Store in a well-ventilated place.** ***– except for temperature controlled self-reactive substances and mixtures or organic peroxides because condensation and consequent freezing may take place.*** **Protect from sunlight.** **Store at temperatures not exceeding [~~…°C/~~]…°F (°C). [~~Keep cool.~~]** ***- if temperature control is required or if otherwise***	**Dispose of contents/ container to...** ... in accordance with local/regional/ national/ international regulations (to be specified). **Chemical manufacturer, importer, or distributor to specify whether disposal requirements apply to contents,**

-may be omitted if storage temperatures are listed on the label. **Ground and bond container and receiving equipment. - *if electrostatically sensitive and able to generate an explosive atmosphere.*** **Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/….** Chemical manufacturer, importer, or distributor to specify [~~type of~~] the **appropriate personal protective** equipment.		***deemed necessary.*** **~~[Keep cool.]~~** ... Chemical manufacturer, importer, or distributor to specify temperature **using applicable temperature scale**. **~~[Protect from sunlight.]~~** **Store separately ~~[away from other materials]~~.**	**container or both.**

C.4.28 ORGANIC PEROXIDES (CONTINUED)
(Classified in Accordance with Appendix B.15 of this section)

Pictogram
Flame

Hazard category	**Signal word**	**Hazard statement**
Type C	Danger	Heating may cause a fire
Type D	Danger	Heating may cause a fire
Type E	Warning	Heating may cause a fire
Type F	Warning	Heating may cause a fire

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep away from heat[~~/~~], hot surfaces, sparks[~~/~~]open flames[~~/hot surfaces~~] and other ignition sources.- No smoking. ~~Chemical manufacturer, importer, or distributor to specify applicable ignition source(s).~~ ~~**Keep/Store away from clothing/.../ combustible materials**~~ ~~... Chemical manufacturer, importer, or distributor to specify incompatible materials.~~ **Keep only in original packaging [~~container~~].**	**In case of fire: Use ... to extinguish. - if water increases risk.** **... Chemical manufacturer, importer, distributor to specify appropriate media.**	**Store in a well-ventilated place. *– except for temperature controlled self-reactive substances and mixtures or organic peroxides because condensation and consequent freezing may take place.***	**Dispose of contents/ container to...** ... in accordance with local/regional/national/ international regulations (to be specified). **Chemical manufacturer, importer, or distributor to specify whether disposal requirements apply to contents, container or both.**

Keep Cool. ***-may be omitted if storage temperatures are listed on the label.*** **Ground and bond container and receiving equipment. *-if electrostatically sensitive and able to generate an explosive atmosphere.*** **Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/….** Chemical manufacturer, importer, or distributor to specify [~~type of~~] the **appropriate personal protective** equipment.		**Protect from sunlight.** **Store at temperatures not exceeding [~~…°C/~~]…°F (°C). [~~Keep cool.~~]** ***- if temperature control is required or if otherwise deemed necessary.*** **[~~Keep cool~~.]** Chemical manufacturer, importer, or distributor to specify temperature **using applicable temperature scale**. **[~~Protect from sunlight.~~]** **Store separately [~~away from other materials~~].**	

C.4.29 CORROSIVE TO METALS
(Classified in Accordance with Appendix B.16 of this section)

Hazard category	Signal word	Hazard statement
1	Warning	May be corrosive to metals

Pictogram

Corrosion

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep only in original packaging [~~container~~].	**Absorb spillage to prevent material damage.**	**Store in [~~corrosive~~] corrosion resistant/...container with a resistant inner liner.** ***- may be omitted if "Keep only in original packaging" is on the label*** ... Chemical manufacturer, importer, or distributor to specify other compatible materials.	

C.4.30 DESENSITIZED EXPLOSIVES
(Classified in Accordance with Appendix B.17 of this section)

Hazard category	**Signal word**	**Hazard statement**	**Pictogram** Flame
1	**Danger**	**Fire, blast or projection hazard; increased risk of explosion if desensitizing agent is reduced.**	
2	**Danger**	**Fire or projection hazard; increased risk of explosion if desensitizing agent is reduced.**	
3	**Warning**	**Fire or projection hazard; increased risk of explosion if desensitizing agent is reduced.**	

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. **Avoid heating under confinement or reduction of the desensitizing agent.** **Keep wetted with…**	**In case of fire: Evacuate area. Fight fire remotely due to the risk of explosion.**	**Store in accordance with…** **... Chemical manufacturer, importer, or distributor to specify local/regional/national/ international regulations as applicable.**	**Dispose of contents/container to...** **...in accordance with local/regional /national/ international regulations (to be specified).** **Chemical manufacturer, importer, or**

<u>...Chemical manufacturer, importer or distributor to specify appropriate material.</u> **<u>Keep container tightly closed.</u>** **<u>Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/...</u>** **<u>Chemical manufacturer, importer or distributor to specify the appropriate personal protective equipment.</u>**			**<u>distributor to specify whether disposal requirements apply to contents, container or both.</u>**

C.4.30 DESENSITIZED EXPLOSIVES
(Classified in Accordance with Appendix B.17 of this section)

Pictogram

Flame

Hazard category	Signal word	Hazard statement
4	Warning	Fire hazard; increased risk of explosion if desensitizing agent is reduced.

Precautionary statements

Prevention	Response	Storage	Disposal
Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Avoid heating under confinement or reduction of the desensitizing agent. Keep wetted with… ... Chemical manufacturer, importer, or distributor to specify appropriate material. Keep container tightly closed.	In case of major fire: Evacuate area. Fight fire remotely due to the risk of explosion.	Store in accordance with… ... Chemical manufacturer, importer, or distributor to specify local/regional /national/ international regulations as applicable.	Dispose of contents/container to... ...in accordance with local/regional/nation al/ international regulations (to be specified). Chemical manufacturer, importer, or distributor to specify whether disposal requirements apply to contents, container, or both.

Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/.... **Chemical manufacturer, importer, or distributor to specify the appropriate personal protective equipment.**			

C.4.[~~29~~]31 [~~CORROSIVE TO METALS~~] Label elements for OSHA defined hazards

~~[(Classified in Accordance with Appendix B.16)]~~

~~**[Pictogram**~~
~~Flame]~~

~~**[Hazard category**~~	~~**Signal word**~~	~~**Hazard statement**~~
~~Pyrophoric Gas~~	~~Danger~~	~~Catches fire spontaneously if exposed to air]~~

Pictogram
No Pictogram

Hazard category	**Signal word**	**Hazard statement**
Simple Asphyxiant	Warning	May displace oxygen and cause rapid suffocation

Pictogram
No Pictogram

Hazard category	**Signal word**	**Hazard statement**
Combustible Dust[2]	Warning	May form combustible dust concentrations in air **[if small particles are generated during further processing, handling or by other means.]** **or** **May form explosible dust-air mixture [if small particles are generated during further processing, handling or by other means.]**

Text in square brackets may be used when the material can only create a combustible dust hazard due to the creation of small particles during the processing or handling of the chemical

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[2] 1)The chemical manufacturer or importer shall label chemicals that are shipped in dust form, and present a combustible dust hazard in that form when used downstream, under paragraph (f)(1~~)[; 2) the chemical~~] **of this section.**

2) the chemical manufacturer or importer shipping chemicals that are in a form that is not yet a dust must provide a label to customers**, that follows the approach described** under paragraph (f)(4) **of this section**

if, under normal conditions of use, the chemicals are processed in a downstream workplace in such a way that they present a combustible dust hazard; and

3) the employer shall follow the workplace labeling requirements under paragraph (f)(6) **of this section** where combustible dust hazards are present.

Appendix D to §1910.1200 – Safety Data Sheets (Mandatory)

A safety data sheet (SDS) shall include the information specified in Table D.1 under the section number and heading indicated for sections 1-11 and 16. **While each section of the SDS must contain all of the specified information, preparers of safety data sheets are not required to present the information in any particular order within each section.** If no relevant information is found for any given subheading within a section, the SDS shall clearly indicate that no applicable information is available. Sections 12-15 may be included in the SDS, but are not mandatory.

Table D.1. Minimum Information for an SDS

	Heading	Subheading
1.	**Identification**	(a) Product identifier used on the label; (b) Other means of identification; (c) Recommended use of the chemical and restrictions on use; (d) Name, **U.S.** address, and **U.S.** telephone number of the chemical manufacturer, importer, or other responsible party; (e) Emergency phone number.
2.	**Hazard identification**	(a) Classification of the chemical in accordance with paragraph (d)**(1)(i)** of §1910.1200; (b) Signal word, hazard statement(s), symbol(s) and precautionary statement(s) in accordance with paragraph (f) of §1910.1200. (Hazard symbols may be provided as graphical reproductions in black and white or the name of the symbol, e.g., flame, skull and crossbones); ~~(c) Describe any hazards not otherwise classified that have been identified during the classification process;~~ **(c) Hazards classified under paragraph (d)(1)(ii) of § 1910.12000;** ~~(d) Where an ingredient with unknown acute toxicity is used in a mixture at a concentration ≥ 1% and the mixture is not classified based on testing of the mixture~~

	Heading	Subheading
		~~as a whole, a statement that X% of the mixture consists of ingredient(s) of unknown acute toxicity is required.~~ **(d) Describe any hazards not otherwise classified that have been identified during the classification process;** **(e) Where an ingredient with unknown acute toxicity is used in a mixture at a concentration ≥1% and the mixture is not classified based on testing of the mixture as a whole, a statement that X% of the mixture consists of ingredient(s) of unknown acute toxicity is required.**
3.	**Composition/ information on ingredients**	Except as provided for in paragraph (i) of §1910.1200 on trade secrets: **For Substances** (a) Chemical name; (b) Common name and synonyms; (c) CAS number and other unique identifiers; (d) Impurities and stabilizing additives **(constituents)** which are themselves classified and which contribute to the classification of the substance. For Mixtures In addition to the information required for substances: (a) The chemical name **CAS number or other unique identifier,** and concentration (exact percentage) or concentration ranges of all ingredients which are classified as health hazards in accordance with paragraph (d) of §1910.1200 and (1) [~~A]~~**a**re present above their cut-off/concentration limits; or (2) [~~P~~]present a health risk below the cut-off/concentration limits. **Note: When CAS number is not available or claimed as a trade secret, the preparer must indicate the**

	Heading	Subheading
		source of unique identifier. (b) The concentration (exact percentage) shall be specified unless a trade secret claim is made in accordance with paragraph (i) of §1910.1200, when there is batch-to-batch variability in the production of a mixture, or for a group of substantially similar mixtures (*See* A.0.5.1.2) with similar chemical composition. In these cases, concentration ranges may be used. For All Chemicals Where a Trade Secret is Claimed Where a trade secret is claimed in accordance with paragraph (i) of §1910.1200, a statement that the specific chemical identity and/or ~~exact~~ ~~percentage (~~concentration~~)~~ **(exact or range)** of **the** composition has been withheld as a trade secret is required. **When the concentration or concentration range is withheld as a trade secret, the prescribed concentration ranges used in §1910.1200(i)(1)(iv) – (vi) must be used.**
4.	**First-aid measures**	(a) Description of necessary measures, subdivided according to the different routes of exposure, i.e., inhalation, skin and eye contact, and ingestion; (b) Most important symptoms/effects, acute and delayed. (c) Indication of immediate medical attention and special treatment needed, if necessary.
5.	**Fire-fighting measures**	(a) Suitable (and unsuitable) extinguishing media. (b) Specific hazards arising from the chemical (e.g., nature of any hazardous combustion products). (c) Special protective equipment and precautions for fire-fighters.
6.	**Accidental release measures**	(a) Personal precautions, protective equipment, and emergency procedures. (b) Methods and materials for containment and cleaning

