

Re: Material Safety Data Sheets (MSDS) Response Letter

To Whom It May Concern:

This letter is in response to your request for Material Safety Data Sheets (MSDS) for the AvPAK solid-dose products from AvKARE. The Hazard Communication regulation, which requires the preparation of MSDS for hazardous chemicals in the workplace, reads as follows:

Title 29 CFR Ch. XVII §1910.1200 – Hazard communication

(b)(6) This section does not apply to: (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., tablet 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);

This paragraph exempts solid-dose finished pharmaceuticals (i.e., tablets and capsules) from the requirements of the Hazard Communication regulation. For this reason, in compliance with the regulation, AvPAK does not provide MSDS for its solid-dose products.

Sincerely,

Clifton Stanfill
V.P. Regulatory Affairs
Pharmaceutical Operations
AvKARE | AvPAK