



1-5-89

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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Amitraz Registration Standard; Avian Reproduction Data Requirement; Study Submission Dated 45639-51; EPA Acc. No. 408403-01 and -02.

FROM: Jim Ackerman, Chief *Wm. J. Cook for 1-5-89*
Ecological Effects Branch
Environmental Fate and Effects Division (TS-769C)

TO: Dennis Edwards, PM 12
Insecticide-Rodenticide Branch
Registration Division (TS-767C)

NOR-AM Chemical Company has submitted the above referenced avian reproduction study to comply with the data requirements of the Amitraz Registration Standard. EEB has reviewed the study and the review results are indicated below.

| <u>Guideline</u> <u>Ref No.</u> | <u>Test</u> <u>Type</u> | <u>%</u> <u>AI</u> | <u>Species</u> <u>Tested</u> | <u>Reported</u> <u>Results</u> | <u>Guideline</u> <u>Fulfillment</u> |
|------------------------------------|----------------------------|-----------------------|---------------------------------|-----------------------------------|--|
| 71-4 | Avian Reprod. | 97.5 | Bobwhite Quail | NOEL \leq 40 ppm | Supplemental |

The attached data evaluation will advise the registrant on the repairability of the study.

John Noles 1/5/89
John Noles, Biologist
Ecological Effects Branch

DATA EVALUATION RECORD

1. CHEMICAL: Amitraz
2. TEST MATERIAL: Technical Amitraz (Batch CR 2057513); 97.5% a.i. (minimum)
3. STUDY TYPE: Avian Reproduction on the Bobwhite Quail
Species tested: Colinus virginianus
4. CITATION: Roberts, N. L., B. Hakin and D. O. Chanter. 1988. W87 TECHNICAL AMITRAZ: Dietary Reproduction Study in Bobwhite Quail. Project ID TOX 87220. Huntingdon Research Centre, Huntingdon, Cambridgeshire, ENGLAND. Submitted by NOR-AM Chemical Co., Wilmington, DE. 311 pp.
5. REVIEWED BY:

Jeffrey L. Lincer, Ph.D.,
Eco-Analysts, Inc. Signature:
Sarasota, Florida Date: 12/8/88
6. APPROVED BY:

James R. Newman, Ph.D.,
Proj. Mgr., KBN Engineering Signature:
and Applied Sciences, Inc. Date:

Henry T. Craven Signature:
Chief EEB/HED Date:
USEPA *Henry T. Craven* 1/5/89
7. CONCLUSIONS This study concluded that dietary administration of technical amitraz to bobwhite quail at up to 40 ppm had no effect on adult birds or their reproductive performance but the 160 ppm group ate marginally less food and the overall mean chick hatching bodyweight was slightly low.

However, the applicant's statistics also indicated that the mean chick hatching bodyweight for the 160 ppm group was significantly lower than that of the control group. The independent statistical analysis by the reviewer, using Big Bird, indicated no statistically significant differences between experimental groups for any of the reproductive parameters tested.

Therefore, based on hatching weight, the NOEL for dietary technical amitraz is 40 ppm. However, these results must be considered in light of the high percentage of cracked eggs in all test groups and deviations from guidelines, as discussed under Section 14.

Study is considered, basically, scientifically sound but deviations from guidelines result in it being classified as Supplemental.

8. RECOMMENDATIONS: Applicant should address all issues raised in Section 14 A-C. In addition, the applicant must repeat the "eggs cracked" parameter of the study in order to address the concerns for the unusually high percentage of eggs cracked in all treatment groups. The repairability of the study is pending the submission of the required information and the partially repeated study.
9. BACKGROUND: N/A
10. DISCUSSION OF INDIVIDUAL TESTS OR STUDIES: Study consists of three (3) volumes: Transmittal Document (Acc.# 408403-00); the reproductive study (Acc.# 408403-01), and; a supplemental, which addresses chemical analyses of the diet containing amitraz (Acc.# 409403-03).

11. MATERIALS AND METHODS (PROTOCOLS):

- A. Test Animals: The birds were obtained from D. R. and R. E. Wise, Monkfield Bourn, Cambridgeshire and were approximately 10 months old at the start of the treatment period. The birds were, therefore, approaching their first egg laying season.

