



Material Safety Data Sheet – Montelukast Sodium Chewable Tablets

As per 29 CFR 1910.1200(b)(6)(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)”, are exempted from the requirements of the Hazard Communication Standard.

Cadista is a solid, oral dosage form (tablets and capsules) manufacturer / distributor, therefore finished pharmaceutical products manufactured/distributed by Cadista are covered under this exemption. Therefore, Material Safety Data Sheets are not available.

All Cadista finished products are labeled in compliance with the requirements of the Food and Drug Administration (FDA) and must be used in the prescribed manner. Each package of the finished pharmaceutical product is supplied with a package insert/insert (approved labeling) which provides necessary drug safety information. Either an approved labeling or the drug information in the Physician’s Desk Reference (PDR) may be considered a MSDS for the purposes of compliance with the standard.

If you need any further information, please contact Cadista Customer Service at 1-800-313-4623.

Sincerely,

Shirish Valsangikar
Associate Vice President of Quality