061601
SHAUGHNESSEY NO.

REVIEW NO.

EEB BRANCH REVIEW

DATE: IN 8/26/82 OUT 11/23/82

FILE OR REG. NO. 239-2116

PETITION OR EXP.

DATE OF SUBMISSION August 6, 1982

DATE RECEIVED BY HED August 25, 1982

RD REQUESTED COMPLETION DATE December 15, 1982

EEB ESTIMATED COMPLETION DATE December 8, 1982

RD ACTION CODE/TYPE OF REVIEW 400/Data Submission

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

DATA ACCESSION NO(S). 248133

PRODUCT MANAGER NO. R. Taylor (25)

PRODUCT NAME(S) Ortho Paraquat CL

COMPANY NAME Chevron Chemical Company

SUBMISSION PURPOSE Submission of Data for Review

SHAUGHNESSEY NO.	CHEMICAL & FORMULATION	% A.I.
061601	Paraquat cation (SX-1305)	31.5% to 33.7%

Paraquat (SX-1305)
Acc. No. 248133

EEB acknowledges the reciept of data package (Acc. No. 148133) containing eight studies that relate to or are avian reproduction studies (mallard and bobwhite). These studies are listed below along with the results of EEB's review.

1. Assessment of Diet Homogeneity/Stability in Gamebird Breeder Ration. Paraquat Technical (SX-1305). Final Report. S-1951. Widelife International. October 7, 1981.

Test Material: Paraquat Technical (SX-1305) 3#/gal. 31.5% cation No. 1-8.

A pre-mix concentrate, and three test diets of Paraquat cation (5 ppm, 50 ppm, 250 ppm) were prepared utilizing Paraquat Technical (SX-1305) and gamebird breeder ration. The test diest were exposed to conditions simulating a reproduction study for one week. Samples of compound containing feed were collected after mixing and following the exposure period aand shipped to Chevron Chemical Company for analysis.

This test was conducted prior to and in relationship to a future reproductive study with bobwhite quail and malllard ducks. The preparation techniques appeared adequate.

2. Addendum to above study entitled "Assessment of Diet Homogeneity and Stability of Paraquat Technical (SX-1305) in Gamebird Ration". Chevron Chemical Company. August 24, 1982. S-1951.

The purpose of this study was to provide analytical data to show that diet mixing procedures (study #1 above) are adequate and to determine diet replacement frequency.

The analytical test of the technical Paraquat cation (SX-1305) gave a 33.7% w/w paraquat cation. This would indicate a 2.2% higher A.I. in the technical than was reported in study #1.

Treatment Level** (ppm)	Sample Type*	Average ppm found	% of Nominal**	Coefficient of variation (N=6)
5	0	4.53	84.7	9.4%
	7Q	4.98	93.1	----
	7D	4.54	84.9	----
50	0	46.7	87.3	4.8
	7Q	44.3	82.8	----
	7D	45.6	85.2	----
250	0	234	87.5	3.2
	7Q	246	92.0	----
	7D	222	83.0	----

2

* Sample type 0 - freshly prepared
7Q - from quail feeders after 7 days
7D - from duck feeders after 7 days

** Diets were mixed according to the protocol which stated that the test substance contained 31.5% (w/w) paraquat cation. However, the test substance actually contained 33.7% (w/w) paraquat cation. In the table "% of Nominal" is corrected for this discrepancy.

The test substance is apparently stable in the diet for at least 7 days.

3. Subacute Feeding - Reproduction Screening Bioassay. Bobwhite Quail. Paraquat Technical (SX-1305). Final Report. Wildlife International. October 30, 1981. S-1994.

Test Chemical: Paraquat Technical (SX-1305) 3#/gal 31.5% cation 7/7/81 No. 1-8 (referred to as Diquat in one instance.)

Objective: To evaluate the subacute toxicity of paraquat technical (SX-1305) and provide information helpful in establishing dietary levels in chronic reproduction studies.

Summary: Bobwhite quail were fed dietary levels of Paraquat Technical (SX-1305) at 10.0 ppm cation, 21.5 ppm cation, 46.4 ppm cation, 100.0 ppm cation, and 215.0 ppm cation for eight weeks. There appeared to be no meaningful compound related effect on appearance, behavior, mortality, average food consumption, or body weight for the test period at dietary levels of Paraquat Technical (SX-1305) up to 100.0 ppm cation.

