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Date Out: **APR 1993**

ENVIRONMENTAL FATE AND GROUND WATER BRANCH

Review Action

To: Bruce Sidwell & Mark Wilhite, PMT #53
Reregistration Division (H7508W)

From: Paul J. Mastradone, Chief *PJM*
Environmental Chemistry Review Section #1
Environmental Fate & Ground Water Branch/EFED (H7507C)

Thru: Henry Jacoby, Chief *Henry Jacoby*
Environmental Fate & Ground Water Branch/EFED (H7507C)

Attached, please find the EFGWB review of...

DP Barcode:	D168540, D171847 and D174150		
Common Name:	Oxyfluorfen	Trade name:	Goal, Koltar
Company Name:	Rohm and Haas Company		
ID #:	111601-000707		
Purpose:	Registrant has submitted photodegradation in water and soil, aerobic and anaerobic soil metabolism, mobility (batch equilibrium) and response to previous fish accumulation review.		

Type Product:	Action Code:	EFGWB #(s):	Review Time:
Herbicide	620, 627	91-0947, 92-0276 and 92-0497	20 days

STATUS OF STUDIES IN THIS PACKAGE:

Guideline #	MRID	Status ¹
161-2	92136108	I
161-2	92136109	I
✓ 161-2	42129101	U
✓ 161-3	41999901	I
✓ 162-1	92136110	U
✓ 162-2	92136111	U
✓ 163-1	92136112	U

STATUS OF DATA REQUIREMENTS:

	Status ²
161-2	N
161-3	N
162-1	N
✓ 162-2	N
✓ 163-1	S

4214311

¹Study Status Codes: A=Acceptable U=Upgradeable C=Ancillary I=Invalid.
²Data Requirement Status Codes: S=Satisfied P=Partially satisfied N=Not satisfied R=Reserved.

①

OXYFLUORFEN

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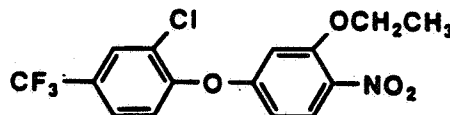
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INTRODUCTION

Oxyfluorfen is a selective herbicide registered for pre- or postemergent control of annual broadleaf and grassy weeds in terrestrial food (field and vegetable, orchard and vineyard) and non-food crops (ornamentals and nursery stock). Oxyfluorfen is not absorbed by roots or foliage, but damages shoots. Single active ingredient formulations include emulsifiable concentrate and granular. Multiple active ingredient formulations include napropamide, glyphosate, oryzaline, paraquat, pronamide, diuron, norflurazon, cyanazine, methazole, and MSMA.

1. CHEMICAL: Common name: Oxyfluorfen.
Chemical name: 2-Chloro-1-(3-ethoxy-4-nitrophenoxy)-4-(trifluoromethyl) benzene.
Trade name(s): Goal, Koltar, RH-2915.

Structure:



Formulations: Emulsifiable concentrate; granular.

Physical/Chemical properties:

Molecular formula: $C_{15}H_{11}ClF_3NO_4$.
Molecular weight: 361.7.
Physical state: Orange crystalline solid.
Melting point: 65-84 °C.
Vapor pressure (25°C): 0.0267 mPa (2×10^{-7} Torr)
Solubility (25°C): 0.116 mg/L water; 725 g/kg acetone;
500-550 g/kg chloroform; 615 g/kg
cyclohexanone; >500 g/kg
dimethylformamide.
Octanol/water: 2.94×10^4 at 25 °C

2. TEST MATERIAL:

Studies 1-6: Active ingredient.
Study 7: Emulsifiable concentrate.

3. STUDY/ACTION TYPE:

Review of photodegradation in water and soil, aerobic and anaerobic soil metabolism, mobility (batch equilibrium) and response to previous fish accumulation review.

4. STUDY IDENTIFICATION:

Kesterson, A.L., B. Lawrence, D.L. King, and L.J. Lawrence. 1989a. Aqueous photolysis of [^{14}C]oxyfluorfen (chlorophenyl ring-labelled) in natural sunlight. PTRL Project No. 259. Report No. 1195. Rohm and Haas Report No. 34-89-54. Unpublished study performed by Pharmacology and Toxicology Research Laboratory, Lexington, KY, and submitted by Rohm and Haas Company, Spring House, PA. (92136109)

Kesterson, A.L., B. Lawrence, D.L. King, and L.J. Lawrence. 1989b. Aqueous photolysis of [^{14}C]oxyfluorfen (nitrophenyl ring-labelled) in natural sunlight. PTRL Project No. 261. Report No. 1194. Rohm and Haas Report No. 34-89-53. Unpublished study performed by Pharmacology and

Toxicology Research Laboratory, Lexington, KY, and submitted by Rohm and Haas Company, Spring House, PA. (92136108)

Korsch, B.H., and T.J. Doran. 1988a. Aerobic soil metabolism of oxyfluorfen. Document No. 1548-87-0092-EF-001. Rohm and Haas Technical Report No. 34C-88-55. Project No. 87-0092. Protocol No. 31P-87-05. Unpublished study performed by Ricerca, Inc., Painesville, OH, and submitted by Rohm and Haas Company, Spring House, PA. (92136110)

Korsch, B.H., and T.J. Doran. 1988b. Anaerobic soil metabolism of oxyfluorfen. Document No. 1668-87-0093-EF-001. Rohm and Haas Technical Report No. 34C-88-61. Project No. 87-0093. Protocol No. 31P-87-54. Unpublished study performed by Ricerca, Inc., Painesville, OH, and submitted by Rohm and Haas Company, Spring House, PA. (92136111)

Reibach, P.H. 1988. Adsorption/desorption of ¹⁴C-oxyfluorfen. Rohm and Haas Technical Report No. 34C-88-64. Unpublished study performed and submitted by Rohm and Haas Company, Spring House, PA. (92136112)

Reibach, P.H. 1990a. Phase 3 summary of MRID 92136108 and 92136109: Oxyfluorfen aqueous photolysis: PTRL studies 259 and 261. Unpublished summary prepared and submitted by Rohm and Haas Company, Spring House, PA. (92136096)

Reibach, P.H. 1990b. Phase 3 summary of MRID 92136110: Oxyfluorfen aerobic soil metabolism: TR No. 34C-88-55. Unpublished summary prepared and submitted by Rohm and Haas Company, Spring House, PA. (92136097)

Reibach, P.H. 1990c. Phase 3 summary of MRID 92136111: Oxyfluorfen anaerobic soil metabolism: TR No. 34C-88-61. Unpublished summary prepared and submitted by Rohm and Haas Company, Spring House, PA. (92136098)

Reibach, P.H. 1990d. Phase 3 summary of MRID 92136112. ^{92136023 in SMART} ¹⁴C-Oxyfluorfen adsorption/desorption: TR No. 34C-88-64. Unpublished summary prepared and submitted by Rohm and Haas Company, Spring House, PA. (92136099) ?

Reibach, P. 1991. Aqueous photolysis of [¹⁴C]oxyfluorfen. Rohm and Haas Report No. 34-91-47. Unpublished study performed by Rohm and Haas Company, Spring House, PA and Xenobiotics Laboratories, Princeton, NJ, and submitted by Rohm and Haas Company, Spring House, PA. (42129101)

Reibach, P. 1991. ¹⁴C-Oxyfluorfen photolysis on soil under natural sunlight. Rohm and Haas Report No. 34-91-46. Unpublished study performed by Rohm and Haas Company, Spring House, PA and Pharmacology and Toxicology Research Laboratory, Richmond, KY, and submitted by Rohm and Haas Company, Spring House, PA. (41999901)

The following report is the registrant's response to EFGWB's review of a previously submitted study:

Lynch, W.T. 1991. Rohm and Haas response to the fish accumulation study¹ (reviewed March 14, 1991, EFGWB # 91-0244, DP Barcode D158921, MRID 96883). Submitted by Rohm and Haas Company, Spring House, PA. (42098303)

The following study cannot be used towards the fulfillment of data requirements at this time because of the allegations concerning the reliability of environmental fate studies conducted by Craven Laboratories, consequently the study was not reviewed:

Reibach, P.H., S. Smith, Jr., and W.J. Zogorski. 1989. Goal herbicide soil dissipation. Rohm and Haas Technical Report No. 34C-88-65. Unpublished study prepared by Rohm and Haas Company, Spring House, PA; Pan-Agricultural Associates, Madera, CA; and Craven Laboratories, Austin, TX; and submitted by Rohm and Haas Company, Spring House, PA. (92136113)

5. REVIEWED BY:

Richard Mahler, Hydrologist
Review Section #1
EFGWB/EFED/OPP

Signature: Richard J. Mahler

Date: APR 5 1993

6. APPROVED BY:

Paul Mastradone, Chief
Review Section 1
EFGWB/EFED/OPP

Signature: Paul J. Mastradone

Date: APR 5 1993

7. CONCLUSION:

The registrant submitted environmental fate studies present no coherent description of the fate of oxyfluorfen in the environment at this time.

Acceptable, supplemental and unacceptable laboratory data indicate that oxyfluorfen is persistent (fastest half-life) and slightly mobile to immobile in soils (K_d s range from 8.5 to 228).

The field dissipation data are of uncertain value and were not reviewed since the laboratory analysis of these studies was performed by Craven Laboratories.

In summary, except for the photolysis in water study which indicates rapid degradation, the laboratory data indicate that oxyfluorfen is a moderately stable to a very persistent compound that does not degrade appreciably and

¹ Fisher, J. D. and W. M. Pierson. March 22, 1990. A residue and metabolism of ¹⁴C-RH 2915 in Bluegill sunfish: TR No. 34-23. Rohm and Haas Company, Spring House, Pennsylvania. MRID 00096883.

does not appear to be very mobile, except perhaps when used on very sandy soils.

7.1 SUMMARY OF STUDIES REVIEWED TO DATE:

The following data summary is derived from studies considered acceptable by EFGWB:

Hydrolysis--161-1

In a hydrolysis study, a concentration of 0.05 ppm oxyfluorfen was stable in aqueous buffered pH 4, 7 and 10 solutions, since >97% of the radioactivity present after 30 days was parent oxyfluorfen. Other than parent, the only compound detected was RH-34670 [(2-chloro-1-(3-hydroxy-4-nitrophenoxy)-4-(trifluoromethyl) benzene] at 1.2-1.7% of the applied radioactivity. *Accepted R.:*

Leaching/adsorption/desorption--163-1

In an unaged column leaching study, oxyfluorfen did not leach below four inches in any soil, except sand, where traces were found at 9 inches. The majority of the radioactivity was detected in the 0-2 inch soil depth. In an aged column leaching study, between 1.35 and 1.85% of the radioactivity was detected in the leachate. Greater than 82% of the radioactivity was detected in the top 2 inches of soil, indicating slight mobility. TLC analysis of the methanol extractable residues was shown to be all parent compound. Approximately 15% of the radioactivity was unaccounted for and was attributed, by the study author, to volatilization.

Confined accumulation in rotational crops--165-1

Crop accumulation studies indicate that ¹⁴C-radioactivity in all non-grain rotated crops and the grain component of wheat was ≤ 0.01 ppm. Residues were only found in the wheat chaff and straw, ranging from 0.01-0.06 ppm. The rotational intervals are 30 days for transplanted crops, 60 days for seeded crops, other than grains, and 10 months for small grains.

Bioaccumulation in fish--165-4

The data indicates that the compound can accumulate in bluegill sunfish, since bioconcentration factors were 450 and 605X in muscle, 3265 and 4360X in viscera and 1075 and 2200X in whole fish. However, rapid loss of the compound occurred out of tissues, since after 14 days of depuration, 86 and 94% elimination of ¹⁴C-residues in the muscle tissue, 83 and 94% elimination in the viscera and 82 and 91% elimination in whole fish.

Drift-field evaluation--202-1

In field drift evaluation studies using lettuce as a bioassay, lettuce plants showed visible symptoms as far as 800 meters downwind from the point of application, but was only quantifiable up to 100 meters.

