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Corporate Quality Assurance/Regulatory Affairs

February 22, 2018

Subject: Safety Data Sheets

Item Description: Optifoam Gentle Silicone Face Non Border Dressings

Item: MSC2244EP, MSC2244EPH, MSC2244EPZ, MSC2266EP, MSC2266EPH, MSC2266EPZ, MSC2288EP, MSC2288EPH, MSC2288EPZ

The item(s) referenced above for which you have requested a Safety Data Sheet are manufactured or distributed by Medline Industries, Inc. and are retailed as a medical device, drug, cosmetic or article. Products of this type are not subject to the Hazard Communication Standard (29 CFR 1910.1200). This exemption is set forth in the following sections:

Section b (6) This section does not apply to:

Section b (6) (v) Articles (as that term is defined in paragraph (c) of this section);

Section b (6) (vii) Any drug, as that term is defined in the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 *et seq.*), when it is in solid, final form for direct administration to the patient (e.g., tablets or pills); drugs which are packaged by the chemical manufacturer for sale to consumers in a retail establishment (e.g., over-the-counter drugs); and drugs intended for personal consumption by employees while in the workplace (e.g., first aid supplies);

Section b (6) (viii) Cosmetics which are packaged for sale to consumers in a retail establishment, and cosmetics intended for personal consumption by employees while in the workplace;

Section 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;

Section b (6) (Xii) Biological hazards.

Section (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.

These products, in their marketed packaging, are generally not considered hazardous under normal conditions of use when used in accordance with labeling instructions.

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