

~~125301~~
128801

Shaughnessy No.: 125301

Date Out of EAB: JUL 28 1985

To: A. Heyward
Product Manager 17
Registration Division (TS-767)

From: Samuel Creeger, Chief 
Review Section #1
Exposure Assessment Branch
Hazard Evaluation Division (TS-769)

Attached, please find the EAB review of...

Reg./File # : 35977-U
Chemical Name: Fenoxycarb
Type Product : Insecticide
Product Name : LOGIC
Company Name : MAAG Agrochemicals
Purpose : Submission of fish accumulation study to support use
as fire ant insecticide

Action Code(s): 121

EAB #(s) : 5581

Date Received: 5/2/85

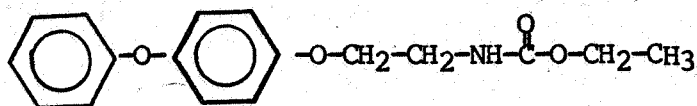
TAIS Code: _____

Date Completed: JUL 28 1985

Total Reviewing Time: 2.0 days

Deferrals to: _____ Ecological Effects Branch
_____ Residue Chemistry Branch
_____ Toxicology Branch

1.a CHEMICAL:



RO 13-5223/024

Fenoxycarb, LOGIC™

1.b Physical Properties: Reported earlier in earlier reports.

2. TEST MATERIAL:

Ethyl [2-(2-phenoxophenoxy-1,4-¹⁴C)ethyl] carbamate

3. STUDY/ACTION TYPE:

Submission of fish bioaccumulation studies to support use.

4. STUDY IDENTIFICATION:

- o Accumulation and Elimination of ¹⁴C-RO 13-5223/024 by Bluegill Sunfish in a Dynamic Flow Through System.
- o Nature of the Radioactive Residues in ¹⁴C-RO 13-5223/024-Treated Bluegill Sunfish.

5. REVIEWED BY:

Akiva D. Abramovitch, Ph.D.
Chemist
Environmental Chemistry Review Section 1/EAB/HED/OPP

Akiva D. Abramovitch
Date: 7/28/85

6. APPROVED BY:

Samuel M. Creeger, Chief
Supervisory Chemist
Environmental Chemistry Review Section 1/EAB/HED/OPP

Samuel M. Creeger
JUL 28 1985
Date: 7/28/85

7. CONCLUSIONS:

The EAB accepted the fish accumulation study in fulfillment of the data requirements. The data submitted indicated that the bioaccumulation factor for RO 13-5223 was 277.6 (whole fish), 138.9 (edibles) and 439.6 (non-edibles) but 99.0, 98.1 and 98.4% of the initially accumulated organic material was eliminated in two weeks of depuration. Most of the residual material (94%) in the edible portion was the parent RO 13-5223. The non-edible portion contained in addition to the parent compound (64%), some polar degradates of which hydroxylated metabolites were positively identified at less than 5%. The other highly polar and water soluble degradates were not identified. Based on the low use rates associated with the proposed fire ant bait use, potential for impact on aquatic systems and accumulation by aquatic organisms is low.

8. RECOMMENDATIONS:

The fish accumulation study was accepted and satisfied the EAB data requirement. A previous summary of the data requirements reviewed in an April 25, 1985 memorandum on the subject of registration standard for Fenoxycarb, was attached to this report.

9. BACKGROUND:

A. Introduction:

Please see the attached April 25, 1985, memorandum and earlier reports.

B. Directions for Use:

As noted above.

10. DISCUSSION OF INDIVIDUAL TESTS OR STUDIES:

10.1 A. Study Identification: Accumulation and Elimination of ^{14}C -RO 13-5223/024 by Bluegill Sunfish in a Dynamic Flow Through System.

