US ERA ARCHIVE DOCUMENT

REVIEW NO.

EEB BRANCH REVIEW

OUT_DEC 2 0 1982

DATÉ	: IN	10/26/82		OUT_	DEC 2 0 1982	
ILE OR REG. NO.		35977 -	EUP -	E		
ETITION OR EXP. PERM	IT NO.			•		
ATE OF SUBMISSION		9/20/82	4.	*		
ATE RECEIVED BY HED		10/25/82				
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YPE PRODUCT(S): I, I), H, F,	N, R, S	Inse	ct gr	owth Regulator	
ATA ACCESSION NO(S).						
RODUCT MANAGER NO.		A. Hey	ward (17)		
RODUCT NAME(S)		RO 13-522	3 1% B	ait		
					<u>and the state of </u>	
OMPANY NAME	<u>M</u>	IAAG Agroch	<u>emiçal</u>	<u>s</u>		
UBMISSION PURPOSE	Propos	ed EUP for	use i	n non	crop areas for	fire ants
•						
						
HAUGHNESSEY NO.		CHEMICAL,	& FORMU	LATION		% A.I.
	Ethy1	(2-(p-phen	oxy ph	enoxy) ethyl)	1%
	Carb	amate				
in the second se						
	.		, , . , . ,			

RO 13-5223

100 Experimental Use Label Information

100.1 Pesticide Use

Fire ant control in non-cropland sites.

100.2 Formulation Information

RO 13-5223 1% bait is 1% Ethyl (2-(p-phenoxyphenoxy) ethyl) carbamate.

100.3 Application Methods, Directions and Rates

Broadcast RO 13-5223 1% bait should be uniformly distributed over the infested area. Application could be with ground or air equipment.

Single Mound

Apply 1 to 3 level teaspoons of RO 13-5223 1% bait per mound by uniformly distributing material 3 to 4 feet around the base of the mound.

Rate

1.0 to 1.25 lbs/Acre

(4.5 to 5.6 grams a.i./Acre)

100.4 Target Organism

Imported Fire Ant

100.5 Precautionary Labeling

Keep out of lakes, streams and ponds. Do not contaminate water by cleaning of equipment or disposal of wastes.

100.6 Proposed EUP Program

100.6.1 Objectives

The objective of the program will be to establish the effectiveness of RO 13-5223 formulated as a 1% bait on

for control of fire ants, and to obtain additional residue information.

100.6.2 Date, Duration

The time period of March 1, 1983, through February 28, 1984, is proposed.

100.6.3 Amount shipped, Geographical Information

Maximum requirement is 6250 lbs. of bait or 62.5 lbs of active ingredient

	Total Acres Proposed	Maximum Pounds of Bait Required
<u>State</u>	Froposed	
Texas	1500	1875
Louisiana	500	625
Arkansas	300	375
Mississippi	500	625
Alabama	500	625
Georgia	850	1062.5
Florida	850	1062.5
Tota	and the second second	6250

100.6.4 Other Test Features

Trials will be established to determine the effectiveness of RO 13-5223 Formulated as a 1% a.i. bait for control of the red imported fire ant (Solenopsis invicta) on noncropland area. Sites will be selected on the basis of infestation and accessibility. Possible sites include airport grass areas, golf courses, atheletic fields, building grounds, pastureland not to be grazed, non-bearing citrus groves, etc. Applications will be made in the spring of the year with repeat fall applications if necessary to provide control. Some sites will receive only fall application. Plot size will vary depending on availability of infested sites. Ideally, non-replicated plots 400-500 A in size will allow the side by side comparison

101 Physical and Chemical Properties

101.1 Chemical Name

Ethyl (2-(p-phenoxyphenoxy)ethyl)carbamate

101.2 Structural Formula

101.4 Trade Name

RO 13-5223

101.6 Physical State

White odorless crystalline powder

101.7 Solubility

Solvent	Solubility % (w/w)
Water Acetone Diethyl Ether Dimethyl Formamide Ethyl Acetate Hexane Isopropanol Methanol N-methyl pyrrolidone Toluene	0.0006 (6 ppm) > 24 > 26 > 21 > 22 0.8 > 24 > 24 > 23

102 Behavior in the Environment

No environmental fate information is available now.

