

SDS Exemption for Over-the-Counter Tablets and Pills

Excerpt from a letter written by:

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Occupational Safety and Health Administration's (OSHA) Hazard Communication Standard (HCS), 29 CFR 1910.1200 requirements for Material Safety Data Sheets (MSDS) for drugs.

Drugs regulated by the U.S. Food and Drug Administration (FDA) are covered by the Hazard Communication Standard. However, section (b)(6)(viii) of the HCS exempts drugs when they are in solid final form, such as tablets or pills, for direct administration to the patient.

Hazard Communication Standard

1910.1200(b)

"Scope and application."

1910.1200(b)(1)

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

1910.1200(b)(6)

This section does not apply to:

1910.1200(b)(6)(vii)

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

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Re: Safety Data Sheets (SDSs)

Dear Inquiring Party,

Please be aware that, as provided by the exemption stated in the United State government's Code of Federal Regulations – 29 CFR 1910.1200(b)(6)(v) and 29 CFR 1910.1200(b)(5)(iii), SDSs are not required for certain items. These same documents specifically mention those products which pertain to Ricola USA, Inc. Therefore Ricola USA, Inc. is not required to have SDSs for their products.

Best regards,

DocuSigned by:

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5/8/2020

Donald W. Parriott
VP, Quality & Regulatory
Ricola USA, Inc.