The following data summary is derived from studies considered supplemental but unacceptable by EFGWB:

Photodegradation in water--161-2

In an aqueous photolysis study, [¹⁴C]oxyfluorfen (1 ppm) degraded with registrant-calculated half-lives of 2 to 7.5 days in sterile pH 7 aqueous buffer solutions (1% acetonitrile), that were irradiated with 12 hours light/dark with a xenon arc lamp at 25 ± 1 °C for 30 days. In contrast, 94% of the radioactivity was identified as [¹⁴C]oxyfluorfen, in the dark controls, after 30 days. The study was not acceptable because radioactivity in the extracts present at up to 48% were not identified. Identification of residues present at concentrations ≥0.01 ppm or 10% is needed to identify the photodegradates formed after incubation of the active ingredient. Failure to identify all significant degradates limits the understanding of the aqueous photolysis under actual use conditions and therefore the environmental fate of oxyfluorfen is unclear. The storage stability of parent and degradates and conditions of storage was not addressed. This information is needed to assess the effects, if any, of storage on samples that were collected but not analyzed immediately.

Aerobic soil metabolism--162-1

Nitrophenyl ring-labeled and chlorophenyl ring-labeled [¹⁴C]oxyfluorfen added to a soil at 8.83-9.64 ppm dissipated aerobically from a sandy loam soil with half-lives of 556-596 days; while the compound dissipated from a clay loam soil with half-lives of 291-294 days. The degradate, RH-34800, was identified in the extracts from the clay loam soil treated with the chlorophenyl ring-labeled compound. The study was not acceptable because up to 11.2% of the applied radioactivity in the extracts was not identified. This data is required in order to understand the metabolism of oxyfluorfen so that dissipation under actual (field) use conditions is clear. 92136110 → 96883, 149203 ^{see} also 42142309?

Anaerobic soil metabolism--162-2

Nitrophenyl ring-labeled [¹⁴C]oxyfluorfen (uniformly labeled; radiochemical purity >93%), at 8.83 ppm, and chlorophenyl ring-labeled [¹⁴C]oxyfluorfen (uniformly labeled; radiochemical purity 96%), at 9.46 ppm, degraded with registrant-calculated half-lives of 603 and 554 days, respectively, in sandy loam soil that was incubated in the dark under aerobic conditions for 30 days and under anaerobic conditions (flooding plus nitrogen atmosphere) for 60 days at 25 ± 1 C. This study is unacceptable because the methodology was not clearly stated; the methods used for the analysis of the water were not reported; actual material balances apparently were not determined for the anaerobically incubated samples; radioactivity in the methanol:water extracts present at up to 9.7% (approximately 0.86 ppm) of the applied was not characterized. Subdivision N guidelines state that degradates present at ≥0.01 ppm should be identified. ^{see} also 42142310?

92136111 → 149203

8

Leaching/adsorption/desorption--163-1

The leaching data indicate that the compound is slightly mobile in sandy soils and immobile in sandy loam, clay loam and silty clay loam soils (K_d 's = 8.5, 62, 99, 228). The study was not acceptable because the effect of chemical binding to the teflon tube on the K_d values was not discussed, and the concentration range was too narrow. *92136112 → 90882 see 4214311? also*

The following data summary is derived from studies considered unacceptable by EFGWB:

Photodegradation in water--161-2

Nitrophenyl ring-labeled and chlorophenyl ring-labeled [14 C]oxyfluorfen added to sterile aqueous solution at about 1 ppm and irradiated with natural sunlight, photodegraded with half-lives of 4-5 days. The study was not acceptable because oxyfluorfen was applied to the test solution at about 10 times its solubility in water and may not have been in solution at all sampling times, material balances were incomplete and the storage stability of residues was not addressed. *(42129101) see 42142307? also*

Photodegradation on soil--161-3

Nitrophenyl ring-labeled and chlorophenyl ring-labeled [14 C]oxyfluorfen added to a sandy loam soil and irradiated by natural sunlight for 30 days degraded with a half-life of 28 days. The study was not acceptable because the soil was autoclaved prior to use. Since several processes occur simultaneously during autoclaving, changes in soil behavior after autoclaving and its influence on soil photolysis cannot be predicted. *(41999901)*

Terrestrial field dissipation--164-1

Two field dissipation studies (MRID 92136113) were submitted to EFGWB for review in which Craven Laboratories performed all laboratory soil analyses. These studies cannot be used towards the fulfillment of data requirements at this time because of the uncertainty concerning the reliability of environmental fate studies conducted by Craven Laboratories. Until the issues surrounding the validity of data generated by Craven Laboratories are resolved, EFGWB does not believe it is appropriate to complete the review of these studies.

7.1.1 ENVIRONMENTAL FATE ASSESSMENT:

The registrant submitted many environmental fate studies in support of the reregistration of oxyfluorfen; however, the studies present no coherent description of the environmental fate of oxyfluorfen at this time. Since available data are insufficient, final environmental fate, ground-water leaching and surface runoff assessments cannot be made; however, some preliminary estimates, based on acceptable, partially acceptable, supplemental and unacceptable data, are summarized below.

7.1.2 ENVIRONMENTAL FATE SUMMARY

At the present time, 5 data requirements are fulfilled and 7 data requirements remain unfulfilled. Based on all the data submitted (acceptable, supplemental and unacceptable) EFGWB cannot, nor did the registrant attempt to identify a route of dissipation of oxyfluorfen in surface soils. Acceptable laboratory data (hydrolysis, leaching/adsorption/desorption², confined accumulation in rotational crops, accumulation in fish and drift-field evaluation), supplemental laboratory data (aqueous photodegradation, aerobic and anaerobic soil metabolism and leaching/adsorption/desorption³), as well as unacceptable laboratory data (aqueous and soil photolysis) appears to indicate that the compound is persistent (hydrolysis, >97% parent after 30 days at pH 4, 7 and 10; aerobic soil metabolism half-lives of 291 and 294 in a clay loam soil and 556 and 596 in a sandy loam soil; and anaerobic soil metabolism, half-lives between 554 and 603 days). Conversely, the compound is readily degraded by sunlight when dissolved in water (half-lives = 2 and 7.5 days), and is probably moderately degraded by sunlight when on soil surfaces (half-life = 28 days). Soil binding and aqueous photodegradation are probably major routes of dissipation.

The leaching data indicate that the compound is slightly mobile in sandy soils and immobile in sandy loam, clay loam and silty clay loam soils (K_d 's = 8.5, 62, 99, 228). In an unaged column leaching study, oxyfluorfen did not leach below four inches in any soil, except sand, where traces were found at 9 inches. The majority of the radioactivity was detected in the 0-2 inch soil depth. In an aged column leaching study, between 1.35 and 1.85% of the radioactivity was detected in the leachate. Greater than 82% of the radioactivity was detected in the top 2 inches of soil, indicating slight mobility of aged degradates.

Crop accumulation studies indicate that ¹⁴C-radioactivity in all non-grain rotated crops and the grain component of wheat was ≤ 0.01 ppm. Residues were only found in the wheat chaff and straw, ranging from 0.01-0.06 ppm. The rotational intervals are 30 days for transplanted crops, 60 days for seeded crops, other than grains, and 10 months for small grains.

Fish accumulation studies indicate that the compound bioconcentrates in bluegill fish, with no significant mortality; and 82 to 94% depurates within 14 days.

² These leaching/adsorption/desorption studies were reviewed previously by EFGWB and found acceptable [EFGWB (EFB) # 3353, June 29, 1983, Accession Numbers 094336, 096882 and 096884]. However, in the Phase IV response, the registrant submitted a new and previously unreviewed study.

³ Leaching/adsorption/desorption studies (Accession Numbers 094336, 096882 and 096884) were submitted in the past and found acceptable [EFGWB (EFB) # 3353, 6/23/89]; however, the registrant has submitted this new study, and it is reviewed in the DER for Study 6.

Of the studies submitted (several were previously reviewed and the balance were new submissions), 5 studies are acceptable and the remainder are either supplemental or unacceptable. Several of the supplemental and unacceptable studies reviewed may be upgradable to acceptable with the submission of additional information or explanation.

EFGWB notes that field dissipation studies were submitted. However, these studies cannot be used towards the fulfillment of data requirements at this time because Craven Laboratories performed the laboratory analysis and the studies were not reviewed. Until the issues surrounding the validity of data generated by Craven Laboratories are resolved, EFGWB does not believe it is appropriate to complete the review of these studies.

7.1.3 ENVIRONMENTAL FATE REQUIREMENTS:

At the present time, five studies completely satisfy the data requirements of 40 CFR part 158.290 and the guidance of Subdivision N for reregistering oxyfluorfen:

161-1--HYDROLYSIS,

163-1--LEACHING/ADSORPTION/DESORPTION,

165-1--CONFINED ACCUMULATION IN ROTATIONAL CROPS,

165-4--ACCUMULATION IN FISH and

202-1--DRIFT-FIELD EVALUATION⁴.

The following studies are still required for reregistration of oxyfluorfen:

161-2--PHOTODEGRADATION IN WATER,

161-3--PHOTODEGRADATION ON SOIL,

162-1--AEROBIC SOIL METABOLISM,

162-2--ANAEROBIC SOIL METABOLISM⁵,

⁴ EFGWB reviewed a spray drift study for oxyfluorfen and found it to be acceptable (MRID 144894; 10/10/84). Upon further review (Memorandum dated 5/1/91 from E. Resek to M. Wilhite) EFGWB concluded that the study remains acceptable and fulfills the data requirement.

⁵ The submitted anaerobic soil metabolism study does not satisfy the data requirements. If the registrant cannot adequately respond to the reviewer's comments and decides to repeat the anaerobic soil metabolism study, EFGWB would prefer that the anaerobic aquatic metabolism study be performed for reasons listed under footnote # 6.

162-3--ANAEROBIC AQUATIC METABOLISM⁶,
164-1--TERRESTRIAL FIELD DISSIPATION and
201-1--DROPLET SIZE SPECTRUM.

The following study is reserved pending results of other specific studies:

164-5--LONG-TERM FIELD DISSIPATION⁷.

The following studies are not required at the present time because the vapor pressure (2.5×10^{-7}) indicates that volatility is not likely to be an important route of dissipation:

161-4--PHOTODEGRADATION IN AIR,
163-2--LABORATORY VOLATILITY and
163-3--FIELD VOLATILITY.

7.2 BIOACCUMULATION IN FISH

In the Phase IV review (EFGWB # 91-0224, 3/14/91) of the fish accumulation study, it was stated that the study as submitted was not acceptable. However, it was noted that it could be made acceptable with the submission of the nominal concentration of test substance used in the study. The registrant submitted the required information and therefore, the fish accumulation study is now acceptable.

The data shows that bioconcentration factors were 450 and 605X in muscle, 3265 and 4360X in viscera and 1075 and 2200X in whole fish. After 14 days of depuration 86 and 94% elimination of ¹⁴C-residues in the muscle tissue, 83 and 94% elimination in the viscera and 82 and 91% elimination in whole fish. Cumulative mortalities for bluegill in the control and treated aquaria were 2 and 1%, respectively.

8. RECOMMENDATIONS:

Inform the registrant of the points identified in the submitted studies that need to be addressed before the studies can be accepted as satisfying

⁶ EFGWB requests this study because the anaerobic aquatic metabolism study provides more information related to patterns of formation and decline of parent and major degradates, half-life, etc., through the use of more frequent sampling intervals and a longer sampling period (generally up to a year). It should be noted that an acceptable anaerobic aquatic metabolism study can substitute for the anaerobic soil metabolism study.

⁷ This study is reserved pending the results of the field dissipation studies.

the data requirements. Specific problems with each study are listed in the individual Data Evaluation Records (DER).

EFGWB believes that photodegradation in water and soil, aerobic and anaerobic soil metabolism, anaerobic aquatic metabolism and terrestrial field dissipation studies are needed to complete the environmental fate assessment of oxyfluorfen.

Photodegradation studies are necessary because they, along with the hydrolysis study, are crucial for assessing abiotic degradation of oxyfluorfen in soil and aquatic environments.

Aerobic and anaerobic metabolism studies are needed to determine the chemical and microbiological rates of parent pesticide and residue degradation in soil/sediment/water systems.

Field dissipation studies are used to assess the rate and route of oxyfluorfen dissipation under actual field use conditions. The results of these studies can be used to determine if additional groundwater monitoring and/or surface water runoff studies are needed.

9. BACKGROUND:

The registrant has submitted environmental fate studies and a response to a previous review for the reregistration of the List B chemical oxyfluorfen.

Oxyfluorfen is a selective herbicide registered for pre- or postemergent control of annual broadleaf and grassy weeds in terrestrial food (field and vegetable, orchard and vineyard) and non-food crops (ornamental and nursery stock). Oxyfluorfen is not absorbed by roots or foliage, but damages shoots. Single active ingredient formulations include emulsifiable concentrate and granular. Multiple active ingredient formulations include napropamide, glyphosate, oryzaline, paraquat, pronamide, diuron, norflurazon, cyanazine, methazole, and MSMA.