103 Toxicological Properties

The following studies were submitted with this submission.

Test Type	<u>Species</u>	Test Material % active ing.	Category	Results LC50/LD
Avian dietary	Mallard	95%	Core	>20,000 ppm
Avian dietary	Bobwhite	95%	Supp.'4	11574 ppm
Avian acute oral	Mallard	95%	Core	>3000 mg/kg
Avian acute oral	Bobwhite	95%	Core	>7000 mg/kg
Fish 96-hour	Bluegill	97%	Core	2.9 ppm
Fish 96-hour	Rainbow Trout	97%	Core	1.6 ppm
Fish 96-hour	Carp	97%	Supp.	10.3 ppm
Aquat Inv. 48-hour	Daphnids	95%	Core	0.4 ppm
Bee 24-hour	Honey bee	95%	Invalid	1174 ppm

104 Hazard Assessment

104.1 <u>Discussion</u>

RO 13-5223 is practically non-toxic to birds, moderately toxic to fish but highly toxic to $\underline{\text{Daphnia}}$ $\underline{\text{magna}}$.

104.2 Liklihood of Adverse Effects to Non-target Organisms

This EUP should have minimal effects on non-target organisms because of the limited acreage and low application rate.

104.3 Endangered Species

This EUP should not have any effect on endangered species.

104.4 Adequacy of Toxicity Data

The toxicity data were adequate to complete the review of this submission.

104.5 Additional Data Required

No additional data are required for this submission. However, for full registration at least one additional study would be needed, an avian 8-day dietary study with Bobwhite quail. Further data requirements would depend on fate information and proposed usage.

105 Conclusions

105.4 Data Requests

The available data are sufficient to review this EUP proposal. However for full registration at least one study will be required (Avian 8-day dietary with Bobwhite quail). Further studies could be requested depending on environmental fate information and proposed usage.

105.6 Recommendations

The EEB concludes that this EUP should not have an adverse effect on non-target organisms

Daniel Rieder
Wildlife Biologist
Ecological Effects Branch

Norm Cook
Head, Section #2
Ecological Effects Branch

Clayton Bushong, Chief Ecological Effects Branch

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Data Evaluation Record

- 1. Chemical: Ethyl (2-(p-phenoxyphenoxy)ethyl)-carbamate
- 2. Formulation: RO 13-5223 95% a.i.
- 3. Citation: Roberts, Nicholas L. 1982. The Acute Oral Toxicity (LD50) of RO 13-5223 to the Bobwhite Ouail. An unpublished report prepared by Huntingdon Research Center for F. Hoffman La Roche and Company Ltd. Data Accession # 248412.
 - 4. Reviewed by: Daniel Rieder Wildlife Biologist
 - 5. Date Reviewed: Dec 6, 1982
 - 6. Test Type: Avian acute oral

Species: Bobwhite Ouail

Test Material: RO 13-5223 95% a.i.

- 7. Results: Acute oral LD50 greater than 7000 mg/kg
- 8. Conclusion: This study fulfills the requirements for an avian acute oral toxicity test with an upland game bird. It shows that RO 13-5223 is practically non-toxic to birds.

Sixty young adult bobwhite quail were tested ten each at 5 dose levels (2867, 3584, 4480, 5600, and 7000 mg/kg) and with a control. The test material, RO 13-5223 is 95% Ethyl (2-(p-phenoxyphenoxy)ethyl)-carbamate. Birds were housed in wire cages and temperature was maintained around 20° c (15° - 23° c). Body weight and food consumption were both recorded.

Results

There were no treatment related deaths. The LD50 is greater than 7000 mg/kg.

