240201
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RECORD NO.

110201
SHAUGHNESSEY NO.

REVIEW NO.

EEB REVIEW

DATE: IN 2-22-89 OUT 5/5/89

FILE OR REG. NO 55947-UR, -UE, - UG

PETITION OR EXP. NO.

DATE OF SUBMISSION 4-14-88, 5-26-87

DATE RECEIVED BY EFED 2-22-89

RD REQUESTED COMPLETION DATE 8-18-89

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RD ACTION CODE/TYPE OF REVIEW 116

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

DATA ACCESSION NO(S). 402293-03 405934-04 thru-20 AND -27

PRODUCT MANAGER NO. L. Schnaubeit (23)

PRODUCT NAME(S) Technical Prodiamine: 55947-UR; [redacted]

[redacted] Prodiamine US WDG: 55947-UG

COMPANY NAME Sandoz Crop Protection Corporation

SUBMISSION PURPOSE Resubmission with data to support proposed registration of new chemical for use on turf and non-bearing trees, nuts, and vines

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

PENDING REGISTRATION INFORMATION IS NOT INCLUDED

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT; Resubmission of Data to Support Proposed Registration of the New Herbicide Prodiamine for use on Turf and Non-bearing Trees, Nuts and Vines SN 110201

FROM: James W. Akerman, Chief for H.T. Craven
Ecological Effects Branch
Environmental Fate and Effects Division (H7507C)

TO: Lawrence J. Schnaubelt
Registration Division (H7505C)

The Ecological Effects Branch has reviewed the studies listed below and application for registration of Prodiamine.

1. Grimes, J., and M. Jaber. 1987. Technical Prodiamine: An acute Oral Toxicity Study with the Bobwhite. Submitted by Sandoz Corp Protection Corporation, Chicago, Illinois. Study performed by Wildlife International Ltd., Easton, Maryland. Laboratory Study No. 131-125. MRID No. 402293-03.

2. Bowman, J. H. 1987. Acute Toxicity of Prodiamine Technical to Sheepshead Minnow in a Static Renewal Test System. Submitted by Sandoz Crop Protection Corp., Chicago, Illinois. Study performed by ABC Laboratories, Columbia, Missouri. MRID No. 405934-04.

3. Burgess, D. 1987. Acute Toxicity of Prodiamine Technical to Mysid Shrimp (Mysidopsis bahia); Final Report No. 36265. Prepared by Analytical Bio-Chemistry Laboratories, Inc., Columbia, Missouri. Submitted by Sandoz Crop Protection Corporation, Des Plaines, Illinois. Accession No. 405934-06.

4. Ward, G.S. 1987. Acute Toxicity of Prodiamine Technical to Embryos and Larvae of the Eastern Oyster. Prepared by ESE, Gainsville, Fl. Submitted by Sandoz Crop Protection Corp.

Chicago, Ill. MIRD No. 405934-08.

5. Bowman, J. H. 1987. Acute Toxicity of Prodiamine (5%) Clay Formation to Rainbow Trout in a Static Renewal Test System. Prepared by ABC Laboratories, Inc. Columbia, Missouri. Submitted by Sandoz Crop Protection Corp. Chicago, Ill. MIRD No. 405934-09.

6. Bowman, J. H. 1987. Acute Toxicity of Prodiamine (5%) Clay Formulation to Bluegill Sunfish in a Static Renewal Test System. Prepared by ABC Laboratories, Inc. Columbia, Missouri. Submitted by Sandoz Crop Protection Corp., Chicago, Ill. MIRD No. 405934-11.

7. Forbis, A. D. 1987. Acute Toxicity of Prodiamine (5%) Clay Formulation to Daphnia magna. Prepared by ABC Laboratories, Inc., Columbia, Missouri. Submitted by Sandoz Crop Protection Corp. Chicago, Ill. MIRD No. 405934-13.

8. Bowman, J. H. 1987. Acute Toxicity of Prodiamine (5%) Clay Formulation to Sheepshead Minnow in a Static Renewal Test System. Prepared by ABC Laboratories, Inc. Columbia, Missouri. Submitted by Sandoz Corp Protection Corp. Chicago, Ill. MIRD No. 405934-15.