The study was conducted by RCC of Itingen, Switzerland-project 034841

B. Materials and Methods:

The study was conducted with a ^{14}C radiolabeled RO 13-5223/024 of a specific radioactivity of 36.06 microCi/mg and 98% radiochemical purity. This material was mixed with unlabeled active ingredient resulting in a specific activity of 0.832 microCi/mg. The flow through system contained three individual water tanks containing 100 liters of water. Two tanks received the test material from a stock solution via a Hamilton dispenser unit and one served as control. The level of active ingredient in the exposure tanks was about 0.27-0.28 mg/l. The treated tanks received 150 fish each and the control tank 50 fish. The fish (average weight of 3 gm) were acclimated for four weeks prior to experimentation and during that period only 0.6% mortality was observed. The temperature was maintained at 20°C (19.5-20.0°C) throughout the experiment. The pH and the temperature, were recorded when samples were taken at days 0, 1, 3, 7, 14, 21 and 28 of the exposure period and days 1, 3, 7, 10 and 14 of the depuration period. The pH range was 7.4-8 and the oxygen concentration averaged 7.4 mg/l. Samples of 15 fish were taken at the specified time intervals. Additional fish (12-30) were taken for future analysis of metabolites. Control fish were taken for analysis at days 0 and 28. The fish samples were separated into edible and non-edible portions and homogenized. Aliquots of the homogenized fish samples were placed in 25 ml glass scintillation vials and 2.0 ml of tissue solubilizer was added and incubated at 50°C for 24 hours. Then 20 ml of scintillation mixture were added and the radioactivity was determined. For control purposes, the radioactivity in various samples was also determined also by combustion. Water samples were extracted with chloroform and analyzed on TLC plates in reference to authentic samples of RO 5223/024 and potential metabolites.

C. Reported Results:

The accumulation in fish reached a plateau in about 7 days and reached values of 77.04 ± 8.38 mg/kg for the whole fish, 38.52 ± 4.8 mg/kg for the edible parts and 121.99 ± 25.6 mg/kg for the non-edible parts.

A bioaccumulation factor of 277.6, 138.9 and 439.6 was obtained for the whole fish, edible and non-edible parts, respectively.

Depuration was fast within the initial 7 days and the residual radioactivity dropped to 1.5, 2.4 and 2.1% of their plateau values for the edible, non-edible and whole fish, respectively. The elimination rate of residual radioactivity can be described by a second order reaction kinetics. Based on the octanol/water partition coefficient, a value of 227, the registrant calculated a BCF value of 69.6 based on $\log P = 4.28$ and the formula $\log BCF = 0.83 \times \log P - 1.71$.

D. Study Author's Conclusions:

The author concluded that the bioaccumulation factors of 277.6 (whole fish), 138.9 (edible) and 439.6 cannot be considered critical since the compound and its metabolites are very efficiently eliminated from the fish with a half life of 2.6, 4.1 and 3.7 hours, respectively and after two weeks of depuration 99.0, 98.1 and 98.4% of the accumulated radioactivity (based on final residues) were eliminated from edibles, non-edibles and whole fish, respectively.

E. Reviewer's Discussions and Interpretation of Study Results:

Based on the 28 day data, BCFs of 163, 572 and 319 were obtained in the edibles, non-edibles and whole fish, respectively. Please see discussion in 10.2 E.

10.2 A. Study Identification: Nature of Radioactive Residues in ^{14}C -RO 13-5223/024-Treated Bluegill Sunfish.

The study was conducted by Dr. P. A. Vonder Muhll of Maag

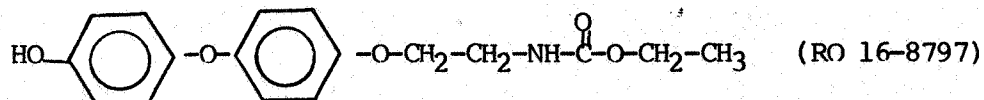
B. Materials and Methods.

This report is a continuation of the previous study. Fish samples that were removed after 21 and 28 days of exposure were separated into edible and non-edible portions and homogenized. Aliquots were combusted to determine the total amount of radioactivity. Other portions were extracted with chloroform in a soxhlet for 24 hr, the chloroform was evaporated to dryness and the residue was then dissolved in hexane (100 ml) and partitioned into acetonitrile (100 ml). Additional extraction was accomplished with methanol/water (3:1)

C. Reported Results:

99.2% of the accumulated radioactivity in the edible sample was extracted with chloroform, the remainder 4.1% with methanol/water (3:1) and unextracted residues (2.1%) were accounted by combustion for a total of 105.5%. 96.0% of the radioactivity in the chloroform extract, was found in the acetonitrile and 5.5% in the hexane for a total of 101.5%.

