



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

4-12-91

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

FROM: *JW* James W. Akerman *LaRocca 4/12/91*
Ecological Effects Branch
Environmental Fate and Effects Division (H-7507-C)

TO: George LaRocca, (15)
Insecticide and Rodenticide Branch
Registration Division (H-7505-C)

SUBJECT: Asana (Esfenvalerate) Acute Testing

The Ecological Effects Branch has completed its review of the following study with the subsequent results.

Study Identification: Baer, K.N. (1991) Static Acute 48 hour EC50 of YB656-59 to Daphnia magna. Haskell Laboratory for Toxicity and Industrial Medicine Project ID #505-90. Submitted by E.I. Du pont de Nemours, Newark, Delaware. Acc # 417983-01.

Conclusions: This study is rated supplemental due to an unidentified contaminant which appeared in all test solutions. The EC50 for this study, based on mean measured concentrations of the technical a.i., is 8.3 ng/l with 95% confidence limits of 7.0 - 10.0 ng/l. The EEB is concerned that the formulation may produce an impurity which may be even more toxic than the active ingredient, esfenvalerate. (The EC50 for testing of technical Asana was reportedly 0.9 ug/l). The registrant should be required to repeat the study using the same formulation and an additional study testing the formulation without the active ingredient in an attempt to identify the subject "contaminant" and characterize its toxicity. Until the toxicity of the formulation is further identified, the EEB may use the results of this study for the purposes of a risk assessment.

If you have any questions concerning the above matter, please contact Jeffrey Bigler (557-0783) of my staff.



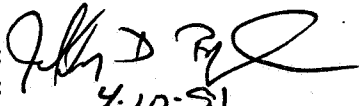
Printed on Recycled Paper

Ecological Effects Branch Review

1. Chemical: Esfenvalerate
2. Test Material: Asana (IN YB656-59): 8.4%, 0.66 EC Formulation
3. Study Type: Acute Toxicity, Freshwater Invertebrates
4. Study Identification: Baer, K.N. (1991) Static Acute 48 hour EC50 of YB656-59 to Daphnia magna. Haskell Laboratory for Toxicity and Industrial Medicine Project ID #505-90. Submitted by E.I. Du pont de Nemours, Newark, Delaware. Acc # 417983-01.

5. Reviewed By:

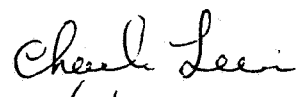
Jeffrey Bigler
Fishery Biologist
Ecological Effects Branch
Environmental Fate and Effects Division (H7507C)

Signature: 

Date: 4.10.91

Approved By:

Charlie Lewis
Acting Head, Section 3
Ecological Effects Branch
Environmental Fate and Effects Division (H7507C)

Signature: 

Date: 4/11/91

6. Conclusions: This study is rated supplemental due to an unidentified contaminant which appeared in all test solutions. The EC50 for this study, based on mean measured concentrations of the technical a.i., is 8.3 ng/l with 95% confidence limits of 7.0 - 10.0 ng/l. The EEB is concerned that the formulation may produce an impurity which may be even more toxic than the active ingredient esfenvalerate. (The EC50 for testing of technical Asana was reportedly 0.9 ug/l). The registrant should be required to repeat the study as a formulation with the active ingredient and an additional study testing the formulation without the active ingredient in an attempt to identify the subject "contaminant" and characterize its toxicity. Until the toxicity of the formulation is further identified, the EEB may use the results of this study for the purposes of a risk assessment.

7. Recommendations: N/A

8. Background: N/A.

9. Discussion of Individual Results: N/A

10. Materials and Methods:

A. Test Animals: Daphnia magna were obtained from an inhouse Haskell lab culture and were obtained from 20 day old parent daphnids. The age of the daphnids was < 24 hours old at test initiation. The daphnids were fed Purina trout chow and Fleischmann's yeast three times daily prior to the initiation of the study. The test animals were not fed during the test.

B. Dose: A dilution water control, solvent control (DMF) and nominal total formulation concentrations test doses of 0.031, 0.052, 0.086, 0.14, 0.24, and 0.40 ug/l. Mean measured concentrations of the mixture of active and inactive isomers (9.72%) of IN656-59 were 0.0011, 0.0016, 0.0032, 0.0059, 0.0081, and 0.016 ug/l.

C. Test System: The exposure system consisted of six sets of 250 ml pyrex beaker test chambers, plus solvent and water controls. Each replicate (four reps per test level) contained 5 daphnids each. Test solution temperatures were collected with an calibrated mercury thermometer. The unaerated test solutions were maintained at $19.9^{\circ} \pm 1^{\circ}\text{C}$.

D. Design: Twenty Daphnia magna were tested per treatment level; five daphnids per replicate; four replicates per treatment level. The loading rate was roughly one daphnid per 10 ml of solution. The photoperiod was 16 hours light and 8 hours dark. The temperature, DO, pH, and were measured in one replicate of the controls, and the low, middle, and high concentrations at zero and 48 hours of testing. Chemical concentrations were measured at 0 and 48 hours in all test aquaria. Observations for mortality and sublethal effects were recorded every 24 hours.

