



October 30, 2024

This letter is in reference to your request for an SDS (formally known as MSDS sheet). Based on our review, CareALL® 2 oz. Hemorrhoidal Ointment with Applicator (NBE Preparation H) / Item # HEM2 is exempt from the OSHA Hazardous Communication Standard (29 CFR 1910.1200), SDS and/or labeling requirements based on one or more of the exceptions in the standard as outlined below.

1910.1200(b)(6)(ix)

Any consumer product or hazardous substance, as those terms are defined in the Consumer Product Safety Act (15 U.S.C. 2051 *et seq.*) and Federal Hazardous Substances Act (15 U.S.C. 1261 *et seq.*) respectively, where the employer can show that it is used in the workplace for the purpose intended by the chemical manufacturer or importer of the product, and the use results in a duration and frequency of exposure which is not greater than the range of exposures that could reasonably be experienced by consumers when used for the purpose intended;

1910.1200(b)(6)(v)

Articles as that term is defined in paragraph (c) of this section: 1910.1200(c) *Definitions - 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.

And specific to labeling:

1910.1200(b)(5)(iii)

Any food, food additive, color additive, drug, cosmetic, or medical or veterinary device or product, including materials intended for use as ingredients in such products (*e.g.* flavors and fragrances), as such terms are defined in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*) or the Virus-Serum-Toxin Act of 1913 (21 U.S.C. 151 *et seq.*), and regulations issued under those Acts, when they are subject to the labeling requirements under those Acts by either the Food and Drug Administration or the Department of Agriculture;

1910.1200(b)(5)(v)

Hazardous Substances Act (15 U.S.C. 1261 *et seq.*) respectively, when subject to a consumer product safety standard or labeling requirement of those Acts, or regulations issued under those Acts by the Consumer Product Safety Commission.

The information above can be found in the Occupational Safety and Health Standard for Hazard Communication (29 CFR 1910.1200). Please keep this information on file for your records. Our policy has been updated and aligned with the UN Globally Harmonized System of Classification and Labeling of Chemicals (GHS).

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