

192722
RECORD NO.

SHAUGHNESSEY NO.

REVIEW NO.

EEB REVIEW

DATE: 4-3-87 OUT 3/15/89

FILE OR REG. NO. 52904-C
PETITION OR EXP. NO. _____
DATE OF SUBMISSION 1-21-87
DATE RECEIVED BY HED 3-31-87
RD REQUESTED COMPLETION DATE 5-29-87
EEB ESTIMATED COMPLETION DATE 5-29-87
RD ACTION CODE/TYPE OF REVIEW 660

TYPE PRODUCT(S) : I, D, H, F, N, R, S Insecticide

DATA ACCESSION NO(S). 40 056104

PRODUCT MANAGER NO. G. LaRocca(15)

PRODUCT NAME(S) Lindane

COMPANY NAME CIEL

SUBMISSION PURPOSE Submmission of R-Winged Blackbird 14-day
dietary toxicity study in ~~response~~ to
Reg. Standard

SHAUGHNESSEY NO. CHEMICAL, & FORMULATION % A.I.

ECOLOGICAL EFFECTS BRANCH

CHEMICAL: Lindane

100.0 Purpose of Submission

The Registrant (Centre International d' Etudes du Lindane (CIEL) has submitted a 14-day free choice avian dietary toxicity study to satisfy the data requirements set forth in the Reregistration Standard.

101.0 Background Discussion

When first reviewing Lindane the EEB had originally assumed that it was unlikely that a bird could consume enough treated seeds under field conditions to get a lethal dose. However, subsequent calculations by A. Stavola (see Lindane Standard) showed that, based on a seed treatment rate of 2 oz. a.i./100 lbs. of seed (corn), a red-winged blackbird would only have to consume 9 seeds to get a lethal dose.

In addition to toxicity, a major factor complicating the question of hazard from Lindane treated seeds to avian species is repellency. Early avian studies indicate that Lindane acts as a repellent to birds. If this is the case, birds may not eat enough seed to pose a hazard from a seed treatment use. Therefore, in order to address the toxicity and repellency questions, the EEB requested that forced and free-choice dietary studies, using red-winged blackbirds and bobwhite quail, be conducted to support the Reregistration Standard.

In response to this request, the Registrant submitted a protocol to conduct a 14-day avian dietary free choice study. The EEB found the protocol to be acceptable provided the following study design changes were made:

1. food consumption was to be measured daily
2. feed hoppers are to be randomized daily to prevent conditioning
3. the control group would have 2 feed hoppers with untreated seeds
4. treatment 1 would have 2 feed hoppers with treated seeds
5. treatment 2 would consist of 2 feed hoppers, 1 with treated seeds and 1 with untreated seeds

102.0 Data Adequacy

The submitted study was found to be adequate to satisfy the data requirement. The results of the study show that Lindane can act as a repellent to blackbirds (at least on sorghum seeds) and that free ranging birds may be able to avoid feeding on Lindane contaminated feed.

103.0 Discussion

It's important to keep in mind that this was a laboratory study, conducted under somewhat favorable and constant conditions, and, as such, may not be indicative of avian feeding behavior, or subsequent response, under natural environmental conditions. For instance, there may be situations, caused by biotic or abiotic factors, where, because food is scarce or limited, free ranging birds may not have the luxury to selectively feed on uncontaminated feed. It's also important to note that this study was conducted with a specific formulation and that other formulations may not have similar repellency.

It is this reviewer's opinion, however, based upon the results of this study, which clearly shows that blackbirds actively select for untreated seed, as well as data from other studies which suggests that Lindane repels birds, that the acute hazard to birds is reduced by the repellent nature of the compound.

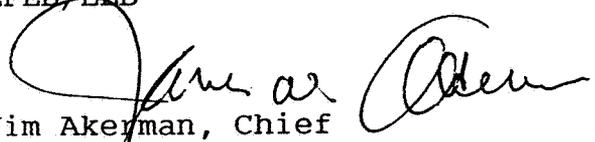
104.0 Conclusions

The EEB has reviewed the 14-day free choice avian dietary feeding study and has determined that the study is scientifically sound and satisfies the 71-2 Reregistration data requirement. Results from this study clearly show that blackbirds, when given a free choice, will avoid Lindane contaminated seeds.

The EEB notes that there are still some data requirements outstanding. Thus, the EEB will withhold from making a comprehensive hazard assessment until all data requirements have been satisfied.

