Re: Safety Data Sheets

To Whom It May Concern:

This letter is in response to your request for Safety Data Sheets (SDS) for a Perrigo product. The general purpose of an SDS is to provide appropriate warnings and safety information to employees about potentially hazardous chemicals handled in an occupational setting. SDSs are regulated by OSHA's Hazard Communication Standard, which includes several exemptions from the requirement to provide an SDS for certain products.

- 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 drugs[1] and cosmetics[2] manufactured or distributed by Perrigo in final retail packaging fall within this exemption.

- Products sold as food[3] are not generally considered hazardous and are specifically exempted from the requirement to have an SDS. Infant formula, nutritional drinks, and electrolyte 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. Toothbrushes, floss and other dental devices[5] and Mederma Scar® 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."

[5] The FDA defines medical devices as articles inclusive of dental devices such as oral rinse and dental floss among others. Per section 201(h) of the Food, Drug, and Cosmetic Act, a device is:
"An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

1. recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
2. intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
3. intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER H--MEDICAL DEVICES
PART 872 -- DENTAL DEVICES

Subpart F--Therapeutic Devices Sec. 872.5580 Oral rinse to reduce the adhesion of dental plaque.
(a) Identification. The device is assigned the generic name oral rinse to reduce the adhesion of dental plaque and is identified as a device intended to reduce the presence of bacterial plaque on teeth and oral mucosal surfaces by physical means. The device type includes those devices that act by reducing the attachment and inhibiting the growth of bacterial plaque.

Subpart G--Miscellaneous Devices Sec. 872.6390 Dental floss.
(a) Identification. Dental floss is a string-like device made of cotton or other fibers intended to remove plaque and food particles from between the teeth to reduce tooth decay. The fibers of the device may be coated with wax for easier use.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 872.9. [52 FR 30097, Aug. 12, 1987, as amended at 61 FR 1121, Jan. 16, 1996; 65 FR 2315, Jan. 14, 2000]

Sec. 872.6855 Manual toothbrush.
(a) Identification. A manual toothbrush is a device composed of a shaft with either natural or synthetic bristles at one end intended to remove adherent plaque and food debris from the teeth to reduce tooth decay.
(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files. [52 FR 30097, Aug. 12, 1987, as amended at 54 FR 13831, Apr. 5, 1989; 66 FR 38800, July 25, 2001]

Sec. 872.6865 Powered toothbrush.

(a) Identification. A powered toothbrush is an AC-powered or battery-powered device that consists of a handle containing a motor that provides mechanical movement to a brush intended to be applied to the teeth. The device is intended to remove adherent plaque and food debris from the teeth to reduce tooth decay.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9. [55 FR 48440, Nov. 20, 1990, as amended at 59 FR 63009, Dec. 7, 1994; 66 FR 38800, July 25, 2001]