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From: Peggy Munsell, Manager of Standards & Technical Resources

Subject: MSDS Requirements for Dietary Supplements

The following was our response to an e-mail from an employer.

Question:

Would you address the issue of dietary supplements and the requirement for MSDSs. Specifically this company produces herbal extracts which are usually carried in alcohol. They produce 86% of their products that go to retail establishments. As much as 9% of their customers may be practitioners which may have employees handle and repackage the extracts according to physician instructions. For the lack of regulations defining these products the company has to follow FDA requirements for food.

Is this company required to provide an MSDS? Does it have to be for anything other than the alcohol? Will this requirement change any if they label their products for sale to the user in final form? Do they have to send the MSDS to everyone who has bought their product or just have it available for those few customers who determine if employees may use the product?

Answer:

The hazard communication rule, OAR 437-002-1910.1200, does exempt foods and drugs, but only in very specific circumstances.

For example, paragraph (b)(6)(vi) exempts, "**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**"

What this means is that foods or beverages that are NOT prepared in a retail establishment ARE covered by 1910.1200 if any of the ingredients meet the rule's definition of "hazardous chemical." For example, if a large bakery uses a very fine flour that can cause inhalation and/or explosive hazards, then that flour for that particular use falls within the scope of 1910.1200. The next paragraph of the rule, (b)(6)(vii), reads, "**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)"

Again, this exemption applies only in specific circumstances, where the drug is only in its solid, final form, when it is packaged only for sale to consumers, or only intended for personal consumption. Anything else, again if it meets the definition of "hazardous chemical," falls within 1910.1200. As an example of this, liquid chemotherapy drugs do pose health hazards, so 1910.1200 applies to the pharmacist who prepares the doses and the nurse or doctor who administers the dose to the patient.

If the manufacturer intends the product to only be sold in retail establishments, then they do not need to produce a material safety data sheet "MSDS", but there are two caveats to this. First, if the manufacturer sells the product to both retail establishments and employers, then an MSDS must be created for the employers. If the product is sold to distributors who then sell the product to employers, then the manufacturer must provide an MSDS to the distributor, and the distributor must provide the MSDS to their employer clients.

Secondly, if the manufacturer sells the product to only retail establishments, and an employer purchases the product from that retail establishment, the retail establishment essentially becomes a distributor, and must provide an MSDS to the employer customer. As soon as the manufacturer becomes aware that the product is being sold to employers, they are required to provide an MSDS, even though they have no control over to whom the product is sold and their intention was sell to employers.

As far as what would need to be on the MSDS, the rule requires an MSDS for all hazardous chemicals. A hazardous chemical, as defined by 1910.1200, which includes health hazards and/or safety hazards to employees. In this case, if there are no known studies that the herbal extracts pose a health and/or safety hazard to how employees would use or handle the materials, then they do not need to be included on an MSDS. For example, if the only known hazard from an extract is through ingestion of large quantities, and this is not an expected route of exposure for employees who may prepare doses for patients, then it does not need to be listed on the MSDS. On the other hand, if it is known that ingestion of small or trace amounts can cause illness, then it would need to be listed because of the potential for cross-contamination to food, cigarettes, cosmetics, and the like.

Since the carrier is an alcohol, and it is known that alcohols can present health and physical hazards, including dermatitis and flammability, it must be listed on the MSDS.