 3/2/89
Richard W. Felthousen, Wildlife Biologist
EFED/EEB

 3.15.89
Norm Cook, Head- Section II
EFED/EEB

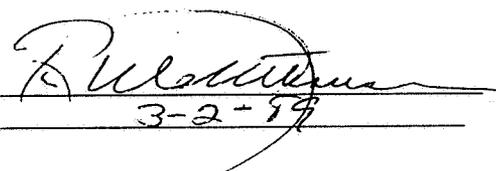
 3/15/89
Jim Akerman, Chief
EFED/EEB

DATA EVALUATION RECORD

1. Chemical: Lindane
2. Test Material: Lindane 40% Flowable
3. Study Type: 14-Day Free Choice Dietary Toxicity Study.
4. Test Species: Red-winged blackbirds
5. Study ID:
Title: 14-Day Dietary Toxicity Study with Lindane
Formulated Product in Red-winged Blackbirds.
Author: Dale W. Fletcher
Date: October 3, 1986
Laboratory: Bio-Life Associates, Ltd.

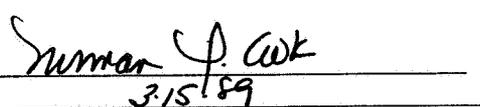
6. Reviewed By:

Richard Felthousen
EFED

Signature: 
Date: 3-2-89

7. Approved By:

Norm Cook,
Head Section 2
EFED

Signature: 
Date: 3-15-89

8. Conclusions:

The study is scientifically sound and satisfies the test requirement set forth in the Standard.

9. Recommendations:

N/A

10. Background:

The study was submitted to satisfy Reregistration Standard Data Requirements.

11. Materials and Methods:

- A. Test Animals: Red-winged Blackbirds (adult males)
- B. Treatments (Nominal concentrations):

1. T-I-A= 130 ppm and untreated
2. T-II-A= 1,040 ppm and untreated
3. T-I-B= 130 ppm
4. T-II-B= 1,040 ppm
5. Control= untreated

Lindane treated sorghum seeds were the test vehicle.

C. Design:

Birds were randomly divided equally into one control and four treatment groups of 10 adult males each. Observations were made daily. All birds were housed individually in steel wire mesh pens (20"X10"x8"). A thermostatically control environment between 61-89 degrees F was maintained throughout the test. Fluorescent lighting was left on for 8 hours per day. Two feeders were placed at random locations within each pen on a daily basis.

D. Parameters Investigated:

Body weight, food consumption, necropsy, clinical observation

E. Reported Results:

Toxicological symptoms included anorexia and lethargy. Abnormal activity was observed within 25 hours of initial exposure to the treated diet (1 bird in the T-I-B group). A total of 20 birds died during the study (9 in the T-I-B group; 1 in the T-II-A group and 10 in the T-II-B group). Death occurred within 2 days of exposure. Birds preferred to eat untreated feed.

F. Reviewers Discussion and Interpretation of the Study:

A. Test Procedures: The study was conducted in accordance with those procedures described by the EEB in meetings and correspondence with the registrant.

B. Statistical Analysis: No statistical analysis of the data are necessary. The EEB agrees with the reported results.

C. Discussion/Results:

Dietary analysis of the treated feed showed that actual residues (ppms) were higher than the theoretical mixture (actual residues ranged from 155-170 and 1250-1430 ppms, for the 130 and 1040 ppm treatment levels, respectively).

Analysis of the food consumption data shows that the birds clearly selected untreated over treated feed. The random placement of the feeders demonstrates that the birds were able to discern and avoid the treated feed. When birds were not provided a free choice of diet, decreased food consumption, weight loss and mortality occurred (see attached data tables).

These data suggest that free-ranging birds may be able to avoid feeding on seeds, and perhaps other food

5

sources, contaminated by Lindane residues.

12. Data Adequacy:

The study was found to be scientifically sound, and conducted in accordance with the testing guidelines. Deviations from acceptable protocols were not sufficient enough to affect the results of the study.

13. Classification: Core

14. Rational: The study meets the data requirements specified in the Standard.

15. Repairability: N/A

BIO-LIFE ASSOCIATES, LTD.

TABLE IV
 TEST MATERIAL: LINDANE-FORMULATED PRODUCT
 14-DAY FREE-CHOICE DIETARY TOXICITY STUDY
 IN RED-WINGED BLACKBIRDS
 MORTALITY DATA

Group	<u>Number Dead</u> <u>Number Tested</u>	percent Dead	Bird #/Time of Death (Days)
Control	0/10	0	-
T-I-A	0/10	0	-
T-I-B	9/10	90	645/2, 738/2, 674/2, 636/3, 667/3, 748/4, 631/4, 633/4, 650/5
T-II-A	1/10	10	656/2
T-II-B	10/10	100	744/2, 662/2, 634/3, 644/3, 640/3, 629/3, 648/4, 646/4, 743/4, 627/5

- = No mortalities

Note: This study was initiated at 2:05 p.m. on June 17, 1986. Test Day 1 extends from 2:05 p.m. on June 17, 1986, to 2:05 p.m. on June 18, 1986.

