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January 29, 1999



FYI-98-001340

TSCA Document Control Office (M/C 7407)
Room G-99, East Tower
Attention: FYI Docket
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
401 M Street, S.W. (M/C 7407)
Washington, D.C. 20460



85990000002

Re: FYI Submission

Dear Sir/Madam:

We are writing to make a correction to a document entitled "Summary and Analysis of SC 90 Genotoxicity Testing," which was submitted to your office as part of an FYI submission on October 1, 1998, enclosing studies regarding the substance which is the subject of the consolidated PMN (No. P-92-778) for an acrylic polymer, CAS No. 109292-17-3. The summary has been corrected to indicate that the sample material tested in Study #3 and Study #9 was from a production batch, not from a pilot batch, as stated originally. A corrected summary is enclosed. Thank you for your assistance.

Very truly yours,

CONTAINS NO CBI

Paul Whitwell
Technical Manager
Ciba Specialty Chemicals Water Treatments, Inc.

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Enclosure

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Value beyond chemistry

Introduction

SC 90 (SALCARE 90) is a formulation of an aqueous emulsion (30% concentration) of an acrylic copolymer that is used in personal care products. SC 90 was tested in several microbial genotoxicity assays and in an *in vitro* human lymphocyte metaphase analysis study. Components of SC 90 were also tested in microbial genotoxicity assays. The results of these assays are discussed below in the order in which they were conducted.

The present conclusions regarding a positive or negative outcome in each study herein reviewed are based upon the generally accepted criteria for evaluating the assay which are used in the scientific literature and used by the EPA. In the case of the Ames assays, the criteria are a doubling of the background incidence, the presence of a dose-response function, and the ability to replicate the observation. In some cases, application of these criteria resulted in a different interpretation of the data from that provided in the original study reports.

Study Results

Study #1 (September 1989). This Ames assay was conducted on a sample from a 200 Kg pilot batch of formulated material for research and development purposes for a new product. Five strains of *Salmonella typhimurium* were assayed (strains TA 1535, 1537, 1538, 98 and 100) both with and without metabolic activation. The results were strongly positive in all strains, with and without metabolic activation in the initial assay and in some cases exceeded the positive control values. In the replicate, the results were strongly positive only with activation. Conclusion - Strong positive.

Study #2 (July 1990). An *in vitro* chromosomal aberration study using human lymphocytes with and without metabolic activation was conducted from another sample from the same pilot batch used in Study #1. A positive response was observed only at relatively high concentrations in the presence of metabolic activation. Conclusion - Positive (with metabolic activation).

Study #3 (October 1990). This Ames assay was conducted with a 1% aqueous solution from a production batch using only strains TA 98 and 100, with and without activation. Doubling of the number of revertants was seen only with TA 100 in the absence of metabolic activation. No dose-response was observed and the result could not be replicated. Conclusion - Negative.

Study #4-8 (October 1990). These Ames assays using strains TA 98 and 100 were conducted with various formulations of the product, including different monomer batches and emulsifiers. Study #5 involved a competitor's similar product. Conclusion - All negative.

Study #9 (October 1990). This Ames assay was conducted with a 0.1% concentration of precipitated polymer from the same production batch used in Study #3 using strains TA 98 and 100. Doubling of the number of revertants was observed at the high concentration with Strain TA 98 both with and without metabolic activation. The result could not be replicated and a clear dose-response was not apparent. Conclusion - Negative.

Study #10 (October 1990). This Ames assay was conducted with a 1% concentration of the monomer used in the manufacture of the pilot batch used in Study #1. Strains TA 98 and 100 were exposed with and without activation. Conclusion - Negative.

Study #11 - 12 (December 1990). These Ames assays were conducted on samples from a typical production batch. (Study 12 was on a 1% concentration of the sodium salt.) Strains TA 98, 100, 1535, 1537, 1538, 98 and 100 were tested with and without metabolic activation. Conclusion - Negative.

Study #13 (May 1996). This study included both an Ames assay and an *E. coli* gene mutation assay and was conducted in a different laboratory than the other assays. The test material was from a typical production batch. Strains TA 1535, 1537, 98 and 100 and *E. coli* strain WP2uvrA were exposed with and without metabolic activation. A doubling or greater response was observed only with TA 1537 in the presence of metabolic activation. A dose-response was not observed. The response was replicated in TA 1537, other strains were negative. Conclusion - Negative/ Equivocal.

Summary and Discussion

Positive responses were observed only in Studies #1 and #2 from a pilot batch of the material formulated for R&D purposes. The genotoxicity of the pilot batch was indicated in these studies by the induction of gene mutations and chromosomal aberrations. Genotoxicity was not observed in the mutagenicity studies performed with subsequent batches (most notably in Studies #11 and 13). These studies demonstrate the absence of genotoxicity of SC 90 produced subsequent to the pilot batch. Studies #3-7, 9, 10, and 12 were also negative. These latter studies provide limited support for the absence of genotoxicity of SC 90.

The strong genotoxic activity observed with the pilot batch was only observed in *in vitro* studies and thus is not conclusive for the purpose of predicting human hazard. The inability to reproduce the clear positive genotoxicity findings associated with the pilot batch in subsequent production batches suggests that this R&D material was atypical. For this reason, the results of the testing of the pilot batch, although demonstrative of genotoxicity *in vitro*, do not seem relevant to the risk assessment of SC 90 produced subsequent to the preparation of the pilot batch in early 1989. Subsequent production batches of SC 90 do not show genotoxic activity in the microbial genotoxicity assays.

The test results taken as a whole indicate that SC 90, as formulated for personal care since 1990, does not appear to have genotoxic activity.

CERTIFICATE OF AUTHENTICITY

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