10. DISCUSSION OF INDIVIDUAL TESTS OR STUDIES: See attached reviews of studies in the Data Evaluation Records where appropriate.

11. COMPLETION OF ONE-LINER: Updated with data from these studies where appropriate.

12. CBI APPENDIX: No claim of confidentiality is made for any information contained in the studies on the basis of them falling within the scope of FIFRA 10 (d) (1) (A), (B), or (C).

DATA EVALUATION RECORD

STUDY 1

CHEM 111601

Oxyfluorfen

§161-2

FORMULATION--00--ACTIVE INGREDIENT

STUDY ID 92136108

Kesterson, A.L., B. Lawrence, D.L. King, and L.J. Lawrence. 1989b. Aqueous photolysis of [¹⁴C]oxyfluorfen (nitrophenyl ring-labelled) in natural sunlight. PTRL Project No. 261. Report No. 1194. Rohm and Haas Report No. 34-89-53. Unpublished study performed by Pharmacology and Toxicology Research Laboratory, Lexington, KY, and submitted by Rohm and Haas Company, Spring House, PA. MRID 42142307

STUDY ID 92136109

Kesterson, A.L., B. Lawrence, D.L. King, and L.J. Lawrence. 1989a. Aqueous photolysis of [¹⁴C]oxyfluorfen (chlorophenyl ring-labelled) in natural sunlight. PTRL Project No. 259. Report No. 1195. Rohm and Haas Report No. 34-89-54. Unpublished study performed by Pharmacology and Toxicology Research Laboratory, Lexington, KY, and submitted by Rohm and Haas Company, Spring House, PA.

STUDY ID 92136096

Reibach, P.H. 1990a. Phase 3 summary of MRID 92136108 and 92136109: Oxyfluorfen aqueous photolysis: PTRL studies 259 and 261. Unpublished summary prepared and submitted by Rohm and Haas Company, Spring House, PA.

DIRECT REVIEW TIME = 20

REVIEWED BY: L. Mickley TITLE: Staff Scientist

EDITED BY: W. Martin TITLE: Staff Scientist
K. Ferguson Task Leader

APPROVED BY: W. Spangler TITLE: Project Manager

ORG:

TEL:

APPROVED BY: Richard J. Mahler

TITLE: Hydrologist

ORG: EFGWB/EFED/OPP

TEL: 703-305-7991

SIGNATURE:

Richard J. Mahler

CONCLUSIONS:

Degradation - Photodegradation in Water

1. ~~This study cannot be used to fulfill data requirements.~~
2. These data are considered to be of uncertain value and should not be used to predict the environmental fate of oxyfluorfen and its degradates.
3. This study is unacceptable for the following reasons:

oxyfluorfen was not in solution at all sampling intervals; oxyfluorfen was applied to the test solutions at approximately 10 times its solubility in water; and,

the material balances were incomplete; at 20 days posttreatment, the material balances of the irradiated solutions were 77.0-84.3% of the applied.

the storage stability of parent and degradates and conditions of storage of the samples collected was not addressed sufficiently.

4. Because the application rate far exceeded the solubility of oxyfluorfen in water and the material balances were incomplete, the problems with this study cannot be resolved by the submission of additional data. A new study must be submitted.
5. EFGWB notes that in the previously reviewed hydrolysis study (MRID 00096882, EFGWB # 91-0244, reviewed 3/14/91) after 30 days >97% of the applied radioactivity was parent. However, in this study, after 20 days, 69.4% and 82.2% of the applied radioactivity was parent, respectively, for the CPR and NPR-label maintained in the dark. The registrant needs to explain the discrepancy, since the results of the dark controls of the aqueous photolysis study do not support the results of the hydrolysis study, and indicate that oxyfluorfen indeed does hydrolyze. Conversely, in the other aqueous photolysis study submitted (MRID 42129101, DER Study 2), after 30 days in the dark, 93.5% of parent remained.
6. Further details related to the review of this study are noted below under the section listed as "REVIEWER'S COMMENTS" and should be addressed in any response to this review.

METHODOLOGY:

Rate determination experiment: Nitrophenyl or chlorophenyl ring-labeled [¹⁴C]oxyfluorfen (uniformly labeled; radiochemical purities ≥97.9%; specific activities 10.79 mCi/mg and 9.12 mCi/g, respectively; Rohm and Haas), dissolved in acetonitrile, were measured into quartz tubes, then mixed with 10-mL aliquots of filter-

sterilized 0.005 M phosphate buffer solution (pH 7). The final concentrations of nitrophenyl and chlorophenyl ring-labeled [¹⁴C]oxyfluorfen were 0.98 and 1.47 ppm, respectively, and of acetonitrile in the solutions was 1% by volume. A portion of each set of tubes was wrapped in aluminum foil to serve as dark controls. Both the irradiated and dark control tubes were immersed at a 30 degree angle with respect to the horizontal in deionized water inside plexiglass tanks (each 4 x 6 feet; 12 tubes/tank). The samples were exposed to natural sunlight for 20 days in January and February 1989, in Lexington, Kentucky (38.05 N, 84.30 W); the average daily light energy was 3.4-4.4 W-minute/cm² (Table III). The intensity of the sunlight was measured using a photodetector equipped with a probe located "near" the irradiation apparatus. The temperature of the solutions was maintained at 22.7-26.9 C by circulating heated water through the plexiglass tanks. In order to trap volatiles, air was drawn through each sample tube in series, then through tubes containing ethylene glycol and 10% NaOH trapping solutions (Figure 2). Duplicate samples were collected for analysis at 0, 4, 8, 12, 15, 18, and 20 days posttreatment. At each sampling interval, the pH of each test solution was measured and the volatile trapping solutions were replaced.

Ethyl acetate was added to the test solutions, and the mixture was transferred to centrifuge tubes. The empty sample tubes were then rinsed with additional ethyl acetate, and the rinses were combined with the appropriate test solution. The mixture was shaken, then centrifuged, and the aqueous and organic fractions were separated. Aliquots of both phases were analyzed by LSC. The ethyl acetate extracts were concentrated by rotary evaporation, and both the ethyl acetate concentrates and the aqueous fractions were stored at -20 C for up to 24 hours prior to analysis. The photolysis tubes, which had been rinsed with ethyl acetate, were then rinsed with scintillation cocktail and the rinsate was analyzed by LSC.

On the basis of the LSC analyses, the ethyl acetate-extracted samples (aqueous fraction) containing >10% of the applied radioactivity were thawed, acidified to pH 1.5 with phosphoric acid, and again partitioned with ethyl acetate. Aliquots of both phases were analyzed by LSC. Then, the ethyl acetate extracts were concentrated using either rotary evaporation (nitrophenyl label) or under nitrogen (chlorophenyl label) and stored frozen (-20 C) until analysis using HPLC. The nitrophenyl ring-labeled treatments were stored for up to 5 days; the chlorophenyl ring-labeled treatments were stored for up to 16 days. The extracted aqueous solutions were also stored frozen (length of storage not reported).

Aliquots of the ethyl acetate extracts were analyzed by reverse phase HPLC using a Supelco LC-18 column eluted with a linear gradient of methanol:phosphate buffer (pH 2.5); the initial extract from the immediate posttreatment sampling was eluted with methanol:phosphate buffer (pH 2.5):water. The columns were equipped with a UV (254 nm) detector; fractions of the eluate were collected and analyzed by LSC.

Unlabeled oxyfluorfen reference standards were chromatographed with the extracts.

Additional aliquots of the initial ethyl acetate extracts for both the irradiated and dark control samples were analyzed by TLC on silica gel plates developed in hexane:benzene (1:3). Unlabeled reference standards of oxyfluorfen, RH-4800, 3-chloro-4-hydroxy benzoic acid, RH-4670, RH-5298, and RH-5451 were cochromatographed with the samples and visualized under UV light. [¹⁴C]Residues were located using autoradiography; the radioactive areas were scraped from the plate and analyzed by LSC. In an effort to identify degradates that remained at the origin of the TLC plates, the initial ethyl acetate extracts from the irradiated, 20-day posttreatment samples were analyzed by TLC on silica gel plates developed with acetone:toluene:acetic acid (30:70:2). Reference standards were visualized under UV light; [¹⁴C]compounds were located using autoradiography and identified by comparison to the standards.

Aliquots of the trapping solutions were analyzed by LSC.

Degradate characterization experiment: In an attempt to identify unknown photoproducts, additional test solutions containing nitrophenyl or chlorophenyl ring-labeled [¹⁴C]oxyfluorfen at 1.03 or 1.0 ppm, respectively, were prepared as previously described, then irradiated for 20 (chlorophenyl ring) or 26 days (nitrophenyl ring). To confirm the application rate, a single tube was collected immediately posttreatment and partitioned once with ethyl acetate. At 20 or 26 days, tubes containing similar solutions were pooled, and the pooled samples were extracted with ethyl acetate. Aliquots of the ethyl acetate extracts and the extracted aqueous solutions were analyzed by LSC. The extract of the chlorophenyl ring-labeled [¹⁴C]oxyfluorfen solution was concentrated prior to further analysis. The solution extracts and the ethyl acetate-extracted solutions were stored at -20 C for an unspecified period. Then, aliquots of the ethyl acetate extracts were analyzed by TLC on silica gel plates developed in acetone:toluene:acetic acid (30:70:2). Aliquots of the ethyl acetate-extracted solutions were analyzed by TLC on silica gel plates developed in ethyl acetate:ethanol:ammonium hydroxide:water (40:40:2:4). The radioactive areas on the plates were located by autoradiography and identified by comparison to cochromatographed standards.

DATA SUMMARY:

Nitrophenyl and chlorophenyl ring-labeled [¹⁴C]oxyfluorfen (uniformly labeled; radiochemical purities $\geq 97.9\%$), at approximately 1 ppm, photodegraded with a half-life of 4-5 days in sterile aqueous solutions that were irradiated with natural sunlight (average daily light energy 3.4-4.4 W-minute/cm²) at 22.7-26.9 C in Kentucky during January and February 1989. No degradates were identified in either test solution. The pH of the test solutions in all samples ranged from 7.0-7.2 throughout the study period.

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Nitrophenyl ring-labeled [¹⁴C]oxyfluorfen: Nitrophenyl ring-labeled [¹⁴C]oxyfluorfen (radiochemical purity 99.0%), at 0.98 ppm, photodegraded with a registrant-calculated half-life of 5.4 days in sterile pH 7 aqueous buffered solutions that were irradiated with natural sunlight for 20 days. In the irradiated samples, parent oxyfluorfen was 95.2-95.6% of the applied radioactivity immediately posttreatment, 51.6-60.3% at 4 days, 13.7-22.0% at 12 days, and 9.5-10.4% at 20 days (Table VIA). In the pre-acidification ethyl acetate extracts from the irradiated solutions, nonpolar unidentified [¹⁴C]residues were a maximum of 15.3-16.8% of the applied at 8 days, and were 6.3-7.4% at 20 days; polar [¹⁴C]residues (residues remaining at the TLC origin) were a maximum of 37.2-41.3% at 15 and 20 days. Nonpolar unidentified [¹⁴C]residues in the post-acidification ethyl acetate extract were a maximum of 14.3-23.8% of the applied at 18 days posttreatment. Unextracted [¹⁴C]residues were 3.9-8.0% of the applied. Carbon dioxide totaled 4.5% of the applied radioactivity at 18 and 20 days posttreatment; no [¹⁴C]residues were detected in the ethylene glycol traps (Table IVA). In the dark controls, [¹⁴C]oxyfluorfen decreased from 92.5% of the applied immediately posttreatment to 82.2% at 20 days; a registrant-calculated half-life of 81.9 days was determined (Table VIA). Material balances of the irradiated samples were 96.1-97.0% of the applied immediately posttreatment and 77.0-84.3% at 20 days; material balances of the dark control samples ranged from 43.9 to 99.7 of the applied with no discernable pattern (Table IVA).

In the ethyl acetate extract of the 26-day irradiated "batch samples" used for degradate identification, oxyfluorfen was 13.7% of the recovered radioactivity, radioactivity remaining at the origin of the TLC plate was 43.6%, and radioactivity in other individual zones was 0-12.1% (Table IXA). In the aqueous fraction of this sample, radioactivity remaining at the origin was 44.5% of the recovered and the radioactivity in individual zones was 1.2-10.0% (Table XIIA).

