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A.0.1.3		**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.0.4.1	A.0.4.1 **~~For most hazard classes,~~** the **~~recommended~~** process of classification of mixtures is based on the following sequence:	A.0.4.1 **Except as provided in A.0.4.2**, the process of classification of mixtures is based on the following sequence:
	See **~~chapters~~** A.5, A.6, and A.7 for further information on case-by-case bases.	See A.5, A.6, and A.7 of **this section** for further information on case-by-case bases.
A.0.5.1.2	For mixtures classified in accordance with A.1, A.2, A.3, 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.	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	A.0.5.1.4 Interpolation within one **~~toxicity~~** category:	A.0.5.1.4 Interpolation within one **hazard** category
A.1.1	Acute toxicity refers to **~~those~~** adverse effects occurring **~~following~~** oral or dermal administration of a single dose of a substance, or multiple doses given within 24 hours, or an inhalation exposure of 4 hours .	Acute toxicity refers to **serious** adverse **health** effects **(i.e., lethality)** occurring after a single or short-term oral, dermal,or inhalation exposure to a substance or mixture.
A.1.2.1	A.1.2.1 Substances can be allocated to one of four **~~toxicity~~** 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) LD50 (oral, dermal) or LC50 (inhalation) values or as acute toxicity estimates (ATE). See the footnotes following Table A.1.1 for further explanation on the application of these values.	A.1.2.1 Substances can be allocated to one of four **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) LD50 (oral, dermal) or LC50 (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.

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	Table A.1.1: **~~Acute toxicity hazard categories and acute toxicity estimate (ATE) values defining the respective categories~~**	**Table A.1.1: Acute toxicity estimate (ATE) values and criteria for acute toxicity hazard categories**
Table A.1.1	Table contents	**Table contents changed by addition of "ATE" in each cell. Note: Category 1/Dermal showing ATE<=5 possibly in error, same cell in previous table shows <=50.**
A.1.2.3	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 LD50 value from among scientifically validated tests .	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 LD50 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		**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.**

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A.1.2.4.1		**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		**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.1.3.6.1(c)	Ci in formula under A.1.3.6.1(c)	**C_i (all occurances)**
A.1.3.6.2.2	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~~**.	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.1.3.6.2.4.**

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A.1.3.6.2.3	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 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.1.3.6.2.3 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 **appendix C** to this section, Allocation of Label Elements and **appendix D** to this section, Safety Data Sheets).
A.1.3.6.2.3	~~**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 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.)**~~	**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 appendix C to this section, Allocation of Label Elements and appendix D to this section, Safety Data Sheets).**
A.1.3.6.2.4	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:	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: (**Format of the formula)**

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A.2.1.1	A.2.1.1 Skin corrosion is the production of irreversible damage to the skin; namely, visible necrosis through the epidermis and into the dermis, ~~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 .~~	A.2.1.1 Skin corrosion 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.**
A.2.1.1	Skin irritation ~~is the production of reversible damage to the skin following the application of a test substance for up to 4 hours.~~	Skin irritation **refers to the production of reversible damage to the skin occurring after initial exposure to a substance or mixture.**
A.2.1.2	~~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.**

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A.2.1.3	not present	**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	~~**A.2.2 Classification criteria for substances using animal test data:**~~	**Classification criteria for substances** **A.2.2 Classification criteria for substances** **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)**

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A.2.2.1	~~**A.2.2.1.1 A corrosive substance is a chemical that produces destruction of skin tissue, namely, visible necrosis through the epidermis and into the dermis, in at least 1 of 3 tested animals after exposure up to a 4-hour duration. 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 discern questionable lesions.**~~	**A.2.2.1 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.**
A.2.2.1.2	~~**A.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.2.1: Skin corrosion category and sub-categories	Table A.2.1 moved to section A.2.2.2.1.2
A.2.2.2	~~**A.2.2.2 Irritation**~~	**A.2.2.2 Classification based on standard animal test data** **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	~~**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.**~~	A.2.2.2.1 Skin corrosion
A.2.2.2.1.1		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.