This study was ran with 36 bobwhite quail. The study design was patterned after the one to be used in the reproductive study. This study was a range finding test.

One hen at 46.4 ppm during week 6 died. One hen and one cock at 215 ppm during week 4 died.

Egg Production at 8-weeks

	3 pens (e.g., 3 hens)	
	Range	Total
Controls	0-8	8
10.0 ppm cation	0-17	17
21.5 ppm cation	2-47	54
46.4 ppm cation	0-10	10
100.0 ppm cation	1-23	25
215.0 ppm cation	0-24	26

Egg production was sporadic per pen among the 3 pens tested at each level. Usually one pen produced all of the eggs (control, 10 ppm, 46.4 ppm) or nearly all of the eggs (21.5 ppm 47 out of 54, 100 ppm - 23 out of 25, 215 ppm - 24 out of 26 eggs). No treatment levels had less egg production than the controls.

4. Addendum to above study entitled "Addendum to Subacute Pilot Feeding Study in Bobwhite Quail with Paraquat Technical (SX-1305). Chevron Chemical Company. June 2, 1982. S-1994.

This study was conducted to assure that the diets contained a constitent level of the test material through the subacute pilot feeding study in bobwhite quail (above test #3).

The analysis of the technical paraquat (SX-1305) gave 33.7% active cation versus the 31.5% active cation. This would affect the dose levels by making higher ppm's available.

The following table indicates the results of the analytical determination of paraquat cation versus the nominal concentration on day one time zero of test #3.

Treatment Level (ppm)	Average ppm Paraquat Found	% of Nominal	Coefficient of Variation
10	8.85	88.5	6.6%
21.5	19.7	91.6	14.0
46.4	43.7	94.2	9.7
100	96.8	96.8	7.2
215	198.0	92.1	8.0

This table raises a question as to the mixing of the test diet. The original "technical" was said to contain 31.5% a.i., whereas analysis indicates that it is 33.7% a.i. This equates to an approximate 7% increase in a.i. However, we see that upon analysis of these nominal test levels that the percent of active ingredient is below 100% (variation 11.5 to 3.2%) instead of the expected above 100%. Therefore, the treatment levels, nominal versus measured, are deficient from 10.2% to 18.5% in regards to ppm.

Treatment Level (ppm)*	Corrected ppm Level**	Difference of 100% minus (% of nominal + 7%)
10	8.2	18%
21.5	18.2	15.4%
46.4	40.5	12.8%
100.	99.0	10.2%
215.	211.8	14.9%

* Wildlife Internation Reported Nominal concentrations.
** EEB's correct nominal concentrations based on the results of analysis's in this report.

Treatment level ppm	Study Week	Date Prepared	ppm Found Sample Type* 0	7
10	1	8/14/81	8.85	9.26
	4	9/4/81	7.12	9.20
	8	10/2/81	9/27	10.6
21.5	1	8/14/81	19.7	21.4
	4	9/4/81	18.3	21.1
	8	10/2/81	20.0	21.6
46.4	1	8/14/81	43.7	51.2
	4	9/4/81	39.3	45.2
	8	10/3/81	40.2	52.2
100	1	8/14/81	96.8	117
	4	9/4/81	86.4	107
	8	10/2/81	84.2	97.3
215	1	8/14/81	198	220
	4	9/4/81	184	220
	8	10/2/81	186	227

* Sample type - 0 - Freshly prepared diet
7 - From feeders after 7 days

Day 0 samples appear to vary by 10-20% less than what is available on day 7. However, this appears acceptable based on Ecological Effects Branch expertise. (p.c. Balcomb)

5. One-Generation Reproduction - Bobwhite Quail. Paraquat Technical (SX-1305). Final Report. Wildlife International. July 27, 1982.

This bobwhite quail reproduction study (see DER) indicates that the NOEL for Paraquat Technical (SX-1305) 31.5% cation with bobwhite quail is 100 ppm. This study was considered acceptable in relationship to the July 10, 1978 guidelines.

6. Addendum to above report entitled (Addendum to One-Generation Reproduction Study in Bobwhite Quail tihe Paraquat Technical (SX-1305). Chevron Chemical Company. June 16, 1982. S-2071.