TABLE VI
 TEST MATERIAL: LINDANE-FORMULATED PRODUCT
 14-DAY FREE-CHOICE DIETARY TOXICITY STUDY - RED-WINGED BLACKBIRDS
 FOOD CONSUMPTION DATA (grams)

Group	Dietary Level (ppm)	Bird #	Sex	TEST DAY								RECOVERY DAY								
				1	2	3	4	5	6	7	8	9	10	11	12	13	14			
Feeder 1																				
C	0	641	M	7	6	5	5	9	19	14	14	10	11	5	13	3	21	19	18	
		741	M	5	12	2	12	12	5	15	15	7	10	10	10	10	0	13	48	8
		742	M	7	12	7	12	19	12	12	12	6	8	6	6	7	0	30	0**	10
		750	M	4	2	11	0	4	4	12	7	5	0	0	0	16	1	18	0	16
		647	M	9	17	1	9	3	4	4	9	17	3	3	3	5	0	9	3	6
		739	M	7	10	5	6	3	3	13	20	5	5	0	0	16	12	15	7	7
		660	M	5	3	9	7	5	5	18	14	11	1	1	1	15	0	14	3	7
		658	M	3	3	8	5	11	11	11	9	9	3	3	5	11	2	33	0**	8
		672	M	8	10	9	14	9	4	4	6	7	7	1	1	9	0	27	0**	8
		524	M	7	1	10	6	13	9	9	9	9	9	4	4	16	3	8	0	7
Feeder 2																				
C	0	641	M	3	5	6	5	14	26	14	32	7	7	1	7	0	6	0	63*	
		741	M	8	12	10	8	16	12	12	8	8	7	7	7	4	5	14	0**	17
		742	M	9	15	5	13	12	8	18	15	15	12	12	3	3	13	5	0**	10
		750	M	6	10	2	13	17	0	14	10	10	2	2	2	5	0	11	8	0
		647	M	2	5	7	5	9	22	9	9	12	7	7	2	4	4	4	12	4
		739	M	5	12	7	10	13	1	5	12	7	7	7	7	10	12	15	7	1
		660	M	11	9	9	7	11	5	13	7	9	9	1	1	18	4	5	23	7
		658	M	12	18	2	20	16	13	13	7	20	9	0	0	15	4	1	0**	4
		672	M	9	14	16	4	10	16	16	22	19	3	3	3	20	8	11	0**	13
		524	M	8	10	2	11	8	11	11	8	6	2	2	2	15	2	20	13	9

* This is not an accurate representation of the amount of food consumed because excess spillage of food had occurred.
 ** This is not an accurate representation of the amount of food consumed because excess spillage of food had occurred. This excess spillage was picked up and added back to the feeder.

88

TABLE VI (Cont.)

TEST MATERIAL: LINDNE-FORMULATED PRODUCT
 14-DAY FREE-CHOICE DIETARY TOXICITY STUDY - RED-WINGED BLACKBIRDS
 FOOD CONSUMPTION DATA (grams)

Group	Dietary Level (ppm)	Bird #	Sex	Test Day							Recovery Day						
				1	2	3	4	5	6	7	8	9	10	11	12	13	14
Feeder 1																	
T-1-B	130	636	M	9	0	2	-	-	-	-	-	-	-	-	-		
		645	M	2	2	-	-	-	-	-	-	-	-	-	-		
		738	M	3	1	-	-	-	-	-	-	-	-	-	-		
		667	M	4	1	2	-	-	-	-	-	-	-	-	-		
		669	M	1	4	5	3	3	4	7	6	0	3	0	14	1	
		674	M	5	0	-	-	-	-	-	-	-	-	-	-	-	
		650	M	1	3	0	6	1	-	-	-	-	-	-	-	-	
		748	M	2	5	3	3	-	-	-	-	-	-	-	-	-	
		631	M	2	1	2	0	-	-	-	-	-	-	-	-	-	
		633	M	3	2	3	1	-	-	-	-	-	-	-	-	-	
Feeder 2																	
T-1-B	130	636	M	2	2	2	-	-	-	-	-	-	-	-	-		
		645	M	1	1	-	-	-	-	-	-	-	-	-	-		
		738	M	13	3	-	-	-	-	-	-	-	-	-	-		
		667	M	2	1	3	-	-	-	-	-	-	-	-	-		
		669	M	3	3	22*	5	3	2	4	9	1	4	1	1	11	
		674	M	7	2	-	-	-	-	-	-	-	-	-	-	-	
		650	M	19*	2	2	2	0	-	-	-	-	-	-	-	-	
		748	M	12	4	4	1	-	-	-	-	-	-	-	-	-	
		631	M	3	3	1	1	-	-	-	-	-	-	-	-	-	
		633	M	1	1	3	1	-	-	-	-	-	-	-	-	-	

- Indicates that this bird was found dead prior to this interval.
 * This is not an accurate representation of the amount of food consumed because excess spillage of food had occurred.

