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Corporate Quality Assurance/Regulatory Affairs

January 16, 2018

Subject: Safety Data Sheets

Item Description: **Coude Silicone-Elastomer Coated Latex Foley Catheters**

Item: **DYND11214; DYND11214H; DYND11216; DYND11216H; DYND11218; DYND11218H; DYND11220; DYND11220H**

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.

Medline Corporate Quality
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