

(1-23-90)

12/89

25193  
RECORD NUMBER

097801,006601  
Shaughnessey Code

REVIEW NUMBER

ECOLOGICAL EFFECTS BRANCH REVIEW

DATE: IN 09-25-89 OUT \_\_\_\_\_

FILE OR REG. NO. \_\_\_\_\_ 432-596 \_\_\_\_\_

PETITION OR EXP NO. \_\_\_\_\_

DATE OF SUBMISSION \_\_\_\_\_ 02-07-89 \_\_\_\_\_

DATE RECEIVED BY EFED \_\_\_\_\_ 09-21-89 \_\_\_\_\_

RD REQUESTED COMPLETION DATE \_\_\_\_\_ 01-17-89 \_\_\_\_\_

EEB ESTIMATED COMPLETION DATE \_\_\_\_\_ 01-17-89 \_\_\_\_\_

RD ACTION CODE/TYPE OF REVIEW \_\_\_\_\_ 330 \_\_\_\_\_

TYPE PRODUCT(S): I, D, H, F, N, R, S Pyrethroid

DATA ACCESSION NO(S). \_\_\_\_\_

PRODUCT MANAGER NO. \_\_\_\_\_ P.Hutton (17) \_\_\_\_\_

PRODUCT NAME(S) SBP-1382-40MF and

SBP-1382-40MF Formulation 1

COMPANY NAME Roussel Bio Corporation

SUBMISSION PURPOSE Submission of data to support

a variety of uses

SHAUGHNESSEY CODE	CHEMICAL AND FORMULATION	% A.I.
_____	<u>SBP-1382-40MF and SBP-1382-40MF</u>	_____
_____	<u>Formulation 1</u>	_____
<u>097801</u>	<u>Resmethrin</u>	<u>40%</u>
<u>006601</u>	<u>Aromatic petroleum solvent</u>	<u>52.6%</u>

## DATA EVALUATION RECORD

1. Chemical: Resmethrin 097801: 40% a.i.  
 Aromatic petroleum solvent 006601: 52.60% a.i.  
 Related compounds: 5.45% a.i.

2. Test Material SBP-1382-40 MF Formulation 1

3. Study Type: Acute Toxicity Test for Freshwater Invertebrates. Species tested: Daphnia magna

4. Study ID: SBP-1382-40 MF: Static Acute Toxicity Test to Daphnia magna 432-596; Submitted by: Analytical Bio-Chemistry Laboratories, Inc. 1984; Submitted to: Penick Corporation

5. Reviewed by: Daniel Balluff  
 Biologist  
 EEB/EFED

Signature:

Date:

*Daniel Balluff*  
 1/23/90

6. Approved by: Henry Craven  
 Head Section IV  
 EEB/EFED

Signature:

Date:

*Henry T. Craven*  
 1/23/90

7. Conclusion:

This study is scientifically sound and would fulfill EPA's guidelines for an acute toxicity test for freshwater invertebrates. However, for this formulated product, since resmethrin has a photodegradation rate of less than four hours when exposed to laboratory lighting, SBP-1382-40MF Formulation 1 may have a higher level of toxicity under conditions with less exposure to light. The 48-hour LC<sub>50</sub> based upon nominal concentrations of SBP-1382-40MF Formulation 1 (formulated product) to Daphnia magna was 0.10 mg/l. Therefore, SBP-1382-40MF Formulation 1 is classified as very highly toxic to freshwater invertebrates. The 48-hour NOEC was determined to be = 0.032 mg/l.

8. Recommendations: N/A

*2*

## 9. Materials and Methods:

- a. Test Animals - The adult Daphnia magna used in the test were cultured at ABC facilities.
- b. Test System - The static bioassay was conducted in 250 ml glass beakers containing 200 ml of ABC aged well water. Temperature: 20 - 21°C; Photoperiod: 16L:8D; Hardness (CaCO<sub>3</sub>): 225 - 275 mg/l; Alkalinity: (CaCO<sub>3</sub>) 325 - 375 mg/l; The adult Daphnia were fed algae Selenastrum capricornutum at least every three days prior to testing and supplemented with a suspension of tetramin/cerophyl.
- c. Dosing - The following nominal concentrations of the product were tested: 0.018, 0.032, 0.056, 0.10, 0.18, and 0.32 (mg/l).
- d. Design - Six concentrations in duplicate, one control, and one solvent control were tested with ten Daphnia (first instar less than 24 hours old) per beaker. Water samples were taken from test solutions at 0 and 48 hours. Dissolved oxygen concentration range: 7.2 - 8.8 mg/l (78 - 96% saturation); pH range: 8.4 to 8.5; (See table 3).
- e. Statistics - The 48-hour LC<sub>50</sub> values and 95% confidence intervals were calculated using the binomial, moving average, and probit methods. (Stephan 1978).