There seemed to be a dose related reduction in weight gain following the initial drop in weight experienced by birds in all groups.

		average wei	ght (g/bi	rd) at day	<u>7</u> :
Group	Sex	Dose	-14*		14
1	M	Control	204	181	198
	F	ti-	217	206	225
6	M	7000	200	174	174
	F	II	217	208	214

^{* 14} days before treatment

Conclusion

Category: Core

Data Evaluation Record

- 1. Chemical: Ethyl(2-p(p-phenoxypenoxy)Ethyl)Carbamate
- 2. Formulation: RO 13-5223 95% a.i.
- 3. Citation: Nicholas, Robert L. 1982. The Acute Oral LD50 of RO 13-5223 to the Mallard Duck. An unpublished report prepared by Huntingdon Research Center for the F. Hoffman-La Roche and Co Ltd. Data Accession # 248412
- 4. Reviewed by: Daniel Rieder Wildlife Biologist
- 5. Date Reviewed: Dec 6, 1982
- 6. Test type: Acute Oral LD50

Species: Mallard duck

Test Material: RO 13-5223 95% a.i.

- 7. Results: Acute Oral LD50 > 3000 mg/kg
- 8. Conclusion: This study fulfills the guideline requirements for an avian acute oral LD50 with a waterfowl. It shows that RO 13-5223 is practically non-toxic to birds.

Sixty young adult mallard ducks were tested, ten each, at 5 dose levels (1229, 1536, 1920, 2400, and 3000 mg/kg) and with a control. The birds were observed for 14 days following treatment, during which time both weight and food consumption were recorded.

Results

One mortality occurred, it is not considered to be dose related. The LD50 is considered to be greater than 3000 mg/kg.

There does appear to be a dose related reduction in weight gain.

Group	Dose level	Sex	Grou Body	p Mean weights (day 14)
1	control	М		1220 g/bird
	ú	F		1050 "
6	3000 mg/kg	M		1081 "
6	3000 "	F		1027 "

There was also lower food consumption in the higher test levels than in the control

Conclusion

Category: Core

Data Evaluation Report

- 1. Chemical: RO 13-5223
- 2. Formulation: Ethyl(2-(p-phenoxyphenoxy)ethyl)carbamate ... 95%
 - 3. Citation: Roberts, Nicholas L. 1982. The Subacute Dietary Toxicity (LC50) of RO 13-5223/000 to the Mallard Duck. Received at EPA 10/19/82. An unpublished report prepared by Huntingdon Research Centre for MAAG Agrochemicals. (Data Accession No. 248576)
 - 4. Reviewed By: Daniel Rieder Wildlife Biologist
 - 5. Date Reviewed: 11/19/82
 - 6. Test-Type: 8-day Avian dietary LC50

Species: Mallard Duck

Test Mat: RO 13-5223

- 7. Results: The LC50 for mallards would be greater than 20,000 ppm based on this study.
- 8. Conclusion: This study is scientifically sound and fulfills the guideline requirements for an avian 8-day dietary toxicity test. It shows that RO-13-5223 is practically non-toxic to mallards.

Ten 13-day old mallards were tested in each of 3 controls, in each of 4 treatment levels (100, 1000, 5000, annd 20,000 ppm) and in each of 5 positive control levels of dieldrin (50, 88, 153, 268 and 469 ppm).

Temperature was 30° c (range $20^{\circ}-34^{\circ}$ c) Relative Humidity was 55° . Lighting was 24-hours a day pens were approximately 1.2 X 1.5 meters, galvanized steel with wire mesh floor.

All diets were prepared immediately prior to the start of the treatment period and were stored at room temperature throughout the study.

Results

No mortality occurred at any treatment level or in the controls.

The positive control LC50 value (dieldrin) = 203 ppm with 95% C.L. of 158 to 260 ppm.

