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17
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DATA ACCESSION NO(S). _____

PRODUCT MANAGER NO. R. Mountfort (23)

PRODUCT NAME(S) Goal 2E

COMPANY NAME Rohm & Haas Company

SUBMISSION PURPOSE Submission of Avian Reproduction studies

LAUGHNESSEY NO.	CHEMICAL, & FORMULATION	% A.I.
<u>111601</u>	<u>Oxyfluorfen</u>	
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Goal 2E

103 Toxicological Properties

103.3.1 Avian Reproduction Studies

The purpose of this submission was to provide two avian reproduction studies that had been requested. Both studies were validated as core and fulfill the requirements.

Mallard Duck

This study meets the guideline requirements for an avian reproductive study with a waterfowl. It shows that exposure to 100 ppm throughout their reproductive season should not effect reproduction.

Bobwhite Quail

This study meets guideline requirements for an avian one-generation reproduction study with an upland gamebird species and shows no effect at 100 ppm.

Daniel Rieder 12/10/82
Daniel Rieder
Wildlife Biologist

Norman Cook 12.10.82
Norman Cook
Head, Section 2

Clayton Bushong 12/10/82
Clayton Bushong, Chief
Ecological Effects Branch

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Data Evaluation Report

1. Chemical: Oxyflourfen
Sha #: 111601
2. Formulation: Goal 2E
3. Citation: Piccirillo, V.J. 1982. One Generation Reproduction Study in Mallard Duck with RH-2915 technical. An unpublished report prepared by Borriston Laboratories for Rohm and Haas Company. Data Accession No. 248736
4. Reviewed by: Daniel Rieder
Wildlife Biologist
5. Date Reviewed: Dec 1, 1982
6. Test Type: One generation reproduction test
Species: Mallard Duck
Test Material: RD-2915 is 72.5 % pure oxyfluorfen. It is considered technical grade.
7. Results: The study showed no difference between the reproductive capabilities of the control group and the 100 ppm test group.
8. Conclusion: This study meets the guideline requirements for an avian reproductive test. It shows that if birds were exposed to 100 ppm throughout their reproductive season, they should experience no adverse effects.

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Methods

Test Material

The test material was referred to as RH-2915. It was 72.5% active ingredient (oxyfluorfen). A premix was prepared every two weeks from RH-2915, corn oil and basal diet. This premix was later used to make the final diet of 100 ppm (adjusted at the premix stage so that it was equivalent to 100 ppm of 100 % pure active ingredient).

Test Animals

Sixty four ducks (16 male, 48 female) were divided into two treatment groups, a control and a 100 ppm test level. Each group consisted of 8 pens containing 1 male and 3 female. The test group was fed the treated diet ad libitum for 21 weeks (11 weeks prelaying and 10 weeks laying cycle). The birds were 6 months old at the beginning of the study.

Husbandry

Pens for parents were 14 feet by 4 feet by 7 feet. Temperature ranged from 33° to 64° F and humidity ranged from 33%-77%. Light cycle was 6 hours light per day for 9 weeks then it was increased to 16 hours of light per day. At initiation, mean light intensity was 6.4 foot candles in control and 6.8 foot candles in the test group. This light intensity induced early egg laying so the light intensity was reduce to 1-2 foot candles at week 7.

Collection of Eggs

Eggs were collected daily, marked by pen and stored at 65°F. Each week the eggs were placed in an incubator at 99.9°F. On days 0, 14 and 21 the eggs were candled for eggshell cracks, fertility and death of embryos and embryo viability respectively. On day 23 the remaining eggs were allowed to hatch. On day 7 of weeks 1, 3, 7 and 9 egg shell thickness was measured.

Observations

Parents were observed twice a day for toxic effects. Individual body weights were recorded at week 0, week 10, and at termination. Hatchlings were observed twice daily for toxic effects.

Reproductive factors observed were: eggs laid; eggs cracked; eggs set; viable embryos; live 21-day embryos; and hatchability.

Results

Mortality

One female died in the treatment group about halfway through egg-laying phase.

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Mean Reproductive Indices and Eggshell Thickness

Factor		Group	
		1 (control)	2 (100 ppm)
Eggs Cracked/Eggs laid	Ratio	10/1371	15/1339
	Percent	0.73	1.12
14-Day Embryos/Eggs Set	Ratio	1152/1264	1079/1231
	Percent	91.1	87.7
21-Day Viable Embryos/ 14-Day Viable Embryos	Ratio	1135/1152	1062/1079
	Percent	98.5	98.4
Eggs Hatched/21-Day Viable Embryos	Ratio	953/1135	832/1062
	Percent	84	78.3
14-Day Survivors/Eggs Hatched	Ratio	942/953	831/832
	Percent	98.8	99.9
14-Day Survivors/ Eggs Laid	Ratio	942/1371	831/1339
	Percent	68.7	62.1
Eggshell thickness (mm)	Mean and S.D.	0.40 \pm 0.032	0.401 \pm 0.027
	Total Eggs Meas.	97	93
Parental Body Weight (grams)	Week 0 Male	1232.1 \pm 98.5	1217.4 \pm 79.3
	Female	1127.9 \pm 122.6	1077.2 \pm 126.0
	Week 10 Male	1228.9 \pm 78.0	1225.1 \pm 92.7
	Female	1124.6 \pm 104.6	1139.8 \pm 139.4
	Week 21 Male	1290.3 \pm 77.8	1224.9 \pm 88.8
	Female	1233.3 \pm 145.6	1232.2 \pm 148.8

Reviewer Evaluation

This study fulfills the guideline requirements for an avian reproduction study. It shows that 100 ppm oxyfluorfen should not have an adverse effect on avian reproduction.