Eighty male and eighty female young adult Bobwhite quail (Colinus virginianus) were randomly allocated to treatments together with an additional 16 male and 16 female birds to be used as possible replacements for birds which died or showed signs of ill health during the pre-treatment and pre-egg production periods. Each bird was individually identified using a numbered metal wing tag.

- B. Dosage and Design:

Protocol: "The protocol followed was based on that given in the United States Environmental Protection Agency (EPA) Pesticide Assessment Guidelines, Subdivision E, Hazard Evaluation, Wildlife and Aquatic Organisms, Series 71 - Avian and Mammalian Testing, October 1982, §71-4 Avian Reproduction Test, pages 48 to 57."

Design. The major phases of the study were as follows:

- 1-week pre-treatment period (untreated diet)
- 12-week pre-egg production period (test diet)
- 12-week egg production period (test diet)

Seven days prior to the start of the treatment period, the birds were randomly allocated to cages with one male and one female in each cage. There were three treatment groups plus a control group and 20 cages (replicates) for each treatment. Allocation to treatments was as follows:

| <u>Group</u> | <u>Dose</u> <u>(ppm)</u> | <u>No. of replicates/sexed birds</u> <u>per treatment</u> |
|--------------|-----------------------------|--|
| A (Control) | 0 | 20 |
| B | 10 | 20 |
| C | 40 | 20 |
| D | 160 | 20 |

Diet/Dosage. The basal diet used was quail layer diet, manufactured by Special Diets Services, Witham, Essex. It contained no added antibiotics or other growth promoters. Feed and domestic drinking water were available ad libitum.

"During the 24-week treatment period (comprising pre-egg production and egg production periods), control birds were given basal diet. For the remaining dose levels, birds were fed basal diet containing either 10, 40 or 160 ppm of technical amitraz. Test diets were prepared freshly each week. Dose levels were selected on the basis of known residue levels of amitraz in crops, this information being provided by the Sponsor.

"Because technical amitraz was unstable in the basal diet, immediately after each test diet concentration was prepared, the weekly mix was divided into seven equal portions, one for each day of the week. They were stored at -20° until used. Any residual diet remaining from the previous day was discarded before the fresh portion of diet was added to the food hoppers. Basal diet for the control birds was similarly subdivided frozen and fed as a daily ration.

"Diets were prepared once weekly. A weighed amount of amitraz was added to a small quantity of basal diet to give a pre-mix, which was mixed by being shaken in an inflated polythene bag for a minimum of three minutes.

For each of the lower dose levels a separate aliquot of this pre-mix was taken and further diluted with basal diet to give the required nominal concentrations. All diets were then mixed in a double-cone blender for a minimum of 7 minutes. Each concentration of test diet, including the control, was then divided into seven equal lots and frozen immediately.

"Because of predicted instability of amitraz in the basal diet, prior to the start of the main study, trial mixes of test compound and basal diet were prepared on 29 April 1987 and 19 May 1987; samples to be analysed for stability, homogeneity and achieved concentration were taken....

"The birds were housed in [a] building...in 6 batteries of cages, each battery consisting of 4 tiers of 4 cages. Each cage, which housed a replicate of 1 male and 1 female bird, was constructed from polythene-coated steel wire and measured 30 x 40 x 25 cm. The cages had sloping floors with 10 cm egg-catchers and had externally attached food hoppers. Domestic quality tap water was available in each pen through automatic nipple drinkers.

"The room in which the birds were housed...was designed to provide suitable environmental conditions for the species. The minimum and maximum room temperatures, together with the relative humidity, were recorded once daily throughout the study and had the following mean values:

| | <u>Mean</u> | <u>Standard deviation</u> |
|--------------------------|-------------|---------------------------|
| Maximum temperature (°C) | 23 | 1 |
| Minimum temperature (°C) | 20 | 2 |
| Relative humidity (%) | 66 | 13 |

"The birds were maintained under a restricted lighting regime of 7 hours light, 17 hours darkness from the time of arrival at HRC until the end of Week 6, when the photoperiod was gradually increased to 16 hours and maintained at this level until study termination.

"Egg collection. Eggs were collected and the number recorded daily for each pen over the 12-week egg production period, i.e. from the start of Week 13 to the end of Week 24. Each egg was labelled with the study number, replicate number and treatment group,

together with the date collected. The eggs were then stored on plastic egg trays in a refrigerator which was set to operate at 16° C. At the end of each 7-day period, eggs were removed from the refrigerator and the total weight of eggs from each replicate was recorded. Each egg was then candled and any broken or cracked eggs were recorded and discarded. The remaining eggs, except those removed for shell thickness measurement, were incubated....

