6-8-94

DP Barcode : D197918
PC Code No : 128725
EEB Out : 4/14/94

JUN 8 1994

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To:
Product Manager Robert Forrest
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From: Anthony F. Maciorowski, Chief
Ecological Effects Branch/EFED (H7507C)

Attached, please find the EEB review of...

Reg./File # : Registration Division (7505C)
Chemical Name : Methyl anthranilate
Type Product : 066550
Product Name : repellent
Company Name : Bird Shield Repellent
Purpose : New chemical review.

Action Code: Dolphin Trust / Date Due: /
Reviewer: Regina Hirsch

EEB Guideline/MRID Summary Table: The review in this package contains an evaluation of the following:

GDLN NO	MRID NO	CAT	GDLN NO	MRID NO	CAT	GDLN NO	MRID NO	CAT
71-1(A)			72-2(A)			72-7(A)		
71-1(B)			72-2(B)			72-7(B)		
71-2(A)			72-3(A)			122-1(A)		
71-2(B)			72-3(B)			122-1(B)		
71-3			72-3(C)			122-2		
71-4(A)			72-3(D)			123-1(A)		
71-4(B)			72-3(E)			123-1(B)		
71-5(A)			72-3(F)			123-2		
71-5(B)			72-4(A)			124-1		
72-1(A)			72-4(B)			124-2		
72-1(B)			72-5			141-1		
72-1(C)			72-6			141-2		
72-1(D)						141-5		

Y=Acceptable (Study satisfied Guideline)/Concur
P=Partial (Study partially fulfilled Guideline but additional information is needed
S=Supplemental (Study provided useful information but Guideline was not satisfied)
N=Unacceptable (Study was rejected)/Nonconcur

DATA EVALUATION RECORD

1. **CHEMICAL:** Methyl Anthranilate.
Shaughnessey No. 128725.

2. **TEST MATERIAL:** Methyl Anthranilate; CAS No. 134-20-3; Lot No. 5260; 99.6% active ingredient; a colorless liquid.

3. **STUDY TYPE:** 71-1A. Avian Single Dose Oral LD_{50} Test. Species Tested: Bobwhite quail (*Colinus virginianus*).

4. **CITATION:** Ahmed, M.S. 1993. Acute Oral LD_{50} with Bobwhite Quail (*Colinus virginianus*) Using Methyl Anthranilate. Conducted by Genesis Laboratories, Inc., Wellington, CO. Study No. GL No. 93007. Submitted by Bird Shield Repellent Corporation, Pullman, WA. EPA MRID No. 429669-02.

5. **REVIEWED BY:**

Charles G. Nace Jr., M.S.
Associate Scientist
KBN Engineering and
Applied Sciences, Inc.

Signature: Michael L. Whitten for C.G. Nace
Date: 3/31/94

6. **APPROVED BY:**

Michael L. Whitten, M.S.
Wildlife Toxicologist
KBN Engineering and
Applied Sciences, Inc.

Signature: Michael L. Whitten
Date: 3/31/94

James J. Goodyear, Ph.D.
Project Officer, EEB/EFED
USEPA

Signature:
Date:

5/19/94

7. **CONCLUSIONS:** This study is scientifically sound and fulfills the requirements for an avian single dose oral LD_{50} test using the bobwhite quail (*Colinus virginianus*). The LD_{50} was greater than 2036 mg a.i./kg (mean calculated dose), which classifies Methyl Anthranilate as practically non-toxic to bobwhite quail. The no-observed-effect level (NOEL) was 2036 mg a.i./kg.

8. **RECOMMENDATIONS:** N/A

9. **BACKGROUND:**

10. **DISCUSSION OF INDIVIDUAL TESTS:** N/A.

11. **MATERIALS AND METHODS:**

A. **Test Animals:** The birds used in the study were bobwhite quail (*Colinus virginianus*) obtained from a commercial supplier in Houston, TX. All birds were from the same hatch and were phenotypically indistinguishable from wild birds. The test birds were acclimated to the caging and facilities for 26 days prior to the initiation of the study. All the quail were 20.7 weeks of age and appeared to be in good health at the initiation of the study.

