215 Wood Ave., Middlesex, NJ 08846
(732) 868-1090 Fax: (732) 868-1091
Web: http://www.impaxlabs.com

September 10, 2015

Subject: Safety Data Sheets (SDS) formerly Material Safety Data Sheets

To Whom It May Concern:

This letter is in response to your request for SDS for Impax solid-dose products.

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

Title 29 Section 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., 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, Impax does not provide MSDS for its solid-dose products.

Should you have any questions or require any additional information concerning the above, please contact me at 732-667-6128.

Respectfully Submitted,

John A. Harrison
Manager – Environmental, Health and Safety