10-7-91

Data Evaluation Record

1. Chemical: XRM 5160 (Microencapsulated Insecticide)
Shaughnessy No.:059101

2. Test Material: XRM 5160 (Dursban 20, microencapsulated), 25.65% a.i. as chlorpyrifos, CAS#002921-88-2, AGR#286398; a white suspension.

3. Study type: Avian Dietary LC_{50}

Test Species: Mallard duck (Anas platyrhynchos)

4. Study ID: Long, Ronald D., Smith, Gregory J. and Beavers, Joann B., "XRM 5160 (microencapsulated insecticide): A dietary LC_{50} study with the mallard duck. Performed by Wildlife International, 305 Commerce Drive, Easton, MD for The Dow Chemical Co., Midland, MI, for DowElanco, Indianapolis, IN. WI study ID #103-351A. Dow contract #ES-DR-0320-1647-1 **MRID 419655-01.** Study dated June 7, 1991

5. Reviewed by: Kathryn Valente
Biologist
EEB/EFED
Signature: Kathryn F. Valente
Date: 10/7/91

6. Approved by: Allen Vaughan
Acting Head, Section II
EEB/EFED
Signature: Allen W. Vaughan
Date: 10.7.91

7. Conclusions: The study is scientifically sound and is classified as core for formulated product. With an LC_{50} of 4223 ppm, the test material is considered to be slightly toxic to the mallard. The NOEL was <156 ppm.

8. Recommendations: N/A nominal LC_{50} 1083 (736-2941) ppm a.i.
measured LC_{50} 803 (546-2278) ppm a.i.

9. Background information: This study was submitted in support of reregistration.

10. Discussion of Individual Tests: N/A

11. Materials and Methods:
a. Test animals: Mallard ducklings were obtained from Whistling Wings in Hanover, Illinois. The birds were 10 days old at test initiation. All test birds were acclimated to the caging and facilities from the time of receipt until testing. The birds were maintained on a 16 hour light/8 hour dark photoperiod at an average temperature of 34° C+/- 1° C in the brooder compartment (22° C +/- 6° C average ambient temperature) and average relative humidity of 65% +/- 13%.

b. Dosing regime: The test substance was dissolved in corn oil and mixed into the basal diet (Wildlife International's Game Bird Ration) with a Hobart mixer. The concentration of corn oil in the test and control diets was 2%. One hundred Ml of acetone was used in the preparation of each of the test diets. There was no acetone added to the control diet. Nominal dietary test concentrations of XRM 5160 were 156, 313, 625, 1250, 2500 and 5000 ppm. Birds were maintained on the test diets for 5 days, followed by a 3 day post-exposure observation period during which the birds were maintained on the untreated basal diet.

c. Study design: Ten birds were assigned to each treatment level, including three control groups. The birds could not be differentiated by sex due to age. Observations for mortality and sublethal effects were made daily throughout the exposure and post-exposure periods. Individual body weights by group were measured at test initiation, on day 5 and at the end of the test, day 8. Average estimated feed consumption was determined for each group for days 0-5, and 6-8.

d. Statistics: Data was analyzed using the computer program of Stephan. The probit method was used to determine the LC_{50} and corresponding 95% confidence limits for this data set.

12. Reported Results: Mallards were exposed to six nominal concentrations of XRM 5160: 156, 313, 625, 1250, 2500 and 5000 ppm. There were no control mortalities nor any mortalities at 156, 313, 625 or 1250 ppm. There were 4 mortalities at 2500 ppm, and 5 at 5000 ppm. There were no signs of toxicity at 156, 313 or 625 ppm. Signs of toxicity were prevalent in the three highest treatment levels beginning on day 3 and lasting until day 7. At 1250 ppm, birds showed a ruffled appearance and lethargy during the exposure period (days 0-5). At 2500 and 5000 ppm, birds showed depression, reduced reaction to external stimuli, loss of coordination, prostration, loss of righting reflex, ruffled appearance, lower limb weakness and lethargy. There was a reduction in body weight gain at all test concentrations compared to the controls during the exposure period (days 0-5), and this decrease in body weight gain showed a dose-response effect. There was a decrease in food consumption relative to the controls at the 5 highest concentrations, and a possible slight reduction in food consumption at 156 ppm.