Chlorophenyl ring-labeled oxyfluorfen: Chlorophenyl ring-labeled [¹⁴C]oxyfluorfen, at 1.47 ppm, photodegraded with a registrant-calculated half-life of 3.7 days in sterile pH 7 aqueous buffered solutions that were irradiated with natural sunlight for 20 days. In the irradiated samples, parent oxyfluorfen was 94.2-95.8% of the applied radioactivity immediately posttreatment, 29.1-37.2% at 4 and 8 days, and 1.3-4.2% at 20 days (Table VIB). In the pre-acidification ethyl acetate extracts from the irradiated solutions, nonpolar unidentified [¹⁴C]residues were a maximum of 19.7% of the applied at 4 days, and were 10.6-13.0% at 20 days; polar [¹⁴C]residues (residues remaining at the TLC origin) were a maximum of 30.8-33.5% at 12 days, and were 19.9-22.6% at 20 days. Nonpolar unidentified [¹⁴C]residues in the post-acidification ethyl acetate extract were a maximum of 27.2-30.1% of the applied at 20 days posttreatment. Unextracted [¹⁴C]residues were 1.8-13.7% of the applied. Carbon dioxide totaled 4.5% of the applied radioactivity at 18 and 20 days posttreatment; no [¹⁴C]residues were detected in the ethylene glycol traps (Table IVB). In the dark controls,

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[¹⁴C]oxyfluorfen was 92.7% of the applied radioactivity immediately posttreatment and 63.7-75.1% at 20 days; the registrant-calculated half-life was 70.9 days (Table VIB). Material balances of the irradiated samples were 98.9-101.3% of the applied immediately posttreatment and 82.0-83.2% at 20 days; material balances of the dark control samples were 97.7% of the applied immediately posttreatment and 72.6-84.3% at 20 days (Table IVB).

In the ethyl acetate extract of the 20-day irradiated "batch samples" used for degradate identification, oxyfluorfen was 17.5% of the recovered radioactivity, radioactivity remaining at the origin of the TLC plate was 7.8%, and the radioactivity in other individual zones was 0.1-8.8% (Table IXB). In the aqueous fraction of this sample, radioactivity remaining at the origin was 7.2% of the recovered and the radioactivity in individual zones was 1.1-16.2% (Table XIIB).

REVIEWER'S COMMENTS:

1. The test material was not in solution at all sampling intervals. The study was conducted at oxyfluorfen concentrations of 0.98-1.47 ppm; however, the aqueous solubility of oxyfluorfen was reported to be 0.116 ppm.
2. The material balances were incomplete; at 20 days posttreatment, the material balances of the irradiated samples (nitrophenyl ring-label) were 77.0-84.3% of the applied.
3. The sampling intervals were inadequate to accurately establish the half-life of the test substance for the portion of the study conducted with chlorophenyl ring-labeled [¹⁴C]oxyfluorfen. Approximately 63% of the test substance degraded (from an average of 95.0% to 32.2% of the applied) between the immediate and the 4 days posttreatment sampling intervals.
4. The analytical procedures were inadequate to completely separate the degradates in the extracts. The study authors stated that the major degradates in the irradiated samples remained at the TLC origin and attempts were made to refine the TLC system using different development solutions. The study authors reported (MRID 92136109) that "In an effort to characterize the unknown polar products, samples were repeatedly chromatographed until there was not enough radiocarbon to detect chromatographically. The investigators realize the value of chromatographing certain samples in a more polar system." When the ethyl acetate extracts from the "batch" (degradate identification) experiment conducted with nitrophenyl labeled oxyfluorfen were analyzed using the more polar TLC system, up to 16 zones of interest were detected. Analysis by HPLC of selected aqueous fractions of the chlorophenyl ring labeled oxyfluorfen showed that a "multitude of diverse polar materials" were present; it was reported that none of these compounds were $\geq 10\%$ of the applied. The registrant reported that "The Study Sponsor has discussed plans with PTRL to generate new samples of Days 4, 8, and 12 irradiated samples

for this purpose." No further information was reported regarding this additional characterization. Subdivision N guidelines require that degradates present at $\geq 10\%$ of the applied be characterized.

5. The study authors reported that the day 4 irradiated sample #2 of the test solution treated with chlorophenyl ring-labeled [¹⁴C]oxyfluorfen was diluted with water and that "radiocarbon recovery data would cause misleading quantitative characterization results"; therefore, only one sample was available for analysis. Likewise, the recovery of day 20 dark control sample #2 of the test solution treated with nitrophenyl ring-labeled oxyfluorfen was not reported; the authors stated that "This sample's values were considered to be outliers. Values were omitted because radiocarbon recovery data would cause misleading quantitative characterization."
6. If the samples were collected and stored before analysis, as appears to have occurred in this study, then a storage stability study is required in order to assess the effects of storage on the samples. Furthermore, details of the storage conditions should be elucidated.

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RIN 0637-00

EFED Review - Oxyfluorfen

Page is not included in this copy.

Pages 21 through 51 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.

DATA EVALUATION RECORD

STUDY 2

CHEM 111601

Oxyfluorfen

S161-2

FORMULATION--00--ACTIVE INGREDIENT

STUDY ID 42129101

Reibach, P. 1991. Aqueous photolysis of [¹⁴C]oxyfluorfen. Rohm and Haas Report No. 34-91-47. Unpublished study performed by Rohm and Haas Company, Spring House, PA and Xenobiotics Laboratories, Princeton, NJ, and submitted by Rohm and Haas Company, Spring House, PA.

DIRECT REVIEW TIME = 5

REVIEWED BY: Richard J. Mahler, Hydrologist
Environmental Chemistry Review Section 1, EFGWB

SIGNATURE: Richard J. Mahler

DATE: 5 APR 1993

APPROVED BY: Paul J. Mastradone, Chief
Environmental Chemistry Review Section 1, EFGWB

SIGNATURE: Paul J. Mastradone

DATE: 5 APR 1993

CONCLUSIONS:

Degradation - Photodegradation in Water

1. This study is scientifically valid and provides supplemental information that shows oxyfluorfen to photodegrade in water with a registrant's calculated half-life between 2-3 days.

Although the study was conducted for 30 days, the registrant used only data from the first seven days to determine the half-lives "due to the relatively rapid decline of oxyfluorfen..." EFGWB recalculated the half-lives using all the data. The results indicated half-lives of 6.27 and 7.56 days, respectively, for the CPR- and NPR-labeled samples.

2. ~~The study provides only limited information because:~~

radioactivity in the extracts present at up to approximately 48% was not characterized, and

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the storage stability of parent and degradates and conditions of storage of the samples collected was not addressed.

3. In order for this study to fulfill the aqueous photolysis data requirement, the registrant should characterize the extracted radioactivity and identify any degradates present at $\geq 10\%$ of the applied radioactivity, and address the comments related to storage stability.
4. Furthermore, the registrant needs to explain the discrepancy between this aqueous photolysis study and the previous aqueous photolysis study (MRID 92136108, DER Study 1) since in this study, after 30 days in the dark, 93.5% of parent remained; while in Study 1, after 20 days, 69.4% and 82.2% of the applied radioactivity was parent.
5. Further details related to the review of this study are noted below under the section listed as "REVIEWER'S COMMENTS" and should be addressed in any response to this review.

METHODOLOGY:

Oxyfluorfen or 2-chloro-1-(3-ethoxy-4-nitrophenol)-4-(trifluoromethyl) benzene labeled with carbon-14 at two different positions of the molecule (chlorophenyl ring (CPR), specific activity 4.56 mCi/g, radiopurity 97.66% or nitrophenyl ring (NPR), specific activity 5.38 mCi/g, radiopurity 97.50%) was used in the study. In addition to carbon-14, the CPR ring also contained carbon-13. For half-life determinations CPR- or NPR-ring labeled oxyfluorfen was dissolved in 0.01M sodium phosphate buffer, pH 7.0 at a concentration of 1 ppm and placed into duplicate tubes. In addition, four tubes were prepared and wrapped in foil as dark controls. Four tubes were also prepared with 40 ml of solution at 3 ppm radiolabeled CPR and NPR oxyfluorfen to have sufficient material for identification of degradates. All tubes were sealed and placed into sample chambers (Figure 3) and maintained at a constant temperature of 25.0 °C for the 12-hour light/dark irradiation cycles. Duplicate samples were collected at 0, 1, 2, 3, 7, 14, 17 and 30 days post treatment. At each sampling time, the sample container headspace was purged with CO₂ free air through polyurethane plugs to collect volatile organic materials, a 0.01N KOH trap for any ¹⁴CO₂ and 0.1M H₂SO₄ to trap any volatile basic molecules. The irradiated samples were extracted (Figure 4) with methylene chloride and the extracts analyzed for total radioactivity, oxyfluorfen and degradation products by LSC, TLC and HPLC, respectively.

The xenon arc lamp used in the study was equipped with a UV filter to filter out wavelengths of <290 nm. The spectral distribution of the output of this lamp was determined before and at 15 and 30 days after the start of the experiment. A spectroradiometer was used to measure spectral distribution (Figure 1). The average light flux in the wavelength range of 330-800 nm was used for comparison. The average light flux for the xenon lamp was measured to be about 150 watts/M². The light flux of natural sunlight, in the same spectral range measured on 6/13/90 and 8/7/90, is shown in Figure 2.

The half-life of oxyfluorfen was calculated from a plot of the log of percentage of oxyfluorfen remaining versus time. From this plot, a linear regression was determined, and the half-life was derived from its slope using the following first-order kinetic reaction equation:

$$T_{1/2} = \log(2)/K, \text{ where } \log(2) = 0.301.$$

The calculation of the half-life was carried through 7 days, due to the rapid degradation rate of the parent compound.

DATA SUMMARY:

Oxyfluorfen in pH 7 aqueous solutions at 1 ppm, under simulated sunlight conditions, degraded with half-lives of 3.0 and 2.34 days in the CPR- and NPR-labeled samples, respectively (Table XVIII and Figures 33 and 34).

The average recoveries of the irradiated samples for CPR- (overall recovery, 95.5%) and NPR-labelled samples (overall recovery, 92.5%) ranged from 83.3 to 106.5% and 76.2 to 103.5%, respectively (Summary Table and Tables VI and VIII). Dark control samples had an average recovery of 94.2 and 99.2% for the CPR- and NPR-labeled samples, respectively.

After 30 days the combined volatile traps were found to contain only 1.3% and 0.74% of the applied radioactivity in the NPR and CPR samples, respectively.

Methylene Chloride Fraction:

Analysis (Summary Table) of the methylene chloride fraction from the CPR-labeled samples showed that parent was 102.4% of applied radioactivity at day-0, and then decreased to 18.2% and 2.9% of applied by day 7 and day 30, respectively. The methylene fraction from the NPR-labeled samples showed a similar pattern of decline. At day 0, 98.9 % of the applied radioactivity was still parent, and then it decreased to 11.8 and 5.1% on days 7 and 30, respectively. The parent concentration in the dark control samples remained stable throughout the study for both CPR- and NPR-labeled samples, where 93.6% of the applied radioactivity was identified as parent after 30 days.

Six photodegradates were observed by TLC throughout the sampling intervals in the methylene chloride fraction (Table XIV). A major degradate, R6, was found at or near the origin ($R_f = 0.03$). This fraction increased up to 31.55% of applied on day 7 and then decreased to 7.31% of applied on Day 30 for the CPR-label. The NPR-label showed a similar pattern, but increased more significantly than the CPR-labeled samples. For example, at Day 7, R6 accounted for 48.23% of the recovered radioactivity, while by day 30 this metabolite had decreased to 20.25%.

Two other degradates, designated R3 and R4 were observed in both CPR and NPR-labeled samples. For the CPR-label, R3 increased to a maximum of 7.62% at Day 2 and then decreased to 2.26% of applied at Day 30. R4 increased to 10.12% at Day 7 and then decreased to <1% of applied by Day 30. For the

NPR-label, R3 increased to 8.61% at Day 3 and then decreased to 4.05% by Day 30; while R4 reached a maximum of 4.37% by Day 7 and decreased to 0.5% by Day 30.

Another degradate in the NPR-labeled samples, designated R5, increased to 5.75% of the applied by Day 30; while in the CPR-labeled samples R5 peaked at 2.76% at day 17 and the decreased to 1.91% by Day 30.

