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

DEC 24 1991

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT. SACB Clarification of the Relationship of Expanded Certified Limits for Centari Technical Powder and Mammalian Toxicity Issues.

TO: Mike Mendelsohn (PM-18)
Insecticide-Rodenticide Branch
Registration Division (H7505C)

FROM: Roy D. Sjoblad, Ph.D., Microbiologist
Science Analysis and Coordination Branch
Health Effects Division (H7509C)

THROUGH: Reto Engler, Ph.D., Senior Science Advisor
Health Effects Division (H7509C)

SACB wishes to clarify the statement made in a December 12, 1991 Memorandum from Rita Briggs to Mike Mendelsohn/Phil Hatton on B. thuringiensis var. aizawai ABG-6305 (Centari) Technical Powder: Review of HPLC Assay for Betaexotoxin, Status of Data Gaps, and Justification for Expanded Certified Limits. Specifically in the Discussion/Conclusion section, at #2, 11/12/91 Letter re: Justification for Expanded Certified Limits for Centari Technical Powder.

The first sentence should be modified to read:

"Based on the non-toxicity of Centari, as demonstrated in acute toxicity studies previously submitted, SACB can support the expanded certified limits [REDACTED]"

QUALITY CONTROL PROCEDURE INFORMATION IS NOT INCLUDED

The rationale for this change is that the mammalian toxicology data represent a maximum hazard dose approach, and results from these studies are used to support an exemption from the requirement for a tolerance. If a tolerance exemption is supported by the data, then SACB has no toxicity concerns related to the percent active ingredient in the technical powder. Namely, the certified limits issue is not a toxicity issue.