9. Burgess, D. 1987. Acute Toxicity of Prodiamine (5%) Clay Formulation to Mysid Shrimp. Prepared by ABC Laboratories, Inc., Columbia, Missouri. Submitted by Sandoz Crop Protection Corp., Chicago, Ill. MIRD No. 405934-17

10. Burgess, D. 1987. Acute Toxicity of Prodiamine (5%) Clay Formulation to Mysid Shrimp. Prepared by ABC Laboratories, Inc. Columbia, Missouri. Submitted by Sandoz Crop Protection Corp., Chicago, Ill. MIRD No. 405934-18.

11. Ward, G. S. 1987. Acute Toxicity of Prodiamine (5%) Clay Formulation to Embryos and Larvae of the Eastern Oyster. Prepared by ESE, Inc., Gainsville, Fl. Submitted by Sandoz Crop Protection Corp., Chicago, Ill. MIRD No. 405934-20.

The avian single dose oral LD50 test (number one) is scientifically sound and meets the guideline requirements. With a NOEL of 2250 mg/kg technical Prodiamine is practically non-toxic to bobwhite quail.

The remaining ten acute studies (numbers 2-11) are for various reasons unacceptable and must be repeated. These studies are unacceptable due to the following:

1) Number of analytical measures insufficient and no correlation between nominal and 96-hr measured concentrations. Therefore LC50 values are unreliable. Should have conducted flow-through assays and based LC50's on measured not nominal concentrations. (Numbers 2, 3, 5, 6, 7, 7, 9)

2) No analytical measurements submitted. (Numbers 4, 10, 11)

3) Data from a five percent formulated product cannot be substituted for data required on the technical pesticide. Solvent studies were not submitted to indicate that the registrant had made a reasonable attempt to get the technical material into solution. The Guidelines allow for substituting an end-use product instead of the technical material if solubility problems cannot be overcome, however there is no justification for using a 5% a.i. when both proposed end-use products are 65% a.i. (Numbers 5, 6, 7, 8, 9, 10 and 11).

4) Prodiamine technical (96.3% a.i.) was dissolved in acetone and slurried with amorphous fumed silica (clay) known as "Cab-O-Sil EH-5" at a w/w ration of 5.25% to 94.75%, respectively. No data was submitted to show that this "attached" test material is as available to fish and other aquatic biota as is the technical Prodiamine alone. There is concern the fish may be less exposed to the pesticide when it is attached or absorbed to clay particles and result in unreliable LC_{50} values. (Numbers 5, 6, 7, 8, 9, 10 and 11).

EEB cannot assess aquatic risk to non-target or endangered species until the required aquatic studies (as listed above) are repeated and acceptable results are obtained. Solvent studies or use of flow-thru test systems may be helpful in obtaining accurate LC_{50} values for technical Prodiamine. Clay or other absorptive materials should not be used in acute assays. Although technical material studies are preferred, studies may be done on an end-use product (i.e., the 65% a.i.) if solubility problems prevent testing the technical product successfully.

The available data indicate minimal acute hazards exist for mammalian and avian organisms, although EEB is unable to fully assess terrestrial (or aquatic) acute or chronic risk until finalized EFGB and Toxicology Branch reviews are available.

Otto Gutenson
Biologist, Ecological Effects Branch
Environmental Fate and Effects Division (H7507C)
557-3449

Note: DERs were done only on studies Numbers 1 and 3. All others were given preliminary review and judged so flawed as to not merit full review.

Accession No. 405934-06

DATA EVALUATION RECORD

1. **CHEMICAL:** Prodiamine
Shaughnessey No. 110201

2. **TEST MATERIAL:** Prodiamine Technical; Lot No. C84268; 91.7% Active Ingredient; a dark yellow powder

3. **STUDY TYPE:** Shrimp 96-hour Acute Toxicity Test
Species Tested: Mysid shrimp, (Mysidopsis bahia)

4. **CITATION:** Burgess D. 1987. Acute Toxicity of Prodiamine Technical to Mysid Shrimp (Mysidopsis bahia); Final Report No. 36265. Prepared by Analytical Bio-Chemistry Laboratories, Inc., Columbia, Missouri. Submitted by Sandoz Crop Protection Corporation, Des Plaines, Illinois. Accession No. 405934-06.

5. **REVIEWED BY:**

Kimberly D. Rhodes
Associate Scientist
KBN Engineering and
Applied Sciences, Inc.