"Egg shell thickness measurement. The egg(s) laid on the first day of Weeks 13, 15, 17, 18, 21 and 23 in each replicate was selected for shell thickness examination. The eggs were cracked open at the widest point and the contents washed out with tap water. The shells were then left to dry at room temperature for a minimum of 48 hours. The shell thickness of each egg was measured at 4 points around the circumference using a micrometer calibrated to 0.01 mm.

"Incubation. Eggs were incubated in a Sologne 36 incubator at weekly intervals. The incubator was set to operate at a temperature of 37.7°C and 55% relative humidity. The eggs were turned automatically once every hour through 90° (45° each side of the horizontal) through the incubation period. After 21 days the eggs were transferred to a hatcher where hatching took place within 3 to 4 days.

"Candling. Eggs were candled for cracks prior to incubation...and then on Days 11 and 18 of the incubation period. On Day 11, all infertile eggs and eggs showing early embryonic death were recorded and discarded. On Day 18 late embryonic deaths were recorded and discarded. Early and late embryonic deaths were removed on the basis of candling only and the eggs were not cracked open unless the candling result was difficult to assess.

"Hatching. After 21 days incubation, the eggs were transferred to a still air Bristol PH 90 hatcher, which was set to operate at a temperature of 37.5°C. The eggs were placed on wire mesh trays according to the replicates. All chicks which hatched were transferred to pens within 24 hours of hatching and any remaining unhatched eggs were classed as 'dead in shell'.

"Identification. On removal from the hatcher, chicks were individually weighed and identified by means of coloured plastic leg bands.... Each replicate was allocated a separate series of... numbers, with letter suffix so that each chick had a unique identification comprising colour code, number and letter suffix.

"Housing. The chicks were housed in wooden pens with concrete floors in [a] building ...in continuous light. Each pen contained two drinking founts and two food hoppers. Wood shavings were used as bedding. Each pen contained two 300-watt infra-red lamps placed at bird level to supply additional heat to the chicks. Maximum and minimum room temperatures and relative humidity were recorded once daily throughout the study, with the following mean values:

| | <u>Mean</u> | <u>Standard deviation</u> |
|--------------------------|-------------|---------------------------|
| Maximum temperature (°C) | 31 | 2 |
| Minimum temperature (°C) | 28 | 2 |
| Relative humidity (%) | 46 | 9 |

"Feed and water. All chicks were fed standard HRC chick meal...made by Joseph Odam Ltd., ...Cambridge-shire, England... The diet contained no added antibiotic or other growth promoter, but was not analysed for contaminants. Food and domestic quality drinking water were available ad libitum.

"Observations.

Adults.

| | |
|--|--|
| Mortalities: | Daily. |
| Clinical observations: | Daily. |
| Individual bodyweights: | Days -7, 0*, 14, 28, 42, 56, 70, 84 and 168. |
| Replicate food consumption: | Daily during treatment (weekly during pre-treatment period). |
| Macroscopic <u>post-mortem</u> examination | At termination of the study birds were sacrificed by cervical dislocation and examined <u>post-mortem</u> for gross macroscopic changes. |

* Immediately prior to introduction of the test diets.

Eggs.

| | |
|------------------------------|--|
| Collection: | Daily. |
| Replicate group egg weights: | Weekly. |
| Cracked and broken eggs: | Weekly. |
| Egg shell thickness: | Examined at Weeks 13, 15, 17, 19, 21 and 23. Eggs laid on the first day of |

the appropriate week for each replicate.

Infertile eggs:

Recorded and discarded at Day 11 candling during the incubation period.

Early embryonic death:

Recorded and discarded at Day 11 candling during the incubation period.

Late embryonic death:

Recorded and discarded at Day 18 candling during the incubation period.

Dead in shell:

Any eggs remaining after hatching of chicks were classified as "dead in shell".

Chicks.

Number of chicks hatched:

Weekly.

Clinical observations:

Daily.

Individual bodyweights:

Within 24 hours of hatching and 14 days later.

Mortalities:

Daily.