Two other degradates, designated R1 and R2 accounted for no more than 2.3% of the applied radioactivity at any sampling day.

Several degradates were also identified by irradiation of 3 ppm of oxyfluorfen (Figure 2). In addition to parent oxyfluorfen, the following degradates were identified: RH-34800, RH-34670, RH-45469, RH-34860, degradate MW 180, degradate MW 327 and degradate MW 332.

In the dark control samples, after 30 days, approximately 94% of the radioactivity was identified as parent oxyfluorfen.

Aqueous Fraction:

About 11 to 24 different photodegradation products were detected in the Day-1 and Day-2 fraction. At Day-1, the most abundant product in the aqueous fraction was parent compound which accounted for about 2.14% of the total radioactive residues. With the exception of parent compound and metabolite #14 (CPR-label), less than 1% of the TRR was detected in any one photodegradation product from the Day-1 or -2 sampling.

No parent compound was detected in the Day-7 or day-14 aqueous fraction. The number of degradation products declined to 4-6 for CPR and 6-8 for NPR-labeled samples. At Day-7, degradates amounting to between 5 to 13.94% of the TRR were detected but not identified. At Day-14, degradates amounting to between 3 and 26.62% of the TRR were detected but not identified.

A proposed degradation pathway is depicted in Figure 3.

REVIEWER'S COMMENTS:

1. Only parent oxyfluorfen was identified in the extracts. There were numerous compounds observed in the TLC plates that were identified but not quantified. The Subdivision N guidelines state that degradates present at $\geq 10\%$ of the applied be identified and quantified.

In this study, reference is made to regions on TLC plates that were designated as R1 through R6. Although the various regions were quantitated based on % TRR, the degradates contained in the regions were not characterized.

Conversely, various compounds were identified (i.e., RH-34670, RH-34800, RH-34670 and RH-45469). However, no attempt was made to determine the concentration of these compounds in the various

extractants, nor to relate them to the regions on TLC plates designated as R1 through R6..

2. It was difficult to determine from the text which tables were being referred to in the appendices. For example, on page 20 of the report, reference is made to various tables in Appendix 2; however, Appendix 2 could not be located in the report. It should be noted that only Appendices A-E were located.
3. If the samples were collected and stored before analysis, as appears to have occurred in this study, then a storage stability study is necessary in order to assess the effects of storage on the samples. Furthermore, details of the storage conditions should be elucidated.

DATA EVALUATION RECORD

STUDY 3

CHEM 111601

Oxyfluorfen

5161-3

FORMULATION--00--ACTIVE INGREDIENT

STUDY ID ~~11999901~~

Reibach, P. 1991. ¹⁴C-Oxyfluorfen photolysis on soil under natural sunlight. Rohm and Haas Report No. 34-91-46. Unpublished study performed by Rohm and Haas Company, Spring House, PA and Pharmacology and Toxicology Research Laboratory, Richmond, KY, and submitted by Rohm and Haas Company, Spring House, PA.

DIRECT REVIEW TIME = 5

REVIEWED BY: Richard J. Mahler, Hydrologist
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F 5 APR 1993

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Environmental Chemistry Review Section 1, EFGWB

SIGNATURE:

Paul J. Mastradone

DATE:

F 5 APR 1993

CONCLUSIONS:

Degradation - Photodegradation On Soil

EFGWB concludes this ~~study is considered supplemental~~ and provides information that shows oxyfluorfen to degrade on soil surfaces with a half-life of 28 days.

The study does not satisfy the data requirements for the following reasons:

1. The soil was autoclaved prior to use.
2. The storage stability of parent and degradates and conditions of storage of the samples collected was not addressed sufficiently.

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3. It does not appear that the soil moisture content was maintained at the 75% of the 0.33 bar throughout the experiment.

Further details related to the review of this study are noted below under the section listed as "REVIEWER'S COMMENTS" and should be addressed in any response to this review.

METHODOLOGY:

Dose preparation, irradiation and extraction phases of the study were conducted at PTRL East Laboratories, Lexington, KY. Analytical oxyfluorfen labeled with ^{14}C in the nitrophenyl ring (NPR, specific activity 9.12 mCi/g, radiopurity: 96.9%) or the chlorophenyl ring (CPR, specific activity 10.79 mCi/g, radiopurity: 97.7%) was deposited on the surface of a thin film (0.5mm) of an autoclaved sandy loam soil (2 mm sieve, 6.8 pH; 62% sand, 29% silt and 9% clay; 1.2% organic matter, 9 meq/100g cation exchange capacity) at a concentration of 10 ppm. The samples were irradiated during October and November, 1990 by natural sunlight in Lexington, KY. The exposed samples were maintained at an average constant temperature of 23.1°C. Samples were collected at 0, 8, 15 and 30 days after treatment for extraction and radioassay. Ethylene glycol traps were used to collect any volatile organic materials and NaOH traps were used to trap any $^{14}\text{CO}_2$. Duplicate light exposed and dark control samples were removed from their respective soil chambers, covered with parafilm and aluminum foil and immediately placed in the freezer until their extraction on the same day. Figure 1 depicts the irradiation apparatus and the subsequent fractionation scheme performed by PTRL.

Following completion of the irradiation phase of the study, all extracts, soils, and trap solutions which contained radioactivity were shipped frozen to the Rohm and Haas laboratory for further analysis.

Following receipt of the samples by Rohm and Haas all samples were stored frozen at $<-20^\circ\text{C}$ until analyzed. The soil extracts were assayed by liquid scintillation counting (LSC) to determine the amount of radioactivity present and the results were compared with the data from PTRL. Samples were also analyzed for oxyfluorfen content by TLC. Radioactivity on the TLC plates was located and quantitated using a radioanalytic imaging system (RIS). In order to compare the radioactivity determined by the two methods, TLC and RIS, selected plates were scraped and counted by LSC. The TLC results were confirmed by HPLC analysis. Purified volatile material from the ethylene glycol traps was analyzed with a gas chromatograph.

The % oxyfluorfen remaining at each time point for irradiated samples was determined by TLC analysis as describe above. Half-life calculation were based on analysis of the combined data from both the NPR and CPR studies. The % parent remaining from both replicates of each study were averaged. The half-life was calculated by plotting $\ln(\% \text{parent})$ vs. days. This plot is given in Figure 8. The half-life was calculated as follows:

half-life = $(\ln 2)/k$, where k = slope,
half-life = $0.693/0.02455$ = 28 days.

In order to generate sufficient material for identification of unknowns, additional soil plates were dosed at 350 ppm and irradiated. This irradiation is referred to as the batch study. The volatile material from the batch study was isolated from ethylene glycol (EG) traps by HPLC.

DATA SUMMARY:

Extraction results, soil combustion results, trap counting results, and material balance calculations from PTRL can be found in Tables I and II. Recovery of the radiolabel throughout the study was good. The overall recovery in the irradiated samples was 98.2 and 101.8% for the NPR and CPR labeled-samples, respectively. The average recovery of the parent oxyfluorfen in the dark controls was 100.6% (SD = 7.25).

The ethylene glycol traps contained only 0.1% of the radio label for the NPR samples and 11.5% for the CPR samples. The NaOH trap contained 8.1% and 4.0% of the total applied radioactivity for the NPR and CPR samples, respectively. Since the NaOH traps contained <10% of the total applied, no further characterization was performed. The difference in the trap contents for the two labels suggests breakage of the ether linkage between the two ring systems. This is not an unexpected result and has been observed in previous studies.

The extractability of the radiolabel from the irradiated samples declined with time (Tables I and II). For the Day-30 NPR soil, 64.9% of the radiolabel was extractable with aqueous methanol, 7.4% extractable with acidified methanol, 3.7% extractable with NaOH, 0.1% was recovered in the ethylene glycol trap, 8.1% in the NaOH trap and 3.5% remained in the soil. For the Day-30 CPR soil, 70.1% of the radiolabel was extractable with aqueous methanol, 5.5% extractable with acidified methanol, 11.4% was recovered in the ethylene glycol trap, 4.0% in the NaOH trap and 1.3% remained in the soil. NaOH extraction was not necessary for the CPR soil since less than 10% of the radiolabel remained in the soil following acidic methanol extraction. The differences between the two labels with respect to trap contents and extractability suggests breakage of the ether linkage connecting the two systems.

Quantitation of oxyfluorfen for half-life determination was done by normal phase TLC (Table III and IV) and HPLC for confirmation. TLC analysis resolved the samples into two components, parent oxyfluorfen and polar origin materials. Analysis of the polar origins materials by TLC using several polar and non-polar solvent systems were not able to resolve this material into more than one component. The origin material when re-chromatographed either stayed at the origin, migrated as one component, or migrated with the solvent front. None of the components resolved by HPLC was present at >10% of the original dose.

The volatile material from the batch study was isolated from the EG traps by HPLC. A comparison with standards suggested that one component was

phenol, RH-34800; while the second unknown did not match any of the standards tested. The samples were analyzed by GC/Mass Selective Detector (MSD) and showed that the volatile material was composed of two degradates, RH-34800 and RH-36329, the methyl ester of 3-Cl,4-OH benzoic acid.

Analysis of the EG trap from the definitive study gave results different from the batch study. RH-34800 was not present; however, methyl ester of 3-Cl, 4-OH benzoic acid was confirmed, while the other components was not confirmed but is likely 3-Cl,4-OH benzoic acid.

For the Day-30 samples, identified components were 41% parent and 6.5% methyl ester of 3-Cl,4-OH benzoic acid and 6.5% 3-Cl,4-OH benzoic acid. An additional 13% was only characterized by TLC and an additional 16% (at least 4 compounds by HPLC). Materials that were not characterized further included 5.5% acidified methanol extracts, 4.0% in the NaOH traps and 1.3% of non-extractable material.

For the day 30 NPR samples, identified components were 45.5% parent. An additional 1.5% was characterized by TLC and an additional 18.5% (4 compounds by HPLC) was further characterized after TLC. Materials that were not characterized further included the acidified methanol extracts at 7.5%, the NaOH extracts at 3.7%, the NaOH trap at 8.1% and the non-extractable material at 3.5%. The difference in trap contents, especially the CO₂ trap, suggest that once the ether linkage is cleaved, the resulting NPR half of the molecule is more labile than the CPR half.

Since volatile materials were the only degradates present at concentrations >10% in the definitive soil study, a complete identification of the soil extractable degradates was not performed. Additional metabolite characterization of a soil from the batch photolysis study was performed. A sample from the batch study was extracted and compared to a Day-30 definitive soil extract as well as a sample from a batch aqueous photolysis study where samples were irradiated with a xenon lamp. The comparison shows that the photolysis products from both studies are qualitatively similar but not quantitatively the same. This is reasonable since the half-life from the aqueous study was only 2-3 days, significantly shorter than the 28 days from this study. Comparison with the aqueous study suggests the formation of RH-4670, RH-5469, RH-4860 and compound 1 (Figure 21).

A proposed pathway for the degradation of oxyfluorfen under soil photolysis is shown in Figure 22.

REVIEWER'S COMMENTS:

1. The soils were autoclaved prior to use. Autoclaving may have significantly changed the physical and chemical properties of the soils, which, in turn, may have altered the observed photodegradation rate of the pesticide. Autoclaving soils may affect the soil CEC by breaking down organic matter and/or expanding the crystalline structure of clay particles. Autoclaving soils has also been shown to make soils more hydrophobic; the mechanism for this is not fully

understood. Since several processes occur simultaneously during autoclaving, changes in soil behavior after autoclaving and its influence on soil photolysis cannot be predicted.

Generally, photolysis studies performed on autoclaved soils are considered as supplemental information to studies performed on vital soils.

2. If the samples were collected and stored before analysis, as appears to have occurred in this study, then a storage stability study is required in order to assess the effects of storage on the samples. Furthermore, details of the storage conditions should be elucidated.
3. It appears from the methodology section that ambient air was drawn through the chambers using a vacuum pump. Without using moistened air, the moisture content of the soil used in this study was probably somewhat less than the required 75% of the 0.33 bar moisture content.

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RIN 0637-00

EFED Review - Oxyfluorfen

Page is not included in this copy.

Pages 62 through 79 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.