Analysis of the acetonitrile phase by HPLC indicated that 94.5% of the radioactivity initially accumulated in the edible sample was the parent compound (RO 13-5223). Radioactivity recoveries of 73.7% were found in the chloroform extract, 30.4% in the methanol/water extract and 4.6% by combustion of the non-edible sample. HPLC analysis of the chloroform extract indicated that it contained 63% of the radioactivity initially found in the non-edible portion. The methanol water extract only contained 0.7% of the parent compound and 18.5% of the accumulated radioactive material were fast eluting polar compounds. The major polar degradate identified was RO 16-8797 (3.9%). Other polar degradates were not identified.



D. Study Author's Conclusions:

No additional conclusions to those listed in section 10.2 C.

E. Reviewer's Discussions and Interpretations of Study Results:

The studies (10.1 and 10.2) appeared to be conducted carefully and provide valid scientific data. The reviewer did not find a cause to question the results. The only criticisms are (1) that for added clarity the two studies should have been reported as one study and (2) we disagree with the author's position that the accumulation plateau was reached at 7 days (it appears that accumulation was still occurring when exposure was terminated at 28 days).

11. COMPLETION OF ONE LINER

No data included.

12. CBI APPENDIX

No CBI appendix in this review.

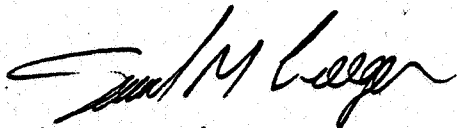
APR 25 1985

MEMORANDUM

SUBJECT: Registration Standard for Fenoxycarb

TO: John Tice
SIS/HED

FROM: Samuel M. Creeger, Chief
Environmental Chemistry Review Section
EAB/HED



Fenoxycarb as a fire ant bait formulation was considered in completing the data tables (attached). According to EAB records, the formulated product is to be broadcast applied to lawns, turf, and other noncrop areas at the rate of 1.0 - 1.25 pounds of product per acre. The formulated product is 1% active ingredient.

Environmental fate data required to support the proposed use are: hydrolysis, photolysis in water, photolysis on soil, aerobic soil metabolism, leaching, field dissipation and fish accumulation. Although photolysis on soil data is not normally required for the subject use pattern, it is being imposed in this case since the pesticide is not soil incorporated and, therefore, will be subjected to sunlight while on the treated, terrestrial surface. Other uses or formulations of fenoxycarb may require additional data.

A summary of the status of the data requirements follows:

HYDROLYSIS - Fenoxycarb is stable to hydrolysis at pHs 3, 7 and 9 and temperatures of 35°C and 50°C. No hydrolysis was detected during 7 - 10 weeks of incubation.

This data requirement is satisfied.

PHOTOLYSIS IN WATER - Fenoxycarb photolyzes in water with a half-life of 5.7 hours. In the presence of acetone (as a photosensitizer), it photolyzed with a half-life of 5.0 hours.

This requirement is only partially satisfied by this study unless the registrant can show that the light source simulated natural sunlight and that the reaction vessels were transparent to wavelengths between 290 and 800 nanometers.

SOIL PHOTOLYSIS - Since the submitted study involved irradiation for only 24 hours and the incident light was not shown to simulate sunlight, the study was found to be unacceptable.

This requirement has not been satisfied.

AEROBIC SOIL METABOLISM - Under laboratory conditions, fenoxycarb will degrade in soil with a half-life of 2 - 3 months. Minor amounts (a total of less than 12%) of two soil degradation products formed and the (inner) benzene ring was mineralized (20% in six months). In this study, a granular formulation was used; degradation did not occur until the active ingredient had migrated from the inert carrier and into the soil. Therefore, fenoxycarb will degrade with a much shorter half-life when it is applied to soil in the pure form.

This data requirement is satisfied.

LEACHING - Column leaching studies indicate fenoxycarb and its soil aged residues have little potential for leaching. Although the studies used about 40% of the required eluate, it is concluded that the results will not be different if the study were to be repeated using the full amount of eluate (i.e., the equivalent of 20 acre inches of water).

An adsorption/desorption study using fenoxycarb was also conducted with four different soils. Freundlich adsorption constants of 18 - 77 were determined and these values support the conclusion of the column study that fenoxycarb has little potential for leaching.

This requirement is satisfied.

FIELD DISSIPATION - When applied at use rates, residues of fenoxycarb will not be detectable after the third day post-application.

This requirement is satisfied.

FISH ACCUMULATION - A flow-through fish accumulation study has not been submitted nor has the registrant requested a waiver from the requirement to do the study.

This requirement is not satisfied.

PENOCALB

Page is not included in this copy.

Pages 8 through 20 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.
 - ☐ 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.