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A.2.2.2.1.2		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	Table A.2.2 Skin irritation category	Table A 2.2 moved to setion A.2.2.2.2.4
A.2.2.2.2	~~**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.**~~	**A.2.2.2.2 Skin Irritation**
A.2.2.2.2.1		**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.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. An irritation category (Category 2) is provided that:** **(a) recognizes that some test substances may lead to effects which persist throughout the lengthof the test; and** **(b) acknowledges that animal responses in a test may be variable.**

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A.2.2.2.2.3		**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.		**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		**Table A.2.2 moved from section A.2.2.2 with added notes**
A.2.2.3		**A.2.2.3 Classification based on in vitro/ex vivo data**
A.2.2.3.1		**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		**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		**A.2.2.3.3 Skin corrosion**

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A.2.2.3.3.1		**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		**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.2.2.3.3.3 A substance identified as not corrosive should be considered for classification as skin irritant.**
A.2.2.3.4		**A.2.2.3.4 Skin irritation**
A.2.2.3.4.1		**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.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.**

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A.2.2.4		**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**
A.2.2.5		**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**
A.2.2.6		**A.2.2.6 Classification based on non-test methods**

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A.2.2.6.1		**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		**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		**A.2.2.7 Classification in a tiered approach**
A.2.2.7.1		**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		**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.**

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A.2.2.7.3		**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.**
Figure A.2.1:		**Figure A.2.1: Application of the tiered approach for skin corrosion and irritation**
Figure A.2.1:		**(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.** **(b) Information may be inconclusive for various reasons, e.g.:** **- The available data may be of insufficient quality, or otherwise insufficient/inadequate for the purpose of classification, e.g., due to quality issues related to experimental designand/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**riteria ~~**for Substances Using Other Data Elements**~~	**A.2.3 Classification criteria for mixtures**

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A.2.3.1	~~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~~	**A.2.3.1 Classification of mixtures when data are available for the complete mixture**

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A.2.3.2	~~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		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.2.3.3
A.2.3.1.2		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		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		A.2.3.2 Classification of mixtures when data are not available for the complete mixture: bridging principles

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A.2.3.2.1		**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	~~**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.**~~	**A.2.3.3 Classification of mixtures when data are available for all ingredients or only for some ingredients of the mixture**
A.2.3.3.1		**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.**

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Number	Current Removed text is bold, underlined with a strike though	NEW New text is bold and underlined
A.2.3.3.2		**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		**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.2.3.3.4	~~**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.**

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A.2.3.3.6		**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		**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)**
Table A.2.4		**Table A.2.4: Concentration of ingredients of a mixture when the additivity approach does not apply, that would trigger classification of the mixture as hazardous to skin**
Figure A.2.1	Figure A.2.1: Tiered evaluation of skin corrosion and irritation potential	not present in this location

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	~~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.~~	
A.2.3		**A.2.3 Classification criteria for mixtures**

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A.2.3.1		**A.2.3.1 Classification of mixtures when data are available for the complete mixture**
A.2.3.1.1		**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		**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		**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		**A.2.3.2 Classification of mixtures when data are not available for the complete mixture: bridging principles**

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A.2.3.2.1		**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		**A.2.3.3 Classification of mixtures when data are available for all ingredients or only for some ingredients of the mixture**
A.2.3.3.1		**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.**

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A.2.3.3.2		**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.2.4	~~**A.2.4 Classification criteria for mixtures:**~~	
A.2.4.1	~~**A.2.4.1 Classification of mixtures when data are available for the complete mixture**~~	
A.2.4.1.1	~~**A.2.4.1.1 The mixture shall be classified using the criteria for substances (See A.2.3).**~~	
A.2.4.2	~~**A.2.4.2 Classification of mixtures when data are not available for the complete mixture: bridging principles**~~	
A.2.4.2.1	~~**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.**~~	

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A.2.4.3	**~~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	**~~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	**~~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.~~**	

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A.2.4.3.3	~~**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.**~~	
Table A.2.3	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)	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)
Table A.2.4	Table A.2.4: Concentration of ingredients of a mixture ~~**for which the**~~ additivity approach does not apply, that would trigger classification of the mixture as hazardous to skin	Table A.2.4: Concentration of ingredients of a mixture **when the** additivity approach does not apply, that would trigger classification of the mixture as hazardous to skin
A.3.1.1	A.3.1.1 Serious eye damage ~~**is 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 ~~**within 21 days of application.**~~ Eye irritation ~~**is 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**~~	A.3.1.1 Serious eye damage **refers to the** production of tissue damage in the eye, or serious physical decay of vision, which is not fully reversible, **occurring after exposure of the eye to a substance or mixture**. Eye irritation **refers to** the production of changes in the eye, which are fully reversible, **occurring after exposure of the eye to a substance or mixture.**

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A.3.1.2	A.3.1.2 Serious eye damage/eye irritation shall be classified using a tiered approach as detailed in figure A.3.1. Emphasis shall be placed upon existing human data (See A.0.2.6), followed by animal data, ~~**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 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.3.1.2 Serious eye damage/eye irritation shall be classified using a tiered approach as detailed in Figure A.3.1. Emphasis shall be placed upon existing human data (See A.0.2.6), followed by **existing** animal data, followed by **in vitro data and then** 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	A.3.2 Classification criteria for substances ~~**using animal test data**~~	A.3.2 Classification criteria for substances 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).