Conclusion

Category: Core

Data Evaluation Record

- 1. Chemical: RO 13-5223
- 2. Shaughnessy No:
- 3. Citation: Roberts, Nicholas L. 1982. The Subacute Dietary Toxicity (LC50) of RO-13-5223/000 to the Bobwhite Ouail. An unpublished report prepared by Huntingdon Research Centre for MAAG Agrochemicals, Inc. Data Accession No. 248577.
- 4. Reviewed by: Daniel Rieder Wildlife Biologist
- 5. Date Reviewed: 11/20/82
- 6. Test type: Avian 8-day dietary LC50 with Bobwhite Ouail.
- 7. Results: The reported LC50 was 25317 ppm, the mortality data were reanalyzed statistically and an approximate LC550 of 11574.2 was generated. Due to the unusual dose interval 100, 1000, 5000, & 20000 ppm, the LC50 will be considered to be greater than 5000 ppm. This is supplemental data.
- 8. Conclusions:

 This avian dietary toxicity study does not fulfill guideline requirements because of the poor dose mortality response for both the treatment and the positive control. It could provide useful supplemental information.

Thirty 15-day old bobwhite quail weighing 19-20g were tested in an untreated control, 10 each were tested at 4 levels of RO 13-5223 (95%-Ethyl[2-p(p-phenoxy phenoxy)ethyl] carbamate) and at 5 levels of dieldrin (positive control).

They were housed in wooden boxes fitted with mesh lids. Temperature averaged 28°c(range 23° 32°c). Relative humidity was 59%. Lighting was continuous. Test diet (test material incorporated with basal diet) was made at beginning of study and stored at room temperature throughout study.

Results

Test Material	Dose level (ppm)	Number Tested	Total Mortality
Control	0	30	0
Dieldrin	15	10	1
si	24	10	7
и	38	10	1
tt	61	10	, <u>1</u>
Ü	98	10	9
RO 13-5223	100	10	4
11	1000	10	0
u ·	5000	10	0
in-	20000	10	9

The reported LC50 was 25317 ppm as calculated by the Finney probit analysis.

Discussion

The mortality data was reanalyzed using Stephans statistical program which includes probit analysis. The probit method did yield an LC50 of 25317 ppm but also showed that these results should not be used because the "goodness of fit" probability was so low (less than 0.001). See the attached computer printout. An approximate LC50 based on the mortality data is presented as 11574 ppm.

No birds died in the control suggesting normal healthy birds, however there was a poor dose/mortality response in both the positive control and the treatment. The report mentions that surviving birds in the 100 and 20,000 ppm test groups had damaged beaks and it attributes this to the birds pecking one another. That explanation permits this study to be considered as supplemental. The report also mentioned a rangefinding study with concentrations of 100, 500, 1000, 5000, 10,000, and 20,000 ppm. The results of that study were not given but they must have been such that the researches thought there would be no mortality at the lower levels tested (i.e. 100, 1000 or 5000 ppm), and that would explain the wide interval between test levels. But since there was substantial mortality at 100 ppm, and no statistically sound LC50 could be calculated with the mortality data I do not consider this study to fulfill the guideline requirements for an avian 8-day dietary toxicity study.

Conclusion:

Category: Supplemental

Rationale: - Poor dose-mortality response.

- Irregular interval between dose levels.

Data Evaluation Record

- 1. Chemical: RO 13-5223
- 2. Formulation: Ethyl [2-(p-phenoxyphenoxy)ethyl]carbamate97%
- 3, Citation: Keller, P. 1982. Acute Toxicity of RO 13-5223 to Bluegill.
 An unpublished report prepared by RCC, Research and Consulting
 Company and sponsored by F. Hoffman La Roche and Co. Ltd: Data
 Accession No. 248412.
- 4. Reviewed by Daniel Rieder Wildlife Biologist
- 5. Date Reviewed 11/23/82
- 6. Test Type: Fish 96-hour acute toxicity
 Bluegill Sunfish (Lepomis macrochirus)
- 7. Results: LC50 = 2.9 ppm (95% C.L. 2.2 3.8 ppm)
- 8. Conclusion: This study fulfills guideline requirements for a fish 96-hour acute toxicity test with warmwater fish. It indicates that RO 13-5223 is moderately toxic to fish.

Six to 8 bluegill were tested at 5 levels (1, 2.8, 3.3, 4.0 and 5.7 ppm) and in an untreated control. Test containers were 15-liter glass tanks. The fish's average weight was 4.2g, length was 63 mm. Loading factor was 2.8g/liter. The test water was aerated but the concentrations were measured.