This study confirmed tha the respective dose levels in test #5 above were present at or near the nominal values.

7. One-Generation Reproduction - Mallard Duck. Paraquat Technical (SX-1305). Final Report. Wildlife International. July 27, 1982.

This mallard reproduction study will support registration and/or guideline requirements in relationship to Paraquat technical (SX-1305) cation. (See DER)

8. Addendum to above report entitled "Addendum to One-Generation Reproduction Study in Mallard Ducks with Paraquat Technical (SX-1305). Chevron Chemical Company. June 25, 1982. S-2072.

This study confirmed that the nominal dose level and the measured dose level were close to equivalent.

Russel T. Farringer, III
Wildlife Biologist
Ecological Effects Branch/HED

Date: 11/30/82

Raymond W. Matheny
Head, Review Section No. 1
Ecological Effects Branch/HED

Date: 11/30/82

Clayton Bushong, Chief
Ecological Effects Branch
Hazard Evaluation Division

Date: 11/30/82

6

DATA EVALUATION RECORD

1. Chemical: Paraquat cation (SX-1305)

2. Formulation: 31.5 a.i. (cation)

3. Citation: One-Generation Reproduction - Mallard Duck. Paraquat Technical (SX-1305). Final Report. Wildlife International. July 27, 1982. For Chevron Chemical Company. Acc. #248133.

4. Reviewed by: Russel Farringer, Wildlife Biologist
Ecological Effects Branch
Hazard Evaluation Division (TS-769)

5. Date Reviewed: November 23, 1982

6. Test Type: Avian Reproduction

A. Test Species: Mallard Ducks

7. Reported Results: Paraquat Technical (SX-1305) was fed to mallard ducks throughout a one-generation reproduction study at dietary concentrations of 10 ppm, 30 ppm, and 100 ppm cation. The 10 ppm and 30 ppm. Cation levels of Paraquat Technical (SX-1305) were no effect levels. Statistically significant ($p. < 0.1$) reproduction impairment was observed at the 100 ppm cation concentration level.

8. Reviewer's Conclusions: This study was scientifically sound. The highest NOEL was 30 ppm.

7

Materials/Methods

Test Procedures

This study generally followed the July 10, 1978 guidelines on avian reproduction with waterfowl.

Statistical Analysis

The analysis on the data consisting of body weight and other "mallard variables" is of the traditional analysis of variance type, partitioning variability into different sources. The analysis on the egg data and other "count variables" is based on Cohrans' concept of extraneous variability or the binomial distribution.

Discussion/Results

(These tables from the report summairze the results of this study.)

REPRODUCTIVE DATA - MALLARD DUCK

	PARAQUAT TECHNICAL (SX-1305) PPM CATION			
	Controls	10	30	100
Eggs Laid	454	496	439	186**
Hens in Production	11	12	12	12
Eggs Cracked	6	8	3	3
Eggs Set	366	395	348	111
Viable Embryos	333	356	303	72
Live Three-Week Embryos	312	334	284	64
Normal Hatchlings	211	221	204	49**
14-Day Old Survivors	205	213	198	49**
Eggs Laid/Hen in 8 Weeks[a]	38	41	37	16
Eggs Laid/Hen in Production	41	41	37	16
14-Day Old Survivors/Hen[a]	17	18	17	4
14-Day Old Survivors/Hen ..... In Production	19	18	17	4

[a]Based on 12 hens

** Statistically Significant Difference ($p. < .01$)

REPRODUCTIVE SUCCESS DATA (%) - MALLARD DUCK

	PARAQUAT TECHNICAL (SX-1305) PPM CATION			
	Controls	10	30	100
Eggs Laid	454	496	439	186**
Eggs Laid/Theo. Max. (%)[a]	68	74	65	28
Eggs Cracked/Laid (%)	1	2	1	2
Viable Embryos/Set (%)	91	90	87	65**
Normal Hatchlings/3-Week (%)	68	66	72	73
14 Day-Old Survivors/Hatch (%) ..	97	96	97	100
14 Day-Old Survivors/Set (%)	56	54	57	44
Normal Hatchlings/Theo. Max. (%)[b]	44	46	43	10**
14-Day Old Survivors/Theo. Max. (%)[b]	43	44	41	10**

[a] Theoretical maximum = 672 eggs or 1 egg per hen per day for laying period.
[b] Theoretical maximum = 420 chicks.

