



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JAN 6 1993

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM:

SUBJECT: Resubmission for Registration of A Me-Too Application, Additional Information Requested by the Agency for BACTEKILLER AC

CHEMICAL: Silver Copper Zeolite (Bactekiller AC)

TOX. CHEM. NO.: 129057

EPA FILE SYMBOL: 059824-R **DP BARCODE:** D175962

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and

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Toxicology Branch II
Health Effects Division (H7509C)

Registrant: Kanebo Zeolite, USA, Inc.

Action Requested:

Toxicology was requested by the Registrant to review additional information in response to the Agency's deficiency letter of October 21, 1991. In addition, another label was submitted incorporating the Agency's comments.

A. Toxicology Branch II has completed the review of additional information submitted by the Registrant on Silver Copper Zeolite. The results for each are given below:

1. Environmental Fate Data: Leaching Study (#163-1) with Bactekiller AC
MRID# 422454-01

The previously submitted Leaching Study (MRID # 416158-18) requested information on pH analyses in the neutral and basic ranges. Silver Copper Zeolite was



evaluated for hydrolysis at pH 5, pH 7, and pH 9. This data shows that the maximum release of silver and copper occurred at pH 5. For this reason, pH 5 was chosen for the leaching study in order to maximize the amount of leachable ions from the polymers and to create a "worst-case" scenario.

CLASSIFICATION: This additional information is acceptable and satisfies additional data requirements for the leaching study. This study can be upgraded to MINIMUM.

2. Dermal Penetration and Risk Analysis Accession No.: 422454-02

The Registrant was asked to evaluate the current scientific understanding of the percutaneous absorption of silver. First, they cited from reviews of available literature on the dermal absorption of silver in several different forms (i.e. soluble and insoluble). Second, they related this information to toxicology data for the silver aluminosilicate complex in order to further estimate potential systemic effects from the dermal exposure route. Finally, the pharmacology and toxicology of silver was summarized so that general conclusions with regard to the safety of using materials into which silver-aluminosilicate has been incorporated for antimicrobial efficacy. This information leads to the conclusion that the application of Bactekiller AC for synthetic fiber and textile finishing is not likely to cause any systemic injury in humans after repeated and prolonged exposure.

This information was not submitted to fill any guideline requirements, but was submitted as additional information to support the registration of Bactekiller AC.

3. Teratology Data (Positive Control Data, Teratology Study in Pregnant Rats)
MRID # 422454-03

This Agency requested historical control data in the deficiency letter of October 21, 1991. The memo dated March 17, 1992 from the registrant refers to historical control data, however, the data submitted was positive control data. This study remains supplementary.

B. Label Review:

The proposed labeling revisions by the Agency were incorporated original label. Toxicology Branch II agrees with the newly revised label for Silver Copper Zeolite (Bactekiller AC).