DP Barcode : D192329
PC Code No : 128725
EEB Out : JUN 8 1994

To: Robert Forrest
Product Manager 14
Registration Division (H7505C)

From: Anthony F. Maciorowski, Chief
Ecological Effects Branch/EFED (H7507C)

Attached, please find the EEB review of...

Reg./File # : 058035-I
Chemical Name : Methyl anthralinate
Type Product : repellent
Product Name : Rejex
Company Name : PMC Specilaties
Purpose : Review new chemical which has passed screen.

Action Code: 146 Date Due: 9/30/93
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 Number: 128725.

2. **TEST MATERIAL:** Methyl Anthranilate; 99.9% purity; a clear liquid.

3. **STUDY TYPE:** 71-2. Avian Dietary LC_{50} Test.
Species Tested: Mallard (*Anas platyrhynchos*).

4. **CITATION:** Campbell, S.M. and M. Jaber. 1992. Methyl Anthranilate (MA): A Dietary LC_{50} Study With the Mallard. Study performed by Wildlife International Ltd., Easton, Maryland. Laboratory Study No. 343-101A. Submitted by ERM Program Management Company, McLean, Virginia. EPA MRID No. 426088-08.

5. **REVIEWED BY:**

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

Signature: Michael L. Whitten
Date: 9/1/93

6. **APPROVED BY:**

Mark A. Mossler, M.S.
Associate Scientist
KBN Engineering and
Applied Sciences, Inc.

Signature: Mark A. Mossler
Date: 9/1/93

Henry T. Craven, M.S.
Supervisor, EEB/EFED
USEPA

Signature:
Date:

7. **CONCLUSIONS:** The study is scientifically sound but does not meet the requirements of an avian LC_{50} study, since the results of the diet analysis were not included in the report. Based upon nominal concentrations, the LC_{50} was greater than 5620 ppm. This classifies the test substance as practically non-toxic to mallard ducklings. The NOEC was 3160 ppm, due to reduced body weight gain at 5620 ppm.

8. **RECOMMENDATIONS:** N/A.

9. **BACKGROUND:**

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

11. **MATERIALS AND METHODS:**

A. **Test Animals:** Mallard ducklings (*Anas platyrhynchos*) were obtained from Whistling Wings, Hanover, Illinois. All birds were from the same hatch, pen-reared and phenotypically indistinguishable from wild birds. The birds could not be differentiated by sex. The birds were acclimated to the facilities for eight days, and were 10-days old at test initiation.

B. **Test System:** Birds were housed indoors in pens constructed of vinyl coated wire mesh. Pen dimensions were 72 cm x 90 cm x 25.5 cm. The photoperiod was 16 hours of light per day. The average temperature in the brooding compartment of the pens was 31 ± 2°C. The average ambient room temperature was 21.9 ± 1.7°C, with an average relative humidity of 76 ± 13%.

C. **Dosage:** Eight-day dietary LC_{50} test. Nominal dietary concentrations were 562, 1000, 1780, 3160, and 5620 parts per million (ppm). The dietary concentrations were not adjusted for purity of the test substance. Therefore, the dietary concentrations and the LC_{50} are reported as ppm of the test substance as received.

D. **Design:** Groups of ten birds were assigned, by indiscriminate draw, to each of three control groups and five treatment groups. All birds were fed Wildlife International Ltd.'s game bird ration. Food and water were supplied *ad libitum* during acclimation and during the test.

The test diets were prepared by mixing the test substance into the diet with acetone and corn oil. The concentration of corn oil in the treatment and control diets was 2%. The birds were fed the appropriate dietary concentrations for five days, and then given untreated food during a three-day recovery period.

Samples of the diets were taken to verify the test concentrations and to confirm the stability and homogeneity of the test substance in the diets. The samples were frozen and shipped to Bushy Run Research Center for analysis.

Observations were made at least twice daily for mortalities, signs of toxicity, and abnormal behavior. Individual body weights were measured daily during the exposure period (days 0-5), and at termination (day 8). Group food consumption was determined daily during the exposure period, and at the end of the observation period.

E. **Statistics:** Due to the absence of mortality in all treatment groups, the LC_{50} was not calculated. An estimation of the LC_{50} was made by a visual inspection of the mortality data.

12. **REPORTED RESULTS:** There were no mortalities in the control groups or in any treatment group during the study. All birds in the control groups and in all treatment groups were normal in appearance and behavior throughout the test period.

When compared to the control groups, there was a reduction in body weight gain in the 5620-ppm group during the first day of the study (Tables 3 and 4, attached). Food consumption was not affected at any of the concentrations tested (Tables 5 and 6, attached).

13. **STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:** The dietary LC_{50} was greater than 5620 ppm, the highest concentration tested. The no mortality concentration was 5620 ppm. The no-observed-effect concentration was 3160 ppm, based on a reduction in body weight gain at 5620 ppm.

Quality Assurance and Good Laboratory Practice statements were included in the report, indicating conformance with GLP regulations as set forth in 40 CFR Part 160, with the exception that "Test substance characterization was not audited by Wildlife International Ltd. It was not known if characterization was conducted in compliance with Good Laboratory Practice standards."

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

A. **Test Procedure:** The test procedures were in accordance with Subdivision E, ASTM, and SEP guidelines except for the following deviations:

The birds were not randomly assigned to pens. Instead, they were assigned by "indiscriminate draw."

