



Food and Drug Administration
Rockville MD 20857-00

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Irving Gottlieb
Director of Sales and
Marketing, Biocides
Clariant Corporation
P.O. Box 866
624 East Catawba Avenue
Mount Holly, North Carolina 28120

Re: Docket No. 75N-183H
Comments No. PR8 and PR3

Dear Mr. Gottlieb:

This letter is in response to your submission dated August 22, 2000, filed as PR8 under Docket No. 75N-183H in the Dockets Management Branch. The submission consists of two items: (1) Dermal Absorption Study with [14C]-Labeled PCMX in Mice and (2) a draft protocol entitled "13 Week Dermal Toxicity Study in Mice." The dermal study was done in accordance with the agency's review of and comments on the previously submitted draft protocol filed as PR3 under Docket No. 75N-183H. Agency comments on the above submission are attached.

Any comment you may wish to make on the enclosed information should be submitted in three copies, identified with the docket number shown at the beginning of this letter, to the Docket Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852.

Sincerely Yours,

Charles Ganley, M.D.

Director

Division of OTC Drug Products

Office of Drug Evaluation V

Center for Drug Evaluation and Research

75N-183H

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