Signature: Kimberly D. Rhodes
Date: April 17, 1989

6. **APPROVED BY:**

Prapimpan Kosalwat, Ph.D.
Staff Toxicologist
KBN Engineering and
Applied Sciences, Inc.

Signature: P. Kosalwat
Date: 4/17/89

Henry T. Craven
Supervisor, EEB/HED
USEPA

Signature: 6/1/89
Date: H.T. Craven 5/31/89

7. **CONCLUSIONS:** This study is scientifically sound but does not fulfill the Guideline requirements for a 96-hour static acute study for estuarine and marine shrimp. The 96-hour LC50 value for Mysidopsis bahia exposed to Prodiamine Technical was 2.1 mg a.i./L, based on mean measured concentration. Therefore, Prodiamine Technical is classified as moderately toxic to mysid shrimp.

8. **RECOMMENDATIONS:** N/A

9. **BACKGROUND:**

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

11. **MATERIALS AND METHODS:**

A. **Test Animals:** Mysid shrimp (*Mysidopsis bahia*) were obtained from a commercial supplier in Florida. Mysid culture techniques used were those described by EPA EG-3, 1982. Mysid shrimp were fed brine shrimp nauplii (*Artemia sp.*) once daily. The test mysids were acclimated to the dilution water and test temperature prior to initiation of the study.

B. **Test System:** The static test was conducted in 400-ml glass vessels containing 300 mL of aged saltwater. This saltwater was prepared by dissolving the appropriate amount of synthetic seawater salts in aged well water. The temperature was maintained by a water bath at 22 ± 2°C.

The saltwater used for culture and testing of the mysid shrimp was prepared to yield a salinity of between 15 and 35 °/oo and a pH of 8.0 to 8.6. The 0-hour measured control water parameters of the dilution water were: dissolved oxygen - 7.6 mg/L; pH - 8.2; and salinity - 23°/oo.

C. **Dosage:** 96-hour static acute test.

D. **Design:** Based on the results of a 72-hour range-finding test, a control, solvent control, and five nominal Prodiamine concentrations of 1.0, 1.8, 3.2, 5.6, and 10.0 mg a.i./L were selected for the definitive test. The solvent control received 0.015 mL of acetone, which was equivalent to the solvent concentration of the highest test level. Ten mysids were randomly added to each concentration (five per replicate) within 30 minutes following addition of test material. All concentrations were observed once every 24 hours for mortality and abnormal effects.

Exposure concentrations of Prodiamine Technical were analytically measured at 0, and 96 hours of exposure. The mean measured concentrations were 0.36, 1.46, 1.16, 3.0, 3.36 mg a.i./L (Table 1, attached). Water quality parameters (temperature, pH, dissolved oxygen, and salinity) were measured in the control at 0-hour and at all concentrations tested, control, and solvent control at 96-hours of exposure.

E. **Statistics:** The concentration of test substance lethal to 50 percent of the test population (LC50) was determined by the computer program developed by Stephan et al. (1977).

12. **REPORTED RESULTS:** Nominal test concentrations, mortality rates, and water quality measurements for Prodiamine Technical are presented in Table 4 (attached). The 24-, 48-, 72-, and 96-hour LC50 values for nominal concentrations of Prodiamine Technical were > 5.6, 6.0, 5.0 and 4.4 mg a.i./L, respectively. The no-effect concentration based on mortality and abnormal effects after 96 hours of exposure was 1.8 mg/L. The abnormal effects of mortality, clear mysids and/or quiescence were observed in the 3.2, 5.6 and 10 mg/L test concentrations during the 96-hour exposure period. The Prodiamine Technical test vessels were observed to have a surface film and/or precipitate throughout the 96-hour exposure period.

Average concentrations of Prodiamine in unfiltered test water are shown in Table 1 (attached). The mean measured concentrations ranged from 34% to 81% of the nominal concentrations throughout the 96-hour exposure period. The dissolved oxygen concentrations, corrected for temperature and salinity, ranged from 5.0 to 7.6 mg/L (67 to 99% saturation at 23 and 22°C, respectively) during the test. Salinity ranged from 23°/oo to 24°/oo during the 96-hour test. The pH ranged from 8.1 to 8.3.

