3-19-82

(TDR03B) DATA EVALUATION RECORD PAGE 1 OF 6

CASE GS0043 METHAMIDOPHOS PM ~~04/16/81~~

CHEM 101201 Methamidophos (O,S-dimethyl phosphoram

BRANCH EEB DISC 40 TOPIC 05050542

FORMULATION 00 = ACTIVE INGREDIENT

FICHE/MASTER ID 00014095 CONTENT CAT 01

Fletcher, D. (1971) Report to Chevron Chemical Company, Ortho Division: Acute Oral Toxicity Study with Monitor Technical in Mallard Ducks: IBT No. J262. (Unpublished study received Mar 22, 1972 under 0F0956; prepared by Industrial Bio-Test Laboratories, Inc., submitted by Chevron Chemical Co., Richmond, Calif.; CDL: 092118-D)

SUBST. CLASS = S.

DIRECT RVW TIME =30 min. (MH) START-DATE 2/10/82 END DATE 2/10/82

REVIEWED BY: Douglas J. Urban
TITLE: Fish and Wildlife Biologist
ORG: Ecological Effects Branch, HED, OPP
LOC/TEL: CS4; 557-5632

SIGNATURE: Douglas J Urban DATE: 3/19/82

APPROVED BY:
TITLE:
ORG:
LOC/TEL:

SIGNATURE: DATE:

Reviewers Conclusions:

A. Validation Category: (Supplemental)

B. Discussion: This study is scientifically sound and with an LD50 of 29.5 mg/kg Methamidophosis highly toxic to mallard ducks. The study does not fulfill the requirement for an LD50 to a species of wild waterfowl because the very poor dose response data precludes the development of a reliable LD50 value.

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101201

DATA REVIEW NUMBER: (ES)163.71-1

TEST: Avian Acute Oral LD_{50}

SPECIES: Mallard Ducks (Young adult)

RESULTS: 1/ LD_{50}=29.5 mg/kg (27.3-31.9 mg/kg)*

2/ No abnormal behavioral reactions were observed.

3/ Postmortem Exam: Dilatation of the intestinal vessels and flaccid cardiac muscle in the majority of birds

*95% confidence limits

CHEMICAL: MONITOR Technical (Assume 75% A.I.)

TITLE: Acute Oral toxicity study with MONITOR Technical in mallard ducks, 5139636, S-342, IBT No. J262.

ACCESSION NO. 092118

STUDY DATE: October 29, 1971

RESEARCHER: Industrial Bio-test Laboratories, Inc.

REGISTRANT: Chevron Chemical Company, Ortho Division

VALIDATION CATEGORY: Supplemental

CATEGORY REPAIRABILITY: None due to poor dose-response data which preclude the development of the best estimate of the LD_{50}.

ABSTRACT: The acute oral LD_{50} of mallard ducks versus MONITOR technical was presented as 29.5 mg/kg.

A. Additional Test Data

1/ Methodology/Protocol

a/ Basically, study was performed as per Proposed Guidelines, July 10, 1978.

b/ The following points are noted:

i/ Five dosage levels were used: 6.81, 10.0, 14.7, 21.6, and 31.7 mg/kg.

ii/ Ten birds (5 males, 5 females)/dose were used.

iii/ Ten controls (5 males, 5 females) were used.

iv/ The toxicant diluent was apparently distilled water.

v/ Birds were observed for 21 days after dosing.

vi/ Statistical analysis was that of Litchfield-Wilcoxon (1949).

2/ Additional Test Results

a/ Researcher's Comments/Conclusions

1/ The following mortality data were presented.

	MORTALITY (No. DEAD/No. DOSED)		
DOSE(mg/kg)	MALES	FEMALES	TOTAL
6.81	0/5	0/5	0/10
10.00	0/5	0/5	0/10
14.70	0/5	0/5	0/10
21.60	0/5	0/5	0/10
31.70	4/5	4/5	8/10

ii/ Time of death at the 31.7 mg/kg level was one hour after dosing.

iii/ Researcher states the body weight for all test groups were considered normal when compared to controls.

iv/ Researcher states the food consumption for all test groups was considered normal when compared to controls.

b/ Reviewer's Comments/Conclusions:

i/ The reviewer was not able to analyze statistically the mortality data due to the poor dose-response pattern observed. Such a poor dose-response pattern indicates poor (or no) screening trials and precludes the development of the best estimate of the LD_{50}. The LD_{50} presented by the researcher is at best a rough estimate of the LD_{50}. To obtain a more accurate estimate the study would have to be rerun at levels which better bracket the LD_{50} and which exhibit a better dose-response relationship.

ii/ Not enough data were available to statistically analyze the body weight/ feed consumption data of Controls versus Treatment Groups.
However, the reviewer did develop the following:

GROUP	$\bar{x}$ BODY WEIGHT (GMS)				
	DAY 0	DAY 3	DAY 7	DAY 14	DAY 21
CONTROLS	989.5	1090.0	1095.0	1100.0	1149.6
TREATMENT GROUPS (6.81-31.70 mg/kg)	1003.68	1146.0	1149.0	1143.0	1121.44

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$\bar{x}$ Feed CONSUMPTION (GMS/BIRD/DAY)

GROUP	TEST WEEK ONE	TEST WEEK TWO	TEST WEEK THREE
CONTROLS	140.0	161.0	140.0
TREATMENT GROUPS (6.81-31.70 mg/kg)	152.42	150.28	145.68

From the above, it can be seen that at Day 0 there is an approximately 14 gm. difference in body weight between Controls and the Treatment Groups. If this difference were to be found statistically significant, then the implication is that the two Groups are not random samples from the same population of mallard ducks. In order to determine this, the individual body weights of Control birds and, if available, those of the Treatment Groups for Day 0 must be submitted.

It is also noted that the average body weights for the Treatment Groups are less than those for Controls throughout the study except for Day 0 and 14 where they are greater than Controls. One can also see a reduction in body weights for Treatment Groups occuring from Day 7 to Day 21. However, an overall increase in body weights for Treatment Groups (and for Controls) does occur from Day 0 to Day 21.

The reduction in body weights from Day 7 to 21 for Treatment Groups is correlated with a reduction in feed consumption during the experiment. Also, note the lack of increase in feed consumption for Controls during the experiment (except from Test Week One to Test Week Two) where an increase does occur. ~~This may be due, though, to the increased size of the bird since layer birds do eat less (as percent of body weight) than smaller birds.~~

iii/ The reviewer notes that the actual age of the birds is not provided. Also, the hours of fasting prior to dosing are not given.

B. Validation Category/Category Repairability

This study is classified SUPPLEMENTAL based upon the following:

1/ Incomplete description of the experimental design as outlined in the Proposed Guidelines of July 10, 1978. Specifically, the age of the birds used and the number of hours birds were fasted prior to dosing are lacking.

2/ The extremely poor dose-response data provided. Such a dose-response pattern indicates a poor (or no) screening trials and precludes the development of the statistically-derived best estimate of the acute oral LD_{50}.

Relative to Category Repairability, this study cannot be considered for reclassification as CORE due to point (B)(2) above. Another study would have to be rerun at levels which better bracket the LD_{50} and which exhibit a better dose-response pattern to qualify as CORE.