



Re: Safety Data Sheets

To Whom It May Concern:

This letter is in response to your request for a Safety Data Sheets (SDS) for a Perrigo product. The general purpose of an SDS is to provide appropriate warnings and safety information about potentially hazardous chemicals handled in an occupational setting. Without an SDS, such information may not be available to employees involved in manufacturing.

- Products packaged for retail sale contain the information necessary to properly warn and advise the consumer and many are specifically exempted from the requirement to have an SDS. Rx/OTC drugs¹ and cosmetics² manufactured or distributed by Perrigo in final retail packaging fall within this exemption.
- Products sold as food³ are not generally considered hazardous and are specifically exempted from the requirement to have an SDS. Infant formula, nutritional drinks, and glucose supplements manufactured or distributed by Perrigo fall within this exemption.
- Products considered ‘articles’⁴ are not generally considered hazardous and are specifically exempted from the requirement to have an SDS. Blood glucose strips, syringes, lancets, cannulas, and ScarAway® discs and sheets manufactured or distributed by Perrigo fall within this exemption.

Based on these exemptions under the federal OSHA Hazard Communication Standard, SDSs 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 me.

Very truly yours,

Rob Somers

Rob Somers, Global EH&S Director
Perrigo Company

¹ The federal Occupational Safety and Health Act provides a specific exemption from the requirements for an SDS 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 SDS requirement.



² The federal Occupational Safety and Health Act provides a specific exemption from the requirements for an SDS for cosmetics 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.

³ The federal Occupational Safety and Health Act provides a specific exemption from the requirements for an SDS for “Food or alcoholic beverages which are sold, used, or prepared in a retail establishment (such as a grocery store, restaurant, or drinking place), ...” 29 C.F.R. § 1910.1200(b)(6)(vi). “Food” is defined under the Federal Food, Drug, and Cosmetic Act as, “(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.” 21 U.S.C. § 321(f) (2007).

⁴ The federal Occupational Safety and Health Act provides a specific exemption from the requirements for an SDS for “articles”. 29 C.F.R. § 1910.1200(b)(6)(v). “Article means a manufactured item other than a fluid or particle:

- (i) which is formed to a specific shape or design during manufacture;
- (ii) which has end use function(s) dependent in whole or in part upon its shape or design during end use; and
- (iii) which under normal conditions of use does not release more than very small quantities, *e.g.*, minute or trace amounts of a hazardous chemical (as determined under paragraph (d) of this section), and does not pose a physical hazard or health risk to employees.”