B. **Test System:** All birds were housed indoors in cages made of galvanized wire mesh. The dimensions of the cages were 90 x 60 x 45 cm. A photoperiod of 10 hours of light was provided by fluorescent lights. The mean minimum and maximum ambient room temperatures were 64 and 74°F (17.8 and 23.3°C), respectively, and the mean minimum and maximum relative humidity was 51 and 64%, respectively, during the test. Feed and water were provided *ad libitum* during the test period.

C. **Dosage:** Fourteen-day single dose oral LD_{50} test. Based upon preliminary data, one nominal concentration of 2000 mg a.i./kg of body weight (2036 mg a.i./kg mean calculated dose) and a blank control were used.

D. **Design:** Groups of ten birds (five males and five females) were randomly assigned to the treatment group and the control group. All birds were fasted for a minimum of 22 hours prior to dosing.

The test substance was volumetrically measured in a 1000 µl gas tight Hamilton syringe, put directly into a gelatin capsule, and administered orally. Each control bird received one empty gelatin capsule.

The birds were observed for 14 days for mortality and morbidity. Food intake was recorded every day during the observation period. Each bird was weighed on day 0, 7, and 14 during the test. The study was terminated on day 14. After the termination of the study, 40% of the surviving birds from each group were necropsied.

E. **Statistics:** Due to a lack of mortality, an LD_{50} value could not be statistically calculated. The LD_{50} is based on visual inspection of the mortality data.

12. **REPORTED RESULTS:** No clinical signs of toxicity related to the test substance were noted in the control group or the test group throughout the test period. Yellowish fecal material was observed in the treatment group for a day after

dosing. None of the birds died during the 14 day observation period. All birds appeared healthy, except one bird in the treatment group had a trauma induced contusion and laceration to the mandible on day 7 and exhibited general unhealthy appearance. The bird was inspected by a veterinarian and treated with antibiotic for three days to prevent secondary bacterial infection. The bird regained her normal activity on day 9 of the test period.

Mean body weight increased in both the control and treatment group during the study (Table 7, attached). Food consumption was low in the control and treatment group during the first day. Consumption increased from the second day and remained consistent throughout the study (Table 8, attached).

No gross lesions were observed in any of the birds at necropsy.

13. **STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:** "Twenty weeks old bobwhite quail were administered Methyl Anthranilate at 2036 (S.D.±15) mg a.i./kg of body weight. None of the test bird died. The LD_{50} of Methyl Anthranilate to Bobwhite Quail is greater than limit dose (2000 mg a.i./kg of body weight)."

Good Laboratory Practice (GLP) and Quality Assurance Inspection statements were included in the report indicating compliance with EPA GLP standards, 40 CFR 160.

14. **REVIEWER'S DISCUSSION AND INTERPRETATION OF STUDY RESULTS:**

A. **Test Procedure:** The test procedures, as described, were in accordance with Subdivision E and SEP guidelines.

B. **Statistical Analysis:** The reviewer agrees with the author's LD_{50} value of >2036 mg a.i./kg.

C. **Discussion/Results:** Individual dosages varied from 2001 to 2051 mg a.i./kg (Table 4, attached). Presumably, the failure to obtain dosages at precisely 2000 mg a.i./kg was due to the increments on the syringe (i.e., the syringe was calibrated in increments of 10 μl). Therefore, a narrow range of dosages was administered rather than a dosage. All dosages were greater than 2000 mg a.i./kg. Since no deaths occurred, a precise LD_{50} was not obtained.

This study is scientifically sound and fulfills the

requirements for an avian single dose oral LD_{50} test using the bobwhite quail (*Colinus virginianus*). The LD_{50} was greater than 2036 mg a.i./kg (mean calculated dose), which classifies Methyl Anthranilate as practically non-toxic to bobwhite quail. The no-observed-effect level (NOEL) was 2036 mg a.i./kg.

D. **Adequacy of the Study:**

(1) **Classification:** Core.

(2) **Rationale:** N/A.

(3) **Repairability:** N/A.

