

SAFETY DATA SHEETS

This SDS packet was issued with item:

078931432

N/A



Global Safety Management

MSDS Not Required

According to Ascend Laboratories Ibuprofen Tablets, USP 600 mg, this product does not require an MSDS as defined by the OSHA Hazard Communication Standard. Products such as drugs, cosmetics, food or alcoholic beverages, wood or wood products, tobacco or tobacco products, or articles (finished goods), as defined in 29CFR1910.1200(b)(6) & (c), are exempt from the MSDS portion of the hazard communication standard.



January, 2017

SDS NOT REQUIRED

Re: ANDA 091625 Ibuprofen Tablets, USP 400 mg, 600 mg, and 800 mg.

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 SDS. 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 marketed under approved ANDA 091625 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

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