13. **STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:** The 96-hour LC50 value for Prodiamine Technical based upon nominal concentrations was estimated to be 4.4 mg/L with a 95 percent confidence interval of 3.5 to 5.6 mg/L. The NOEC (no-observed-effect concentration) was 1.8 mg/L after 96 hours.

The study was audited by the QA unit of Analytical Bio-Chemistry Laboratories. A statement of quality assurance was included in the report, indicating that the study was conducted in accordance with U.S. EPA Good Laboratory Practice Standards: Pesticide Programs (40 CFR 160).

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

A. **Test Procedure:** The test procedures were generally in accordance with protocols recommended by the Guidelines, but deviated from the SEP as follows:

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o The SEP states that natural or reconstituted seawater of 10 to 17 °/oo salinity should be used when testing euryhaline shrimp species. The natural seawater used during the toxicity study had a salinity of 24 °/oo.

o The SEP states that temperature should be recorded every six hours in at least one test vessel during the entire study period if the temperature is controlled by a water bath. During the study, the test temperature was measured and recorded at test initiation and termination (96-hours of exposure).

o The SEP states that each designated treatment group should be exposed to a concentration of toxicant that is at least 60% of the next highest concentration. Each designated treatment group for the test was only 56% of the next highest concentration.

o The SEP states that the dissolved oxygen concentration must be measured at the beginning of the test and every 48 hours thereafter to the end of the test in the control and the high, medium, and low concentrations. The pH should be measured at the beginning and end of the test in the control, high, medium, and low concentrations. This study only reported the water quality parameters (dissolved oxygen concentration, pH, salinity) for the control at test initiation and measured all test concentrations and controls at 96-hours of exposure.

The toxicity report did not provide the following information required by the SEP:

o The report did not provide complete descriptions of holding and acclimation conditions. Furthermore, the report did not mention the percent of mysid mortality during the 48-hour period prior to test initiation.

o The report did not provide information on the photoperiod of the test. The SEP states that the photoperiod should be a 16-hour light and an 8-hour dark photoperiod, with a 15- to 30-minute transition period between light and dark.

B. <u>Statistical Analysis</u>: The reviewer used the Toxanal computer program to calculate the LC50 values and the slope of the concentration-response curve. These calculations are attached. The probit method provides a 96-hour LC50 value of 2.1 mg a.i./L mean measured

concentration with a 95 percent confidence interval of 1.7 to 2.6 mg a.i./L. The slope of the concentration-response curve was 5.7.

C. **Discussion/Results:** Table 1 (attached) shows no correlation between the nominal concentrations and the 96-hour measured concentrations of the unfiltered test solutions, indicating inhomogeneous sampling. Furthermore, the 96-hour measured concentrations, in general, were substantially lower than the initial measured concentrations (0-hour). The aqueous photolysis studies conducted by Yu (1984, Sandoz Crop Protection Corporation Report #414818-1) had actually demonstrated that the half life of Prodiamine was only 7.2 minutes. Therefore, the toxicity test should have been conducted under flow-through conditions since the test compound is relatively insoluble, has a short half-life, and is probably volatile. The 96-hour LC50 value based upon mean measured concentrations was estimated to be 2.1 mg a.i./L. Therefore, Prodiamine Technical is classified as moderately toxic to mysid shrimp (Mysidopsis bahia).

D. **Adequacy of the Study:**

(1) Classification: Supplemental

(2) Rationale: See comments in 14 C.

(3) Repairability: None

15. **COMPLETION OF ONE-LINER FOR STUDY:** Yes, 04-11-89

Prodiamine

Page_____ is not included in this copy.

Pages 11 through 12 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.

X 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.

