

## This month's OSHA "Letter of Interpretation" is now ready



### Topic: Must a Physician Keep MSDS for Prescription Medicines?

This is a great question and one that is asked often.

OSHA has addressed this question via a Letter of Interpretation (see below). Here are some of the main points:

Employers are required to ensure that hazardous chemicals are labeled with chemical identity, appropriate hazard warnings, and name and address of the manufacturer, importer or responsible party; maintain MSDSs for hazardous chemicals in the workplace and make them readily accessible to exposed workers; provide training for employees to understand the chemicals hazards and be able to use the information on the labels and MSDSs to know how to protect themselves.

Must the pharmacy keep MSDSs for hazardous chemical containing products in a solid dosage form (e.g., tablets and capsules) intended for direct administration to the patient -- or -- are these products exempt from the MSDS requirements?

Drugs, as defined in the Federal Food, Drug and Cosmetic Act, in solid, final form for direct administration to the patient (i.e., tablets, pills, capsules) are exempt from coverage under section (b)(6)(viii) of the HCS. MSDSs are required for all other hazardous drugs.

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**WARNING:** Be careful about what is considered "Hazardous". OSHA does not have a list of "Hazardous" products. Simple products such as Windex, White-Out and other common household products may be considered "Hazardous". To be safe, if a product has an MSDS, assume it has a level of hazard that must be addressed.

January 3, 1994

Mr. Charles P. Coe  
Vice President, Quality Improvement  
Owen Healthcare, Inc.  
9800 Centre Parkway, Suite 1100  
Houston, Texas 77274-2587

Dear Mr. Coe:

This is a response to your letter of July 20, concerning the application of the Occupational Safety and Health Administration's (OSHA) Hazard Communication Standard (HCS), 29 CFR [1910.1200](#), to pharmaceutical products. We regret the delay in responding to your inquiry.

Your questions will be answered in the order they were presented in your letter.

1. Does the HCS apply to all pharmaceuticals -- or only to pharmaceuticals that the manufacturer has determined as hazardous?

The HCS only applies to pharmaceuticals that the drug manufacturer has determined to be hazardous and that are known to be present in the workplace in such a manner that employees are exposed under normal conditions of use or in a foreseeable emergency. The pharmaceutical manufacturer and the importer have the primary duty for the evaluation of chemical hazards. The employer may rely upon the hazard determination performed by the pharmaceutical manufacturer or importer.

The HCS provides workers exposed to chemicals with the right to know the chemicals' hazards and associated protective measures. This is accomplished through implementations of a hazard communication program in each workplace where employees are exposed to hazardous chemicals. Employers are required to ensure that hazardous chemicals are labeled with chemical identity, appropriate hazard warnings, and name and address of the manufacturer, importer or responsible party; maintain MSDSs for hazardous chemicals in the workplace and make them readily accessible to exposed workers; provide training for employees to understand the chemicals hazards and be able to use the information on the labels and MSDSs to know how to protect themselves.

The employer is required to develop a written hazard communication program for their workplace that includes an inventory of all the hazardous chemicals in the workplace. The labels and MSDS are developed by the chemical manufacturer or importer of the product. MSDS are to be provided with the initial shipments to downstream users for any item that would expose employees to hazardous chemicals. Labels are required on containers of hazardous chemicals for every shipment.

2. Are pharmaceuticals in a retail establishment which are packaged for sale to consumers exempt from the HCS?

Yes, Section (b)(6)(v & vi) of the HCS exempts, "food, drugs, cosmetics, or alcoholic beverages in a retail establishment which are packaged for sale to consumers", and "foods, drugs, or cosmetics intended for personal consumption by employees while in the workplace".

3. Must the pharmacy keep MSDSs for hazardous chemical containing products in a solid dosage form (e.g., tablets and capsules) intended for direct administration to the patient -- or -- are these products exempt from the MSDS requirements?

Drugs, as defined in the Federal Food, Drug and Cosmetic Act, in solid, final form for direct administration to the patient (i.e., tablets, pills, capsules) are exempt from coverage under section (b)(6)(viii) of the HCS. MSDSs are required for all other hazardous drugs.

4. Must the pharmacy keep MSDSs for hazardous chemical containing products in a solid dosage form (e.g., tablets and capsules) that are intended to be crushed or mixed prior to administration?

5. Must the pharmacy keep MSDSs for hazardous chemical containing products in solid dosage form (e.g., tablets and capsules) that are NOT intended to be crushed or mixed prior to administration -- even though it is possible that a nurse might choose to crush or mix them prior to administration?

9. Are pellet-filled and powder-filled capsules considered to be solid dosage forms?

10. Is a liquid-filled gelatin capsule considered to be a solid dosage form?

Answer to questions 4, 5, 9, and 10

Tablets, capsules or pills which are designed to be dissolved or crushed by employees prior to administration to a patient **are not** in "final form", and **are covered by the HCS**. There may be situations where the tablet, capsule or pill is dissolved or crushed to facilitate patient administration when that is not typically the way it is dispensed. The "final form" exemption would apply in this situation.

6. Must the pharmacy keep MSDSs for products that DO NOT contain hazardous chemicals and that are intended to be crushed or mixed prior to use?

MSDSs are not required for non-hazardous drugs. MSDSs are required to be prepared and transmitted with the initial shipment of all hazardous chemicals including drugs and pharmaceutical products except for drugs as defined by the Federal Food, Drug and Cosmetic Act which are in solid, final form for direct administration to the patient (i.e., tablets, pills, or capsules) or which are packaged for sale to consumers in a retail establishment.

7. Must the pharmacy keep MSDSs for liquid pharmaceuticals (e.g., injectable products and oral liquid products) that DO NOT contain hazardous chemicals?

Liquid drugs which are hazardous chemicals would be covered if there is a potential for employee exposure to them. Non hazardous liquid drugs are not covered by the HCS.

8. Must the pharmacy keep MSDSs for ointments, creams, and other topical preparations that do not contain hazardous chemicals?

If the active ingredients in this dosage form are indeed non-hazardous, then

these chemical containing products are not covered by the HCS and do not require MSDSs.

11. If the manufacturer will not or cannot provide a MSDS for a covered drug, must the pharmacy document its attempt to obtain a MSDS?

Yes, the pharmacy is to contact the drug manufacturer, importer, or distributor to request a MSDS. This action should be documented in the form of a letter. Section (g)(1) of the standard states that "the employer shall have a MSDS for each hazardous chemical they use." However, employers are not to be held responsible for inaccurate information on the MSDS which they did not prepare and they have accepted in good faith from the chemical manufacturer, importer or distributor.

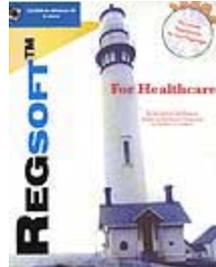
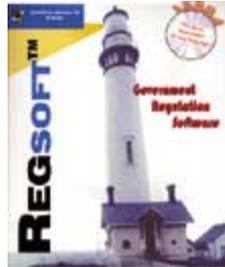
Please bear in mind that the package inserts and the **Physician's Desk References** cannot be accepted in lieu of MSDSs, as these documents do not meet the specification requirements of MSDSs under the present rule.

Sincerely,

Ruth McCully, Director  
Office of Health Compliance Assistance

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