Macroscopic post-mortem examination:

Only chicks which died during the 14-day observations period were examined post-mortem for gross abnormalities.

C. Statistics: "The following parameters were analysed statistically...[:]"

- (i) Adult food consumption
- (ii) Adult bodyweights
- (iii) Number of eggs laid and mean egg weight
- (iv) Proportion of eggs damaged
- (v) Egg shell thickness
- (vi) Number of infertile eggs as a proportion of those set (incubated)
- (vii) Number of early embryonic deaths as a proportion of those fertile
- (viii) Number of late embryonic deaths as a proportion of those set (incubated) on Day 11
- (ix) Eggs hatched as a proportion of those set (incubated) on Day 18
- (x) Eggs hatched as a proportion of those fertile
- (xi) 14-day survivors as a proportion of those hatched
- (xii) Chick bodyweights at hatching and 14 days later

"The analysis of all responses consisted of partitioning the overall variability into three components:

- (i) that due to batteries, and the rows and columns within batteries
- (ii) that due to treatments...
- (iii) that due to random...variation

Williams' test (1) for contrasting increasing dose levels of a compound with a zero dose control was used to compare the treated groups with the control. Proportions were modified before being put through an angular transformation (2).

12. REPORTED RESULTS:

A. Adult Mortalities/Clinical Observations

Two birds in the control group died during the pre-treatment and pre-egg production periods; and two more during the egg production period. One bird, in the 10 ppm group, died during the egg production period. One bird, in the 40 ppm group, died during the pre-treatment/pre-egg production periods and a second died during the egg production period. Finally one 160 ppm bird died during the pre-treatment/pre-egg production periods.

"In general, bird health was good throughout the study....The majority of observations made were of physical injuries and were not considered to be related to treatment."

B. Adult Bodyweight/Food Consumption

"There were no treatment-related effects on bodyweights during the study. Statistical analysis of the results showed that there were no significant differences between the groups."

"Food consumption was similar in all groups, tending to be generally higher during egg production period (Weeks 13 - 24). Statistical analysis of the results showed that the high dose group (160 ppm amitraz) ate significantly less than the control group ($P < 0.05$)."

C. Adult Macroscopic Post-Mortem Examinations

Birds which died or were sacrificed during the study and those which were sacrificed at study termination were examined for macroscopic abnormalities. No dose-related abnormalities were observed.

D. Number of Eggs Laid

The numbers of eggs laid by treatment group and by individual hen, during Weeks 13 to 24, are summarised in Table 1.

"The number of eggs laid increased steadily during the first few weeks of the egg production period. Production was then maintained at a high level until the end of the study. There was no treatment-related effect on egg production [and a] statistical analysis of the results showed no significant difference between treatments."

E. Cracked and Broken Eggs

"The percentages of eggs laid which were cracked varied considerably from week to week, but there were no treatment-related effects. Statistical analysis of the results showed no significant differences between treatments."

F. Egg Weights/Egg Shell Thickness

"No treatment-related effect on egg weight was seen. Mean egg weight tended to increase as the study progressed. This is generally observed in studies of this type. Statistical analysis of the results showed no significant differences between treatments."

"Egg shell thickness was similar in all groups and statistical analysis of the results showed no significant differences between treatments."

G. Infertility and Embryonic Death

"Infertile eggs. The proportions of infertile eggs varied considerably from week to week within treatment groups, but there was no evidence of any treatment-related effect. Statistical analysis of the results showed no significant differences between treatments."

"Early embryonic deaths. The proportions of fertile eggs which were detected as an early embryonic death at Day 11 candling were generally small and no significant treatment differences were found during statistical analysis."

"Late embryonic deaths. The incidence of late embryonic death was low in all groups, particularly the control, and there was no evidence of a treatment-related effect. Values in all amitraz treated groups fell within the historical control range... Although statistical analysis of the results of the intermediate and high dose groups

showed slightly higher proportions of late embryonic death compared with the control ($P < 0.05$), this is not considered to be indicative of toxicological response."

H. Hatching

"The proportions of fertile eggs which subsequently hatched (hatchability) were generally high and statistical analysis of the results showed no significant differences between treatments. No significant differences in numbers of dead in shell were found between treatments."

I. Chick Health and Mortalities

"The majority of chicks were in good health at time of hatching and remained so for the duration of the 14-day observation period. A small number of abnormalities were noted [but they did not appear to be treatment-related]."