DATA EVALUATION RECORD

STUDY 4

CHEM 111601

Oxyfluorfen

§162-1

FORMULATION--00--ACTIVE INGREDIENT

MRID 4214309

STUDY ID 92136110

Korsch, B.H., and T.J. Doran. 1988a. Aerobic soil metabolism of oxyfluorfen. Document No. 1548-87-0092-EF-001. Rohm and Haas Technical Report No. 34C-88-55. Project No. 87-0092. Protocol No. 31P-87-05. Unpublished study performed by Ricerca, Inc., Painesville, OH, and submitted by Rohm and Haas Company, Spring House, PA.

STUDY ID 92136097

Reibach, P.H. 1990b. Phase 3 summary of MRID 92136110: Oxyfluorfen aerobic soil metabolism: TR No. 34C-88-55. Unpublished summary prepared and submitted by Rohm and Haas Company, Spring House, PA.

DIRECT REVIEW TIME = 20

REVIEWED BY: N. Shishkoff

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SIGNATURE: *Richard J. Mahler*

CONCLUSIONS:

Metabolism - Aerobic Soil

1. This study is scientifically valid and provides the following supplemental information:

Nitrophenyl ring-labeled and chlorophenyl ring-labeled [¹⁴C]oxyfluorfen, at 8.83-9.64 ppm, dissipated from sandy loam

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soil with half-lives of 556-596 days. Nitrophenyl and chlorophenyl ring-labeled [¹⁴C]oxyfluorfen dissipated from clay loam soil with half-lives of 291-294 days. The degradate, RH-34800, was identified in the extracts from the clay loam soil treated with chlorophenyl ring-labeled [¹⁴C]oxyfluorfen.

After 52 weeks, between 20 and 43% of the radioactivity was bound (nonextractable) to the soil, and between 53 and 77% was extractable.

2. This study is not acceptable for the following reason:

radioactivity in the methanol:water extracts present at up to approximately 11.2% of the applied (1.06 ppm) in the sandy loam soil and approximately 5.0% of the applied (0.48 ppm) in the clay loam soil was not characterized.

4. In order for this study to fulfill the aerobic soil metabolism data requirement, the registrant should characterize the extracted radioactivity and identify any degradates present at ≥ 0.01 ppm.
5. Further details related to the review of this study are noted below under the section listed as "REVIEWER'S COMMENTS" and should be addressed when responding to this review.

METHODOLOGY:

A sandy loam soil (56.8% sand, 33.2% silt, 10% clay, 1.3% organic matter, pH 6.5, CEC 6.1 meq/100 g) from California and a clay loam soil (26.8% sand, 45.2% silt, 28.0% clay, 3.2% organic matter, pH 6.3, CEC 10.9 meq/100 g) from Pennsylvania were sieved (2 mm) and adjusted to 75% of field moisture capacity. Portions of the soils were treated at 8.83-9.64 ppm or at 40-50 ppm (for degradate analysis) either with nitrophenyl ring-labeled [¹⁴C]oxyfluorfen (uniformly labeled; radiochemical purity >93%, specific activity 10.79 mCi/g, Rohm and Haas) or chlorophenyl ring-labeled [¹⁴C]oxyfluorfen (uniformly labeled; radiochemical purity 96%, specific activity 9.12 mCi/g, Rohm and Haas). To treat the soil, aliquots of a stock solution of [¹⁴C]oxyfluorfen, dissolved in acetone, were transferred to the sides of mixing jars; the jars were rolled and the acetone was allowed to evaporate. After the solvent evaporated, portions of the soil were added to the jars and tumbled for 2-3 days until the distribution of [¹⁴C]oxyfluorfen was uniform as determined by combustion analysis of the soil. Subsamples (25 g) of the treated soils were transferred to "bottles" (not further described) and all the bottles of a single soil type and oxyfluorfen radiolabel position were placed in the same desiccator. The desiccators were equipped with inlet and outlet tubes; humidified, carbon dioxide-free air was passed (5 mL/minute) through the containers and vented through two tubes containing Chromosorb 102 and two tubes containing 1 N NaOH trapping solutions (Figure 6). Containers of untreated sandy loam and clay loam soils were placed in

separate, unvented desiccators. The desiccators were incubated in a darkened environmental chamber at 25 ± 1 C. The containers were weighed at weekly intervals and water was added as needed to maintain 75% of field capacity. Duplicate treated soil samples and single control soil samples were removed at 0, 1, 3, 7, 14, and 30 days, and 8, 13, 17, 26, 39, and 52 weeks posttreatment. The Chromosorb 102 and NaOH trapping solutions were replaced at each sampling interval.

The soil samples were extracted on the day sampled and analyzed immediately (Figure 8). Triplicate subsamples of the soil were analyzed by LSC following combustion to determine total radioactivity. An additional subsample of the soil was extracted three times by blending with methanol:water (90:10). Aliquots of the combined extracts were analyzed by LSC. The extracts were then concentrated by rotary evaporation, acidified with glacial acetic acid, and partitioned three times with methylene chloride. Aliquots of both phases were analyzed by LSC. The methylene chloride phases were concentrated to dryness (rotary evaporation followed by a stream of air), and the residues were redissolved in methanol. Aliquots of the methanol solutions were analyzed by HPLC on a Hypersil ODS column eluted with a gradient of monobasic and dibasic potassium phosphate buffers. Reference standards of unlabeled oxyfluorfen, RH-35450, RH-35451, RH-34670, RH-34800, RH-45452 and RH-42382 were cochromatographed with the extracts. The column eluate was monitored by UV (254 nm) and radioactive flow detectors.

Select subsamples (one sample per sampling interval of interest) of the extracted soils were further extracted as outlined in Figures 10, and 12-15. Nitrophenyl ring-labeled [^{14}C]oxyfluorfen-treated soils (sandy loam and clay loam) from the 13-week posttreatment sampling interval was further extracted with methanol:0.1 N HCl (90:10) or Soxhlet extracted with methanol (Figures 12 and 13). Nitrophenyl and chlorophenyl ring-labeled [^{14}C]oxyfluorfen-treated clay loam soils from the 26- and 52-week posttreatment sampling intervals were further extracted with methanol:0.1 N HCl (90:10), followed by a series of extractions to isolate the humic acid, fulvic acid, and humin fractions (Figure 10). Nitrophenyl and chlorophenyl ring-labeled [^{14}C]oxyfluorfen-treated clay loam soils from the 39-week posttreatment sampling interval were further extracted with methanol:0.1 N HCl (90:10), "washed" with ethyl acetate, and refluxed with methanol:HCl (90:10; Figures 14 and 15).

The Chromosorb 102 was extracted twice with methanol. The methanol extracts were combined and analyzed by LSC. Subsamples of extracted Chromosorb 102 were analyzed by LSC following combustion. Aliquots of the NaOH trapping solutions were transferred to scintillation vials, neutralized with 1 N HCl, and analyzed by LSC.

DATA SUMMARY:

The degradation rates of nitrophenyl ring-labeled [^{14}C]oxyfluorfen (uniformly labeled; radiochemical purity >93%) and chlorophenyl ring-

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labeled [¹⁴C]oxyfluorfen (uniformly labeled; radiochemical purity 96%) were very similar in sandy loam soil and clay loam soil. Oxyfluorfen, at 8.83-9.64 ppm, degraded with registrant-calculated half-lives of 556-596 days and 291-294 days, respectively, in sandy loam and clay loam soils that were incubated in the dark under aerobic conditions at 25 ± 1 C. The degradate identified was

RH-34800,

which was detected in the clay loam soil treated with chlorophenyl ring-labeled [¹⁴C]oxyfluorfen at a maximum of 0.7% of the applied at 26 weeks posttreatment (Table XIX).

In the methanol:water extracts of the clay loam soil, [¹⁴C]oxyfluorfen was 93.8-97.3% of the applied radioactivity immediately posttreatment, 50.7-55.1% at 26 weeks, and 40.5-43.9% at 52 weeks (Table XIII). Soil-bound radioactivity increased from 1.1-1.8% of the applied immediately posttreatment to 34.9-43.3% at 52 weeks posttreatment (Table XI). Organic volatiles were <0.6% of the applied radioactivity during the study period and CO₂ totalled 2.8-5.1% of applied radioactivity by 52 weeks posttreatment (Tables VI and VIII).

Additional extraction of the methanol:water extracted, nitrophenyl ring-labeled [¹⁴C]oxyfluorfen-treated clay loam soil from the 13-weeks posttreatment sampling interval removed an additional 2.4-2.8% of the applied radioactivity, approximately 71-76% of which was parent oxyfluorfen (Figure 13). In the acidified methanol extracts of the methanol:water extracted, chlorophenyl ring-labeled [¹⁴C]oxyfluorfen-treated soil from the 39-week posttreatment sampling interval, RH-34800 was 2.9% of the applied and oxyfluorfen was present but not quantified (Figure 14). The acidified methanol extracts and methanol refluxate of the methanol:water extracted soil treated with nitrophenyl ring-labeled [¹⁴C]oxyfluorfen from the 39-week posttreatment sampling interval contained oxyfluorfen (concentration not reported) and diffuse radioactivity (Figure 15). The acidified methanol extracts of the methanol:water extracted soil treated with [¹⁴C]oxyfluorfen (both label positions) from the 26-week and 52-week sampling intervals contained an additional 5.1-5.4% of the applied radioactivity; in the extracts, oxyfluorfen was 2.7-3.2% of the applied radioactivity, and RH-34800 was ≤0.7% (Table XIX). The humic acid fraction comprised 0.6-1.6% of the applied radioactivity, the fulvic acid fraction comprised 2.1-3.9%, and the humin comprised 3.4-7.3% (Table XVII and Figures 16-19).

Material balances for [¹⁴C]oxyfluorfen in the clay loam soil were 84.2-103.5%.

In the methanol:water extracts of the sandy loam soil, [¹⁴C]oxyfluorfen was 93.1-96.3% of the applied radioactivity immediately posttreatment, 69.9-72.0% at 26 weeks, and 56.1-64.0% at 52 weeks (Table XIV). Soil-bound radioactivity increased from 0.2-

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1.8% of the applied immediately posttreatment to 20.4-25.9% at 52 weeks posttreatment (Table XII). Organic volatiles were $\leq 0.1\%$ of the applied radioactivity during the study period and CO_2 totalled 2.3-3.3% of the applied radioactivity by 52 weeks posttreatment (Tables II and IV).

Additional extraction of the methanol:water extracted sandy loam soil treated with nitrophenyl ring-labeled [^{14}C]oxyfluorfen from the 13-week sampling interval removed an additional 1.6% of the applied radioactivity, approximately 74% of which was parent (Figure 12).

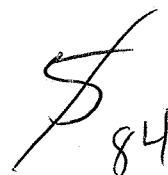
The material balances for [^{14}C]oxyfluorfen in sandy loam soil were 86.9-104.4%.

The half-lives were calculated by linear regression (Tables XV and XVI) on the data in Tables XIII and XIV.

REVIEWER'S COMMENTS:

1. All of the results should have been tabulated as percentages of the original radioactivity applied and not as a percentage of the combusted radioactivity.
2. Although the soil was treated at a rate 5 times greater than the recommended field application rate, radioactivity present at up to approximately 11.2% of the applied (1.06 ppm) and approximately 5.0% (0.48 ppm) in the methanol:water extracts of the sandy loam soil and clay loam soils, respectively, was not characterized¹ (calculated from Tables II, IV, VI, VIII, and XI-XIV). The purpose of performing aerobic soil metabolism studies at elevated rates is to more accurately identify degradates. Subdivision N guidelines state that degradates present at ≥ 0.01 ppm be identified. Examples of chromatograms should also be included. The maximum application rate for oxyfluorfen was reported to be 2 lb/A; the application rate in this study was reported to be the equivalent of 10 lb ai/A.
3. The methods description was poorly organized and difficult to follow. The additional extraction methods were mostly described in schematic figures. These flow charts did not fully describe the reflux conditions (time) or indicate any manipulations prior to the

¹ As an example, from Table II and using the 52 week sample time from the 2nd combustion column, it can be seen that 86.7% of the applied radioactivity was recovered from the sample before the extraction. From Table XII it can be seen that 77.6% of the radioactivity found in the sample by combustion was extractable. These two percentages multiplied produces the amount of extractable radioactivity as a function of the original radioactivity applied ($86.7 \times 77.6\% = 67.3\%$). Since only 56.1% of the extractable was identified as parent, this leaves $67.3\% - 56.1\% = 11.2\%$ as unidentified radioactivity.



methylene chloride extraction. The ethyl acetate wash of the extracted soil was not reported in the methods section of the report. In addition, the "selected samples" that were further extracted were only reported in the figures. It was also unclear which "selected" soil samples were extracted by the procedure illustrated in Figure 9; no data are reported from these extractions.