Results

The 96-hour LC50 for RO 13-5223 to bluegill was 2.9 ppm (nominal concentrations). Based on the measured concentration the LC50 would be closer to 2 ppm.

		ation ppm	Number o	of fis	<u>n</u>
Nominal	Measur 48 hours	96 hours	tested		mortality
0	0	0	8		0
1	0.61	0.64	6		0
2.8	2.54	2.09	8		2
3.3	2.09	1.78	8		4
4.0	3.93	*	8		8
5.7	*	*	8		8

^{* 100%} mortality occurred.

Conclusions

Category: Core

Data Evaluation Report

- 1. Chemical: Ethyl-(2-p(p-phenoxy phonoxy)ethyl) carbamate
- 2. Formulation: RO 13-5223 97% a.i.
- 3. Citation:

 Buchanan, James S. and Pell, Ian B. 1980. The Acute toxicity of RO 13-5223 to Rainbow Trout (Salmo gairdneri). An unpublished report prepared by Huntingdon Research Center and commissioned by F. Hoffman La Roche and Co Ltd. Data Acc. No. 248412.
- 4. Reviewed by: Daniel Rieder Wildlife Riologist
- 5. Date Reviewed: Dec. 3, 1982
- 6. Test Type: Fish 96-hr LC50

Species: Rainbow trout

Test Mat: RO 13-5223

- 7. Results 96-hr LC50 = 1.6 ppm
- 8. Conclusion: This study was scientifically sound and fulfills guideline requirements for a coldwater fish acute toxicity test. It shows that RO 13-5223 is moderately toxic to fish.

The test material was RO 13-5223 which is 97% a.i. This was a static test, non aerated, conducted at 12% for 96 hours. Seventy fish (10 perlevel) were treated in 6 treatment concentrations (0.5, 0.9, 1.5, 3, 5, and 7 ppm) and a solvent control. Temperature, pH and DO were measured at 24-hour intervals. Fish weighed from 2.8 to 6g, the average being 4.05g. Loading Factor was 0.5g fish/liter.

Results

Concentration (ppm)	No. tested	96-hour Mortality
Control 0.5	10 10	0 0
0.9 1.5	10 10 10	3 10
5 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7	10 10	10 10

The 96-hour LC50 was 1.6 ppm with 95% C.L. of 1.4 to 1.7 ppm.

Discussion

This study shows that RO 13-5223 is moderately toxic to coldwater fish.

Conclusion

Category: Core

Data Evaluation Report

1. Chemical: RO 13-5223

2. Formulation: 97% Ethyl (2-(p-phenoxy phenoxy)ethyl) carbamate

3. Citation: Bathe, R. 1982. Acute Toxicity to Carp of RO 13-5223.

An unpublished report prepared by Research and Consulting Company for and commissioned by F. Hoffman La Roche and Co. Ltd. Accession #248412.

4. Reviewed by: Daniel Rieder Wildlife Biologist

5. Review date: 11/30/82

6. Test Type: Acute 96-hour toxicity

Species: Carp

Test material: RO 13-5223

7. Results: 96-hr LC50= 10.3 ppm 95% C.L. 8.7 to 11.9 ppm (this is based on nominal concentrations, the LC50 is closer to 3 ppm if measured concentrations were used).

8. Conclusion: This study is scientifically sound but does not meet guideline requirements because the species, carp, is not acceptable. It does provide supplemental data and shows that RO 13-5223 is moderately toxic to carp.

Ten carp were tested is each of 6 test concentrations (6, 8.5, 10.5, 12, 14, and 20 ppm) and a solvent control. The test solution was aerated, but the concentrations were also measured at 48 and 96 hours. The test material was 97% pure. Loading factor was about 2g/liter.

Results

The reported LC50 was $10.5~\rm ppm$. But that was based on nominal concentrations. According to measured concentrations the LC50 would be closer to 3 ppm.