	Heading	Subheading
		up.
7.	**Handling and storage**	(a) Precautions for safe handling. (b) Conditions for safe storage, including any incompatibilities.
8.	**Exposure controls/personal protection**	(a) **For all ingredients or constituents listed in Section 3,** the OSHA permissible exposure limit (PEL), American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Value (TLV), and any other exposure limit used or recommended by the chemical manufacturer, importer, or employer preparing the safety data sheet, where available. (b) Appropriate engineering controls. (c) Individual protection measures, such as personal protective equipment.
9.	**Physical and chemical properties**	(a) [~~Appearance (physical state, color, etc.);~~]**Physical state.** (b) [~~Odor;~~] **Color.** (c) Odor **(includes odor** threshold**)**[~~;~~]. (d) [~~pH;~~] **Melting point/freezing point.** (e) [~~Melting point/freezing point;~~] **Boiling point (or initial boiling point or boiling range).** (f) [~~Initial boiling point and boiling range;~~] **Flammability.** (g) [~~Flash point;~~] **Lower and upper explosion limit/flammability limit.** (h) [~~Evaporation rate;~~] **Flash point.** (i) [~~Flammability (solid, gas);~~] **Auto-ignition temperature.** (j) [~~Upper/lower flammability or explosive limits;~~] **Decomposition temperature.** (k) [~~Vapor pressure;~~] **pH.** (l) [~~Vapor density;~~] **Kinematic viscosity.** (m) [~~Relative density;~~] **Solubility.** (n) [~~Solubility(ies);~~] **Partition coefficient n-octanol/water**

	Heading	Subheading
		(log value). (o) [~~Partition coefficient: n-octanol/water;~~] **Vapor pressure (includes evaporation rate).** (p) [~~Auto-ignition temperature;~~] **Density and/or relative density.** (q) [~~Decomposition temperature;~~] **Relative vapor density.** (r) [~~Viscosity.~~] **Particle characteristics.**
10.	**Stability and reactivity**	(a) Reactivity; (b) Chemical stability; (c) Possibility of hazardous reactions**, including those associated with foreseeable emergencies**; (d) Conditions to avoid (e.g., static discharge, shock, or vibration); (e) Incompatible materials; (f) Hazardous decomposition products.
	Heading	**Subheading**
11.	**Toxicological information**	Description of the various toxicological (health) effects and the available data used to identify those effects, including: (a) Information on the likely routes of exposure (inhalation, ingestion, skin and eye contact); (b) Symptoms related to the physical, chemical and toxicological characteristics; (c) Delayed and immediate effects and also chronic effects from short- and long-term exposure; (d) Numerical measures of toxicity (such as acute toxicity estimates). **(e)** [~~Whether the hazardous chemical is listed in the National Toxicology Program (NTP) Report on Carcinogens (latest edition) or has been found to be a potential carcinogen in the International Agency for Research on Cancer (IARC) Monographs (latest edition), or by OSHA.~~] **Interactive effects;**

	Heading	Subheading
		information on interactions should be included if relevant and readily available; **(f) Whether the hazardous chemical is listed in the National Toxicology Program (NTP) Report on Carcinogens (latest edition) or has been found to be a potential carcinogen in the International Agency for Research on Cancer (IARC) Monographs (latest edition), or by OSHA.** **(g) When specific chemical data or information is not available, the preparer must indicate if alternative information is used and the method used to derive the information (e.g., where the preparer is using information from a class of chemicals rather than the exact chemical in question and using SAR to derive the toxicological information).**
12.	**Ecological information (Non-mandatory)**	(a) Ecotoxicity (aquatic and terrestrial, where available); (b) Persistence and degradability; (c) Bioaccumulative potential; (d) Mobility in soil; (e) Other adverse effects (such as hazardous to the ozone layer).
13.	**Disposal considerations (Non-mandatory)**	Description of waste residues and information on their safe handling and methods of disposal, including the disposal of any contaminated packaging.
14.	**Transport information (Non-mandatory)**	(a) UN number; (b) UN proper shipping name; (c) Transport hazard class(es); (d) Packing group, if applicable; (e) Environmental hazards (e.g., Marine pollutant (Yes/No)); (f) Transport in bulk (according to [~~Annex II of MARPOL 73/78 and the IBC Code~~] **IMO instruments**); (g) Special precautions which a user needs to be aware of,

	Heading	Subheading
		or needs to comply with, in connection with transport or conveyance either within or outside their premises.
15.	**Regulatory information (Non-mandatory)**	Safety, health and environmental regulations specific for the product in question.
16.	**Other information, including date of preparation or last revision**	The date of preparation of the SDS or the last change to it.

<u>Note: To determine the appropriate flammable liquid storage container size and type, the boiling point shall be determined by methods specified under § 1910.106(a)(5) and then listed on the SDS. In addition, the manufacturer, importer, and distributor shall clearly note in sections 7 and 9 of the SDS if an alternate calculation was used for storage purposes and the classification for storage differs from the classification listed in section 2 of the SDS.</u>

Stat. Auth: ORS 654.025(2) and 656.726(4).
Stats. Implemented: ORS 654.001 through 654.295.
Hist: OR-OSHA Admin. Order 12-1993, f. 8/20/93, ef. 11/1/93.

Appendix E to §1910.1200 – Definition of “Trade Secret” (Mandatory)

The following is a reprint of the "Restatement of Torts" section 757, comment b (1939):

b. "Definition of trade secret." A trade secret may consist of any formula, pattern, device or compilation of information which is used in one's business, and which gives him an opportunity to obtain an advantage over competitors who do not know or use it. It may be a formula for a chemical compound, a process of manufacturing, treating or preserving materials, a pattern for a machine or other device, or a list of customers. It differs from other secret information in a business (see s759 of the Restatement of Torts which is not included in this Appendix) in that it is not simply information as to single or ephemeral events in the conduct of the business, as, for example, the amount or other terms of a secret bid for a contract or the salary of certain employees, or the security investments made or contemplated, or the date fixed for the announcement of a new policy or for bringing out a new model or the like. A trade secret is a process or device for continuous use in the operations of the business. Generally it relates to the production of goods, as, for example, a machine or formula for the production of an article. It may, however, relate to the sale of goods or to other operations in the business, such as a code for determining discounts, rebates or other concessions in a price list or catalogue, or a list of specialized customers, or a method of bookkeeping or other office management.
"Secrecy." The subject matter of a trade secret must be secret. Matters of public knowledge or of general knowledge in an industry cannot be appropriated by one as his secret. Matters which are completely disclosed by the goods which one markets cannot be his secret. Substantially, a trade secret is known only in the particular business in which it is used. It is not requisite that only the proprietor of the business know it. He may, without losing his protection, communicate it to employees involved in its use. He may likewise communicate it to others pledged to secrecy. Others may also know of it independently, as, for example, when they have discovered the process or formula by independent invention and are keeping it secret. Nevertheless, a substantial element of secrecy must exist, so that, except by the use of improper means, there would be difficulty in acquiring the information. An exact definition of a trade secret is not possible. Some factors to be considered in determining whether given information is one's trade secret are: (1) The extent to which the information is known outside of his business; (2) the extent to which it is known by employees and others involved in his business; (3) the extent of measures taken by him to guard the secrecy of the information; (4) the value of the information to him and his competitors; (5) the amount of effort or money expended by him in

developing the information; (6) the ease or difficulty with which the information could be properly acquired or duplicated by others.

"Novelty and prior art." A trade secret may be a device or process which is patentable; but it need not be that. It may be a device or process which is clearly anticipated in the prior art or one which is merely a mechanical improvement that a good mechanic can make. Novelty and invention are not requisite for a trade secret as they are for patentability. These requirements are essential to patentability because a patent protects against unlicensed use of the patented device or process even by one who discovers it properly through independent research. The patent monopoly is a reward to the inventor. But such is not the case with a trade secret. Its protection is not based on a policy of rewarding or otherwise encouraging the development of secret processes or devices. The protection is merely against breach of faith and reprehensible means of learning another's secret. For this limited protection it is not appropriate to require also the kind of novelty and invention which is a requisite of patentability. The nature of the secret is, however, an important factor in determining the kind of relief that is appropriate against one who is subject to liability under the rule stated in this Section. Thus, if the secret consists of a device or process which is a novel invention, one who acquires the secret wrongfully is ordinarily enjoined from further use of it and is required to account for the profits derived from his past use. If, on the other hand, the secret consists of mechanical improvements that a good mechanic can make without resort to the secret, the wrongdoer's liability may be limited to damages, and an injunction against future use of the improvements made with the aid of the secret may be inappropriate.

Stat. Auth.: ORS 654.025(2) and 656.726(4).
Stats. Implemented: ORS 654.001 through 654.295.

Hist: OR-OSHA Admin. Order 4-1994, f. 8/4/94, ef. 8/4/94.

Appendix F to §1910.1200 – Guidance for Hazard Classifications RE: Carcinogenicity (Non-Mandatory)

The mandatory criteria for classification of a chemical for carcinogenicity under HCS (§1910.1200) are found in Appendix A.6 to this section. This non-mandatory Appendix provides additional guidance on hazard classification for carcinogenicity. Part A of Appendix F includes background guidance provided by GHS based on the Preamble of the International Agency for Research on Cancer (IARC) "Monographs on the Evaluation of Carcinogenic Risks to Humans" (2006). Part B provides IARC classification information. Part C provides background guidance from the National Toxicology Program (NTP) "Report on Carcinogens" (RoC), and Part D is a table that compares GHS carcinogen hazard categories to carcinogen classifications under IARC and NTP, allowing classifiers to be able to use information from IARC and NTP RoC carcinogen classifications to complete their classifications under the GHS, and thus the HCS.

Part A: Background Guidance [1]

As noted in Footnote 6 of Appendix A.6. to this section, the GHS includes as guidance for classifiers information taken from the Preamble of the International Agency for Research on Cancer (IARC) "Monographs on the Evaluation of Carcinogenic Risks to Humans" (2006), providing guidance on the evaluation of the strength and evidence of carcinogenic risks to humans. This guidance also discusses some additional considerations in classification and an approach to analysis, rather than hard-and-fast rules. Part A is consistent with Appendix A.6, and should help in evaluating information to determine carcinogenicity.

Carcinogenicity in humans:

The evidence relevant to carcinogenicity from studies in humans is classified into one of the following categories:

(a) **Sufficient evidence of carcinogenicity**: A causal relationship has been established between exposure to the agent and human cancer. That is, a positive relationship has been observed between the exposure and cancer in studies in which chance, bias and confounding could be ruled out with reasonable confidence.

(b) **Limited evidence of carcinogenicity**: A positive association has been observed between exposure to the agent and cancer for which a causal interpretation is considered by the Working Group to be credible, but chance, bias or confounding could not be ruled out with reasonable confidence.

