



CHARTING A COURSE TO WELLNESS

Date: December 30, 2014

To Whom It May Concern:

Subject: Material Safety Data Sheets- Doxycycline Hyclate Capsules, USP 100mg

This letter is in response to your request for Material Safety Data Sheets (MSDS) for Chartwell's solid-dose products.

The Hazard Communication regulation, which requires the preparation of MSDS for hazardous chemicals in the workplace, reads as follows:

Title 29 Section 191 0.1200 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., 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);

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, Chartwell Pharmaceuticals does not provide MSDS for its solid-dose products.

In addition, we certify that this product is Non-Hazardous and Not Regulated when Transporting through air, ground or sea freight:

IATA / ICAO – Non Hazardous - Not Regulated

IATA Proper shipping name: N/A

IATA UN / ID No: N/A

IATA Hazard Class: N/A

IATA Packing Group: N/A

IATA Label: N/A



CHARTING A COURSE TO WELLNESS

IMDG – Non Hazardous - Not Regulated

IMDG Proper shipping name: N/A

IMDG UN / ID No: N/A

IMDG Hazard Class: N/A

IMDG Flash Point N/A

IMDG Label: N/A

DOT – Non Hazardous - Not Regulated

DOT Proper shipping name: N/A

DOT UN / ID No: N/A

DOT Hazard Class: N/A

DOT Flash Point N/A

DOT Packing Group: N/A

DOT Label: N/A

This letter applies to the following NDC numbers:

69097-226-12 and 69097-226-70

Sincerely,

A handwritten signature in black ink, appearing to read "Kimberly Ezdebski".

Kimberly Ezdebski
Vice President Quality & Regulatory Compliance