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A.3.2.1	~~**A.3.2.1 Irreversible effects on the eye/serious damage to eyes (Category 1)**~~ ~~**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 detected in a Draize eye test with rabbits, because severe lesions like these usually do not reverse within a 21-day observation period.**~~	A.3.2.1 Classification based on standard animal test data

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A.3.2.1.1		**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	**Table A.3.1: Irreversible ~~eye~~ effects**	Table A.3.1: **Serious eye damage**/Irreversible effects **on the eye category** [a]
A.3.2.1.2		**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.**

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A.3.2.1.3		**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	~~**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	Table A.3.2 Reversible eye ~~**effects**~~	Table A.3.2: Reversible **effects on the** eye **categories** [a]
A.3.2.2		**A.3.2.2 Classification in a tiered approach**
A.3.2.2.1		**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		**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		**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		**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		**A.3.2.2.5 In some cases sufficient information may be available from structurally related substances to make classification decisions.**

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A.3.2.2.6		**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		**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		**Figure A.3.1 Tiered Evaluation for serious eye damage and eye irritation (See also Figure A.2.1)**
A.3.2.3	~~**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	A.3.3 Classification Criteria for ~~**Substances Using Other Data Elements**~~	**A.3.3 Classification criteria for mixtures**

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A.3.3.1.1	~~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.~~	A.3.3.1 Classification of mixtures when data are available for the complete mixture
A.3.3.1.1		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).

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A.3.3.1.2		**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.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).~~**	**A.3.3.2 Classification of mixtures when data are not available for the complete mixture: bridging principles**
A.3.3.2.1		**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	**~~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.~~**	**A.3.3.3 Classification of mixtures when data are available for all ingredients or only for some ingredients of the mixture**

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A.3.3.3.1		**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		**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		**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.**

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A.3.3.3.4		**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.**

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Number	Current Removed text is bold, underlined with a strike though	NEW New text is bold and underlined
A.3.3.3.5		**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 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 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		**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	~~**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**~~	
Figure A.3.1	~~**Figure A.3.1 Evaluation strategy for serious eye damage and eye irritation (See also Figure A.2.1)**~~	
A.3.4.1	~~**A.3.4.1 Classification of mixtures when data are available for the complete mixture**~~	

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Number	Current Removed text is bold, underlined with a strike though	NEW New text is bold and underlined
A.3.4.1.1	~~**A.3.4.1.1 The mixture will be classified using the criteria for substances**~~	
A.3.4.1.2	~~**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	~~**A.3.4.2 Classification of mixtures when data are not available for the complete mixture: bridging principles**~~	

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A.3.4.2.1	~~**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	~~**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	~~**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.**~~	

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Number	Current Removed text is bold, underlined with a strike though	NEW New text is bold and underlined
A.3.4.3.2	~~**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	~~**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.**~~	

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A.3.4.3.4	**~~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-~~**	

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Number	Current Removed text is bold, underlined with a strike though	NEW New text is bold and underlined
A.4.1.1	A.4.1.1 Respiratory **~~sensitizer~~** **~~means~~** a chemical that will lead to hypersensitivity of the airways **~~following~~** inhalation of the chemical. Skin sensitizer **~~means a chemical that will lead to an allergic response following skin contact.~~**	A.4.1.1 Respiratory **sensitization refers to hypersensitivity of the airways occurring after inhalation of a substance or mixture**. Skin sensitization **refers to an allergic response occurring after skin contact with a substance or mixture.**
A.4.2.1.3	(b) The extent of exposure. A.4.2.1.2.3 The evidence referred to above could be:	A.4.2.1.3 The evidence referred to above could be: (numbering error? Should be A 4.2.1.2.3)
A.4.1 Definitions and general considerations		**1 As of [INSERT DATE of PUBLICATION IN THE FEDERAL REGISTER], 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**
A.4.2.1.2.3	**~~A.4.2.1.3.1~~**	**A.4.2.1.2.3 Data from appropriate animal studies2 which may be indicative of the potential of a substance to cause sensitization by inhalation in humans3 may include: (numbering error?should be A.4.2.1.3.1)**
Table A.4.3		**Table A.4.3: Animal test results for sub-category 1A (check <>= and order/location of notes for table**
A.5.1.1	**~~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.~~**	**A.5.1.1 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.**

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A.5.1.2	~~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.5.1.2 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	~~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.~~	A.5.1.3 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.
Table A.5.1.4	.	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.
Table A.5.1		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 (Titles location has changed but table content remained the same.)
Table A.5.1		Notes: Underline and italic in vivo and in vitro thoughout document. Underline all italics.