In some instances, the above categories may be used to classify the degree of evidence related to carcinogenicity in specific organs or tissues.

[1] The text of Appendix F, Part A, on the IARC Monographs, is paraphrased from the 2006 Preamble to the “Monographs on the Evaluation of Carcinogenic Risks to Humans”; the Classifier is referred to the full IARC Preamble for the complete text. The text is not part of the agreed GHS text on the harmonized system developed by the OECD Task Force-HCL.

Carcinogenicity in experimental animals:

The evidence relevant to carcinogenicity in experimental animals is classified into one of the following categories:

(a) **Sufficient evidence of carcinogenicity**: A causal relationship has been established between the agent and an increased incidence of malignant neoplasms or of an appropriate combination of benign and malignant neoplasms in two or more species of animals or two or more independent studies in one species carried out at different times or in different laboratories or under different protocols. An increased incidence of tumors in both sexes of a single species in a well-conducted study, ideally conducted under Good Laboratory Practices, can also provide sufficient evidence.
Exceptionally, a single study in one species and sex might be considered to provide sufficient evidence of carcinogenicity when malignant neoplasms occur to an unusual degree with regard to incidence, site, type of tumor or age at onset, or when there are strong findings of tumors at multiple sites.

(b) **Limited evidence of carcinogenicity**: The data suggest a carcinogenic effect but are limited for making a definitive evaluation because, e.g. the evidence of carcinogenicity is restricted to a single experiment; there are unresolved questions regarding the adequacy of the design, conduct or interpretation of the studies; the agent increases the incidence only of benign neoplasms or lesions of uncertain neoplastic potential; or the evidence of carcinogenicity is restricted to studies that demonstrate only promoting activity in a narrow range of tissues or organs.

Guidance on how to consider important factors in classification of carcinogenicity (See Reference Section)

The weight of evidence analysis called for in GHS and the HCS (§1910.1200) is an integrative approach that considers important factors in determining carcinogenic potential along with the strength of evidence analysis. The IPCS "*Conceptual Framework for Evaluating a Mode of Action for Chemical Carcinogenesis*" (2001), International Life Sciences Institute (ILSI) "*Framework for Human Relevance Analysis of Information on Carcinogenic Modes of Action*" (Meek, *et al*., 2003; Cohen *et al*., 2003, 2004), and Preamble to the IARC Monographs (2006; Section B.6. (Scientific Review and Evaluation; Evaluation and Rationale)) provide a basis for systematic assessments that may be performed in a consistent fashion. The IPCS also convened a panel in 2004 to further develop and clarify the human relevance framework. However, the above documents are not intended to dictate answers, nor provide lists of criteria to be checked off.

Mode of action

Various documents on carcinogen assessment all note that mode of action in and of itself, or consideration of comparative metabolism, should be evaluated on a case-by-case basis and are part of an analytic evaluative approach. One must look closely at any mode of action in animal experiments, taking into consideration comparative toxicokinetics / toxicodynamics between the animal test species and humans to determine the relevance of the results to humans. This may lead to the possibility of discounting very specific effects of certain types of substances. Life stage-dependent effects on cellular differentiation may also lead to qualitative differences between animals and humans. Only if a mode of action of tumor development is conclusively determined not to be operative in humans may the carcinogenic evidence for that tumor be discounted. However, a weight of evidence evaluation for a substance calls for any other tumorigenic activity to be evaluated, as well.

Responses in multiple animal experiments

Positive responses in several species add to the weight of evidence that a substance is a carcinogen. Taking into account all of the factors listed in A.6.2.5.2 and more, such chemicals with positive outcomes in two or more species would be provisionally considered to be classified in GHS Category 1B until human relevance of animal results are assessed in their entirety. It should be noted, however, that positive results for one species in at least two independent studies, or a single positive study showing unusually strong evidence of malignancy may also lead to Category 1B.

Responses are in one sex or both sexes

Any case of gender-specific tumors should be evaluated in light of the total tumorigenic response to the substance observed at other sites (multi-site responses or incidence above background) in determining the carcinogenic potential of the substance.

If tumors are seen only in one sex of an animal species, the mode of action should be carefully evaluated to see if the response is consistent with the postulated mode of action. Effects seen only in one sex in a test species may be less convincing than effects seen in both sexes, unless there is a clear patho-physiological difference consistent with the mode of action to explain the single sex response.

Confounding effects of excessive toxicity or localized effects

Tumors occurring only at excessive doses associated with severe toxicity generally have doubtful potential for carcinogenicity in humans. In addition, tumors occurring only at sites of contact and/or only at excessive doses need to be carefully evaluated for human relevance for carcinogenic hazard. For example, forestomach tumors, following administration by gavage of an irritating or corrosive, non-mutagenic chemical, may be of questionable relevance. However, such determinations must be evaluated carefully in justifying the carcinogenic potential for humans; any occurrence of other tumors at distant sites must also be considered.

Tumor type, reduced tumor latency

Unusual tumor types or tumors occurring with reduced latency may add to the weight of evidence for the carcinogenic potential of a substance, even if the tumors are not statistically significant.

Toxicokinetic behavior is normally assumed to be similar in animals and humans, at least from a qualitative perspective. On the other hand, certain tumor types in animals may be associated with toxicokinetics or toxicodynamics that are unique to the animal species tested and may not be predictive of carcinogenicity in humans. Very few such examples have been agreed internationally. However, one example is the lack of human relevance of kidney tumors in male rats associated with compounds causing α2u-globulin nephropathy (IARC, Scientific Publication No. 147[2]). Even when a particular tumor type may be discounted, expert judgment must be used in assessing the total tumor profile in any animal experiment.

Part B: International Agency for Research on Cancer (IARC) [3]

IARC Carcinogen Classification Categories:

Group 1: The agent is *carcinogenic to humans*.

This category is used when there is *sufficient evidence of carcinogenicity* in humans. Exceptionally, an agent may be placed in this category when evidence of carcinogenicity in humans is less than *sufficient* but there is *sufficient evidence of carcinogenicity* in experimental animals and strong evidence in exposed humans that the agent acts through a relevant mechanism of carcinogenicity.

Group 2:

This category includes agents for which, at one extreme, the degree of evidence of carcinogenicity in humans is almost *sufficient*, as well as those for which, at the other extreme, there are no human data but for which there is evidence of carcinogenicity in experimental animals. Agents are assigned to either Group 2A (*probably carcinogenic to humans*) or Group 2B (*possibly carcinogenic to humans*) on the basis of epidemiological and experimental evidence of carcinogenicity and mechanistic and other relevant data. The terms *probably carcinogenic* and *possibly carcinogenic* have no quantitative significance and are used simply as descriptors of different levels of evidence of human carcinogenicity, with *probably carcinogenic* signifying a higher level of evidence than *possibly carcinogenic*.

[2] While most international agencies do not consider kidney tumors coincident with α2u-globulin nephropathy to be a predictor of risk in humans, this view is not universally held. (See: Doi et al., 2007)

[3] Preamble of the International Agency for Research on Cancer (IARC) “Monographs on the Evaluation of Carcinogenic Risks to Humans” (2006)

<u>Group 2A: The agent is *probably carcinogenic to humans.*</u>

This category is used when there is *limited evidence of carcinogenicity* in humans and *sufficient evidence of carcinogenicity* in experimental animals. In some cases, an agent may be classified in this category when there is *inadequate evidence of carcinogenicity* in humans and *sufficient evidence of carcinogenicity* in experimental animals and strong evidence that the carcinogenesis is mediated by a mechanism that also operates in humans. Exceptionally, an agent may be classified in this category solely on the basis of *limited evidence of carcinogenicity* in humans. An agent may be assigned to this category if it clearly belongs, based on mechanistic considerations, to a class of agents for which one or more members have been classified in Group 1 or Group 2A.

<u>Group 2B: The agent is *possibly carcinogenic to humans.*</u>

This category is used for agents for which there is *limited evidence of carcinogenicity* in humans and less than *sufficient evidence of carcinogenicity* in experimental animals. It may also be used when there is *inadequate evidence of carcinogenicity* in humans but there is *sufficient evidence of carcinogenicity* in experimental animals. In some instances, an agent for which there is *inadequate evidence of carcinogenicity* in humans and less than *sufficient evidence of carcinogenicity* in experimental animals together with supporting evidence from mechanistic and other relevant data may be placed in this group. An agent may be classified in this category solely on the basis of strong evidence from mechanistic and other relevant data.

Part C: National Toxicology Program (NTP), "Report on Carcinogens", Background Guidance

<u>NTP Listing Criteria</u>:[4]

The criteria for listing an agent, substance, mixture, or exposure circumstance in the Report on Carcinogens (RoC) are as follows:

Known To Be A Human Carcinogen: There is sufficient evidence of carcinogenicity from studies in humans[5] that indicates a causal relationship between exposure to the agent, substance, or mixture, and human cancer.

Reasonably Anticipated To Be A Human Carcinogen: There is limited evidence of carcinogenicity from studies in humans that indicates that a causal interpretation is credible, but that alternative explanations, such as chance, bias, or confounding factors, could not adequately be excluded,

<u>or</u>

[4] See: http://ntp.niehs.nih.gov/go/15209

[5] This evidence can include traditional cancer epidemiology studies, data from clinical studies, and/or data derived from the study of tissues or cells from humans exposed to the substance in question that can be useful for evaluating whether a relevant cancer mechanism is operating in people.

there is sufficient evidence of carcinogenicity from studies in experimental animals that indicates there is an increased incidence of malignant and/or a combination of malignant and benign tumors in multiple species or at multiple tissue sites, or by multiple routes of exposure, or to an unusual degree with regard to incidence, site, or type of tumor, or age at onset,

or

there is less than sufficient evidence of carcinogenicity in humans or laboratory animals; however, the agent, substance, or mixture belongs to a well-defined, structurally-related class of substances whose members are listed in a previous Report on Carcinogens as either known to be a human carcinogen or reasonably anticipated to be a human carcinogen, or there is convincing relevant information that the agent acts through mechanisms indicating it would likely cause cancer in humans.

Conclusions regarding carcinogenicity in humans or experimental animals are based on scientific judgment, with consideration given to all relevant information. Relevant information includes, but is not limited to, dose response, route of exposure, chemical structure, metabolism, pharmacokinetics, sensitive sub-populations, genetic effects, or other data relating to mechanism of action or factors that may be unique to a given substance. For example, there may be substances for which there is evidence of carcinogenicity in laboratory animals, but there are compelling data indicating that the agent acts through mechanisms that do not operate in humans and would therefore not reasonably be anticipated to cause cancer in humans.

Part D. Table Relating Approximate Equivalences among IARC, NTP RoC, and GHS Carcinogenicity Classifications

The following table may be used to perform hazard classifications for carcinogenicity under the HCS (§1910.1200). It relates the approximated GHS hazard categories for carcinogenicity to the classifications provided by IARC and NTP, as described in Parts B and C of this Appendix.