** Statistically Significant Difference (p. <.01)

Reviwer's Evaluation

Test Procedure

Acceptable.

Statistical Analysis

Statistical analysis was not performed since it is intuitively obvious as to the results of the analysis. The 10 ppm and 30 ppm closely relate to the controls while the 100 ppm is significantly different by observation and Wildlife International (p. <0.01) analysis.

Conclusion

Category: Core for Paraquat Technical (SX-1305) cation.

DATA EVALUATION RECORD

1. Chemical: Paraquat cation (SX-1305)

2. Formulation: 31.5% a.i. (cation)

3. Catation: One-Generation Reproduction - Bobwhite Quail. Paraquat Technical (SX-1305). Final Report. Wildlife International. July 27, 1982. For Chevron Chemical Company. Acc.# 248133.

4. Reviewed by: Russel Farringer, Wildlife Biologist
Ecological Effects Branch
Hazard Evaluation Division (TS-769)

5. Date Reviewed: November 23, 1982

6. Test Type: Avian Reproduction

Test Species: Bobwhite Quail

7. Reported Results:

Paraquat Technical (SX-1305) was fed to mature bobwhite quail throughout a one-generation reproduction study at dietary concentrations of 10 ppm, 30-ppm, 100 ppm cation. No biologically significant impairment of reproductive success was observed through 100 ppm cation. In this study the no effect level of Paraquat Technical (SX-1305) in bobwhite quail was 100 ppm cation.

8. Reviewer's Conclusions:

This stidy was scientifically sound. The results indicate that the NOEL on reproduction in bobwhite quail (upland gamebirds) was 100 ppm cation.

Materials and Methods

Test Procedure

This study generally follows guideline requirements of July 10, 1978.

Statistical Analysis

The analysis on the data consisting of body weight and other "measurement variables" is of the traditional analysis of variance type, partitioning variability into different sources. The analysis on the egg data and other "count variables" is based on Cochran's concept of extraneous variability for the binomial distribution.

Discussion/Results

(The following tables from the report sum up the results of this study).

REPRODUCTIVE DATA - BOBWHITE QUAIL

	PARAQUAT TECHNICAL (SX-1305) PPM CATION			
	Controls	10	30	100
Eggs Laid	438	411	390	427
Hens in Production	12	12	11	12
Eggs Cracked	8	4	8	6
Eggs Set	348	330	303	334
Viable Embryos	302	308	272	293
Live Three-Week Embroys	293	305	260	285
Normal Hatchlings	198	208	189	197
14-Day Old Survivors	164	172	161	162
Eggs Laid/Hen in 8 Weeks[a]	37	34	33	36
Eggs Laid/Hen in Production	37	34	35	36
14 Day Old Survivors/Hen[a]	14	14	13	14
14 Day Old Survivors/Hen In Production	14	14	15	14

[a] Based on 12 hens.

REPRODUCTIVE SUCCESS DATA - BOBWHITE QUAIL

	Paraquat Technical (SX-1305) PPM Cation			
	Controls	10	30	100
Eggs Laid	438	411	390	427
Eggs Laid of Theoretical Maximum (%)[a]	65	61	58	64
Eggs Cracked of Eggs Laid (%) ...	2	1	2	1
Viable Embryos of Eggs Set (%) ..	87	93	90	88
Live Three-Week Embryos of Viable Embryos (%)	97	99	96	97
Normal Hatchlings of Live Three-Week Embryos	68	68	73	69
Normal Hatchlings of Live Three-Week Embryos (%)	83	83	85	82
14-Day Old Survivors of Normal Hatchlings (%)	47	52	53	49
Normal Hatchlings of Theoretical Maximum of (%)[b]	41	43	39	41
14-Day Old Survivors of Theoretical Maximum (%)[b]	39	41	38	39

[a] Theoretical maximum = 672 eggs or 1 egg per hen per day for laying period.
[b] Theoretical maximum = 420 chicks.

Reviewer's Evaluation

Test Procedure

Acceptable.

Statistical Analysis

No statistical analysis was performed since the test groups met or exceeded control group and sufficient eggs were laid by all groups.

Conclusions

Category: Core for Paraquat Technical (SX-1305) 31.5% cation.

10