March 28, 2024

Dear Valued Customer:

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

MELATONIN 5MG TAB [RUGBY]

The above listed item(s) are exempt from the requirement to have SDS. Ethical, over-the-counter, supplemental, and cosmetic products in final dosage forms, which are supplied for patient care, are not subject to hazardous materials standards. The items do not pose a danger to persons handling the products in the forms in which they are supplied. Therefore, these products are exempt from SDS Requirements under OSHA Hazard Communication Standards 1910.1200(b)(6)(vii) and 1910.1200(b)(5)(iii), which provide the following exemptions:

1. Any drug, as that term is defined in the Federal Food, Drug, and Cosmetic Act (21 USC § 301), when it is in solid, final form for direct administration to the patient (e.g., tablets or pills)
2. Drugs which are packaged by the chemical manufacturer for sale to consumers in a retail establishment (e.g., over-the-counter drugs)
3. Drugs intended for personal consumption by employees while in the workplace (e.g., first aid supplies)
4. Cosmetics which are packaged for sale to consumers in a retail establishment, and cosmetics intended for personal consumption by employees while in the work place.
5. Any food, food additives, color additives, drug, cosmetic, or medical or veterinary device or product, including materials intended for use as ingredients in such products (e.g. flavors and fragrances).

The Harvard Drug Group drug products are prescribed, stored, prepared, dispensed, and administered according to the directions within the product labeling and packaging and are regulated by the Food and Drug Administration according to 21 CFR § 211.132.

If you have any questions or require additional information, please feel free to contact sdsrequests@thdg.com

Sincerely,

THE HARVARD DRUG GROUP, LLC

The Harvard Drug Group