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631-543-3334 - 631-543-3335 - www.geminipharm.com

Re: Requirement for Safety Data Sheets for Finished
Pharmaceutical or Nutritional Products

Dear Valued Customer:

In response to your request, Gemini Pharmaceuticals, Inc. does not publish or create SD Sheets (Formerly MSD Sheets) for finished Pharmaceutical or Nutritional products as they are an inappropriate document in light of current regulations.

Ethical, over-the-counter drug products and nutritional 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 capsules)
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. Any nutritional product, including materials intended for use as ingredients in such products (e.g. colors and flavors).

Gemini Pharmaceuticals' drug products and nutritional products are prepared, stored, and distributed according to the directions within the product labeling and packaging and are regulated by the Food and Drug Administration according to applicable Title Code 21 of the Federal Regulations Part 111 and Part 211.

For products we manufacture, upon request Gemini Pharmaceuticals will create a Certificate of Analysis, which is the correct document to be used for finished products.

Please do not hesitate to contact us if you have any other questions or concerns.

Sincerely,

Clyde Granger
Quality Assurance
Gemini Pharmaceuticals