

US EPA ARCHIVE DOCUMENT



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

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MEMORANDUM

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

JUL 1993
(1 JUL 1993)

SUBJECT: SAB Review of an Acute Oral Toxicity Study on Azatin Technical Grade, a Biochemical Pest Control Agent Submitted by AgriDyne Technologies (Submission No.: S435967; DP Barcode No.: D188157; ID No.: 062552-0001).

TO: Phillip Hutton/Willie Nelson (PM 18)
Insecticide-Rodenticide Branch
Registration Division (H7505C)

FROM: Cindy Schaffer, Microbiologist
Biological Pesticide Section
Science Analysis Branch
Health Effects Division (H7509C)

C. Schaffer

THROUGH: Roy Sjoblad, Ph.D., Section Head
Biological Pesticide Section
Science Analysis Branch
Health Effects Division (H7509C)

Roy Sjoblad

ACTION REQUESTED:
SAB has been asked to review an acute oral toxicity study submitted by AgriDyne Technologies.

CONCLUSION:
Although the LD₅₀ of Azatin Technical is greater than 5 g/kg body weight in female rats; the actual dose of azadirachtin was approximately 1 g/kg body weight based on the 10% concentration of azadirachtin in the Azatin Technical material (as stated by the registrant).

DATA EVALUATION REPORT

Reviewed by: Cindy Schaffer, Microbiologist, SAB/HED *CS*
Secondary Reviewer: J. Thomas McClintock, Ph.D., Microbiologist, *JTM*
SAB/HED

STUDY TYPE: Oral Toxicity Assay-Rat
MRID NO: 424636-01
TEST MATERIAL: Azatin Technical
SYNONYMS:
PROJECT NO: L08367
SPONSOR: AgriDyne Technologies Inc., Salt Lake City, UT
TESTING FACILITY: IIT Research Institute, Chicago, IL
TITLE OF REPORT: Oral Toxicity Assay of NPI-720, Azatin
Technical Grade, Batches in Female Rats
AUTHOR(S): William M. Mega
STUDY COMPLETED: August 1992
CONCLUSION: Although the LD₅₀ of Azatin Technical is
greater than 5 g/kg body weight in female
rats; the actual dose of azadirachtin was
approximately 1 g/kg body weight based on the
10% concentration of azadirachtin in the
Azatin Technical material (as stated by the
registrant).
CLASSIFICATION: ACCEPTABLE - TOX CATEGORY IV

I. STUDY DESIGN

Test Material: The biochemical pest control agent is Azactin technical grade NPI-720, lot 21380, sublots 1088-44A and 1088-44B at a concentration of 10%. The animals were dosed by oral gavage with 5 g/kg (10 ml @ 0.1 g test material/ml of a 1% carboxymethyl cellulose (CMC) concentration in water).

t Animals: Fifteen female CD rats, approximately 7 weeks old, were obtained from Charles River Laboratories, Portage, MI. The rats weighed between 176 g and 199 g at the beginning of the study.

Methods: Ten female rats were treated with a split dose of the test substance, four hours apart; and five female rats were maintained as untreated controls. The rats were randomly weighed before initial dosing, and at day 7. Animals were observed for clinical signs during the week long study.

II. RESULTS

A. Body Weights:

No abnormalities were noted in body weights or body weight gain.

B. Clinical Observations: