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: Bobwhite quail (Colinus virginianus)

4. Study ID: Long, Ronald D., Smith, Gregory J. and Beavers, Joann B., "XRM 5160 (microencapsulated insecticide): A dietary LC_{50} study with the northern bobwhite. Performed by Wildlife International, 305 Commerce Drive, Easton, MD for The Dow Chemical Co., Midland, MI, for DowElanco, Indianapolis, IN. WI study ID #103-350A. Dow contract #ES-DR-0320-1647-2 MRID 419655-02. 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 2013 ppm, the test material is considered to be slightly toxic to the bobwhite. The NOEL was 313 ppm.

8. Recommendations: N/A nominal LC_{50} 516 (381-702) ppm a.i., measured LC_{50} 387 (300-573) 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: Bobwhite were obtained from Wildlife International's production flock. The birds were 10 days old at test initiation. All test birds were acclimated to the caging and facilities from the time of hatch 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 (23° C +/- 6° C average ambient temperature) and average relative humidity of 54% +/- 11%.

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: Bobwhite 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 or 625 ppm. There were 2 mortalities at 1250 ppm, 6 at 2500 ppm and 10 (100%) at 5000 ppm. There were no signs of toxicity at 156 or 313 ppm. At 625 ppm, 3 birds showed reduced reaction to external stimuli, wing droop, lethargy and a ruffled appearance on day 4. One more bird in this group showed lethargy on day 6. The birds were normal from day 6 until the end of the study. At 1250 ppm, birds showed signs of toxicity from day 3 to day 6. These signs included depression, reduced reaction to external stimuli, wing droop, loss of coordination, loss of righting reflex, ruffled appearance, lower limb weakness and lethargy. The birds appeared normal from day 7 until the end of the study. At 2500 ppm, one bird showed wing droop on the afternoon of day 1. Other signs of toxicity occurred after day 1, and included depression, reduced reaction to external stimuli, loss of coordination, prostration, lower limb rigidity, ruffled appearance, lower limb weakness and lethargy. The 4 surviving birds were normal from the afternoon of day 7 until the end of the study. Signs of toxicity at 5000 ppm began the afternoon of day 1 and included wing droop, loss of coordination, and ruffled appearance. More signs of toxicity appeared after day 3, and included depression, reduced reaction to external stimuli, lower limb weakness, prostration, loss of righting reflex, lower limb rigidity and

lethargy. These signs of toxicity lasted until the final mortality on day 5. There was a reduction in body weight gain from days 0-5 at 1250 and 2500 ppm. There was also a decrease in food consumption for the same time period for 1250, 2500 and 5000 ppm.

13. Study Author's Conclusions/Quality Assurance Report: The LC_{50} value was 2013 ppm, with 95% confidence limits of 1486-2738 ppm. The slope of the dose-response curve was 5. The NOEL was 313 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 in accordance with protocols recommended by the Guidelines. 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.

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.

c. Discussion/Results: The study is scientifically sound and generally in accordance with the Guidelines. The study is classified as core for formulated product.

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

William Rabert Dursban ME 20 Bobwhite Quail Subacute Dietary LC50

****

CONC. (measured)	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB.(PERCENT)
949	10	10	100	9.765625E-02
444	10	6	60.00001	37.69531
270	10	2	20	5.46875
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 132 AND 949 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 393.9962

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
3	.1349365	390.9127	298.6322	532.1355

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
12	.376033	1	.9927458

SLOPE = 6.104943

95 PERCENT CONFIDENCE LIMITS = 2.361299 AND 9.848586

LC50 = 386.7012

95 PERCENT CONFIDENCE LIMITS = 299.551 AND 523.4425

LC10 = 239.5232

95 PERCENT CONFIDENCE LIMITS = 110.0305 AND 306.9267

****

Valente XRM5160 quail dietary

****

CONC. (nominal)	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
5000	10	10	100	9.765625E-02
2500	10	6	60.00001	37.69531
1250	10	2	20	5.46875
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 625 AND 5000 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 2116.55

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
3	.1144044	1971.067	1508.348	2649.212

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
10	.270078	1	.9390261

SLOPE = 4.997285

95 PERCENT CONFIDENCE LIMITS = 2.400244 AND 7.594325

LC50 = 2013.404

95 PERCENT CONFIDENCE LIMITS = 1486.244 AND 2738.081

LC10 = 1121.484

95 PERCENT CONFIDENCE LIMITS = 541.4111 AND 1512.399

****

DP230* 41965502

Page_____ is not included in this copy.

Pages 6 through 8 are not included.

The material not included contains the following type of information:

_____ Identity of product inert ingredients.

_____ Identity of product impurities.

_____ 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.

_____ The document is a duplicate of page(s) _____.

_____ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.
