Re: Material Safety Data Sheets

Acetaminophen 650MG

This letter is in response to your request for a Material Safety Data Sheets (MSDS) for the above listed product supplied to you by Perrigo Company. The general purpose of an MSDS is to provide appropriate warnings and safety information for products packed in bulk. Unlike finished products packaged for retail sale, such information is not typically included or readily available on the bulk packaging. However, a number of products packaged for sale at retail contain the information necessary to properly warn and advise the consumer are specifically exempted from the requirement to have an MSDS. OTC drugs[1] and cosmetics[2] manufactured or distributed by Perrigo in final retail packaging fall within this exemption.

Based on these exemptions under the federal OSHA Hazard Communication Standard, MSDSs are not required for the product requested. Product labels provide health cautions appropriate for the product and should be consulted for any concerns. If you have any questions regarding this issue, please do not hesitate to contact us.

Sincerely,

Consumer Affairs
Perrigo Company

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[1] The federal Occupational Safety and Health Act provides a specific exemption from the requirements for an MSDS for "drugs which are packaged...for sale to consumers in a retail establishment." 29 C.F.R. § 1910.1200(b)(6)(vii). "Drugs" are defined under the Federal Food, Drug, and Cosmetic Act as, "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals." 21 U.S.C. § 321(g)(1)(B) (2007). Communications with the Federal Food and Drug Administration ("FDA") confirmed that treatments for diaper rash, vaginal irritation, and acne are considered over-the-counter drugs by the FDA. Accordingly, such items manufactured by Perrigo are exempt from the MSDS requirement.

[2] Perrigo is not required to supply MSDSs for its cosmetics which are packaged for sale to consumers in a retail establishment. 29 C.F.R. § 1910.1200(b)(6)(viii). The FDA defines "cosmetics" as, "articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and articles intended for use as a component of any such articles; except that such term shall not include soap." Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 321(i)(2007). The FDA has also concluded that skin moisturizers are cosmetics pursuant to this definition.