TABLE VI (Cont.)
 TEST MATERIAL: LINANE-FORMULATED PRODUCT
 14-DAY FREE-CHOICE DIETARY TOXICITY STUDY - RED-WINGED BLACKBIRDS
 FOOD CONSUMPTION DATA (grams)

Group	Dietary Level (ppm)	Bird #	Sex	Test Day							Recovery Day						
				1	2	3	4	5	6	7	8	9	10	11	12	13	14
Feeder 1																	
T-II-A	0	649	M	6	13	17	14	14	20	16	11	12	11	2	0	0	2
		673	M	7	69*	21	5	21	25	114*	25	9	11	10	5	0**	4
		666	M	3	1	5	9	19	30	22	18	3	5	0	39	0**	5
		659	M	27	40	20	19	31+	31	30	25	21	12	8	25	0	7
		670	M	5	2	11	22	19	27	23	14	5	1	3	2	0	0
		638	M	0	2	17	12	18	28	19	5	7	5	0	23	2	11
		642	M	13	17	15	17	14	26	23	4	11	22	2	15	0	5
		656	M	18	10	-	-	14	14	12	18	7	4	13	2	20	0**
		663	M	9	8	5	14	23	23	22	16	18	13	2	1	9	9
		630	M	5	15	9	9	14	14	12	7	4	13	1	1	9	0
Feeder 2																	
T-II-A	1060	649	M	2	3	2	7	0	0	5	7	5	8	0	32	11	7
		673	M	6	74*	11	0	4	10	59*	18	15	0	17	32*	0**	15
		666	M	6	1	0	1	2	3	4	5	13	11	2	4	0**	14
		659	M	2	1	1	3	0	0	0	4	1	5	0	8	13	16
		670	M	2	0	4	1	1	2	17	5	9	14	4	22	17**	40
		638	M	4	1	1	1	0	4	1	11	12	17	5	11	0	0
		642	M	3	4	2	1	1	1	5	11	6	10	0	10	20	11
		656	M	1	0	-	-	-	-	-	-	-	-	-	-	-	-
		663	M	2	4	12	8	0	4	2	1	2	0	20	3	6	0**
		630	M	2	5	2	8	4	5	3	18	0	1	0	20	3	12

- Indicates that this bird was found dead prior to this interval.

* This is not an accurate representation of the amount of food consumed because excess spillage of food had occurred.

** This is not an accurate representation of the amount of food consumed because excess spillage of food had occurred. This excess spillage was picked up and added back to the feeder.

TABLE VI (Cont.)

TEST MATERIAL: LINDANE-FORTIFIED PRODUCT

14-DAY FREE-CHOICE DIETARY TOXICITY STUDY - RED-WINGED BLACKBIRDS

FOOD CONSUMPTION DATA (grams)

Group	Dietary Level (ppm)	Bird #	Sex	Test Day							Recovery Day						
				1	2	3	4	5	6	7	8	9	10	11	12	13	14
Feeder 1																	
T-II-B	1040	629	M	6	2	2	1	-	-	-	-	-	-	-	-	-	
		640	M	0	4	4	0	-	-	-	-	-	-	-	-	-	-
		634	M	0	2	2	-	-	-	-	-	-	-	-	-	-	-
		662	M	0	6	6	-	-	-	-	-	-	-	-	-	-	-
		627	M	2	2	5	2	2	2	1	-	-	-	-	-	-	-
		743	M	1	1	2	1	1	2	2	-	-	-	-	-	-	-
		648	M	3	3	3	2	2	3	3	-	-	-	-	-	-	-
		646	M	4	4	11	2	2	1	1	-	-	-	-	-	-	-
744	M	4	0	0	1	1	-	-	-	-	-	-	-	-	-		
644	M	2	1	1	2	-	-	-	-	-	-	-	-	-	-	-	
Feeder 2																	
T-II-B	1040	629	M	5	0	0	0	-	-	-	-	-	-	-	-	-	
		640	M	4	5	1	1	-	-	-	-	-	-	-	-	-	-
		634	M	5	0	0	-	-	-	-	-	-	-	-	-	-	-
		662	M	3	0	0	-	-	-	-	-	-	-	-	-	-	-
		627	M	0	5	5	2	0	1	-	-	-	-	-	-	-	-
		743	M	3	1	1	5	0	-	-	-	-	-	-	-	-	-
		648	M	2	3	1	1	2	-	-	-	-	-	-	-	-	-
		646	M	4	6	0	0	0	-	-	-	-	-	-	-	-	-
744	M	27*	0	6	0	2	-	-	-	-	-	-	-	-	-		
644	M	5	1	1	8	-	-	-	-	-	-	-	-	-	-		

- Indicates that this bird was found dead prior to this interval.

* This is not an accurate representation of the amount of food consumed because excess spillage of food had occurred.