SAFETY DATA SHEET (SDS)

HAZARD COMMUNICATION STATEMENT

This statement is prepared in accordance with OSHA requirements, 29 CFR 1910.1200(b)(6)(vii), as it relates to hazardous chemicals in the work place.

This regulation was implemented for the safety of the chemical operators who manufacture the finished dosage forms. As such, OSHA 29 CFR 1910.1200(b)(6)(vii) exempts the following:

"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 retail establishment (e.g. over-the-counter drugs); and drugs intended for personal consumption by employees while in the work place (e.g. first aid supplies)."

Therefore this regulation does not apply to pharmaceutical solid finished dosage forms (i.e. tablets and capsules) only to liquids, ointments and creams where the patient has direct contact with the raw material ingredients.

Signed: Dawn Chitty

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