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A.5.4.2	~~**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.5.4.2 Examples of in vivo somatic cell mutagenicity tests are:** (a) Mammalian bone marrow chromosome aberration test (OECD 475) (b) Mammalian erythrocyte micronucleus test (OECD 474)
A.6.1	A.6.1 Definitions ~~**Carcinogen means a substance or a mixture of substances which induce cancer or increase its incidence.**~~ 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.	A.6.1 Definitions **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.
A.6.2	A.6.2 Classification criteria for substances	A.6.2 Classification criteria for substances[6]
Figure A.6.1	Figure A.6.1: Hazard categories for carcinogens	Figure A.6.1: Hazard categories for carcinogens **(update figure)**
	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.	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, chemical manufacturers, importers, and employers shall classify the chemical as a carcinogen.

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A.7.1.1	A.7.1.1 Reproductive toxicity **~~includes~~** adverse effects on sexual function and fertility in adult males and females, as well as adverse effects on development of the offspring. Some reproductive toxic effects cannot be clearly assigned to either impairment of sexual function and fertility or to developmental toxicity. Nonetheless, 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.7.1.1 Reproductive toxicity **refers to** adverse effects on sexual function and fertility in adult males and females, as well as 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 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).
Figure A.7.1(b)	Figure A.7.1(a): Hazard categories for reproductive toxicants	Figure A.7.1(a): Hazard categories for reproductive toxicants **(update table)**
Figure A.7.1(b)	Figure A.7.1(b): Hazard category for effects on or via lactation	Figure A.7.1(b): Hazard category for effects on or via lactation **(update table)**
A.7.2.5.1	**~~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).	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.7.3	A.7.3 Classification criteria for mixtures	A.7.3 Classification criteria for mixtures[9]

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A.7.3	[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.**~~	[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.8.1.1	A.8.1.1 Specific target organ toxicity - single exposure, (STOT-SE) means specific, non-lethal target organ toxicity arising from a single exposure to a ~~**chemical**~~. 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.8.1.1 Specific target organ toxicity – single exposure, (STOT-SE) refers to specific, non-lethal toxic effects on target organs occurring after a single 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 repeated exposure is classified in accordance with SPECIFIC TARGET ORGAN TOXICITY – REPEATED EXPOSURE (A.9 of this Appendix) and is therefore not included here.
Figure A.8.1	Figure A.8.1: Hazard categories for specific target organ toxicity following single exposure	Figure A.8.1: Hazard categories for specific target organ toxicity following single exposure **(update table)**
A.8.2.1.7	Figure A.8.1: Hazard categories for specific target organ toxicity following single exposure	A.8.2.1.7 Effects considered to support classification for Category 1 and 2 **(bold font)**
A.8.2.1.9	A.8.2.1.8 Effects considered not to support classification for Category 1 and 2.	A.8.2.1.8 Effects considered not to support classification for Category 1 and 2 **(bold font)**
A.8.2.1.9	A.8.2.1.9 Guidance values to assist with classification based on the results obtained from studies conducted in experimental animals for Category 1 and 2.	A.8.2.1.9 Guidance values to assist with classification based on the results obtained from studies conducted in experimental animals for Category 1 and 2 (bold font)

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A.8.3.4.6		**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.**
Figure A.9.1:	Figure A.9.1: Hazard categories for specific target organ toxicity following repeated exposure	Figure A.9.1: Hazard categories for specific target organ toxicity following repeated exposure. **(Content is the same, layout has changed slightly.)**
	A.10.1 Definitions and general **~~and specific~~** considerations	A.10.1 Definitions and general considerations
A.10.1.1	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.~~**	A.10.1.1 Aspiration **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		**A.10.1.2 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.10.3.3.1	**~~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 mm2/s, measured at 40 °C, shall be classified in Category 1.~~**	**A.10.3.3.1 The "relevant ingredients" of a mixture are those which are present in concentrations ≥ 1%.**
A.10.3.3.2	**~~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 mm2/s, measured at 40 °C, then the entire mixture shall be classified in Category 1.~~**	**A.10.3.3.2 Category 1**

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A.10.3.3.2.1		**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 mm2/s, measured at 40°C.**
A.10.3.3.2.2		**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 mm2/s, measured at 40°C.**