Conclusion

Category: Core

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Data Evaluation Report

1. Chemical: Oxyfluorfen

Sha #: 111601

2. Formulation: Goal 2E

3. Citation: Piccirillo, V.J. 1982. One generation Reproduction study in Mallard Duck with RH-2915 technical. An unpublished report prepared by Borriston Laboratories for Rohm and Haas Company. Data Accession No. 248736.

4. Reviewed by: Daniel Rieder
Wildlife Biologist

5. Date Reviewed: 12/2/82

6. Test Type: One generation reproduction test

Species: Bobwhite quail

Test Material: RH-2915 is 72.5% pure oxyfluorfen. It is considered technical grade.

7. Results: No effects were observed at up to 100 ppm. The concentrations were adjusted so that birds got the equivalent of 50 and 100 ppm of a 100% a.i. test material.

8. Conclusions: This study meets the guideline requirements for an avian one-generation reproduction study and showed no effect to reproduction at 100 ppm.

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Methods

Test Material

The test material was RH-2915. It was 72.5% active ingredient (oxyfluorfen). A pre-mix was prepared every two weeks from RH-2915, corn oil and a basal diet. This pre-mix was then used to make the final diet of 50 or 100 ppm. The amount of RH-2915 added at the pre-mix stage was adjusted so the test concentration was 50 and 100 ppm of a 100% a.i.

Test Animals

<u>Group</u>	<u>No. of Birds</u>		<u>No. of Birds/Pen</u>		<u>Dosage Level</u>
	<u>M</u>	<u>F</u>	<u>M</u>	<u>F</u>	<u>ppm</u>
1	12	24	1	2	0
2	12	24	1	2	50
3	12	24	1	2	100

The birds received the appropriate diets for a 12-week prelaying period and during a 10 - week laying cycle. All groups were placed on a control diet (no treatment) after ten weeks of laying and eggs were collected for three additional weeks.

Husbandry

During the study one male and two females were housed in 12" X 20" X 12" wire cages. Temperature ranged from 42°F to 65°F (6°C to 18°C)

during the egg laying induction phase (12 weeks) and from 58°F to 76°F (14°C to 24°C) during the egg collection phase. Light cycle during the first 12 weeks was 6 hours of light per day. This was increased to 16 hours a day after week 12. Light intensity ranged from 5.9 to 7.1 foot candles.

Collection of Eggs

Eggs were collected daily and stored at 65°F (18°C) Each egg was marked according to pen. At weekly intervals the eggs were removed from storage and incubated at 99.9°F (37.7°C). On days 0, 11, and 21 of incubation the eggs were candled for eggshell crack and embryo viability. On day 21 the eggs were allowed to hatch. On day 7 of weeks 1, 3, 5, 7, 9 and 11 of the egg laying phase all eggs collected were measured for eggshell thickness.

Hatchlings

Hatchlings were housed according to week of hatch and treatment group in 28" X 32" X 11" wire pens. They were observed for toxic effects for 14 days. Temperature was maintained at 77°F to 94°F (25°C to 34°C), light cycle was 17 hours of light per day.

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Observations

Parents were observed twice a day for toxic effects. Individual body weights were recorded at week 0, week 10 and week 25 (termination).
 Reproduction factors observed were: eggs laid; eggs cracked; eggs set; viable embryos live 21-day embryos and hatchability.

Results

Reproductive Indices

Factor	Group		
	1 (control)	2 (50 ppm)	3 (100 ppm)
Mortality (all females)	2	5	5
Eggs cracked/eggs laid	172/1134	80/1035	63/1055
percent	15.2	7.7	6.0
11 - day embryos/eggs set	779/884	806/887	742/916
percent	88.1	90.9	81
21-day / 11-day viable	773/779	797/806	734/742
percent	99.2	98.9	98.9
egg shatched/21-day viable	688/773	722/797	679/734
percent	89	90.6	92.5
14-day survivors/ eggs hatched	588/688	673/722	552/679
percent	88.5	93.2	81.3
14-day survivors/eggs laid	588/1134	673/1035	552/1055
percent	51.8	66.5	52
Eggshell thickness (mm) eggs measured	0.234+0.015 98	0.24+0.017 81	0.232+0.013 92

Factor		Group		
		1 (control)	2 (50 ppm)	3 (100 ppm)
Parental Body weight (grams)	Week 0			
	Male	204.7 + 8.9	212.5 + 13.4	210.1 + 11.9
	Female	206.5 + 13.7	206.8 + 10.0	205.0 + 13.7
	Week 10			
	Male	216.6 + 14.1	221.1 + 14.5	223.0 + 15.2
	Female	222.0 + 30.7	220.7 + 33.8	214.1 + 29.0
Week 25				
	Male	208.4 + 31.0	217.5 + 16.9	225.3 + 20.5
	Female	232.7 + 29.2	229.1 + 36.7	225.4 + 26.5

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Reviewer Evaluation

This study fulfills the guideline requirements for an avian reproduction study. It shows that 100 ppm of oxyfluorfen should have no adverse effect on avian reproduction.

Conclusion

Category: Core

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