J. Chick Bodyweights

"At 160 ppm amitraz, mean bodyweight at hatching was slightly lower than in the control group, and statistical analysis showed that the difference was significant ($P < 0.05$). However, bodyweights in all amitraz treatment groups were similar to the control at 14 days after hatching."

K. Chick 14-Day Survival

"The proportion of chicks which survived to 14 days after hatching was similar in all groups. Statistical analysis of the results showed no significant differences between treatments."

"There was no evidence of any treatment-related differences in the percentage of 14-day survivors/ number of eggs set or in the number of 14-day survivors per female bird."

L. Analyses of Diets

"Analyses of diets revealed that mixing produced homogeneity. Mean test diet concentrations ranged between 67 and 91 % of nominal. Amitraz was found to be very unstable at room temperature, with losses up to 50% per day."

13. STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES: "It is concluded that dietary administration of technical amitraz to Bobwhite quail at up to 40 ppm had no effect upon the adult

birds or their reproductive performance. At 160 ppm, adult birds ate marginally less food and the overall mean chick bodyweight at hatching was slightly low."

The authors indicated that, "To the best of our knowledge and belief the study described in this report was conducted in compliance with the following Good Laboratory Practice Standards:

United States Environmental Protection Agency,
Title 40 Code of Federal Regulations Part 160,
Federal Register, 29 November 1983.

Organisation for Economic Co-operation and
Development, ISBN 92-64-12367-9, Paris 1982.

Japan Ministry of Agriculture, Forestry and
Fisheries, 59 NohSan, Notification No. 3850,
Agricultural Production Bureau, 10 August 1984.

Good Laboratory Practice, The United Kingdom
Compliance Programme, Department of Health &
Social Security 1986.

Further, "This report has been audited by HRC Quality Assurance Department. It is considered to be an accurate description of the procedures and practices employed during the course of the study and an accurate presentation of the findings."

"Inspections were made by the Quality Assurance Department of the various phases of the study described in this Report. The dates on which inspections were made and the dates on which the findings were reported [were reported] to the Study Director and to HRC Management...."

A total of eight (8) QA inspections/reports were made during the experimental and report writing phases of this study.

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

A. Test Procedure(s):

- (1) Raw data for mortality, adult bodyweight, food consumption and post-mortem examinations, number of eggs laid, cracked and broken, egg weight and egg shell thickness, hatching, chick health and bodyweights, and 14-day survivors support the text. The raw data on infertility and embryonic death, basically, agreed with the text. The following was an exception: Table 9, pg. 30 - The number of infertile eggs, on day 11 for the 160 ppm group during week 14, is indicated as 8. However,

the raw data (App. 8, pg 133) indicated the number to be 7.

(2) Study, basically, followed guidelines. The following are exceptions:

1. No information was given on percent active ingredient of test compound in the methods section. It was only provided in the appendix.
2. No information was given on the feed spillage or accounting for same.
3. The percentage of cracked eggs in the control group (22%) is high compared with what EPA staff indicates as normal (i.e. 0.6 - 2%, rarely exceeding 5%). Authors should comment on this. However, similar levels were reported for the dosed groups, suggesting that this variable impacted all groups to a similar extent.
4. Birds were kept on a lighting regime of 7 hours light per day until the end of week 6. SEP (pg. 4) requires 7 hours light/day for the first 8 weeks.
5. Although authors indicated that, "Dose levels were selected on the basis of known residue levels of amitraz in crops....", no relationship between field levels and dosages chosen was described. SEP (pg. 4) indicates that concentrations should include an expected field residue level and a multiple such as five.
6. SEP (pg. 5) requires eggs to be stored at 16°C and 65% relative humidity. Authors indicated that eggs were stored at 16°C but gave no indication of relative humidity.
7. SEP (pg. 5) recommends 39°C and 70% relative humidity during hatching phase. Authors indicated that the temperature was 37.5°C but did not report relative humidity.
8. SEP (pg. 5) requires hatchability to be recorded on day 24. Authors didn't indicate that this timing was followed.
9. SEP (pg. 7) requires that "Live three-week embryo (%)" be reported. Authors reported number of "late embryonic deaths (Day 18)."