15. **COMPLETION OF ONE-LINER:** Yes, 03/24/94.

Table 4. Amount of Methyl Anthranilate administered to individual birds.

Bird #	Sex	Bird weight (g)	Amount of test substance administered(µl)[a]	Actual dose administered (mg a.i./kg)[b]	Number of capsules used[c]
			Vehicle Control: 0 mg a.i./kg		
20	♂	203	-	-	1
21	♂	253	-	-	1
22	♂	219	-	-	1
5	♂	235	-	-	1
30	♂	238	-	-	1
41	♀	205	-	-	1
32	♀	231	-	-	1
49	♀	219	-	-	1
54	♀	223	-	-	1
37	♀	232	-	-	1
			T-1: > 2000 mg a.i./kg		
18	♂	201	350	2020	1
8	♂	215	380	2051	1
16	♂	234	410	2033	1
10	♂	194	340	2034	1
24	♂	211	370	2035	1
53	♀	222	390	2038	1
51	♀	215	380	2051	1
34	♀	215	380	2051	1
46	♀	232	400	2001	1
59	♀	216	380	2041	1
Mean				2036	
S.D.				±15	

[a] A volumetric syringe (1000 µl gas tight hamilton syringe with 16 gauge 3" length needle) was used to measure the test substance. The syringe was calibrated with analytical balance using the test substance.

$$\text{[b]Active Ingredient (mg/kg)} = \frac{1000\ g \times \text{Amount administered } (\mu l) \times \text{Specific Gravity}}{\text{Bird Weight (g)}} \times \text{Purity \%}$$

[c] Capsule size: No. 0. Capsules manufactured by Eli Lilly and Company, Indianapolis, IN 46285.

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Table 7. Individual body weight (g) of bobwhite quail dosed with Methyl Anthranilate.

Bird #	Sex	Body weights (g)		
		Day 0	Day 7	Day 14
		Vehicle Control: 0 mg a.i/kg		
20	♂	203	216	226
21	♂	253	258	266
22	♂	219	231	243
5	♂	235	248	257
30	♂	238	250	261
41	♀	205	211	223
32	♀	231	238	250
49	♀	219	228	237
54	♀	223	227	243
37	♀	232	244	253
Mean		226	235	246
S.D.		±14	±14	±14
		T-1: 2036 mg a.i./kg		
18	♂	201	211	222
8	♂	215	220	234
16	♂	234	240	249
10	♂	194	195	210
24	♂	211	213	226
53	♀	222	228	239
51	♀	215	191	214
34	♀	215	213	228
46	♀	232	237	251
59	♀	205	220	230
Mean		214	217	230
S.D.		±12	±15	±13

Table 8. Mean daily food consumption (gram/bird/day) for bobwhite quail dosed with Methyl Anthranilate

Days	Dose level (mg a.i./kg)	
	Vehicle Control (0 mg)	T-1 (2036 mg)
1	9	3
2	18	14
3	15	16
4	17	17
5	17	17
6	17	17
7	19	17
8	15	16
9	14	16
10	16	15
11	17	17
12	17	16
13	17	16
14	16	15
Mean	16	15
S.D.	±2.2	±3.5

Ecological Effects Branch One-Liner Data Entry Form

Chemical Methyl Anthranilate **Shaughnessy No.** 128725 **Pesticide Use** _____

AVIAN ORAL TOX SPECIES (AGE)	% AI	LD_{50} (95%CL)	SLOPE	NOEL	STUDY/REVIEW DATES	MRID/ CATEGORY	LAB	RC
1. Bobwhite quail (20.7wks) *Colinus virginianus*	99.16%	>2036 mg ai/kg* (N/A)	N/A	2036 mg ai/kg*	1993/1994	429665-02/ Core	Genesis Laboratory, Inc.	cgn
2.								
3.								
4.								
5.								

AVIAN DIETARY SPECIES (AGE)	% AI	LC_{50} (95%CL)	SLOPE	NOEL	STUDY/REVIEW DATES	MRID/ CATEGORY	LAB	RC
1.								
2.								
3.								
4.								
5.								

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COMMENTS: * mean calculated dose