The individual soil samples were not identified in Tables II-IX, yet the data in the remaining tables refer to the sample number. Thus, it is difficult to assess the data presented in the later tables and figures in terms of the applied radioactivity.

4. The study authors reported that additional soil samples were fortified at 40-50 ppm for degradate identification. No data from the analysis of these samples were provided.
5. No significant radioactivity was detected on the sides of the desiccators or in the Tygon tubing leading to the traps.

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RIN 0637-00

EFED Review - Oxyfluorfen

Page is not included in this copy.

Pages 86 through 132 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.

DATA EVALUATION RECORD

STUDY 5

CHEM 111601

Oxyfluorfen

S162-2

FORMULATION--00--ACTIVE INGREDIENT

STUDY ID 92136111-191-310
Korsch, B.H., and T.J. Doran. 1988b. Anaerobic soil metabolism of oxyfluorfen. Document No. 1668-87-0093-EF-001. Rohm and Haas Technical Report No. 34C-88-61. Project No. 87-0093. Protocol No. 31P-87-54. Unpublished study performed by Ricerca, Inc., Painesville, OH, and submitted by Rohm and Haas Company, Spring House, PA.

STUDY ID 92136098

Reibach, P.H. 1990c. Phase 3 summary of MRID 92136111: Oxyfluorfen anaerobic soil metabolism: TR No. 34C-88-61. Unpublished summary prepared and submitted by Rohm and Haas Company, Spring House, PA.

DIRECT REVIEW TIME = 10

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Richard J. Mahler

CONCLUSIONS:

Metabolism - Anaerobic Soil

1. This study provides supplemental information that shows oxyfluorfen is stable (half-lives 554 and 603 days) under anaerobic conditions, since after 60 days of anaerobic metabolism approximately 82% of the applied radioactivity was extractable parent.

2. This study is ~~unacceptable at this time~~ for the following reasons:
- the methodology was not clearly stated; the methods used for the analysis of the water were not reported;
 - actual material balances apparently were not determined for the anaerobically incubated samples;
 - radioactivity in the methanol:water extracts present at up to 5.13% (approximately 0.49 ppm) of the applied was not characterized, and
 - there was no verification that the incubation conditions were actually anaerobic.
3. ~~In order for this study to be reconsidered for fulfillment of the anaerobic soil metabolism data requirement,~~ the registrant must describe the extraction and methods used for the characterization of the radioactivity in the floodwater and identify all degradates present at ≥ 0.01 ppm. Additionally, since the floodwater apparently was not analyzed, the registrant must provide actual material balances for the anaerobically incubated samples; and show that the incubation conditions during the anaerobic phase of the study were actually anaerobic.
4. Resolution of the above deficiencies probably will not change the conclusion related to the stability of oxyfluorfen in anaerobic conditions.
5. Further details related to the review of this study are noted below under the section listed as "REVIEWER'S COMMENTS" and should be addressed when responding to this review.

METHODOLOGY:

Sandy loam soil (56.8% sand, 33.2% silt, 10% clay, 1.3% organic matter, pH 6.5, CEC 6.1 meq/100 g) was sieved (2 mm) and adjusted to 75% of field moisture capacity. Subsamples of the soil were treated at 8.83-9.46 ppm or 40-50 ppm (for degradate analysis) either with nitrophenyl ring-labeled [^{14}C]oxyfluorfen (uniformly labeled; radiochemical purity $>93\%$, specific activity 10.79 mCi/g, Rohm and Haas) or chlorophenyl ring-labeled [^{14}C]oxyfluorfen (uniformly labeled; radiochemical purity 96%, specific activity 9.12 mCi/g, Rohm and Haas). To treat the soil, aliquots of a stock solution of [^{14}C]oxyfluorfen, dissolved in acetone, were transferred to the sides of foil-covered half-gallon jars; the jars were rolled and the acetone was allowed to evaporate. After the solvent evaporated, portions of the soil were added to the jars and tumbled for 2-3 days until the distribution of [^{14}C]oxyfluorfen was uniform as determined by combustion analysis of the soil. Subsamples (25 g) of the treated soils were transferred to "bottles" (not further described) and all the bottles of a single soil type and oxyfluorfen radiolabel position were placed in the same desiccator. The desiccators were equipped with inlet and outlet tubes, humidified, carbon dioxide-free

air was passed (5 mL/minute) through the containers and vented through two tubes containing Chromosorb 102 and two tubes containing 1 N NaOH trapping solutions (Figure 6). Containers of untreated sandy loam soil were placed in separate, unvented desiccators. The desiccators were incubated in a darkened environmental chamber at $25 \pm 1^\circ\text{C}$. The containers were weighed at weekly intervals; water was added as needed to maintain 75% of field capacity. After the 30-day aerobic incubation period, the tubes were flooded with "de-aerated" water and a flow of nitrogen through the system was established. Duplicate treated soil samples and single control soil samples were removed at 0, 1, 3, 7, 14, and 30 days of aerobic incubation and 16, 28, 45, and 60 days of anaerobic incubation. The Chromosorb 102 and NaOH trapping solutions were replaced at each sampling interval.

The soil samples were extracted and analyzed on the same day.

Triplicate subsamples of the aerobically incubated soil were analyzed by LSC following combustion to determine total radioactivity; combustion analysis was not performed for the anaerobically incubated soils. A subsample of the soil was extracted three times by blending with methanol:water (90:10). Aliquots of the combined extracts were analyzed by LSC. The extracts then concentrated by rotary evaporation, acidified with glacial acetic acid, and partitioned three times with methylene chloride. Aliquots of both phases were analyzed by LSC. The methylene chloride phases were concentrated to dryness (rotary evaporation followed by a stream of air), and the residues were redissolved in methanol. Aliquots of the methanol solutions were analyzed by HPLC on a Hypersil ODS column eluted with a gradient of monobasic and dibasic potassium phosphate buffers. Reference standards of unlabeled oxyfluorfen, RH-35450, RH-35451, RH-34670, RH-34800, RH-45452 and RH-42382 were cochromatographed with the extracts. The column eluate was monitored by UV (254 nm) and radioactive flow detectors.

The methods used for the extraction and analysis of the water were not provided.

The Chromosorb 102 was extracted twice with methanol. The methanol extracts were combined and analyzed by LSC. Subsamples of extracted Chromosorb 102 were analyzed by LSC following combustion. Aliquots of NaOH trapping solutions were transferred to scintillation vials, neutralized with 1 N HCl, and analyzed by LSC.

DATA SUMMARY:

Nitrophenyl ring-labeled [^{14}C]oxyfluorfen (uniformly labeled; radiochemical purity >93%), at 8.83 ppm, and chlorophenyl ring-labeled [^{14}C]oxyfluorfen (uniformly labeled; radiochemical purity 96%), at 9.46 ppm, degraded with registrant-calculated half-lives of 603 and 554 days, respectively, in sandy loam soil that was incubated in the dark under aerobic conditions for 30 days and under anaerobic conditions (flooding plus nitrogen atmosphere) for 60 days at $25 \pm 1^\circ\text{C}$ (Tables XX and XXI and Figures 12 and 13). No degradates were identified.

Oxyfluorfen declined from 93.1-96.3% to 81.2-85.4% of the applied radioactivity at 30 days of aerobic incubation and was 81.4-82.3% after 60 days of anaerobic incubation (Table VII). Unextracted radioactivity was 0.2-7.9% of the applied during the aerobic incubation period and 6.8-12.4% during the anaerobic incubation period (Table VI and Figures 10 and 11). Organic volatiles were <0.1% of applied radioactivity during the study period; CO₂ totalled 0.3-0.4% at the end of the 30-day aerobic incubation period and 0.5-0.6% after an additional 60 days of anaerobic incubation (Tables II and IV).

The material balance for the study ranges from 93.9 to 104.4%.

REVIEWER'S COMMENTS:

1. The study authors only described the extraction of the soil. The extraction of the water was not described, nor were the residues in the water identified or described. The study authors reported the solubility of oxyfluorfen in water to be 0.116 ppm at 25 °C. Thus, it is likely that radioactive residues were present in the aqueous phase at >0.01 ppm, and would need to be characterized as suggested under the Subdivision N guidelines.
2. Since the soil was not analyzed by combustion to determine total radioactivity in the anaerobic portion of the study, the data from the 30-day aerobic samples were used to calculate mass balance for the anaerobic samples. The study authors reported that "This assumption for the anaerobic portion of the study is confirmed by the sum of the extracted and bound dpm being 99.4 to 104.3% of this average combustion value (Tables XVI to XIX)." If this was the case, the material balance should have been tabulated on that basis. Since it would be expected that oxyfluorfen and/or degradates would be expected to partition into the floodwater and the fate of the floodwater and any radioactivity in the floodwater was not reported, the reviewer is uncertain of the accuracy of any material balance determinations for this portion of the study.
4. Although the soil was treated at a rate 5 times greater than the recommended field application rate, radioactivity present at up to approximately 5.13% of the applied (0.49 ppm) was not characterized¹. The registrant stated that the nominal application rate of 10 ppm was 5

¹ As an example, from Table IV and using the 60 day sample time, it can be seen that 95.0% of the applied radioactivity was recovered by combustion from the sample before the extraction. From Table VI it can be seen that an average 91.35% of the radioactivity found in the sample by combustion was extractable. These two percentages multiplied produces the amount of extractable radioactivity as a function of the original radioactivity applied (95.0 x 91.35% = 86.78%). Since, from Table VII, an average of 81.65% of the extractable was identified as parent, this leaves 86.78 - 81.65% = 5.13% as unidentified radioactivity.

times the recommended application rate of 2 lb ai/A. Thus, under actual use conditions, this radioactivity would comprise approximately 0.1 ppm; Subdivision N guidelines state that degradates present at ≥ 0.01 ppm should be identified.

5. There was no verification that the incubation conditions were actually anaerobic. It is generally, best to measure the redox potential to determine the condition of the test system.
6. Furthermore, the floodwater was not characterized. Subdivision N guidelines state that water at least be characterized by pH and source.
7. The study authors stated that the amount of parent oxyfluorfen present in the soil at 30 days posttreatment was "apparently anomalous for both [^{14}C] labels" and therefore these data were excluded from the half-life calculations.

RIN 0637-00

EFED Review - Oxyfluorfen

Page is not included in this copy.

Pages 138 through 160 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) .
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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.

DATA EVALUATION RECORD

STUDY 6

CHEM 111601

Oxyfluorfen

6163-1

FORMULATION--00--ACTIVE INGREDIENT

STUDY ID 92136112

Reibach, P.H. 1988. Adsorption/desorption of ¹⁴C-oxyfluorfen. Rohm and Haas Technical Report No. 34C-88-64. Unpublished study performed and submitted by Rohm and Haas Company, Spring House, PA.

STUDY ID 92136099

Reibach, P.H. 1990d. Phase 3 summary of MRID 92136112. ¹⁴C-Oxyfluorfen adsorption/desorption: TR No. 34C-88-64. Unpublished summary prepared and submitted by Rohm and Haas Company, Spring House, PA.

DIRECT REVIEW TIME = 8

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SIGNATURE:

Richard J. Mahler

CONCLUSIONS:

Mobility - Leaching and Adsorption/Desorption

1. ~~This study is scientifically valid and provides supplemental information that shows oxyfluorfen is slightly mobile in sand soil ($K_d = 8.5$), and somewhat immobile in sandy loam ($K_d = 62$), clay loam ($K_d = 99$), and silty clay loam ($K_d = 228$) soils.~~
2. ~~The study does not meet Subdivision N guidelines for the following reasons:~~

acceptable

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the effect of chemical binding to the teflon tube wall on the K_d was not discussed; therefore, since a substantial amount of the chemical adhered to the teflon tube walls, the K_d values are estimates of the actual values;

the concentration range of oxyfluorfen was too narrow (0.025-0.117 ppm) to allow for accurate calculation of Freundlich constants; and,

the equilibration temperature was not reported.

3. ~~EFGWB does not believe that any further leaching/adsorption/desorption studies are needed at the present time, since previous acceptable leaching/adsorption/desorption studies (Accession Numbers 094336, 096882 and 096884) generally confirm the results presented in this study. Therefore, the leaching/adsorption/desorption study (Subdivision N Guideline 163-1) is satisfied.~~
4. Further details related to the review of this study are noted below under the section listed as "REVIEWER'S COMMENTS" and should be addressed when responding to this review.