E. Statistics: The nominal concentrations and the corresponding mortality data were used to determine the 48-hour EC_{50} using Stephans' computer program.

11. Reported Results: "Earlier, unfed, rangefinding studies were conducted. The concentrations for the definitive test were based on the following rangefinding study; nominal, total formulation concentrations were 0.031, 0.063, 0.13, 0.25 and 0.50 ug/l and immobilities of 0, 20, 40, 100 and 100%, respectively, were observed.

All chemical and physical parameters (Tables 3 and 4) in the definitive study were within acceptable ranges."

Nominal, total formulation concentrations of IN YB656-59 were 0.031, 0.052, 0.086, 0.14, 0.24, and 0.40 ug/l. IN YB656-59 is a mixture of active and inactive isomers as well as inert ingredients. The active isomer plus three inactive isomers make up 9.72% of the formulation. Mean, measured concentrations of the mixture of active and inactive isomers were 0.0011, 0.0016, 0.0032, 0.0059, 0.0081, and 0.016 ug/l. However, a large degree of uncertainty exists in the measured values due to the presence of a contaminant. The origin of the contaminant is unknown. The 48-hr EC50 was calculated using nominal, total formulation concentrations of IN YB656-59. The 48-hr EC50 was 0.24 ug/l with a 95% fiducial interval of 0.21 and 0.28 ug/l."

12. Study Authors' Conclusions/QA Measures: "IN YB656-59 (nominal total formulation concentrations) was highly toxic in the static, unaerated, 48-hour Daphnia magna test."

Adequate GLP and QA statements were provided with the study.

13. Reviewers' Discussion and Interpretation of the Study:

A. Test Procedures: The test procedures were generally in accordance with accepted guidelines. However, the submission did not include all data relevant to the study due to the registrants opinion that the study was unacceptable due to evidence of a contaminant in the test solutions. The EEB does feel that enough data has been submitted to at least rate the study supplemental until such time as the registrant submits additional data which the EEB may use to characterize the toxicity of the Asana 0.66 EC formulation to freshwater invertebrates.

B. Statistical Analysis: Based on immobility data and mean measured concentrations of the technical material, the EEB has calculated an EC50 of 8.3 ng/l with 95% confidence limits of 7.0 - 10.0 ng/l.

C. Discussion and Results: The study author has indicated that the results of this study should be rated invalid due to an unknown contaminant which showed up in recovery in all test solutions. The registrant also indicates that the mesocosm evaluating Asana XL should be used to characterize the toxicity as opposed to the formulated toxicity test. However, the EEB is not convinced that the presence of the contaminant affected the accuracy of the recovery nor the validity of the

study. The EEB is concerned that the formulation may produce an impurity which may be even more toxic than the active ingredient esfenvalerate. The registrant should be required to repeat the study as a formulation with the active ingredient and an additional study testing the formulation without the active ingredient in an attempt to identify the "contaminant" that showed up in this study. Until the toxicity of the formulation is further identified, the EEB may use the results of this study for the purposes of a risk assessment. The EC50 for this study, based on mean measured concentrations of the technical a.i., is 8.3 ng/l with 95% confidence limits of 7.0 - 10.0 ng/l.

D. Adequacy of Study:

Classification - Supplemental.

Rational - As noted under Section 14.

Repairability - This study not repairable due to the inability to identify the contaminant.

15. Completion of One-liner: N/A.

DP BARCODE: D162198

CASE: 282169
SUBMISSION: S392319

DATA PACKAGE RECORD
BEAN SHEET

DATE: 03/07/91
Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: MISCELLANEOUS
CHEMICAL:

ACTION: 405 DATA-ADVERSE DATA

ID#: 282169

COMPANY: E. I. DU PONT DENEMOURS AND COMPANY, INC.

PRODUCT MANAGER: 15 GEORGE LARocca

703-557-2400 ROOM: CM#2 204

PM TEAM REVIEWER: ADAM HEYWARD

703-557-4421 ROOM: CM#2 200

RECEIVED DATE: 03/01/91

DUE OUT DATE: 05/10/91

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 162198

EXPEDITE: Y

DATE SENT: 03/07/91

DATE RET.: / /

DP TYPE: 001 Submission Related Data Package

ADMIN DUE DATE: 04/01/91

CSF: N

LABEL: N

ASSIGNED TO

DATE IN

DATE OUT

DIV : EFED

03/11/91

/ /

BRAN: EEB

/ /

/ /

SECT: IO

/ /

/ /

REVR : JAKERMAN

/ /

/ /

CONTR:

/ /

/ /

* * * DATA PACKAGE REVIEW INSTRUCTIONS * * *

Please review review the attached 6(a)2 data.

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL
-------	----------------	----------	----------	-----	-----	-------

6