English:

3E verified with the supplier provided that no SDS has been created for this product.
3E will periodically contact the supplier to reconfirm no SDS is available.

Deutsch:

3E bestätigt, dass für dieses Produkt kein Sicherheitsdatenblatt (SDB) vom Lieferanten erstellt wurde. 3E wird regelmäßig Kontakt mit dem Lieferanten aufnehmen, um sich bestätigen zu lassen, dass (weiterhin) kein SDB erforderlich ist.

Français:

3E a vérifié avec le fournisseur approprié qu'aucune FDS n'a été créée pour ce produit.
3E recontactera périodiquement le fournisseur pour confirmer qu'aucune FDS n'existe pour ce produit.

Español:

3E ha comprobado que el proveedor no ha creado ninguna SDS para este producto.3E contactará periódicamente con el proveedor para asegurarse de que no exista ninguna SDS disponible.

Italiano:

3E ha verificato che nessuna SDS è stata creata per questo prodotto.3E contatterà periodicamente il fornitore per confermare che nessuna SDS è disponibile.

中文:

3E公司已与供货商确认，本产品没有SDS。 3E公司将会定期与供货商联系，重新确认本产品没有SDS。

Copyright© 2013 3E Company, 3E® is a registered trademark of 3E Company

Perrigo

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 over-the-counter (OTC) drug or food 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 are specifically exempted from the requirement to have an SDS. Rx/OTC drugs[1] and cosmetics[2] manufactured or distributed by Perrigo in final retail packaging fall within this exemption. Likewise, products sold as food are not generally considered hazardous and are specifically exempted from the requirement to have an SDS[3]. Infant formula, nutritional drinks, and glucose supplements 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 an emergency which requires additional guidance, please call 1-888-464-2986 for further assistance. 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 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.

[3] The federal Occupational Safety and Health Act provides a specific exemption from the requirements for an MSDS 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).

515 Eastern Avenue
Allegan, Michigan 49010
(269) 673-8451