Approximate Equivalences Among Carcinogen Classification Schemes		
IARC	**GHS**	**NTP RoC**
Group 1	Category 1A	Known
Group 2A	Category 1B	Reasonably Anticipated (See Note 1)
Group 2B	Category 2	Reasonably Anticipated (See Note 1)

Note 1:

1. *Limited evidence of carcinogenicity from studies in humans (corresponding to IARC 2A / GHS 1B);*
2. *Sufficient evidence of carcinogenicity from studies in experimental animals (again, essentially corresponding to IARC 2A / GHS 1B);*
3. *Less than sufficient evidence of carcinogenicity in humans or laboratory animals; however:*
    a. *The agent, substance, or mixture belongs to a well-defined, structurally-related class of substances whose members are listed in a previous RoC as either "Known" or "Reasonably Anticipated" to be a human carcinogen, or*
    b. *There is convincing relevant information that the agent acts through mechanisms indicating it would likely cause cancer in humans.]*

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Stat. Auth: ORS 654.025(2) and 656.726(4).
Stats. Implemented: ORS 654.001 through 654.295.

Hist: OR-OSHA Admin. Order 5-2012, f. 9/25/12, ef. 9/25/12.
OR-OSHA Admin. Order 4-2013, f. 7/19/13, ef. 7/19/13.

437-002-0378 Oregon Rules for Pipe Label[~~l~~]ing

(1) Scope and Application. This division shall apply to all piping systems containing hazardous substances or that use asbestos as a pipe insulation material in buildings, structures and workplaces. This division does not apply to buried piping.

(2) Definitions.

(a) Hazardous substances: any substance which is a physical or health hazard.

(b) Health [~~H~~]**h**azard: A chemical which is classified as posing one of the following hazardous effects: acute toxicity (any route of exposure); skin corrosion or irritation; serious eye damage or eye irritation; respiratory or skin sensitization; germ cell mutagenicity; carcinogenicity; reproductive toxicity; specific target organ toxicity (single or repeated exposure); or aspiration hazard. The criteria for determining whether a chemical is classified as a health hazard are detailed in Appendix A to 1910.1200 - Health Hazard Criteria.

(c) Physical [~~H~~]**h**azard: A chemical that is classified as posing one of the following hazardous effects: explosive; flammable (gases, [~~aerosols~~], liquids, or solids); **aerosols;** oxidizer ([~~liquid, solid or gas~~] **gases, liquids, or solids**); self-reactive; pyrophoric (liquid or solid); self-heating; organic peroxide; corrosive to metal; gas under pressure; [~~or~~] in contact with water emits flammable gas**; or desensitized explosive**. **The criteria for determining whether a chemical is classified as a physical hazard are detailed in** Appendix B [~~to 1910.1200~~] Physical Hazard Criteria **(Mandatory) to 1910.1200.**

(d) Piping system: includes pipes, single or multiple, of any kind and, in addition, valves and pipe coverings.

(e) Pipes: conduits for the transport of gases, liquids, semiliquids or fine particulate dusts.

(3) Purpose. The purpose of this division is to prescribe minimum label[~~l~~]ing requirements for all piping systems which contain hazardous substances, transport substances in a hazardous state, or which use asbestos as a pipe insulation material.

(4) Label[~~l~~]ing.

(a) Pipes and piping systems which contain hazardous substances or transport substances in a hazardous state shall be label[~~l~~]ed in accordance with subsections (A), (B), (C) and (D) or other- wise identified in accordance with subsection (c) of this rule:

(A) Positive identification of the hazardous contents of a piping system shall be by lettered labels. The label shall give the name of the contents in full or abbreviated form.

(B) Contents shall be identified by label[~~l~~]ing with sufficient detail to identify the hazard.

(C) Label wording shall be brief, informative and simple.

(D) Label[~~l~~]ing shall be accomplished by stencilling, the use of tape, adhesives, markers or approved alternative means.

(b) Pipes or piping systems which use asbestos as a pipe insulation material shall be label[~~l~~]ed in accordance with [~~subsection (b)(A)~~] **the following language**, or otherwise identified in accordance with subsection (c) below[~~:~~]**.** [~~(A)~~]The label for pipe insulation containing asbestos shall include the following:

DANGER

CONTAINS ASBESTOS FIBERS

MAY CAUSE CANCER

CAUSES DAMAGE TO LUNGS

DO NOT BREATHE DUST

AVOID CREATING DUST

(c) The employer may use signs, placards, process sheets, batch tickets, operating procedures, or other such written materials in lieu of affixing labels to individual pipes, as long as the alternative method identifies the pipe(s) to which it is applicable and conveys the information required by this rule. The written materials shall be readily accessible to the employees in their work areas during each shift. (OAR 437, Division 2/Z, Hazard Communication, 1910.1200.)

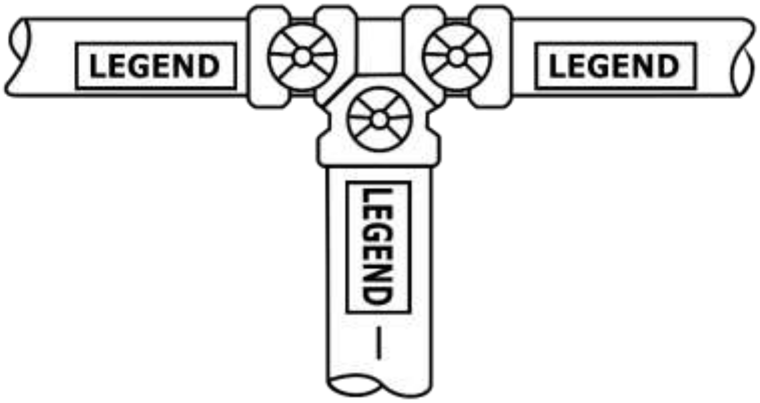
(5) Location of Label[~~l~~]ing.

(a) Label[~~l~~]ing shall be applied where confusion may occur, such as close to valves or flanges and adjacent to changes in direction, branches and where pipes pass through walls, floors or ceilings.

(b) Label[~~l~~]ing shall be applied, at a minimum, at the beginning and end of continuous pipe runs.

(c) For asbestos insulation, label[~~l~~]ing shall be at a minimum, on unobstructed continuous pipe runs, every 75 feet. Illustration **1**.

Illustration 1 Location of Labeling



(6) Visibility.

(a) Where pipes are located above or below the normal line of vision, the lettering shall be placed below or above the horizontal centerline of the pipe.

(b) Where pipes are inaccessible and/or at a distance which precludes clear identification of the letters on label[~~l~~]ing, alternatives to the label[~~l~~]ing which meet all other requirements of this rule may be used (i.e., schematics posted on walls in work areas). Appendix **A for Pipe Labeling (Non-Mandatory)**.

N[~~OTE~~]**ote**: Former division 153, Pipe Label[~~l~~]ing, has been redesignated, renumbered, and amended as Oregon-initiated Rule 437-002-0378, to continue coverage not provided in federal standards.

Statutory/Other Authority: ORS 654.025(2) & 656.726(4)
Statutes/Other Implemented: ORS 654.001 - 654.295

History:
WCD 8-1986, f. 9-4-86, cert. ef. 10-1-87
OSHA 12-1993, f. 6-20-93, cert. ef. 11-1-93, Renumbered from 437-153-004-0025
OSHA 5-2012, f. & cert. ef. 9-25-12
OR-OSHA Admin. Order X-2024, f. XX/XX/XX, ef. XX/XX/XX

Appendix A for Pipe Label[~~l~~]ing (Non-Mandatory)

Table 1
Classification of Hazards of Materials and Suggestions of Colors

Classification	Color Field**	Color of Letters For Legends
Materials Inherently Dangerous		

Flammable or Explosive	Yellow	Black
Chemically Active or Toxic	Yellow	Black
Extreme Temperatures or Pressures	Yellow	Black
Radioactive	Yellow	Magenta
Materials of Inherently Low Hazard		
Liquid or Liquid Admixture	Green	White
Gas or Gaseous Admixture	Blue	White

** Alternatives to the colors suggested by Table 1 may be acceptable if they meet all other requirements of this appendix and are used consistently on all pipes in a given location.

(1) Color may be displayed on the piping by any physical means, but when it is used it shall be in combination with labels.

(2) Color may be used in continuous, total length, or in intermittent displays.

Types and Sizes of Letters

(1) Contrast shall be provided between color field and letters for readability.

(2) Use of letters of block lettering in sizes 1/2 inch (13 mm) and larger, is recommended. (Table 2)

Table 2

Types and Styles of Letters

Outside Diameter of Pipe or Covering		**Length of Color Field**		**Size of Letters**	
in.	**mm.**	**in.**	**mm.**	**in.**	**mm.**
3/4 to 1-1/4	19 to 32	8	200	1/2	13
1-1/2 to 2	38 to 51	8	200	3/4	19
2-1/2 to 6	64 to 150	12	300	1-1/4	32
8 to 10	200 to 250	24	600	2-1/2	64
over 10	over 250	32	800	3-1/2	89

(3) For identification of materials in pipes less than 3/4 inch (19 mm.) in diameter, and for value and fitting identification, the use of a legible tag is recommended.

Stat. Auth: ORS 654.025(2) and 656.726(4).
Stats. Implemented: ORS 654.001 through 654.295.

Hist: WCD Admin. Order, Safety 8-1986, f. 9/4/86, ef. 10/1/87.
OR-OSHA Admin. Order 12-1993, f. 8/20/93, ef. 11/1/93.
OR-OSHA Admin. Order 5-2012, f. 9/25/12, ef. 9/25/12.
OR-OSHA Admin. Order X-XXXX, f. XX/XX/XXXX, ef. XX/XX/XXXX

437-004-0100 Universal Definitions

(1) These definitions apply throughout Division 4, Agriculture, except that the definitions in Subdivision 4/W, adopted from 40 CFR 170, Worker Protection Standard, apply to the rules within that Subdivision.

(a) Accepted — Something is accepted if:

(A) A nationally recognized testing laboratory has inspected it and found it to conform to specified plans or to procedures of applicable codes; or

(B) It is verified by design, evaluation, or inspection by a registered professional engineer; or

(C) It is acknowledged by the authority having jurisdiction, the agency, office, or organization that is responsible for approving specific equipment, materials, installations, or procedures. (Examples of such authorities include the U.S. Department of Transportation, the U.S. Coast Guard, the Oregon Building Codes Division, and the Office of the State Fire Marshal.)

(b) Agricultural employer — means any person, corporation, association, or other legal entity who meets the definition of an employer in ORS 654.005(5) and who:

(A) Owns or operates an agricultural establishment; or

(B) Recruits and supervises employees who work for an agricultural establishment; or

(C) Is responsible for the management or condition of, or exercises direction and control over the production on, an agricultural establishment.

(c) Agricultural establishment — means a farm, ranch, nursery, greenhouse, or production facility that is a place of employment and is engaged in the activities described in Division 4/A, 437-004-0002 Scope.

(d) Approved — means acceptable for the purposes of rule compliance, under the following criteria:

(A) It is accepted, or certified, or listed, or labeled or otherwise determined to be safe by a nationally recognized testing laboratory; or

(B) If an installation or equipment is of a kind which no nationally recognized testing laboratory accepts, certifies, lists, labels, or determines to be safe, it has been inspected or tested by another authority having jurisdiction and found to be in compliance with the provisions of the applicable code; or

(C) Custom-made equipment or related installations that are designed and fabricated for a certain intended use by its manufacturer. The employer must keep and make available the test data that is used as the basis of this approval, for inspection.)