Nominal	Concentration 48 hr	96 hr	<u>Carp</u> tested	Mortality
Control 6 8.5 10.5 12 14 20	2.69 3.07 2.44 3.34	2.24 2.39 2.77 1.6	10 10 10 10 10 10 10	0 0 5 4 5 10

^{* 100%} mortality before 48 hours.

Conclusion:

Category: Supplemental

Rationale: Unacceptable test species

Repairability: Not Repairable

Data Evaluation Report

- 1. Chemical: Ethyl (2-p(p-phenoxy phenoxy) Ethyl) Carhamate
- 2. Formulation: RO 13-5223 95% a.i.
- 3. <u>Citation</u>: Ellgehausen, H. 1982. The Acute Toxicity of RO 13-5223 to <u>Daphnia magna</u> (48 Hours FC50). An unpublished report prepared by Research and Consulting Company Ltd. and sponsored by F. Hoffman La Roche and Co. Ag. Acc # 248412.
- 4. Reviewed by: Daniel Rieder Wildlife Biologist
- 5. Date Reviewed: Dec. 3, 1982
- 6. Test Type: 48-hour FC50 with aquatic invertebrate

Species: Daphnia magna

Test Material: RO 13-5223 95% a.i.

- 7. Results: 48-hour LC50 = .4 ppm 95% C.L. 0.31 to 0.55 ppm.
- 8. Conclusion: This study fulfills the guideline requirements for a 48-hr aquatic invertebrate acute toxicity test. It shows that RO 13-5223 is highly toxic to Daphnids.

Twenty daphnids were test at each of 10 test levels and a control. Duplicates were used, 10 organisms in each 50 ml beaker (containing 20 ml test solution). Temperature was kept at 20°c± 1°c. Test animals were less than 24 hours old.

Results

	Concentratio	n ppm		
Nominal	Measured 0-hours	48 hours	No. Tested	48-hr. Mortality
0	0	0	20	0
0.025	0.07	0.06	20	$oldsymbol{0}$
0.050			20	0
0.100		$\frac{\overline{\overline{A}}}{\overline{A}}$	20	1
0.125			20	1
0.250			20	7
0.500	0.37	0.44	20	13
1.000			20	16
2.000	منسيد	· 	20	20
4.000	e sta		20	20
8.000	7.24	4.69	20	20

48-Hour LC50 = 0.40 ppm 95% C.L. = 0.31 to 0.55 ppm

Dissolved Oxygen ranged from 7.5 to 8.0 mg/l.

Discussion

This study showed that RO 13-5223 is highly toxic to daphnids. The test containers were smaller than that recommended by Stephan, but there was no control mortality so the test will be accepted.

Conclusion

Category: Core

1. CHEMICAL: RO 13-5223

2. FORMULATION: Technical

3. CITATION: Keller, P. 1982. Acute Oral Toxicity Test on RO 13-5223 in Honey Bees. Report No. 041/2992 in EPA Acc. No. 248412. Submitted by MAAG Agrochemicals, September 20, 1982.

4. <u>REVIEWER</u>: Allen W. Vaughn Entomologist EEB/HED

5. DATE REVIEWED: Dec. 15, 1982

6. TEST TYPE: Bee Toxicity

A. Test Species: Honey bee (Apis mellifera)

Information provided in this study is insufficient to allow evaluation of results.

Product Manager Registration Division (TS-767) From: Emil Regelman, Acting Chief Review Section No.1 Environmental Fate Branch Attached please find the environmental fate review of: Req./File No.: 35977-EUP-E Chemical: Ethyl[2-(p-phenoxyphenoxy) ethyl] carbamate Type Product: Insect growth regulator Product Name: MAAG RO 13-5223 1% Bait Company Name: MAAG Agrochemicals Submission Purpose: EUP to control fire ants ACTION CODE: 700 ZBB Code: Sec 5 Date in: 10/26/82 EFB # 33 Date Completed: 1/6/83 TAIS (level II Days 52 5 Deferrals To: Ecological Effects Branch Residue Chemistry Branch

Toxicology Branch Date Out:

TO: Frank Gee

1.0 INTRODUCTION

Chemical Name and Type of Pesticide: Ro 13-5223, ethyl[2-(p-phenoxyphenoxy)ethyl]carbamate, 1% ai, insecticide.

