

February 22, 2016

RE: SDS Exemption for Hibiclens

To Whom It May Concern,

Per Occupational Safety and Health (OSHA) regulation 29 CFR 1910.1200(b)(5)(iii), the following are exempt from the hazard communication system requirements (including hazard labels and safety data sheets):

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

Hibiclens is considered an OTC drug regulated under a New Drug Application (NDA) by the US Food and Drug Administration (FDA) and, as such, is exempt from SDS requirements.

If you have any questions or need additional information, I can be contacted by email at Jennifer.register@molnlycke.com or by phone at (470) 375-0050, ex: 9050.

Sincerely,

Jennifer Register

Sr. Regulatory Affairs Specialist

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