



Dear Valued Customers,

This letter is in reference to your request for a Safety Data Sheet (SDS) for the following product(s):

Donepezil Hydrochloride Tablets, 23mg

The above listed item is exempt from the requirement to have a SDS pursuant to the OSHA Hazard Communication Standard at 29 C.F.R. § 1910.1200(b)(6)(vii), which states:

“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)”.

All TWi finished products are labeled in compliance with the requirements of the Food and Drug Administration (FDA). Each package of the finished pharmaceutical product is supplied with a package insert/insert (approved labeling) which provides required drug safety information.

If you have any questions or require additional information, please feel free to contact info.us@twipharma.com or 201-762-1410.

Sincerely,

TWi Pharmaceuticals, Inc.

TWi Pharmaceuticals USA