(e) Boiling point — The temperature at which the liquid form of a substance changes into a vapor, at a standard atmospheric pressure. The initial boiling point of a substance is determined according to test methods specified in Appendix B to Division 2/Z, 1910.1200, Hazard Communication Standard.

(f) CAS — is the Chemical Abstracts Service Registry Number, a unique numerical identifier assigned by the Chemical Abstracts Service to every chemical described in the open scientific literature.

(g) Capacity — is the maximum load or severity of service (determined by the manufacturer or a qualified engineer) that a tool, machine, equipment, structure, or material is expected to withstand without failure, deformation, separation or fracture.

(h) Certified — is something that:

(A) Was tested and found by a nationally recognized testing laboratory to meet recognized standards or to be safe for use in a specified manner, or

(B) Is of a kind whose production is periodically inspected by a nationally recognized testing laboratory, and

(C) Shows a label, tag, or other record of certification.

(i) Combustible — A substance or material that is able or likely to catch fire and burn.

(j) Combustible liquid — The “combustible liquid” classification is no longer used in Division 4 rules because it was eliminated by the globally harmonized classification and labeling system (GHS) adopted in OSHA’s Hazard Communication Standard. Any liquid with a flash point of 199.4°F (93 degrees C.) or less is considered to be one of the four categories of flammable liquids. (See “Flammable liquids,” below.)

N[~~OTE~~]**ote**: The term “combustible liquid” is still used by the National Fire Protection Association (NFPA) system of classification and by the Oregon State Fire Marshal to classify liquids that will burn but do not ignite as easily as flammable liquids. The NFPA system defines some chemicals as “combustible liquids” that would be included as a category of “flammable liquid” in the OSHA/GHS classification system. (See Appendix A to Subdivision 4/H, 437-004-

0720 Flammable Liquids, for a comparison of the GHS and NFPA systems of classification of flammable/combustible liquids.)

(k) Competent person – is a person who, because of training and experience, can identify existing and predictable hazards in equipment, material, conditions or practices; and, who has the knowledge and authority to take corrective steps.

(l) Explosive — something capable of causing damage to the surroundings by chemical reaction. Explosives are defined in Appendix B to 1910.1200 – Physical Hazard Criteria at B.1 EXPLOSIVES.

(m) Farming — Is the production of agricultural field crops, tree crops; horticultural specialties, greenhouse crops; and the production of livestock and animal specialties. Farming includes farm labor and management services; agricultural services and support activities (such as soil preparation; crop cultivation, protection, and harvesting;) and, the basic preparation of the crop or commodity for market. The farming production process is typically completed at the "farm gate" – that is, at the point of first sale or price determination.

N[~~OTE~~]**ote**: Throughout this division, the term "farming," "agriculture," "production agriculture," and "agricultural operations" are synonymous.

(n) Flammable — Capable of being easily ignited, burning intensely, or having a rapid rate of flame spread. Flammable substances are defined in Appendix B to 1910.1200 — Physical Hazard Criteria at B.2 FLAMMABLE GASES, B.3 FLAMMABLE AEROSOLS **AND CHEMICALS UNDER PRESSURE**, B.6 FLAMMABLE LIQUIDS, and B.7 FLAMMABLE SOLIDS.

(o) Flammable liquids — are liquids having a flash point at or below 199.4 degrees F. (93 degrees C.) As defined in the globally harmonized system of classification and labeling (GHS) adopted in OSHA's Hazard Communication Standard, flammable liquids are divided into four categories as follows:

(A) Category 1 includes liquids that have a flashpoint below 73.4 degrees F. (23 degrees C.) and have a boiling point at or below 95 degrees F. (35 degrees C.)

(B) Category 2 includes liquids that have a flashpoint below 73.4 degrees F. (23 degrees C.) and have a boiling point above 95 degrees F. (35 degrees C.)

(C) Category 3 includes liquids that have a flashpoint in a temperature range from at or above 73.4 degrees F. (23 degrees C.) to at or below 140 degrees F. (60 degrees C.)

(D) Category 4 includes liquids that have a flashpoint in a temperature range from above 140 degrees F. (60 degrees C.) to at or below 199.4 degrees F. (93 degrees C.)

N[~~OTE~~]**ote**: Examples of some common flammable liquids are:

Category 1: Diethyl ether (solvent sometimes used in starting fluid).

Category 2: Gasoline (Benzene, Ethanol).

Category 3: Kerosene, Stoddard Solvent.

Category 4: Diesel fuel, Naphthalene.

(p) Flashpoint — is the minimum temperature at which a liquid gives off vapor within a test vessel in sufficient concentration to form an ignitable mixture with air near the surface of the liquid, as determined by specific testing methods. These test methods are specified in Appendix B to Division 2/Z, 1910.1200, Hazard Communication Standard.

(q) Hazardous Chemical — is any chemical which is classified, under the requirements of the Hazard Communication Standard, as a physical hazard or a health hazard, a simple asphyxiant, combustible dust[~~, pyrophoric gas~~], or hazard not otherwise classified.

N[~~OTE~~]**ote**: See Division 2/Z, 1910.1200 Hazard Communication Standard, for more information.

(r) Ignition source — the origin of something that results in a fire or an explosion. Examples include open flames; smoking; cutting and welding; hot surfaces and radiant heat; frictional heat; static, electrical, and mechanical sparks; chemical and physical-chemical reactions; spontaneous ignition; and lightning.

(s) Labeled — Something is labeled if:

(A) It has an attached label, symbol, or other identifying mark of a nationally recognized testing laboratory that makes periodic inspections of the production of such equipment; or

(B) The attached information indicates compliance with nationally recognized standards or tests to determine safe use in a specified manner.

(t) Listed — is something mentioned in a list that:

(A) Is published by a nationally recognized laboratory that makes periodic inspection of the production of such equipment, and

(B) States such equipment meets nationally recognized standards or was tested and found safe for use in a specified manner.

(u) Nationally Recognized Testing Laboratory — (NRTL) is defined in 1910.7 Definition and Requirements for a Nationally Recognized Testing Laboratory and OAR 437-002-0007 Oregon Rule on Testing and Certification Program. (Examples of organizations in this category are Factory Mutual Engineering Corporation, and Underwriters' Laboratories.)

(v) Place of employment — is every place (fixed, movable or moving) where an employee works or is intended to work. It includes every place where (either temporarily or permanently) there is any activity related to an employer's business, including a labor camp.

N[~~OTE~~]**ote**: "Place of employment" does not include a place where the only employment involves nonsubject workers employed in or about a private home; or a farm where only the farm's family members are employed.

(w) Qualified person — is a person who has a recognized degree, certification, professional standing, knowledge, training or experience; and has successfully demonstrated the ability to perform the work, or solve or resolve problems relating to the work, subject matter, or project.

(x) Reasonable means — is what a prudent person, familiar with the circumstances of the industry would do to work in a safe and healthful manner.

(y) Safeguard — is any form of safety device or equipment; personal protective equipment; guard or barricade; warning device, sign, or method; or a process prescribed or adopted for the protection of an employee.

(z) Substantial — means constructed with sufficient strength or installed to provide ample support to withstand loads to which the structure or device may be subjected.

(aa) Worker — is identical in every respect to "employee" as defined in ORS 654.005(4) including:

(A) Any individual, including a minor, whether lawfully or unlawfully employed, who engages to furnish services for a remuneration, financial or otherwise, subject to the direction and control of an employer; and

(B) Any individual who is provided with workers' compensation coverage as a subject worker pursuant to ORS chapter 656, whether by operation of law or by election.

(bb) Workplace — See "Place of Employment," above.

(2) Reserved.

Statutory/Other Authority: ORS 654.025(2) & 656.726([~~3~~]**4**)
Statutes/Other Implemented: ORS 654.001 - 654.295

History:
OSHA 4-1998, f. 8-28-98, cert. ef. 10-1-98
OSHA 3-2014, f. & cert. ef. 8-8-14
OSHA X-20XX, f. XX/XX/XXXX, ef. XX/XX/XXXX

437-004-9800 Hazard Communication Standard for Agricultural Employers

N[~~OTES~~]**otes**: The Division 4, Hazard Communication Standard for Agricultural Employers (OAR 437-004-9800), focuses on those parts of the General Industry Hazard Communication Standard (Division 2/Z, 1910.1200) that describe the employer's responsibility to establish a workplace program and to communicate information to workers about the hazards of the chemicals used in their workplace. The Division 4 standard does not include the parts of the Division 2, Hazard Communication Standard that apply only to producers, distributors, and importers of chemicals because these are not typical activities for agricultural employers. As stated in 437-004-9800(2) Scope and application, any agricultural employer who produces, imports, or distributes chemical products must follow the more detailed rules that apply to those general industry activities in Division 2/Z, 1910.1200. The requirements of this Division 4, Hazard Communication Standard, are intended to be consistent with the Hazard Communication Standard for general industry as aligned with the provisions of the United Nations Globally Harmonized System of Classification and Labeling of Chemicals (GHS.)

(1) Purpose. The purpose of this Division 4 Hazard Communication Standard (HCS) is to ensure that agricultural employers provide appropriate information to their employees about the hazardous chemicals to which they can be exposed at their workplaces. The responsibility of chemical manufacturers, importers, and distributors to provide this information is described in Division 2/Z, 1910.1200. The HCS for agricultural employers describes how this information is to be provided: through a comprehensive hazard communication program, including container labels and other forms of warning, safety data sheets and employee training.

(2) Scope and application.

(a) This standard applies to agricultural employers when a hazardous chemical is known to be present in the workplace in a way that employees may be exposed under normal conditions of use or in a foreseeable emergency.

(b) This standard also applies to agricultural employers engaged in crop- or product-related quality control- or quality assurance-type laboratory work.

N[~~OTE~~]**ote**: See Division 4/Z, 437-004-9860, Hazardous Chemicals in Laboratories, for rules that apply to other types of laboratory activities.

(c) Division 2/Z, 1910.1200, the Hazard Communication Standard for General Industry, including all mandatory appendices, applies to any agricultural employer who is a producer, importer, or distributor of hazardous chemicals, as those activities are defined in this standard.

(d) The following types of hazardous substances are exempted from the requirements of this standard, under the stated conditions or circumstances:

(A) Any hazardous waste defined by the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act of 1976, as amended (42 U.S.C. 6901 et seq.), when subject to regulations issued under that Act by the Environmental Protection Agency;

(B) Any hazardous substance as such term is defined by the Comprehensive Environmental Response, Compensation and Liability ACT (CERCLA) (42 U.S.C. 9601 et seq.), when the hazardous substance is the focus of remedial or removal action being conducted under CERCLA (such as a “Superfund” site) in accordance with Environmental Protection Agency regulations;

(C) Tobacco or tobacco products;

(D) Wood or wood products, including lumber if it will not be processed, where the manufacturer or importer has established that the only hazard posed to employees is the potential for combustibility;

N[~~OTE~~]**ote**: Wood and wood products that are treated with a hazardous chemical covered by this standard (such as chemically pressure-treated wood); and wood that will later be sawed, cut or sanded, generating dust, is covered by this standard.

