



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

MAR 30 1994

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM:

SUBJECT: BACTEKILLER AC (Silver Copper Zeolite): Additional Data
Submission for Registration of Bactekiller AC

FROM: SanYvette Williams-Foy, D.V.M. *SWF 3/29/94*
Review Section IV, Tox. Branch II (H7509C)

TO: Valdis Goncarovs/John Lee, PM 17
Registration Division

THRU: Jess Rowland, M.S., Acting Section Head *Jess Rowland*
Section IV, Tox. Branch II (H7509C) *3/28/93*

and

Marcia van Gemert, Ph.D., Chief
Toxicology Branch II
Health Effects Division (H7509C)

mvngemert
3/29/94

EPA IDENTIFICATION NUMBERS: PC Code: 072501 [Silver] and 022501
[Copper]
DP Barcode: D193817
MRID #: 428457-01
Submission: S445655

Registrant: Kanebo Zeolite, USA, Inc.

Action Requested: Toxicology was requested to review and address the additional information (historical control data) submitted for Bactekiller AC in support of its registration.

Background: A request for historical control data from developmental toxicity studies in rats was made in order to assist in the further evaluation of a developmental toxicity study [MRID #416385-02, memo by S. Williams, October 8, 1991). In response to resubmitted material, a memo (by S. Williams, January 6, 1993) stated that the information was entitled "historical control data", but the body contained information on positive control animals. Therefore, the supplementary classification remained.

Response: In this submission the Registrant stated that developmental studies from the performing lab did not routinely contain data on untreated animals. Therefore, the Agency stated that it would consider using studies on untreated control rats of



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the same species submitted from other labs for comparison and to satisfy this deficiency. This comparison has been made and found to be within historical control ranges, thus allowing this study to be upgraded to core-minimum.