



May, 2016

SDS NOT REQUIRED

Re: Silver Sulfadiazine Cream 1%, 20 grams, 25 grams, 50 grams, 85 grams, and 400 grams

As stated in 29 CFR 191 0.1200(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); and drugs which are packaged by the chemical manufacturer for sale to consumers in a retail establishment (e.g., over-the-counter drugs); are exempted from the requirement of an MSDS. I write to claim an exception of SDS for the above referenced FDA approved drug product.

On the basis of the foregoing, Ascend Laboratories, LLC submits that an SDS statement is not required for the listed product and, therefore, requests that it be categorically excluded from the requirement to submit SDS.

If you need any additional information, please contact me directly.

Sincerely,

Hindy Schiff

Director Regulatory Affairs/Compliance

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