KIMBERLY RHODES PRODIAMINE MYSIDOPSIS BAHIA 04-11-89

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Nom.	CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
10.0	3.36	10	10	100	9.765625E-02
5.4	3	10	7	70	17.1875
1.8	1.46	10	0	0	9.765625E-02
3.2	1.16	10	2	20	5.46875
1.0	.36	10	0	0	9.765625E-02

THE BINOMIAL TEST SHOWS THAT .36 AND 3.36 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 2.545211

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
4	8.502532E-02	1.832338	1.476246	2.379538

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
5	.2055837	1	7.056213E-02

SLOPE = 5.692957

95 PERCENT CONFIDENCE LIMITS = 3.111694 AND 8.27422

LC50 = 2.113876

95 PERCENT CONFIDENCE LIMITS = 1.690676 AND 2.633181

LC10 = 1.264727

95 PERCENT CONFIDENCE LIMITS = .7628754 AND 1.601257

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Shaughnessey No. 110201 Chemical Name Prodiamine Technical Chemical Class ____ Page ____ of ____

Study/Species/Lab/ Accession	Chemical % a.i.	Results	Reviewer/ Date	Validat Status
14-Day Single Dose Oral LD_{50}		LD50 = . mg/kg (95% C.L.) Contr. Mort.(%)=		
Species	____	Slope= # Animals/Level= Age(Days)= Sex =		
Lab		14-Day Dose Level mg/kg/(% Mortality) ( ), ( ), ( ), ( ), ( )		
Acc.		Comments:		
14-Day Single Dose Oral LD_{50}		LD50 = mg/kg. (95% C.L.) Contr. Mort.(%)=		
Species	____	Slope= # Animals/Level= Age(Days)= Sex =		
Lab		14-Day Dose Level mg/kg/(% Mortality) ( ), ( ), ( ), ( ), ( )		
Acc.		Comments:		
8-Day Dietary LC_{50}		LC50 = ppm (95% C.L.) Contr. Mort.(%)=		
Species		Slope= # Animals/Level= Age(Days)= Sex =		
Lab	____	8-Day Dose Level ppm/(%Mortality) ( ), ( ), ( ), ( ), ( )		
Acc.		Comments:		
8-Day Dietary LC_{50}		LC50 = ppm (95% C.L.) Contr. Mort.(%)=		
Species		Slope= # Animals/Level= Age(Days)= Sex =		
Lab	____	8-Day Dose Level ppm/(%Mortality) ( ), ( ), ( ), ( ), ( )		
Acc.		Comments:		
48-Hour LC_{50}		LC50 = pp__ (95% C.L.) Contr. Mort.(%)= Sol. Contr. Mort.(%)=		
Species		Slope= # Animals/Level= Temperature =		
Lab	____	48-Hour Dose Level pp /(%Mortality) ( ), ( ), ( ), ( ), ( )		
Acc.		Comments:		
96-Hour LC_{50}		LC50 = 2.1 ppm (95% C.L. 1.7 - 2.6) Probit analysis Con. Mor.(%)= 0 Sol. Con. Mor.(%)= 0	K.R. 04-11-89	Suppl
Species Mysidopsis bahia		Slope= 5.7 # Animals/Level= 10 Temp.= 22°C		
Lab Analytical Bio Chemistry 91.7%		96-Hour Dose Level pp /(%Mortality) 0.36(0), 1.16(20), 1.46(0), 3.0(70), 3.36(100)		
Acc. 405934-06		Comments: Based on mean measured concentrations.		
96-Hour LC_{50}		LC50 = 2.1 ppm (95% C.L.) Con. Mort.(%)= Sol. Con. Mort.(%)=		
Species		Slope= # Animals/Level= Temp.=		
Lab	____	96-Hour Dose Level pp /(%Mortality) ( ), ( ), ( ), ( ), ( )		
Acc.		Comments:		

DATA EVALUATION RECORD

1. **CHEMICAL:** Prodiamine.
   Shaughnessey Number: 110201.

2. **TEST MATERIAL:** Technical Prodiamine. 96.3% active ingredient.

3. **STUDY TYPE:** Avian Single-Dose Oral LD50 Test.
   Species Tested: Bobwhite quail (Colinus virginanius).

4. **CITATION:** Grimes, J., and M. Jaber. 1987. Technical Prodiamine: An Acute Oral Toxicity Study with the Bobwhite. Submitted by Sandoz Crop Protection Corporation, Chicago, Illinois. Study performed by Wildlife International Ltd., Easton, Maryland. Laboratory Study No. 131-125. MRID No. 402293-03.

5. **REVIEWED BY:**

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

   Signature: Michael L. Whitten
   Date: 4-14-89

6. **APPROVED BY:**

   James R. Newman, Ph.D.
   Project Manager/
   Principal Scientist
   KBN Engineering and
   Applied Sciences, Inc.

