

LUPIN SOMERSET

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Date: July 25, 2017

To: Any customer requesting Safety Data Sheets (SDS) for Lupin products
From: Lupin Somerset (an Operating Division of Lupin, Inc.)
Subject: SDS - OSHA Requirements

This correspondence has been drafted in response to numerous inquiries and requests that Lupin Somerset receives for Safety Data Sheets (SDS). The Code of Federal Regulations, Title 29-Labor, §1910.1200, section (b), addresses the scope and application of an employee hazardous communication standard. Subsection (6) indicates that the hazardous communication program specified previous **does not apply to:** ... §1910.1200(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); 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)" – **29 CFR 1910.1200 Revision 3, issued in the Federal Register, March 26, 2012. This rule became effective May 25, 2012.**

In support and in addition of above reference, the Hazard Communication Standard (HCS) has conformed to the United Nations' Globally Harmonized System of Classification and Labeling of Chemicals (GHS). According with the GHS scope, section 1.1.2.5, subsection (a)(iii) "At other stages of the life cycle for these same products, the GHS may not be applied at all. For example, at the point of intentional human intake or ingestion, or intentional application to animals, products such as human or veterinary pharmaceuticals are generally not subject to hazard labelling under existing systems. Such requirements would not normally be applied to these products as a result of the GHS. (It should be noted that **the risks to subjects associated with the medical use of human or veterinary pharmaceuticals are generally addressed in package inserts and are not part of this harmonization process.**)..." [emphasis added by writer] - **Globally Harmonized System of Classification and Labelling of Chemicals (GHS) (Rev.2)(2007) United Nations** (http://www.unece.org/trans/danger/publi/ghs/ghs_rev02/02files_e.html)

Therefore, SDS is not required under OSHA requirements, nor under GHS scope for any of Lupin Somerset finished pharmaceutical products.

Sincerely,

Constantino Rodriguez
Acting Dir. EH&S