9-12-91

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REVIEW NO.

EEB REVIEW

DATE IN: 07-11-91 OUT:

CASE # : 816452 REREG CASE #: 2605
SUBMISSION # : S398103 LIST B
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DATE OF SUBMISSION 06-24-91

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SRRD/RD REQUESTED COMPLETION DATE 10-22-91

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SRRD/RD **ACTION** CODE/TYPE OF REVIEW 627 - Generic Data Sub

MRID #(S) 418912-07

DP TYPE 102 - Phase V Review

PRODUCT MANAGER, NO. C. Rice (52)

PRODUCT NAME(S) Sodium acifluorfen

TYPE PRODUCT F R I N H D Herbicide

COMPANY NAME BASF Corp.

SUBMISSION PURPOSE Review oyster shell deposition

INCLUDE USE(S) study

COMMON CHEMICAL NAME Sodium acifluorfen

DATA EVALUATION REPORT

1. Chemical: Acifluorfen-sodium

2. Test Material: 43.9 % a.i.
amber, viscous liquid

3. Study Type: Mollusc 96-hour flow through shell deposition

4. Study Identification: Dionne, Emily, Holohan, Marlene, T. Shepherd, Susan, P., and Atella, Michael D. Acifluorfen-sodium (BAS 9048 H) Acute Toxicity of Acifluorfen-sodium to Eastern Oysters (Crassostrea virginica) under flow through conditions. Study performed by Springborn Bionomics, Inc. 790 Main Street, Wareham, Massachusetts 02571 in March 1986 for BASF Corporation, 2505 Meridian Parkway, Durham, NC 27713. MRID No. 418912-07. SLI Report # 91-4-3736. DP Barcode 165549.

5. Reviewed By:
Heather N. Mansfield, Zoologist
Ecological Effects Branch
Environmental Fate and Effects Division
Signature: Heather Mansfield
Date: 9/12/91

6. Approved by:
for Norman J. Cook, Head, Section 2
Ecological effects Branch
Environmental Fate and Effects Division
Signature: Allen W. Vaughan
Date: 9.12.91

7. Conclusions: This study has been reviewed and has been found to be scientifically sound, It does not, however, fulfill the requirements for a mollusc shell deposition test as the raw data was not provided.

The reported results indicate that Acifluorfen-sodium (BAS 9048 H) with 43.9 % active ingredient is practically non-toxic to the Eastern oyster. It is assumed that the tested substance is the formulated product, although this is not specifically stated by the study author. The testing of the formulated product, rather than technical, is acceptable for this compound (see EEB memo dated August 30, 1983).

The EC_{50} is 110 ppm, with a confidence interval of 69-170 ppm.

The NOEC is 43 ppm.

8. Recommendations: EEB needs the raw data on mortality and shell deposition of oysters at all test concentrations in order to do a complete evaluation of this study.

9. Background: This study was reviewed as a part of the reregistration of Acifluorfen-sodium.

10. Discussion of individual studies: N/A

11. Materials and Methods:

Test Material: Acifluorfen-sodium (BAS 9048 H)
Test Organism: Eastern Oyster
Source: Aquaculture Research Corporation, Dennis Massachusetts--reared in natural flowing seawater from Massachusetts Bay
Size (mean valve height): 35 ± 3mm

Acclimation: 48 hours
Oysters were held in a wooden, epoxy-painted tray through which sea water was continuously pumped. The oysters were examined to confirm that no parasites were present and checked to make sure that they were reproductively immature.
Feeding: Isochrysis galbana and Tetraselmis maculata

Container: Glass aquaria 60 x 30 x 30 cm
Test Solution Volume: ≈ 18 L
Test dilution water: Unfiltered seawater from Cape Cod Canal, Bourne, Massachusetts (originating either from Buzzards Bay or from Massachusetts Bay).
Preparation of solution: 263.42 mg A.I./L stock solution was made by dissolving ≈ 904 g (395.13 g A.I.) Acifluorfen-sodium (BAS 9048 H) in 1500 mL distilled water. 0.1993 mL/min of this solution was then mixed with .375 L dilution water.
Nominal concentrations: 140, 84, 50, 30, and 18 ppm.
Concentration: Measured day 0 and day 4
Salinity: 31 ppt
Temperature: 20 ±2°C
Photoperiod: 16:8 light (Vita-Lite): dark
Flow speed (test solution to each aquarium): 75 mL/min
Flow speed (recirculating test solution): 1.75 L/min
Aeration: No

Control(s): Unfiltered sea water
Replicates: 2 per treatment level
Organisms per treatment level: 20 per replicate
Feeding: Before and during the study, oysters were fed algae (Isochrysis galbana and Tetraselmis maculata) such that the density was 10^5 cells/mL.

3

Organism preparation: 24 hrs. before test initiation, 3-5 mm of peripheral shell growth was ground off of each oyster. Immediately before test initiation, the shell edge was buffed. At test start, oysters were spaced equally and situated with their valve openings toward the flow of the circulator tube.

12. Reported Results:

DO : 84-103 %
pH : 7.8 - 8.1 (table 1, attached).

Mean measured concentrations of Acifluorfen-sodium were 110, 71, 43, 26, and 16 ppm (table 2, attached).

13 % mortality was observed among oysters of the 110 ppm group. Neither mortality or sublethal effects were seen among oysters at of the other treatment levels. Oysters in the 110 and 71 ppm groups had shell growth reduced by 57 and 21 % respectively. This reduction is statistically significant. In the 43, 26, and 16 ppm groups, shell growth was reduced by 12, 7.1, and 0 % respectively (table 3, attached).

13. Study Author's Conclusions/Quality Assurance Measures:

96 hour EC_{50}: 110 ppm (Calculated by linear regression)
95% Confidence Limits: 69-170 ppm.
Slope: 3.4
NOEC: < 43 ppm (Williams' Test)

Acifluorfen-sodium is practically non-toxic to Eastern oysters (Crassostrea virginica).

A GLP statement complying with FIFR, 40 CFR part 160 was signed by the study director, Ms. Emily Dionne on May 1, 1991. A quality assurance statement was included and a quality assurance audit was performed to ensure that the study was conducted in accordance with Good Laboratory Practice regulations and the protocols for individual laboratory studies.

14. Reviewer's Discussion:

A. **Test Procedure**-The test procedures were in accordance with Subdivision E and SEP guidelines with the following exceptions:

Raw data was not submitted.

Temperature was monitored daily, not hourly as suggested by SEP guidelines.

B. **Statistical Analysis** No statistical analysis was performed as the raw data on shell growth was not submitted.

C. **Discussion of Results** From visual inspection, the EC_{50} was over 100 ppm. However, neither a precise EC_{50} nor NOEC could be determined as no raw data was submitted.

Measuring the temperature daily, rather than hourly, is not thought to have affected the results of the study.

The results indicate that Acifluorfen-sodium is practically nontoxic to the Eastern oyster.

REPAIRABLE-Yes, if the raw data is submitted.

D. **Category of Study**-Supplemental, Acifluorfen-sodium (BAS 9048 H)

15. Completion of One Liner: Not completed

16. CBI Attachments: N/A

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RIN 7330-94

SODIUM ACIFLUROFEN REVIEW

Page____ is not included in this copy.

Pages 6 through 8 are not included.

The material not included contains the following type of information:

____ Identity of product inert ingredients.

____ Identity of product 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.

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✓ FIFRA registration data.

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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.