Trade Name: Ro 13-5223 1% Bait

Chemical Structure:

Maag Agrochemicals is requesting a one year experimental use permit (EUP) for use on non-cropland to control fire ants. The areas to be treated include airport grass areas, golf courses, athletic fields, building grounds, non-grazed pasture land, etc. Five thousand (5000) acres will be treated in the states of TX, LA, AR, MS, AL, GA, and FL using a total of 6250 lbs of 1% bait or 62.50 lbs ai.

2.0 DIRECTIONS FOR USE

Proposed program and label for EUP is attached.

3.0 DISCUSSION OF DATA

3.1 HYDROLYSIS

3.1.1 Hydrolysis study with the radiolabelled insecticide Ro 13-5223/024, Dieterle P. and R. Kaufmann, 25 May 1982, Report No. 041/2922, p. 103, Acc. # 248411.

Experimental Procedure

Ro 13-5223/024, $^{14}\text{C-labeled}$ in the dioxyphenyl ring was used in the study in buffer solutions of pH 3.0 (0.1M KH₂ Po₄), pH 7.0 (0.1M KH₂Po₄/Na₂HPo₄), and pH 9.0 (0.2M sodium borate/HCl). A typical procedure for the hydrolysis of a.i. at pH 3.0/1 ppm/35°C is shown below.

A 100 ml Sovirel screw-cap bottle containing 50 ml pH 3.0 buffer solution was sterilized by autoclaving (120°C, 20 minutes), then theromstatted at 35°C. Acetonitrile (1.0 ml)

and an aliquot of the radioactive dosage solution (0.5 ml = 4.0×10^6 dpm = 50 ug a.i.) were added to give an a.i. concentration of 0.97 ppm. The flask was capped, shaken vigorously and incubated in the dark at 35°C in a thermostatted oven.

Duplicate samples were worked up at various time intervals (at 35°C incubated samples after 0,3,4,7, and 10 weeks; at 50 °C incubated samples after 0,2,3,5, and 7 weeks) by extracting three times with ethyl acetate (90 ml; 80 ml). The ethyl acetate extracts were filtered through sodium sulphate, the sodium sulphate washed with ethyl acetate 20 ml) and the radioactivity in the extracted aqueous phase and in the combined ethyl acetate phases determined by LSC. The ethyl acetate extract was evaporated to dryness, redissolved in acetonitrile (2 ml) and analysed by LSC. The nature of the radioactivity in each of the duplicate samples was investigated by radio-HPLC.

Results

Table 1 summarizes the results of the study under the various test conditions. Even under extreme temperature (50° C) and time (7 weeks), only traces of radioactivity that did not correspond to Ro 13-5223 (less than 9%) were present.

Conclusion

Ro 13-5223 is stable to hydrolysis. The study is acceptable

3.2 PHOTOLYSIS

3.2.1 Photolysis of 14C-Ro13-5223/024 in solution and on soil surfaces, P. Dieterle and R. Kaufmann, 16 July 1982, Report No. 041/3061, Acc.# 248411.

This parameter is not an EUP data requirement and will only be briefly reviewed here. A complete review will be done when application is made for full registration.

The photolytic half-life in distilled water was 5.7 hour. Degradation produced 3.5% volatile organics, as well as two isomers that were less than 3% of the total radioactivity.

3.3 AEROBIC SOIL METABOLISM

3.3.1 Half year Interim Report of the one year aerobic soil metabolism study with \$14C-Ro\$ 13-5223/024, P. Dieterle and R. Kaufman, 21 June 1982, Report No. 041/2977, Acc. #248411

Although aerobic soil metabolism is a data requirement for an EUP, this is an interim report, so only a summary of the data will be given.