13. Study Author's Conclusions/Quality Assurance Report: The LC_{50} value was 4223 ppm, with 95% confidence limits of 2869-11466 ppm. The slope of the dose-response curve was not reported. The NOEL could not be determined due to the effect on body weight gain seen at the lowest level tested (156 ppm).

Quality Assurance and Good Laboratory Practice statements were included in the report. One exception to Good Laboratory

Practices was noted: feed samples were not collected to test for homogeneity.

14. Reviewer's Discussion and Interpretation of the Results:

a. Test Procedure: The test design and procedure were generally in accordance with protocols recommended by the Guidelines. However, there was no acetone added to the control diet, whereas 55 mL of acetone was added to each test diet; however, this is not expected to affect the results. Also, the NOEL was not determined, but the test will not need to be redone unless EEB determines that a NOEL is necessary in order to complete a hazard assessment for XRM 5160.

b. Statistical Analysis: The LC_{50} calculation and its corresponding confidence limits were verified using EPA's Toxanal computer program (see attached). Results were in agreement with the reported results. The slope of the dose-response curve was determined to be 3.09.

c. Discussion/Results: The study is scientifically sound and in accordance with the Guidelines.

d. Adequacy of the study:
(1) Classification: Core for formulated product.
(2) Rationale: N/A
(3) Repairability: N/A

William Rabert Dursban ME 20 Mallard Duck Subacute Dietary LC50

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CONC. (measured)	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB.(PERCENT)
949	10	5	50	62.30469
444	10	4	40	37.69531
270	10	0	0	9.765625E-02
132	10	0	0	9.765625E-02
63.2	10	0	0	9.765625E-02
31.3	10	0	0	9.765625E-02

THE BINOMIAL TEST SHOWS THAT 270 AND +INFINITY CAN BE USED AS STATISTICALLY SOUND CONSERVATIVE 95 PERCENT CONFIDENCE LIMITS, BECAUSE THE ACTUAL CONFIDENCE LEVEL ASSOCIATED WITH THESE LIMITS IS GREATER THAN 95 PERCENT.

AN APPROXIMATE LC50 FOR THIS SET OF DATA IS 949.0002

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
1	21.70016	949.0002	0	+INFINITY

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
8	.4344532	1	.5254598

SLOPE = 3.046907

95 PERCENT CONFIDENCE LIMITS = 1.038598 AND 5.055217

LC50 = 803.0565

95 PERCENT CONFIDENCE LIMITS = 546.4897 AND 2277.803

LC10 = 307.5599

95 PERCENT CONFIDENCE LIMITS = 91.59238 AND 456.2574

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Valente XRM5160 Mallard dietary

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CONC. (nominal)	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
5000	10	5	50	62.30469
2500	10	4	40	37.69531
1250	10	0	0	9.765625E-02
625	10	0	0	9.765625E-02
313	10	0	0	9.765625E-02
156	10	0	0	9.765625E-02

THE BINOMIAL TEST SHOWS THAT 1250 AND +INFINITY CAN BE USED AS STATISTICALLY SOUND CONSERVATIVE 95 PERCENT CONFIDENCE LIMITS, BECAUSE THE ACTUAL CONFIDENCE LEVEL ASSOCIATED WITH THESE LIMITS IS GREATER THAN 95 PERCENT.

AN APPROXIMATE LC50 FOR THIS SET OF DATA IS 4999.999

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
1	21.70016	4999.999	0	+INFINITY

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
7	.4468413	1	.6792166

SLOPE = 3.087476

95 PERCENT CONFIDENCE LIMITS = 1.023616 AND 5.151337

LC50 = 4223.312

95 PERCENT CONFIDENCE LIMITS = 2869.271 AND 11466.95

LC10 = 1638.001

95 PERCENT CONFIDENCE LIMITS = 437.5407 AND 2448.855

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MRID# 41965501

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Pages 6 through 8 are not included.

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_____ Identity of product inert ingredients.

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_____ Description of the product manufacturing process.

_____ Description of quality control procedures.

_____ Identity of the source of product ingredients.

_____ Sales or other commercial/financial information.

_____ A draft product label.

_____ The product confidential statement of formula.

_____ Information about a pending registration action.

✓ FIFRA registration data.

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