## 10. Reported Results:

The 24 and 48-hour LC<sub>50</sub> values for SBP-1382-40 MF Formulation 1 were > 0.32 and 0.11 mg/l, respectively. The no observed effect concentration was = 0.032 mg/l after 48 hours.

## 11. Study Authors Conclusion:

The acute toxicity of SBP-1382-40 MF Formulation 1 to Daphnia magna:

- 48-hour LC<sub>50</sub> = 0.11 mg/l      95% C.I. = 0.095 - 0.13 mg/l
- No observed effect level = 0.032 mg/l after 48 hours

3

12. Reviewers Discussion and Interpretation of the Study:

a. Test Procedures - The following discrepancies were noted in the study:

- The photodegradation rate of Resmethrin is less than four hours when exposed to laboratory lighting (EPA Registration Standard, 28 July 1988). Therefore, in order to determine the 48-hour LC<sub>50</sub> of SBP-1382-40MF Formulation 1 to Daphnia magna with a constant concentration level of Resmethrin 40% a.i. in the test solutions throughout the entire 48 hours, it would be recommended that the test be carried out in one of two possible ways: a flow-through test with measured concentrations or a static test under dark conditions.
- Table 3 reports the second highest nominal concentration to be 0.56 mg/l. It should be 0.18 mg/l.
- Table 3 reports the second control to be the soil control. It should be the solvent control.
- The 48-hour LC<sub>50</sub> was calculated to be .11 mg/l. EEB calculated the 48-hour LC<sub>50</sub> to be .10 mg/l.

b. Statistical Analysis - EEB computed the LC<sub>50</sub> values for the six doses. The Moving average test calculated:

$$LC_{50} = 0.10 \text{ mg/l} \quad 95\% \text{ C.I.} = 0.09 - 0.12 \text{ mg/l}$$

c. Discussion / Results - A 48-hour LC<sub>50</sub> value of 0.10 mg/l indicates that Resmethrin SBP-1382-40MF Formulation 1 is very highly toxic to freshwater invertebrates.

d. Adequacy of Study

- 1) Classification: Core
- 2) Rationale: The study fulfills EPA's guideline requirements.
- 3) Repairability: N/A

13. Completion of One-Liner:

The One-liner was completed on 11-03-89.

4

Resmethrin

CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
.32	20	20	100	9.536742E-05
.18	20	20	100	9.536742E-05
.1	20	5	25	2.069473
.056	20	1	5	2.002716E-03
.032	20	0	0	9.536742E-05
.018	20	0	0	9.536742E-05

THE BINOMIAL TEST SHOWS THAT .1 AND .18 CAN BE USED AS STATISTICALLY SOUND CONSERVATIVE 95 PERCENT CONFIDENCE LIMITS, BECAUSE THE ACTUAL CONFIDENCE LEVEL ASSOCIATED WITH THESE LIMITS IS GREATER THAN 95 PERCENT.

AN APPROXIMATE LC50 FOR THIS SET OF DATA IS .1171309

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	6	LC50	95 PERCENT CONFIDENCE LIMITS
4	4.918725E-02	.1045023	.0878982
.1247687			

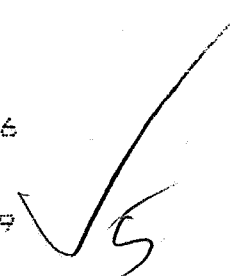
RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	3	H
GOODNESS OF FIT PROBABILITY	7	.1746076
.2778267		1

SLOPE = 7.835709  
 95 PERCENT CONFIDENCE LIMITS = 4.561455 AND 11.10596

LC50 = .109673  
 95 PERCENT CONFIDENCE LIMITS = 9.454066E-02 AND .1273499

LC10 = 7.551286E-02  
 95 PERCENT CONFIDENCE LIMITS = 5.493493E-02 AND .0897231



---

Page 6 is not included in this copy.

Pages \_\_\_ through \_\_\_ are not included in this copy.

---

The material not included contains the following type of information:

- Identity of product inert ingredients.
- Identity of product inert impurities.
- Description of the product manufacturing process.
- Description of quality control procedures.
- Identity of the source of product ingredients.
- Sales or other commercial/financial information.
- A draft product label.
- The product confidential statement of formula.
- Information about a pending registration action.
- FIFRA registration data.
- The document is a duplicate of page(s) \_\_\_\_\_.
- The document is not responsive to the request.

---

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

---