   Signature: James R Newman
   Date: 4/14/89

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

   Signature: 5/1/89
   Date: H. T. Craven 5/1/89

7. **CONCLUSIONS:** This study is scientifically sound and meets the requirements for an avian single dose oral LD50 test. The acute oral LD50 of Technical Prodiamine was determined to be greater than 2250 mg a.i./kg of body weight, the highest dosage tested. This value classifies Technical Prodiamine as practically non-toxic to bobwhite quail. The no-observed effect dosage was 2250 mg/kg.

8. **RECOMMENDATIONS:** N/A

9. **BACKGROUND:**

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

11. **MATERIALS AND METHODS:**

A. **Test Animals:** The birds used in the study were 39-week old Bobwhite quail (Colinus virginanius), obtained from Fritts' Quail Farm, Phillipsburg, New Jersey. All birds were acclimated to the facilities for six weeks prior to initiation of the study. Birds exhibiting abnormal behavior or physical injury during acclimation were not used in the test.

B. **Test System:** All birds were housed indoors in 78 cm x 51 cm wire pens. Floors were sloped resulting a ceiling height of 20 to 25 cm. Fluorescent lights provided eight hours of light per day. The temperature averaged 19°C ± 2°C with an average relative humidity of 24%.

C. **Dosage:** 14-day single dose oral LD50 test. Based on "known toxicity data" nominal dosages selected for the definitive study were 292, 486, 810, 1350, and 2250 milligrams active ingredient (a.i.) of Technical Prodiamine per kilogram of body weight.

D. **Design:** Groups of ten birds (five males and five females) were randomly assigned to each of the five treatment groups and the control group. Each group was assigned two pens. One pen contained five males and the other five females. The birds were fed a game bird ration formulated to Wildlife International Ltd.'s specifications. Food and water were supplied ad libitum except for a period of "at least 15 hours" prior to dosing when the birds were fasted, with water allowed. At test initiation, a single dose of test material in diluent (corn oil) was orally intubated into the crop or proventriculus of each bird using a stainless steel catheter. Each bird was individually weighed and dosed on the basis of milligrams of test substance per kilogram of body weight. The control birds received diluent only. All treatment and control birds received a constant dosage volume of 6 milliliters per kilogram of body weight. The birds were individually weighed at test initiation and by group on days 3, 7, and 14. Group food consumption was recorded on test days 3, 7, and 14. Observations were conducted at least twice daily for potential clinical signs indicative of test material effect.

E. **Statistics:** The LD50 was not calculated, since no mortalities occurred. No statistical analyses of body weight or food consumption were reported.

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

When compared to controls, there was no effect on body weight or food consumption.

13. **STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:** The acute oral LD50 of Technical Prodiamine was determined to be greater than 2250 mg/kg a.i., the highest dosage tested. The no-observed effect dosage was 2250 mg/kg.

The study was designed and conducted in conformance with Good Laboratory Practice regulations. The data were inspected and the final report signed by the Quality Assurance Officer of Wildlife International Ltd.

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

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

Body weights were measured by group at the end of the study. According to the SEP, individual body weights should be measured.

The SEP recommends that gross necropsies be performed on some survivors. This was not done.

The length of the acclimation period was not clear. The report states that birds were acclimated to the facilities for a minimum of 14 days (page 6) but also states that all birds were acclimated for six weeks (page 7).

B. **Statistical Analysis:** Since no birds died during the study, the LD50 can not be calculated and is assumed to be greater than the highest dosage tested.

C. **Discussion/Results:** An examination of Table 2 (attached) indicates that there was no effect on body weight gain or food consumption. It is noted that the average total weight gain in each treatment group was less than in the controls. The differences, however, are minor and do not appear to be treatment related.

The acute oral LD50 of Technical Prodiamine was determined to be greater than 2250 mg a.i./kg, the highest dosage tested. This value classifies Technical Prodiamine as practically non-toxic to bobwhite quail. The no-observed effect dosage was 2250 mg a.i./kg.

The study appears to be scientifically sound and meets the requirements for an avian single dose oral LD50 test.

D. **Adequacy of the Study:**

(1) Classification: Core

(2) Rationale: N/A

(3) Repairability: N/A

15. **COMPLETION OF ONE-LINER:** Yes; April 11, 1989.