METHODOLOGY:

Sand, sandy loam, clay loam, and silty clay loam soils (Table 1) were air-dried and sieved (2 mm). Based on preliminary experiments to define test parameters, a soil:solution ratio of 1:30 and an equilibration time of 24 hours were selected for the definitive experiment. It was also determined that adsorption of the test substance to the walls of Teflon tubes was less than adsorption to polyethylene and polycarbonate tubes.

For the definitive study, uniformly ring-labeled [^{14}C]oxyfluorfen (radiochemical purity $\geq 95\%$, specific activity 10.79 mCi/g, source unspecified) was dissolved at nominal concentrations of 0.025, 0.050, 0.075, and 0.100 ppm in a 0.01 M CaCl_2 solution. Triplicate soil subsamples (1 g) and aliquots (30 mL)² of the treated solutions were placed in Teflon centrifuge tubes. The soil:solution slurries were equilibrated on a horizontal shaker for 24 hours (temperature and light conditions unspecified). Following equilibration, the samples were centrifuged and decanted, and duplicate 1-mL aliquots of the supernatants were analyzed for total radioactivity by LSC. The method detection limit was 0.00015 ppm. The soils in two of the three tubes were air-dried and analyzed for total radioactivity by LSC following combustion. The method detection limit was 0.0004 ppm. Following soil combustions, the tubes were rinsed twice with methanol and the methanol rinses were analyzed using LSC.

The decanted supernatant from the single remaining tube for each soil type was replaced with an equivalent amount of pesticide-free 0.01 M CaCl_2 solution in order to determine desorption potential. The soil:solution slurries were equilibrated on the horizontal shaker for

24 hours (temperature and light conditions unspecified). The samples were centrifuged, and the supernatant was decanted and duplicate 1-mL aliquots were analyzed by LSC. The method detection limit was 0.00015 ppm. Following desorption, portions of each soil were air-dried and analyzed for total radioactivity by LSC following combustion. The method detection limit was 0.0004 ppm. Following soil combustions, the tubes were rinsed twice with methanol and the methanol rinses were analyzed using LSC.

To determine the stability of oxyfluorfen following the 24-hour equilibration period, supernatants from a separate set of solutions were analyzed by LSC, and then passed through a C-18 Sep-Pak column that was subsequently eluted with methanol. The aqueous and methanol fractions were analyzed by LSC. Additional aliquots of the methanol fractions were chromatographed on silica gel TLC plates developed in chloroform. Radioactive areas were quantified with a radioscanner and compared to a reference standard of unlabeled oxyfluorfen.

DATA SUMMARY:

Based on batch equilibrium studies, uniformly ring-labeled [¹⁴C]oxyfluorfen (radiochemical purity $\geq 95\%$), at 0.025, 0.050, 0.075, and 0.100 ppm, was determined to be mobile in sand and somewhat immobile in sandy loam, clay loam, and silty clay loam soil:0.01 M CaCl₂ solution slurries (1 g:30 mL) equilibrated for 24 hours at an unspecified temperature. Freundlich K_{ads} values were 8.50 for the sand soil, 228.61 for the silty clay loam soil, 98.58 for the clay loam soil and 61.78 for the sandy loam soil (Table 4). Adsorption increased with increasing soil clay content. Freundlich K_{des} values were 9.44, 30.28, 88.12, and 125.37, respectively (Table 5). K_{oc} values ranged from 2891 to 32381 for adsorption and from 3211 to 11518 for desorption (Table 6).

Based on TLC analyses of the adsorption supernatants, oxyfluorfen comprised 81-96% of the total radioactivity (Table 7). At the completion of the study, the material balances averaged 101% of the applied for the sandy loam soil, 96% for the clay loam soil, 84% for the silty clay loam soil, and 73% for the sand soil (Table 8).

REVIEWER'S COMMENTS:

1. The nominal concentrations of [¹⁴C]oxyfluorfen in the original solutions ranged from 0.025 to 0.100 ppm. Freundlich constants calculated from such a narrow range of concentrations may not accurately predict the behavior of the pesticide at other concentrations; a range of at least 10-fold is preferred. As stated by the study author, the maximum nominal concentration of 0.100 ppm was selected because oxyfluorfen has a water solubility of 0.116 ppm. Since the detection limit for LSC analyses of the solutions was 0.00015 ppm, a minimum nominal concentration of ≤ 0.010 ppm could have been selected to satisfy the requirement that the test concentration range varies by a factor of at least 10.

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However, EFGWB does not believe that any further information would be gained by using a lower concentration of material, since it appears from this study and other leaching/adsorption/desorption studies that oxyfluorfen does not readily leach.

In future leaching/adsorption/desorption studies submitted to the Agency, it is suggested that the range of concentration used provide at least a 10-fold difference in the range of concentrations used to calculate Freundlich K_{ads} and K_{des} values.

2. The temperature at which the experiment was conducted was not reported. In addition, it was not stated that the experiment was conducted in the dark. The reviewer assumed that the environmental chamber was not illuminated by an internal light source.
3. Based on the results of the preliminary study, oxyfluorfen was found to strongly adhere to all surfaces when dissolved in water. An average of 95% of the oxyfluorfen adhered to empty polyethylene tubes at 16 hours, 61% adhered to polycarbonate tubes, and 48% adhered to Teflon (Figure 9). Teflon tubes were selected for the definitive study to minimize binding to the container walls.

In the definitive study, the study author accounted for the radioactivity that adhered to the walls of the Teflon tubes. The total radioactivity for each sample was determined by summing the total amount of oxyfluorfen present in the aqueous phase, adsorbed to the soil and two methanol tube rinses, divided by the starting total amount (Table 8). In addition, blank tubes containing test solution but no soil were included as part of the adsorption/desorption experiments. An average recovery of 53% was obtained for the blank tubes, including the radioactivity from two methanol rinses. No rationale was offered as to the reason for the difficulty in removing oxyfluorfen from the tube wall of the blank tubes as compared to tubes with soil in them.

4. The source of the test substance was not reported.
5. The actual concentrations of oxyfluorfen were 0.024, 0.059, 0.087, and 0.117 ppm.
6. The study author attributed the low recovery (73%) for the sand soil to adsorption of the test substance to the tube walls which was not recovered with the methanol washes.

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Page is not included in this copy.

Pages 165 through 174 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.

REFERENCES

The following studies were reviewed:

Kesterson, A.L., B. Lawrence, D.L. King, and L.J. Lawrence. 1989a. Aqueous photolysis of [¹⁴C]oxyfluorfen (chlorophenyl ring-labelled) in natural sunlight. PTRL Project No. 259. Report No. 1195. Rohm and Haas Report No. 34-89-54. Unpublished study performed by Pharmacology and Toxicology Research Laboratory, Lexington, KY, and submitted by Rohm and Haas Company, Spring House, PA. (92136109)

Kesterson, A.L., B. Lawrence, D.L. King, and L.J. Lawrence. 1989b. Aqueous photolysis of [¹⁴C]oxyfluorfen (nitrophenyl ring-labelled) in natural sunlight. PTRL Project No. 261. Report No. 1194. Rohm and Haas Report No. 34-89-53. Unpublished study performed by Pharmacology and Toxicology Research Laboratory, Lexington, KY, and submitted by Rohm and Haas Company, Spring House, PA. (92136108)

Korsch, B.H., and T.J. Doran. 1988a. Aerobic soil metabolism of oxyfluorfen. Document No. 1548-87-0092-EF-001. Rohm and Haas Technical Report No. 34C-88-55. Project No. 87-0092. Protocol No. 31P-87-05. Unpublished study performed by Ricerca, Inc., Painesville, OH, and submitted by Rohm and Haas Company, Spring House, PA. (92136110)

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Reibach, P.H. 1990c. Phase 3 summary of MRID 92136111: Oxyfluorfen anaerobic soil metabolism: TR No. 34C-88-61. Unpublished summary prepared and submitted by Rohm and Haas Company, Spring House, PA. (92136098)

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Reibach, P.H. 1990e. Phase 3 summary of MRID 92136113: Goal herbicide soil dissipation: TR No. 34C-88-65. Unpublished summary prepared and submitted by Rohm and Haas Company, Spring House, PA. (92136122)

Reibach, P.H., S. Smith, Jr., and W.J. Zogorski. 1989. Goal herbicide soil dissipation. Rohm and Haas Technical Report No. 34C-88-65. Unpublished study prepared by Rohm and Haas Company, Spring House, PA; Pan-Agricultural Associates, Madera, CA; and Craven Laboratories, Austin, TX; and submitted by Rohm and Haas Company, Spring House, PA. (92136113)

Reibach, P. 1991. Aqueous photolysis of [¹⁴C]oxyfluorfen. Rohm and Haas Report No. 34-91-47. Unpublished study performed by Rohm and Haas Company, Spring House, PA and Xenobiotics Laboratories, Princeton, NJ, and submitted by Rohm and Haas Company, Spring House, PA. (42129101)

Reibach, P. 1991. ¹⁴C-Oxyfluorfen photolysis on soil under natural sunlight. Rohm and Haas Report No. 34-91-46. Unpublished study performed by Rohm and Haas Company, Spring House, PA and Pharmacology and Toxicology Research Laboratory, Richmond, KY, and submitted by Rohm and Haas Company, Spring House, PA. (41999901)

Reibach, P.H. 1990e. Phase 3 summary of MRID 92136113: Goal herbicide soil dissipation: TR No. 34C-88-65. Unpublished summary prepared and submitted by Rohm and Haas Company, Spring House, PA. (92136122)

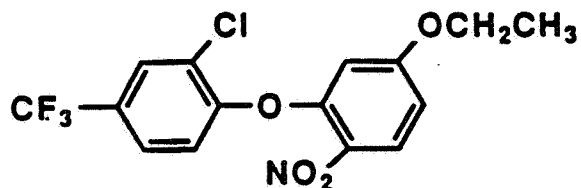
Reibach, P.H., S. Smith, Jr., and W.J. Zogorski. 1989. Goal herbicide soil dissipation. Rohm and Haas Technical Report No. 34C-88-65. Unpublished study prepared by Rohm and Haas Company, Spring House, PA; Pan-Agricultural Associates, Madera, CA; and Craven Laboratories, Austin, TX; and submitted by Rohm and Haas Company, Spring House, PA. (92136113)

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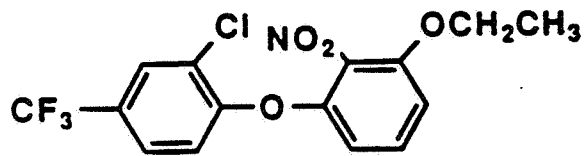
APPENDIX

OXYFLUORFEN AND ITS DEGRADATES

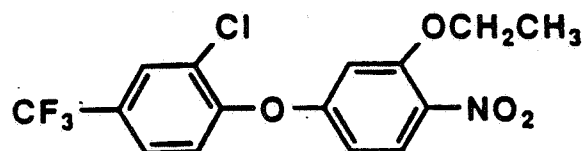
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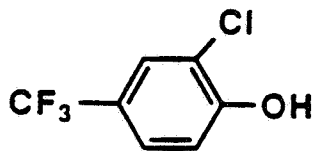
2-Chloro-1-(3-ethoxy-6-nitrophenoxy)-4-(trifluoromethyl) benzene
(RH-34672; 6'-NO₂ Isomer; Compound III)



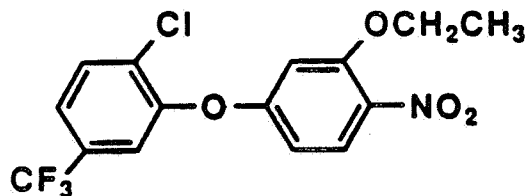
2-Chloro-1-(3-ethoxy-2-nitrophenoxy)-4-(trifluoromethyl) benzene
(RH-50671; 2'-NO₂ Isomer; Compound IV).



2-Chloro-1-(3-ethoxy-4-nitrophenoxy)-4-(trifluoromethyl) benzene
(Oxyfluorfen; RH-2915)



2-Chloro-4-(trifluoromethyl) phenol
(RH-34800)



2-Chloro-1-(3-ethoxy-4-nitrophenoxy)-5-(trifluoromethyl) benzene
(RH-42382; 5CF, Isomer; Compound II)

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