The mallards were 10 days of age at test initation; 5-day old mallards are preferred.

The pen floor space (72 cm x 90 cm = 6480 cm^2) was smaller than recommended (70 cm x 100 cm = 7000 cm^2).

The brooder temperature was approximately 31°C; the guidelines recommend a brooder temperature of approximately 35°C.

The reported average relative humidity (76 ± 13%) indicates that the value was sometimes greater than the maximum recommended value (80%).

B. **Statistical Analysis:** Due to the absence of mortality during the test, the LC_{50} could not be calculated and is assumed to be greater than 5620 ppm.

C. **Discussion/Results:** The report stated that the birds were assigned to groups by indiscriminate draw. Strictly speaking, "indiscriminate draw" is not the same as "random" assignments. However, this method of assignment probably did not affect the results of the test.

Results of the chemical analyses of the test diets were not submitted with the report. These data should be submitted so that the stability of the chemical in the diets and verification of treatment concentrations can be determined.

Based upon nominal concentrations, the LC_{50} was greater than 5620 ppm. This classifies the test substance as practically non-toxic to mallard ducklings. The NOEC was 3160 ppm, due to reduced body weight gain at 5620 ppm.

The study is scientifically sound but does not meet the requirements of an avian LC_{50} study.

LWT 8-27-94

D. **Adequacy of the Study:**

CORE

(1) **Classification:** ~~Supplemental~~.

DATA SUBMITTED MRID. 433041-01

(2) **Rationale:** Results of the chemical analyses of the test diets were not submitted with the report.

(3) **Repairability:** The study can be upgraded to "Core" if the registrant can provide satisfactory results of the diet analyses.

15. **COMPLETION OF ONE-LINER:** Yes; August 13, 1993.

TABLE 3
BODY WEIGHT OF CONTROL MALLARDS

Concentration	Average Body Weight (Grams)													
	Exposure											Observation		Total
ppm	Day 0	Change	Day 1	Change	Day 2	Change	Day 3	Change	Day 4	Change	Day 5	Change	Day 8	Change
0	132±17	15	147±15	27	174±16	29	203±19	24	227±18	29	256±19	87	343±17	211
0	125±13	12	137±14	19	156±19	28	184±24	18	202±22	24	226±25	76	302±31	177
0	111±7	17	128±10	25	153±9	27	180±14	18	198±16	22	220±18	70	290±19	179

TABLE 4
BODY WEIGHT OF MALLARDS
EXPOSED TO METHYL ANTHRANILATE (MA) FOR FIVE DAYS

Concentration	Average Body Weight (Grams)													
	Exposure											Observation		Total
ppm	Day 0	Change	Day 1	Change	Day 2	Change	Day 3	Change	Day 4	Change	Day 5	Change	Day 8	Change
562	139±22	15	154±25	29	183±24	24	207±29	15	222±29	29	251±29	68	319±37	180
1000	137±22	14	151±21	29	180±24	33	213±27	18	231±25	14	245±20	88	333±32	196
1780	144±9	14	158±10	25	183±11	32	215±12	21	236±16	31	267±19	93	360±21	216
3160	139±14	12	151±18	25	176±19	23	199±21	15	214±22	29	243±24	60	303±25	164
5620	152±16	4	156±14	19	175±14	30	205±16	28	233±23	21	254±23	75	329±29	177

* Actual loss in body weight was only noted in three out of ten birds.

TABLE 5

AVERAGE ESTIMATED FEED CONSUMPTION OF CONTROL MALLARDS

Concentration ppm	Estimated Feed Consumption Grams Per Bird Per Day Exposure Days 0-1	1-2	2-3	3-4	4-5	Obs. 6-8
0	38	38	48	56	66	68
0	35	40	48	56	70	79
0	45	44	51	57	69	88

TABLE 6

AVERAGE ESTIMATED FEED CONSUMPTION OF MALLARDS EXPOSED TO METHYL ANTHRANILATE FOR FIVE DAYS

Concentration ppm	Estimated Feed Consumption Grams Per Bird Per Day Exposure Days 0-1	1-2	2-3	3-4	4-5	Obs. 6-8
562	46	47	50	44	69	88
1000	54	54	67	63	77	82
1780	52	56	62	64	81	85
3160	41	45	53	55	82	87
5620	34	47	58	61	70	91

Ecological Effects Branch One-Liner Data Entry Form

Chemical Methyl anthranilate Shaughnessy No. 128725 Pesticide Use Repellent

AVIAN ORAL TOX SPECIES (AGE)	% AI	LD_{50} (95%CL)	SLOPE	NOEL	STUDY/REVIEW DATES	MRID/ CATEGORY	LAB	RC
1.								
2.								
3.								
4.								
5.								
AVIAN DIETARY SPECIES (AGE)	**% AI**	**LC_{50} (95%CL)**	**SLOPE**	**NOEC**	**STUDY/REVIEW DATES**	**MRID/ CATEGORY**	**LAB**	**RC**
1. Anas platyrhynchos 10 days old	99.9%	>5620 ppm *	N/A	3160 ppm *	1992/1993	Supplemental	WLI	new
2.								
3.								
4.								
5.								

COMMENTS: * nominal concentration