Medline Industries, Inc. One Medline Place
Mundelein, IL 60060.4486

Corporate Quality Assurance/Regulatory Affairs

May 29th 2015:

Subject: Safety Data Sheets

Item Description: **Sterile Piston Irrigation Syringes**

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 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 s in the following sections:

Section b (5) (iii) Any food, food additive, color additive, cosmetic, drug, medical 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*.) and regulations issued under the Act, when they are subject to the labeling requirements of the Act and labeling regulations issued under that Act by the Food and Drug Administration;

Section b (5) (v) 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 the Federal Hazardous Substance Act (15 U.S.C 1261 *et seq.*) respectively. When subject to a consumer product safety standard or labeling requirements of those Acts, or regulations issued under those Acts by the Consumer Product Safety Commission;

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 (ix) Any consumer product or hazardous substance, as those terms are defined in the Consumer Product Safety Act (15 U.S.C. 1261 *et seq*.) and Federal Hazardous Substance Act (15 U.S.C. 1261 *et seq*.) respectively, where the employer can demonstrate it is used in the work place in the same manner as normal consumer use, and which use results in a duration and frequency of exposure which is not grater that exposures by consumers.

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

Every effort is made to provide products which are properly labeled and safe for their intended use. It is the user's responsibility both to determine safe conditions for use of this product and assume liability for loss, injury, damage or expense resulting from any misuse of the product.

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

Sincerely,
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