CALAMINE LOTION PLAIN

MSDS WAIVER

Item #0395-0413
In reply to your request for Material Safety Data Sheets on substances provided by us, the products supplied are over-the-counter drugs and as such, are regulated by the FDA. In accordance with the office of Management and Budget determination under the Paperwork Reduction Act (52FR46075, Dec. 4, 1987), no Material Safety Data Sheets are required by the Food and Drug Administration in the non-manufacturing sector.

The product information sheet included with each drug adequately describes its safety and recommended use. In the form and packaging in which these products are supplied, they do not constitute a danger to your employees or to the environment.

You requested a Material Safety Data Sheet as part of a compliance program for the OSHA Hazard Communication Standard and or SARA Title III.

As you know, our products are consumer products which are regulated under the Federal Food, Drug and Cosmetic Act by the Food and Drug Administration. It is our understanding that OSHA has provided several exemptions for these products. The following is a brief summary of OSHA's exemptions:

29-CFR 1910.1200 (b) (6) (vi)
Exempts foods, drugs, and cosmetics when they are intended for personal consumption by employees while in the workplace.

29-CFR 1910.1200 (b) (6) (v)
Exempts foods, drugs, or cosmetics in retail establishments (packaged for sale to consumers).

52 FR 31862
In addition, since these products are exempted, employers who package them for retail sale would not have to furnish Material Safety Data Sheets to distributors receiving the products.

29-CFR 1910.1200 (b) (6) (viii)
Exempts drug as defined by the Federal Food, Drug and Cosmetic Act when they are in solid final form (i.e., tablets or pills)

These products, in their marketed packaging, are not hazardous under normal conditions of use and when used in accordance with labeling instructions. We, therefore, are not providing Material Safety Data Sheets for the product(s) in question.

PREPARED DATE: 07/09/01