(E) Articles as defined in OAR 437-004-9800(11);

(F) Food or alcoholic beverages sold, used, or prepared in a retail establishment (such as a grocery store, restaurant, or drinking place), and foods intended for personal consumption by employees while at work;

(G) Any drug, defined in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), when it is in solid, final form for direct administration to the patient (e.g., tablets or pills); drugs packaged by the chemical manufacturer for sale to consumers in a retail establishment (e.g., over-the-counter drugs); and drugs intended for personal consumption by employees while at work (e.g., first aid supplies);

(H) Cosmetics which are packaged for sale to consumers or intended for personal consumption by employees while in the workplace;

(I) Any consumer product or hazardous substance, defined in the Consumer Product Safety Act (15 U.S.C. 2051 et seq.) and Federal Hazardous Substances Act (15 U.S.C. 1261 et seq.) respectively, where the employer can show that it is used in the workplace for the purpose intended by the chemical manufacturer or importer of the product, and the use results in a duration and frequency of exposure not more than the range of exposures that could reasonably be experienced by consumers;

(J) Nuisance particulates where the chemical manufacturer or importer has established that they do not pose any physical or health hazard covered under this standard;

N[~~OTE~~]**ote**: Nuisance particulate is synonymous with “particulate not otherwise regulated” (PNOR.) PNOR includes all inert or nuisance dusts, whether mineral, inorganic, or organic, that are not specifically listed in Division 4/Z, OAR 437-004-9000, Oregon Rules for Air Contaminants.

(K) Ionizing and non-ionizing radiation; and,

(L) Biological hazards.

N[~~OTES~~]**otes**: In addition to these exempted hazardous substances, the general industry Hazard Communication Standard [at 1910.1200(b)(5)] lists additional types of hazardous chemicals whose manufacturers are not covered by the Hazard Communication labeling requirements, because the products are already regulated by other labeling regulations. (For example, labeling of consumer products is regulated by the Consumer Product Safety Commission; and labeling of pesticide products is regulated by the Environmental Protection Agency.) Nonetheless, employers must ensure that hazardous chemicals are properly identified in their workplaces, as described in 437-004-9800(5).

(3) Reserved.

(4) Written hazard communication program.

(a) Employers must develop, implement, and maintain an effective written hazard communication program that is specific to their workplace. It must include the following:

(A) A list of all the hazardous chemicals in the workplace using a product identifier that allows cross-referencing to both the product label and a Safety Data Sheet. (Lists may be developed for individual work areas, but the program-required list must include all hazardous chemicals present in the workplace to which the written hazard communication program applies.)

(B) A description of their procedures or methods for meeting the requirements of this Hazard Communication Standard for Agricultural Employers including paragraphs (5) Labels and other forms of warning, (6) Safety data sheets, and (7) Employee information and training.

(C) A description of the methods for informing their employees about the hazards of nonroutine tasks and the hazards associated with chemicals contained in any unlabeled pipes in their work areas.

(b) At multi-employer workplaces, employers who use or store hazardous chemicals in a way that may expose other employer's workers must also ensure that their hazard communication program includes their methods for:

(A) Making safety data sheets available to the workers of other employers;

(B) Informing other employer(s) of any precautionary measures needed for the other employer to protect their employees during normal operating conditions and foreseeable emergencies;

(C) Informing other employer(s) about the labeling system and other forms of warning in use. This includes how the employer will notify other employer(s) about areas where pesticides will be or are being applied and areas under a Restricted Entry Interval.

(c) Upon request, the employer must make their written hazard communication program available to employees, the employee's designated representatives, and the Administrator.

N[~~OTE~~]**ote**: Where employees work at more than one workplace, the written hazard communication program may be kept at the primary workplace as long as the information is made available for routine reference during the employee's regular shift and is readily available in an emergency.

(5) Labels and other forms of warning.

N[~~OTE~~]**ote**: Chemical producers, importers, and distributors have responsibilities for labeling products that are shipped and for providing those labels to end-users.

(a) Workplace labeling. The employer must ensure that the primary (shipped) labels are legible, in English, and prominently displayed on the container in the work area. Employers with employees who communicate in languages other than English may include information in the other languages, as long as it is also in English.

(b) Except as provided in (5)(d), (5)(e), and (5)(f), the employer must ensure that each container of hazardous chemicals is labeled, tagged or marked with either:

(A) The same elements required on the shipped label:

(i) Product identifier,

(ii) Signal word,

(iii) Hazard statement(s),

(iv) Pictogram(s),

(v) Precautionary statement(s), and

(vi) Name, address, and telephone number of the chemical manufacturer, importer, or other responsible party; OR

(B) The product identifier (that allows cross-referencing with the product's safety data sheet), and

(i) Words, pictures, symbols, or a combination that provide at least general information about the hazards of the chemical;

(ii) This alternative in conjunction with the other information readily available to employees under the employer's hazard communication program, must provide employees with specific information about the hazards of the chemical and appropriate protective measures.

(c) If an employer becomes aware of new information from an up-dated, product label about the hazards of a chemical, or ways to protect against the hazards, affected employees must be trained on this new information before the chemical is used again in the workplace.

(d) The employer may use signs, placards, or other written materials instead of labels on individual, stationary process containers. This alternative method must identify the specific container, meet the requirements in (5)(a) and (b) and be readily accessible to the employees in their work area.

(e) Labels are not required on portable, secondary containers of hazardous chemicals that are for immediate use.

(f) Pesticide application equipment (such as spray tanks and backpack-type sprayers) do not require labeling if the pesticide handlers have access to the pesticide product label during handling activities.

(6) Safety data sheets.

(a) Employers must have a safety data sheet (SDS) for each hazardous chemical that is used or present in the workplace in a way that may expose employees under normal conditions of use or in a foreseeable emergency. This includes residual pesticides encountered by workers doing field hand-labor operations.

(b) SDSs must be readily accessible to all employees on all shifts. Where employees work at more than one workplace, the SDSs may be kept at the primary workplace.

(c) SDSs may be kept electronically if they are readily accessible to employees during their work shifts and available at all times, especially during an emergency such as a power failure.

(d) SDSs must be in English. Employers with employees who communicate in other languages may maintain copies of SDSs in other languages as well.

(e) Where complex mixtures of chemical products have similar hazards and contents (for example, the chemical ingredients are the same, but the specific composition varies from mixture to mixture), the employer may use one SDS to apply to all of these essentially similar mixtures. The product identifier of each mixture, as identified on the product label, must be cross-referenced to the SDS used.

(f) If an employer becomes aware of new information from an up-dated SDS about the hazards of a chemical or about ways to protect employees from the hazards, affected employees must be trained on this new information before the chemical is used again in the workplace.

(g) Safety data sheets as employee exposure records. In accordance with Division 4/A, OAR 437-004-0005, Access to Employee Medical and Exposure Records, employers must retain either the SDS or some record of the identity of the substance or agent, where it was used, and when it was used; and, make this record available upon request to employees, employee’s designated representatives, and to the Administrator.

N[~~OTE~~]**ote**: OAR 437-004-0005 refers employers to Division 2/Z 1910.1020. For more information about this requirement, see 1910.1020(d)(1)(ii)(B).

(7) Employee information and training.

(a) Give employees effective information and training on hazardous chemicals in their work area at the time of their initial assignment, and when a new physical or health hazard is introduced into their work area. Information and training may cover categories of hazards (examples include flammable liquids and pesticides) or specific chemicals.

(A) Chemical-specific information must always be available through labels and safety data sheets. Agricultural employees who mix, load, or apply pesticides; or otherwise handle hazardous chemicals must receive the full information and training required by this standard.

(B) If employees only handle chemicals in sealed, unopened containers, give them training to the extent necessary to protect them in the event of a spill or leak of a hazardous chemical from a sealed container.

(b) Inform employees of:

(A) The requirements of this training paragraph;

(B) Any operations in their work area where hazardous chemicals are present; and,

(C) The location and availability of the written hazard communication program, including the required list(s) of hazardous chemicals, and safety data sheets.

(c) Employee training must include at least:

(A) Methods and observations to detect the presence or release of a hazardous chemical in the work area (such as monitoring done by the employer, alarm systems, or characteristic odors;)

(B) The physical and health hazards of the chemicals in the work area;

(C) The measures employees can take to protect themselves from these hazards, including specific procedures the employer has implemented to protect employees from exposure to hazardous chemicals, such as appropriate work practices, emergency procedures, and personal protective equipment; and,

(D) The details of the hazard communication program as it relates to the employee's work activities, including an explanation of any alternative labeling or warning systems, possible exposures from non-routine tasks, and how employees can get and use the right hazard information.

(d) Agricultural employers must give all of their employees a copy of, or provide them with training that covers the information in the Oregon OSHA publication #1951 "Safe Practices When Working Around Hazardous Agricultural Chemicals."

(e) For employees doing only field hand-labor operations where their only potential exposure is to residual pesticides, employers may meet the training and information requirements of this rule by:

(A) Giving each employee a copy of or providing training that covers the information in the Oregon OSHA publication #1951, "Safe Practices When Working Around Hazardous Agricultural Chemicals"; and

(B) Providing information about the location and availability of, and ensuring that employees have access to safety data sheets.

(8) Trade secrets. There are special standards about the relationship of this standard to trade secrets. If those circumstances apply, follow Division 2/Z, 1900.1200(i) and its Appendix E.

N[~~OTE~~]**ote**: Division 2/Z 1910.1200(i) provides guidance for emergency medical personnel who need to obtain more detailed safety and health information about products with Trade Secret-protected ingredients. Appendix E to Division 2/Z, 1910.1200(i), Definition of Trade Secret, sets out the criteria to be used in evaluating trade secret claims.

(9) Subpoenas, citations, penalties.

(a) The Oregon Occupational Safety and Health Division has the authority under ORS Chapter 654 to issue a subpoena or any protective orders.

(b) Agency actions under ORS Chapter 654 and this Hazard Communication Standard for Agricultural Employers are enforceable by the issuance of additional citations and penalties pursuant to 654.071(4), 654.086(1)(d), or 654.086(3). The Oregon Occupational Safety and Health Division may refer the matter to the Circuit Court in the county in which the proceedings are pending for enforcement of the subpoena.

(10) [~~Phase-in dates for new rule requirements.~~] **Dates –**

~~[(a) By February 1, 2015, agricultural employers must train their employees about the new label elements (product identifier, signal word, hazard statements,~~

~~pictograms, and precautionary statements); and, about the new, standardized, 16-section, safety data sheet (SDS) format. After this phase-in date has passed, this information must be included in the initial employee training in accordance with paragraph (7)~~

~~NOTES: Chemical producers have until June 1, 2015 to be in compliance with all the modified provisions of the Division 2/Z Hazard Communication Standard (1910.1200) including those concerning classification, labeling, and safety data sheets.~~

~~(b) By June 1, 2016, employers must, as necessary, based on any new hazards identified by chemical manufacturers on updated labels and SDSs:~~

> ~~(A) Update their workplace hazard communication program, as required by paragraph (4); and~~
>
> ~~(B) Update any alternative workplace labeling used under paragraph (5); and~~
>
> ~~(C) Provide additional employee training in accordance with paragraph (7).~~]

(a) Effective date. This section shall become effective July 19, 2024.

(b) Substances.

> **(A) Manufacturers, importers, and distributors, evaluating substances shall be in compliance with all modified provisions of this section no later than January 19, 2026.**
>
> **(B) For substances, all employers shall, as necessary, update any alternative workplace labeling, update the hazard communication program, and provide any additional employee training for newly identified physical hazards, or health hazards or other hazards covered under this section no later than July 20, 2026.**

(c) Mixtures.