TABLE 2

AVERAGE BODY WEIGHT AND ESTIMATED FEED CONSUMPTION OF BOBWHITE GAVAGED WITH TECHNICAL PRODIAMINE

Dosage mg/kg a.i.	Average Body Weight in Grams								Estimated Feed Consumption Grams/Bird/Day		
	Day 0	Change	Day 3	Change	Day 7	Change	Day 14	Total Change	Days 0-3	Days 4-7	Days 8-14
Control											
Males	184	9	193	0	193	4	197	13	14	17	13
Females	196	9	205	-1	204	5	209	13	16	24	16
292											
Males	196	5	201	0	201	1	202	6	15	31	17
Females	188	4	192	1	193	4	197	9	12	20	14
486											
Males	189	6	195	1	196	2	198	9	14	20	14
Females	190	6	196	0	196	5	201	11	16	31	17
810											
Males	191	6	197	-1	196	3	199	8	16	30	15
Females	187	7	194	1	195	2	197	10	16	27	17
1350											
Males	196	5	201	0	201	0	201	5	14	22	16
Females	186	9	195	0	195	2	197	11	15	18	14
2250											
Males	198	6	204	1	205	3	208	10	14	23	16
Females	186	6	192	3	195	0	19	9	14	19	14

Shaughnessey No. 110201 Chemical Name Prodiamine Chemical Class ____ Page 1 of 1

Study/Species/Lab/ Accession	Chemical % a.i.	Results	Reviewer/ Date	Validat Statu
14-Day Single Dose Oral LD_{50} Bobwhite quail		LD50 = * mg/kg (95% C.L. N/A) Contr. Mort.(%) = 0		
Species Colinus virginianus	96.3%	Slope= N/A # Animals/Level= 10 Age(Days)= 273 Sex = 5M/5F	4-11-89 MLW	CORE
Lab Wildlife International Ltd		14-Day Dose Level mg/kg/(% Mortality) 0 (0), 292 (0), 486 (0), 810 (0), 1350 (0), 2250 (0)		
Acc. MRID# 402293-03		Comments: * LD_{50} GREATER THAN HIGHEST TEST DOSAGE (2250 mg a.i./kg)		
14-Day Single Dose Oral LD_{50}		LD50 = mg/kg. (95% C.L.) Contr. Mort.(%) =		
Species ____		Slope= # Animals/Level= Age(Days)= Sex =	____	____
Lab		14-Day Dose Level mg/kg/(% Mortality) ( ), ( ), ( ), ( ), ( )		
Acc.		Comments:		
8-Day Dietary LC_{50}		LC50 = ppm (95% C.L.) Contr. Mort.(%) =		
Species		Slope= # Animals/Level= Age(Days)= Sex =		
Lab ____		8-Day Dose Level ppm/(%Mortality) ( ), ( ), ( ), ( ), ( )	____	____
Acc.		Comments:		
8-Day Dietary LC_{50}		LC50 = ppm (95% C.L.) Contr. Mort.(%) =		
Species		Slope= # Animals/Level= Age(Days)= Sex =		
Lab ____		8-Day Dose Level ppm/(%Mortality) ( ), ( ), ( ), ( ), ( )	____	____
Acc.		Comments:		
48-Hour L_{50}		LC50 = ___ (95% C.L.) Contr. Mort.(%) =		
Species		Sol. Contr. Mort.(%) =		
		Slope= # Animals/Level= Temperature =		
Lab ____		48-Hour Dose Level /(%Mortality) ( ), ( ), ( ), ( ), ( )	____	____
Acc.		Comments:		
96-Hour LC_{50}		LC50 = pp___ (95% C.L.) Con. Mor.(%) =		
Species		Sol. Con. Mor.(%) =		
		Slope= # Animals/Level= Temp.=		
Lab ____		96-Hour Dose Level pp /(%Mortality) ( ), ( ), ( ), ( ), ( )	____	____
Acc.		Comments:		
96-Hour LC_{50}		LC50 = pp___ (95% C.L.) Con. Mort.(%) =		
Species		Sol. Con. Mort.(%) =		
		Slope= # Animals/Level= Temp.=		
Lab ____		96-Hour Dose Level pp /(%Mortality) ( ), ( ), ( ), ( ), ( )	____	____
Acc.		Comments:		