



87 MODULAR AVENUE, COMMACK, NY 11725
631-543-3334 - 631-543-3335 - www.geminipharm.com

Re: Requirement for Material Safety Data Sheets (MSDS) for Finished
Pharmaceutical or Nutritional Products

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

For further information, we would like to refer you to the Hazard Communication regulation codified as 29 CFR 1910.1200 (b) (6) vii in the United States Federal Register. The section states that MSD sheets are not applicable to any tablet or pill, as the term is defined in the Federal Food, Drug and Cosmetic Act (21 USC 301), when the tablet or pill is in solid, final form for direct administration to the patient, or for that tablet or pill which is ultimately sold or provided to a customer.

As the tablets/ capsules manufactured by Gemini Pharmaceuticals for your company meets the stated exception as per the FDA, the Hazard Communication Standard requiring MSD sheets does not apply, so MSD sheets neither are needed nor are appropriate.

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,

CJ Dholakia
Regulatory Affairs
Gemini Pharmaceuticals

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