> **(A) Chemical manufacturers, importers, and distributors evaluating mixtures shall be in compliance with all modified provisions of this section no later than July 19, 2027.**
>
> **(B) For mixtures, all employers shall, as necessary, update any alternative workplace labeling, update the hazard communication program, and provide any additional employee training for newly**

identified physical hazards, health hazards, or other hazards covered under this section no later than January 19, 2028.

(d) Compliance. Between May 20, 2024 and the dates specified in paragraphs 10(b) and (c) of this section, as applicable, chemical manufacturers, importers, distributors, and employers may comply with either this section or the previous version of this section or both during the transition period.

(11) Definitions.

(a) Agricultural employer — See definition in Division 4/B, OAR 437-004-0100. Also, see "Employer" below.

(b) Article — A manufactured item other than a fluid or particle:

(A) Formed to a specific shape or design during manufacture; and

(B) With end use function(s) dependent in whole or in part on its shape or design during end use; and

(C) That under normal conditions of use does not release more than minute or trace amounts of a hazardous chemical and does not pose a physical hazard or health risk to employees.

(c) Administrator — The Administrator of the Oregon Occupational Safety and Health Division, or their designee.

(d) Biological hazard (or biohazard) — An infectious or other biological agent (bacteria, virus, fungus, etc.) presenting a risk of death, injury or illness to employees. (Biohazards are excluded from the requirements of the HCS.)

(e) Chemical — Any element, chemical compound or mixture of elements or compounds. Chemicals may be in solid, liquid, or gaseous form.

(f) Chemical name — The scientific designation of a chemical according to the nomenclature system developed by the International Union of Pure and Applied Chemistry (IUPAC) or the Chemical Abstracts Service (CAS) rules of nomenclature, or a name that clearly identifies the chemical for the purpose of conducting a hazard classification.

(g) Classification — The process of identifying the relevant data about the hazards of a chemical; reviewing that data to determine the hazards or effects associated with the chemical; and deciding whether the chemical meets the criteria and definitions in this standard. Classification for health and physical hazards includes the determination of the degree of hazard, where appropriate, by comparing the data with the criteria for the health and physical hazard categories.

(h) Container — Any bag, barrel, bottle, box, can, cylinder, drum, reaction vessel, storage tank, or the like that contains a hazardous chemical. Pipes or piping systems, and engines, fuel tanks, or other operating systems in a vehicle, are not considered to be containers.

(i) Crop- or product-related quality control — or quality assurance-type laboratory work — The sampling or testing of crops or agricultural products to discover defects, with the goal of improving or stabilizing production standards. This type of laboratory work at agricultural workplaces is covered by the requirements of the HCS.

N[~~OTE~~]**ote**: See Division 4/Z, 437-004-9860, Hazardous Chemicals in Laboratories, for rules that apply to other types of laboratory work.

(j) Designated representative — Any individual or organization to whom an employee gives written authorization to exercise such employee’s rights. A recognized or certified collective bargaining agent is automatically a designated representative without regard to written employee authorization.

(k) Distributor — Any business, other than a chemical manufacturer or importer, that supplies hazardous chemicals to other distributors or to employers.

(l) Employee — For the purpose of this rule, any worker who may be exposed to hazardous chemicals under normal conditions of use or in a foreseeable emergency. (Also, see definition of “Worker” in Division 4/B, OAR 437-004-0100.)

(m) Employer — For the purposes of this rule, any person, corporation, association, or other legal entity, including a contractor or subcontractor, engaged in a business where employees may be exposed to chemicals. (Also, see definition of “Agricultural employer” in Division 4/B, OAR 437-004-0100.)

(n) Exposure or exposed — An occurrence when an employee is subjected, in the course of employment, to a chemical that is a physical, health, or other listed hazard, including accidental or reasonably anticipated exposure. “Subjected” in terms of health hazards includes any route of entry into the body, including inhalation, ingestion, percutaneous, and skin contact or absorption.

(o) Field hand-labor operations — Agricultural work done by hand or with hand tools, including the cultivation, weeding, planting, and harvesting of crops (including mushrooms) and the packing of produce into containers, whether done on the ground, on a moving machine, or in a temporary packing shed in the field.

(p) Flammable liquids — See definition in Division 4/B, OAR 437-004-0100.

(q) Foreseeable emergency — Any potential event that could result in an uncontrolled release of a hazardous chemical into the workplace. Examples include equipment failure, rupture of containers, or failure of control equipment.

(r) GHS — Globally Harmonized System — The United Nations' system of classification and labeling of chemicals; an international approach to hazard communication that provides specific criteria for classification of chemical hazards and a standardized approach to label elements and safety data sheets. In 2012, OSHA revised the Hazard Communication Standard (29 CFR 1910.1200) to be consistent with the GHS.

(s) Hand-labor operations — See, Field hand-labor operations.

(t) Handler (or Pesticide Handler) — includes any person, who is employed for any type of compensation by an agricultural establishment and who:

(A) Mixes, loads, transfers, or applies pesticides;

(B) Disposes of pesticides or pesticide containers;

(C) Handles opened containers of pesticides;

(D) Acts as a flagger for equipment or aircraft applying pesticides;

(E) Cleans, adjusts, handles, or repairs the parts of mixing, loading, or application equipment that may contain pesticide residues;

(F) Assists with the application of pesticides; or

(G) Performs other activities included within the definition of Handler by the Environmental Protection Agency.

N[~~OTE~~]**ote**: For more information, see the pesticide Worker Protection Standard in Division 4/W, §170. The term "handler" does not include an employee who only handles sealed, unopened pesticide containers or empty pesticide containers.

(u) Hazard category — The divisions within a hazard class that compare the degree or severity of the hazard. For example, the chemical hazard classifications "oral acute toxicity" and "flammable liquid" both include four hazard categories based on specific criteria. Categories within a hazard class should not be compared with the categories of different hazard classes.

(v) Hazard class — Describes the nature and effect of a physical or health hazard, such as "flammable solid", "carcinogen", and "oral acute toxicity". (Also, see "Classification".)

(w) Hazard not otherwise classified (HNOC) — An adverse physical or health effect identified through evaluation of scientific evidence during the manufacturer's classification process that does not meet the specified criteria for the physical and health hazard classes addressed in Division 2/Z. 1910.1200. This does not extend coverage to adverse physical and health effects for which there is a hazard class addressed in 1910.1200, but the effect either falls below the cut-off value/concentration limit of the hazard class or is under a GHS hazard category that has not been adopted by OSHA. (One example is Category 5 oral acute toxicity.)

(x) Hazard statement — A statement assigned to a hazard class and category that describes the nature of the hazards of a chemical, including, where appropriate, the degree of hazard.

(y) Hazardous chemical — Any chemical [~~that is~~] **which is** classified as a physical hazard or a health hazard, a simple asphyxiant, combustible dust, [~~pyrophoric gas,~~] or hazard not otherwise classified.

N[~~OTE~~]**ote**: Division 2/Z, 1910.1200, Appendices A and B describe the criteria producers must use for determining whether or not a chemical is a health or physical hazard for purposes of this standard.

(z) Hazard warning — The words, pictures, symbols, or combination on a label (or other appropriate form of warning) that communicate the specific physical and health hazards of the chemical(s) in the container. (See the definitions for "physical hazard" and "health hazard" to determine the hazards which must be covered by the manufacturer.)

(aa) HCS — The Hazard Communication Standard.

(bb) Health hazard — A chemical that is classified as posing one of the following hazardous effects: acute toxicity (any route of exposure); skin corrosion or irritation; serious eye damage or eye irritation; respiratory or skin sensitization; germ cell mutagenicity; carcinogenicity; reproductive toxicity; specific target organ toxicity (single or repeated exposure); or aspiration hazard.

N[~~OTE~~]**ote**: The criteria for determining whether a chemical is classified as a health hazard are detailed in Appendix A to 1910.1200 — Health Hazard Criteria.

(cc) Identity — See Product Identifier.

(dd) Immediate use — For the purpose of this rule, describes when a hazardous chemical will be used only within the work shift in which it is transferred, be under the control of and used only by the person who transfers it from a labeled container. Under these specific conditions, a portable, secondary container is exempted from the requirement for a workplace label. (See 437-004-9800(5)(e).)

(ee) Importer — The first business with employees within the Customs Territory of the United States that receives hazardous chemicals made in other countries for the purpose of supplying them to distributors or employers within the United States.

(ff) Label — An appropriate group of written, printed or graphic information elements concerning a hazardous chemical that is affixed to, printed on, or attached to the immediate container of a hazardous chemical, or to the outside packaging.

(gg) Label elements — The specified product identifier, pictogram(s), hazard statement(s), signal word, and precautionary statement(s) that correlate to each chemical product's hazard class and category. Also, labels must identify and provide contact information for the product's manufacturer or other responsible party.

(hh) Manufacturer — See Producer.

(ii) Material Safety Data Sheet (MSDS) — See, "Safety Data Sheet (SDS)".

(jj) Mixture — A combination or a solution composed of two or more substances in which they do not react.

(kk) Nonroutine task — A work activity that occurs infrequently or that varies from what is considered a regular, standard, or normal task.

(ll) Pesticide handler — See Handler.

(mm) Pesticide, residual — See Residual pesticide.

(nn) Physical hazard — A chemical that is classified as posing one of the following hazardous effects: explosive; flammable (gases, [~~aerosols~~], liquids, or solids); **aerosols**; oxidizer ([~~liquid, solid or gas~~] **gases, liquids, or solids**); self-reactive; pyrophoric (liquid or solid); self-heating; organic peroxide; corrosive to metal; gas under pressure; [~~or~~] in contact with water emits flammable gas**; or desensitized explosive**.

N[~~OTE~~]**ote**: Physical Hazard Criteria is available in Appendix B to Division 2/Z, 1910.1200.

(oo) Pictogram — A composition that includes a red bordered square set on its point, enclosing a black symbol on a white background that is intended to convey specific information about the hazard of a chemical. Eight pictograms are designated under this standard for application to specific hazard categories.

(pp) Precautionary statement — A phrase that describes recommended measures that should be taken to prevent or minimize adverse effects resulting from exposure to, or improper storage or handling of a hazardous chemical.

(qq) Producer — For the purposes of this rule, an employer with a workplace where chemicals are manufactured, processed, extracted, generated, formulated, or repackaged for use or for distribution.

N[~~OTE~~]**ote**: If you mix or blend chemical products for use in your own workplace, and the resulting mixture has no new chemical ingredients or new hazardous characteristics, you can use the SDSs for the component ingredients and you are not considered to be a "producer." (An example is mixing granular fertilizers together for application on your own property.) However, if the combined chemicals react to create a new ingredient or the combination creates a new hazard, you become a "producer" and you must follow the more detailed rule requirements in the Division 2/Z, 1910.1200, Hazard Communication Standard.

(rr) Product identifier — The unique name or number used on the label and in the SDS that provides a means by which the user can identify the hazardous chemical. (Examples include the chemical name, Chemical Abstracts Service (CAS) Registry Number, or other precise designation of the substance.) The product identifier must allow cross-referencing of the product's label with the product's SDS, and the list of hazardous chemicals in the employer's written hazard communication program.