Ro 1-5223, 14 C-labeled in the dioxyphenyl ring, was used to treat three, apparently foreign, soils, the characteristics of which are:

- 1. Commugny soil, "Sandy loam," pH 7.2, 2.1% humus, 15.6% clay, ~
- 2. Dielsdorf soil, "sandy loam," pH6.9, 4.3% humus, 14.7% clay, 30.8% silt.
- 3. Steinmaur soil, "loam," pH7.5, 5.6% humus, 24.6% clay, 36.3% silt.

It is not known what the characteristic "percent humus" refers to.

Test soils came from outdoor, grass-covered plots that had not been treated with pesticide in 3 years. Soil was dried, sived, added to flasks, and conditioned at 25% maximum water capacity. Soils were then treated with 5 ppm a.i. Soils were sampled at 0,1,2, and 7, days, 2 and 3 weeks, and 1,2,3,4 and 6 months, and extracted with acetonitrile/ buffer. Analysis was by LSC, HPLC, and TLC.

After the six months incubation period 5%, 18% and 10% of the initially applied radioactivity were identified as unaltered Ro 13-5223 in Commugny, Dielsdorf and Steinmaur soils, respectively. For these 3 soils, the half-lives, calculated from a program that provides statistics for decline of residues, were 73.7, 127.7, and 85.7 days, respectively. Up to four metabolites were observed in trace amounts. The production of $^{14}\text{CO}_2$ was in the range of 18.0 - 22.8% for all three soils indicating extensive metabolism of a.i. The amount of extractable radioactivity decreased from 95.2% and 98.4% (t = 0) to 16.7%, 27.9% and 19.2% at t = 6 months.

Below is a listing of the studies that were submitted, but have not been summarized. They will be reviewed when application is made for full registration.

3.4 ANAEROBIC SOIL METABOLISM

3.4.1 Laboratory Aerobic Soil Metabolism Study with ¹⁴C-Ro 13-5223/024, P. Dieterle and R. Kaufmann, 28 April 1982, Report No. 041/2841, Acc. #248411.

3.4.2 Laboratory Sterile Soil Metabolism with \$14\text{C-Ro}\$ 13-5223/024, A . Pryde and M. Etterli, 5 March 1982, Report No. 041/2677, Acc. # 248411.

3.5 LEACHING

3.5.1 Laboratory Leaching Studies with \$14\text{C-Ro}\$ 13-5223/024, A Pryde and M. Etterli, 16 April 1982, Report No. 041/2830,

3.6 ADSORPTION/DESORPTION

3.6.1 Freundlich Adsorption and Desorption Constants for $^{14}\text{C-Ro-}13-5223/024$ in four soils, A. Pryde and M. Etterli, 4 March 1982, Report No. 041/2674, Acc # 248411.

3.7 FIELD DISSIPATION

3.7.1 Field dissipation study of Ro 13-5223 when applied to pasture grass as a fire ant bait. J. Fyler, 15 Sept 1982, p. 211, Acc.# 248411.

3.8 FISH ACCUMULATION

3.8.1 Ro 13-5223/024 (¹⁴C); bioconcentration factor and metabolism study in fish, A Pryde and M. Etterli, 22 June 1982, Report No. 041/2986, Acc.# 248411.

4.0 CONCLUSION/RECOMMENDATION

- 4.1 The data requirements for this EUP have been partially satisfied: the hydrolysis study is acceptable and indicates no degradation occurs; half-year interim report on aerobic soil metabolism shows considerable degradation in the test soils.
- 4.2 EFB concurs with the proposed use on fire ants under the EUP because of restriction to non-cropland areas and the low application rate.
- 4.3 The proposed experimental program seems adequate.

Notes to PM: The fish accumulation study employed Bitterling fish.

Our data requirements suggest Bluegill sunfish or channel catfish. When application for full registration is made, the use of Bitterling fish would have to be justified. Laboratory soil studies must use soils with the same characteristics as representative soils in the United States. They must be matched as to soil class, % organic matter, pH soil, ratio of bacteria, to fungi to actinomycetes. Field studies are to be conducted in the United States.

Herbert L. Manning, Ph.D.
Review Section #1
Environmental Fate Branch
Hazard Evaluation Division (TS-769)

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