[~~(ss) Pyrophoric gas — A chemical in a gaseous state that will ignite spontaneously in air at a temperature of 130 degrees F (54.4 degrees C) or below.~~]

([~~tt~~]**ss**) Residual pesticide — Pesticide residue that remains on crops, soil, equipment or other work surfaces, after a pesticide application is completed and any label-required restricted entry interval (REI) has expired. For the purpose of providing hazard information, a Safety Data Sheet must be available for any pesticide that has been used at the workplace within the previous 30 days.

([~~uu~~]**tt**) Responsible party — As used on a Label or Safety Data Sheet, someone who can provide additional information on the hazardous chemical and appropriate emergency procedures, if necessary.

([~~vv~~]**uu**) Restricted entry interval (REI) — The time period that immediately follows a pesticide application (as specified on the product label) during which only trained and protected employees may enter into the treated area. (The treated area is the physical location where a pesticide is being or has been applied.)

([~~ww~~]**vv**) Safety data sheet (SDS) — Written or printed information about a hazardous chemical that is prepared (generally by the manufacturer) in accordance with paragraph (g) of and Appendix D to Division 2/Z, 1910.1200.

([~~xx~~]**ww**) Signal word — A word used to alert the reader of the product label to a potential hazard. The signal words used in this section are ‘‘DANGER’’ and ‘‘WARNING’’ ‘‘DANGER’’ is used for the more severe hazards, while ‘‘WARNING’’ is used for the less severe. These words are chosen by the manufacturer based on the classification and categorization of the chemical’s hazards.

N[~~OTE~~]**ote**: The EPA has jurisdiction over manufacturers of pesticides and currently has its own system of signal words used on pesticide labels.

([~~yy~~]**xx**) Simple asphyxiant — A substance or mixture that displaces oxygen in the ambient atmosphere, and can thus cause oxygen deprivation in those who are exposed, leading to unconsciousness and death.

([~~zz~~]**yy**) Specific chemical identity — See “Product identifier”.

([~~aaa~~]**zz**) Substance — Chemical elements and their compounds in the natural state or obtained by any production process, including any additive necessary to preserve the stability of the product and any impurities deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.

([~~bbb~~]**aaa**) Trade secret — A confidential formula, pattern, process, device, information or compilation of information that is used in an employer’s business, and that gives the employer an opportunity to obtain an advantage over competitors who do not know or use it.

N[~~OTE~~]**ote**: Division 2/Z 1910.1200(i) provides guidance for emergency medical personnel who need to obtain more detailed safety and health information about products with Trade Secret-protected ingredients. Appendix ~~E~~ to Division 2/Z, 1910.1200 —Trade Secret, sets out the criteria to be used in evaluating trade secret claims.

([~~ccc~~]**bbb**) Use — To handle, apply, transfer, or generate as a by-product, any hazardous chemical covered by the requirements of this rule.

([~~ddd~~]**ccc**) Work area — A room or defined space in a workplace where hazardous chemicals are used, and where there are employees.

([~~eee~~]**ddd**) Workplace — An establishment, job site, or project, at one geographical location with one or more work areas.

Note: Appendices and publications referenced are available from the agency.

Statutory/Other Authority: ORS 654.025(2) & 656.726(4)
Statutes/Other Implemented: ORS 654.001 - 654.295

History:
OSHA 4-1998, f. 8-28-98, cert. ef. 10-1-98
OSHA 3-2014, f. & cert. ef. 8-8-14
OSHA X-XXXX, f. XX/XX/XXXX, ef. XX/XX/XXXX

437-004-9850 Pipe Label[~~l~~]ing

(1) Scope and application. This rule applies to all pipes and piping systems that contain hazardous substances, transport substances in a hazardous state, or that use asbestos as insulation material. This rule does not apply to buried pipe.

(2) Definitions:

(a) Asbestos: includes chrysoltile, amosite, crocidolite, tremolite asbestos, anthophyllite asbestos, actinolite asbestos and any of these minerals that have been chemically treated or altered.

(b) Hazardous substances: any substance that is a physical or health hazard.

(c) Health hazard: A chemical that is classified as posing one of the following hazardous effects: acute toxicity (any route of exposure); skin corrosion or irritation; serious eye damage or eye irritation; respiratory or skin sensitization; germ cell mutagenicity; carcinogenicity; reproductive toxicity; specific target organ toxicity (single or repeated exposure); or aspiration hazard. The criteria for determining whether a chemical is classified as a health hazard are detailed in Appendix A to 1910.1200 - Health Hazard Criteria, in Division 2/Z.

(d) Physical hazard: A chemical that is classified as posing one of the following hazardous effects: explosive; flammable (gases, [~~aerosols,~~]liquids, or solids); **aerosols;** oxidizer ([~~liquid, solid~~]**gases, liquids,** or [~~gas~~]**solids**); self-reactive; pyrophoric (liquid or solid); self-heating; organic peroxide; corrosive to metal; gas under pressure; [~~or~~]in contact with water emits flammable gas**; or desensitized explosive**. The criteria for determining whether a chemical is classified as a physical hazard are detailed in Appendix B [~~to 1910.1200 —~~] Physical Hazard Criteria **(Mandatory) to 1910.1200**, in Division 2/Z.

(e) Piping system: includes single or multiple pipes of any kind in addition to valves and pipe coverings.

(3) Labeling.

(a) Label pipes that contain hazardous substances or transport substances in a hazardous state according to (A), (B), (C) and (D) below or otherwise identify them according to (3)(b) below:

(A) Positive identification of the hazardous contents of pipe must be by lettered labels. The label must give the name of the contents in full or abbreviated form.

(B) The label must identify the contents with enough detail to identify the hazard.

(C) Label wording must be brief, informative and simple.

(D) Use stenciling, tape, adhesives, markers or effective alternative means for labels.

[~~NOTE~~]**Note**: Substances “transported in a hazardous state” typically refer to the hazards of pressure and temperature. Examples include compressed air, hot water or steam, and cryogenic liquids or gases.

(b) The employer may use an alternative warning method, instead of affixing labels to individual pipes, if that method identifies the pipe(s) to which the warning applies and conveys the hazard information required by this rule. Examples include signs, placards, process sheets, or schematics posted on walls in the work area; or other such written materials. These alternative written materials must be readily accessible to the employees in their work areas during each shift.

[~~NOTE~~]**Note**: See OAR 437-004-9800(5) Labels and other forms of warning for other related requirements.

(c) Label pipes or piping systems that use asbestos insulation material to include the following statements:

(A) DANGER CONTAINS ASBESTOS FIBERS MAY CAUSE CANCER DO NOT BREATHE THE DUST AVOID CREATING DUST

(B) Or, otherwise identify them according to (3)(b), above.

[~~NOTE~~]**Note**: See OAR 437-004-9800, Hazard Communication for Agricultural Employers and OAR 437-004-9050, Asbestos, for additional requirements.

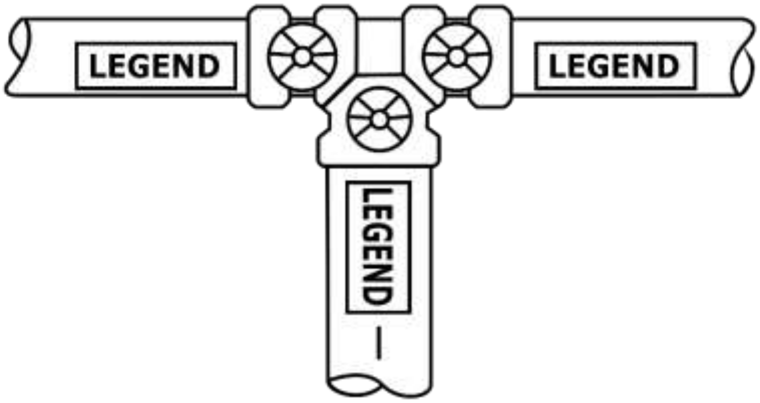
(4) Location of labeling.

(a) Place the labeling near valves or flanges; adjacent to changes in direction or branches; where pipes pass through walls, floors or ceilings; and where confusion about the contents of the piping system may occur.

(b) Labeling must be applied, at a minimum, at the beginning and end of continuous pipe runs.

(c) For asbestos insulation, labeling on unobstructed continuous pipe runs must be at least every 75 feet. **Illustration 1.**

Illustration 2 Location of Labeling



(5) Visibility.

(a) Where pipes are located above or below the normal line of vision, put the lettering below or above the horizontal centerline of the pipe, to facilitate visibility.

(b) If pipes are inaccessible, or at a distance that makes clear identification of the letters on a label difficult, use alternatives to labeling that meet all other requirements of this rule. **Appendix A for Pipe Labeling (Non-Mandatory).**

Statutory/Other Authority: ORS 654.025(2) & 656.726(4)
Statutes/Other Implemented: ORS 654.001 - 654.295
History:
OSHA 4-1998, f. 8-28-98, cert. ef. 10-1-98
OSHA 4-2012, f. 9-19-12, cert. ef. 1-1-13
OSHA 3-2014, f. & cert. ef. 8-8-14
OSHA X-XXXX, f. XX-XX-XXXX, ef. XX-XX-XXXX

Appendix A for Pipe Labeling (Non-Mandatory)

Table 1

Classification of Hazards of Materials and Suggestions of Colors

Classification	Color Field**	Color of Letters For Legends
Materials Inherently Dangerous		
Flammable or Explosive	Yellow	Black
Chemically Active or Toxic	Yellow	Black
Extreme Temperatures or Pressures	Yellow	Black
Radioactive	Yellow	Magenta
Materials of Inherently Low Hazard		
Liquid or Liquid Admixture	Green	White
Gas or Gaseous Admixture	Blue	White

** Alternatives to the colors suggested by Table 1 may be acceptable if they meet all other requirements of this appendix and are used consistently on all pipes in a given location.

(1) Color may be displayed on the piping by any physical means, but when it is used it shall be in combination with labels.

(2) Color may be used in continuous, total length, or in intermittent displays.

Types and Sizes of Letters

(1) Contrast shall be provided between color field and letters for readability.

(2) Use of letters of block lettering in sizes 1/2 inch (13 mm) and larger, is recommended. (Table 2)

Table 2

Types and Styles of Letters

Outside Diameter of Pipe or Covering		Length of Color Field		Size of Letters	
in.	**mm.**	**in.**	**mm.**	**in.**	**mm.**
3/4 to 1-1/4	19 to 32	8	200	1/2	13
1-1/2 to 2	38 to 51	8	200	3/4	19
2-1/2 to 6	64 to 150	12	300	1-1/4	32
8 to 10	200 to 250	24	600	2-1/2	64
over 10	over 250	32	800	3-1/2	89

(3) For identification of materials in pipes less than 3/4 inch (19 mm.) in diameter, and for value and fitting identification, the use of a legible tag is recommended.

Stat. Auth: ORS 654.025(2) and 656.726(4).
Stats. Implemented: ORS 654.001 through 654.295.

Hist: OSHA 4-1998, f. 8-28-98, cert. ef. 10-1-98
OSHA 4-2012, f. 9-19-12, cert. ef. 1-1-13
OSHA 3-2014, f. & cert. ef. 8-8-14