10. SEP (pg. 8) indicates that when necropsies are performed, specific inspections of several organs be carried out. Study provided results of gross clinical observations but no detailed inspections of required organs.

11. The unusually high percentage of eggs cracked in the control group will require the submission of historical data from the laboratory concerning this parameter. Further, the study must be repeated by only retesting this parameter.

B. Statistical Analysis: The following parameters were evaluated using EPA Bigbird program (ANOVA and Duncan's Multiple Range Test): eggs laid, eggs cracked, eggs set, viable embryos, live embryos, normal hatchlings, eggs set/eggs laid, viable embryos/eggs set, live embryos/viable embryos, normal hatchlings/live embryos, eggs defective/eggs laid, infertile eggs/eggs set, early embryonic death/fertile eggs, late embryonic death/viable embryos, normal hatchlings/fertile eggs and 14-day survivors/number hatched. Results (attached) indicated no significant differences between treatment groups and controls.

A power of test was also ran by EEB to determine the statistical strength of the study. The attached results conclude that the statistical strength is not favorable due to the possible effect-masking variability within the parameters.

C. Discussion/Results: Author's conclusion (a) neglected to report that the (transformed) proportions of late embryonic deaths) of those set on Day 11) were significantly different ($P < .05$), from the controls, for the 40 and 160 ppm groups (Table 10 and App. 10, Table S6), and; (b) indicated that "At 160 ppm, ...the overall mean chick bodyweight at hatching was slightly low." In fact, the mean chick bodyweight was significantly lower than those of the controls (Table 12 and App. 10, Table S7).

Based on EPA's Big Bird analysis, the dietary administration of technical amitraz to bobwhite quail at up to 160 ppm had no effect on reproductive performance.

Study authors should provide detailed explanations of: (1) high percentage of cracked eggs in all groups, and; (2) the basis for selecting exposure levels. Other deviations from required/recommended procedures, as discussed in section 14A, should also be discussed as to possible influences on study results. The applicant must repeat the eggs cracked parameter of the study in order

to address the concern for the high percentages seen in all treatment groups, especially in the controls.

D. Adequacy of the Study:

- (1) Classification: Supplemental
- (2) Rationale: Deviations from required test procedures (see Section 14) and high incidence of egg cracking are of concern. Statistical evaluation indicate that there are no significant differences between the experimental groups for any of the reproductive parameters tested.
- (3) Repairability: Subject to the submission and review results of required information and the repeated portion of the study reevaluating the eggs cracked parameter.

15. COMPLETION OF ONE-LINER FOR STUDY: Yes, on 12/8/88

16. CBI APPENDIX: N/A

Literature Cited

1. Williams, D. A. (1971/72). Biometrics, 27: 103-117 and 28: 519-531.
2. Chanter, D. O. (1975). Applied Statistics, 24: 354-539.

Table 1. Analysis of Reproductive Effects of W87
Technical Amitraz on Bobwhite Quail

| Parameter | Concentrations in the Diet (ppm) | | | |
|--|-------------------------------------|-------|-------|------------------|
| | 0 | 10 | 40 | 100 |
| Eggs Laid | 1074 | 974 | 1222 | 1072 |
| Eggs Laid/Hen | 53.7 | 48.7 | 61.1 | 53.6 |
| Eggs Cracked (% of Eggs Laid) | 22 | 20 | 22 | 20 |
| Eggs Set - Total | 775 | 716 | 901 | 790 |
| Eggs Set Per Hen | 38.75 | 35.80 | 45.05 | 39.50 |
| Viable Embryos (Day 11) | 710 | 691 | 840 | 715 |
| Percent of Eggs Set | 92 | 97 | 93 | 91 |
| Live 18-Day Embryos | 698 | 680 | 822 | 689 |
| Percent of Viable Embryos | 98 | 98 | 98 | 96 |
| Hatchlings | | | | |
| Number Hatched | 644 | 630 | 779 | 637 |
| Percent of Eggs Laid | 60 | 65 | 64 | 59 |
| Percent of Viable Embryos | 91 | 91 | 93 | 89 |
| 14-Day Survivors | | | | |
| Total Number | 547 | 509 | 676 | 536 |
| Number per Hen | 27.4 | 25.5 | 33.8 | 26.8 |
| Percent of Hatchlings | 85 | 81 | 87 | 84 |
| Percent of Eggs Set | 71 | 71 | 75 | 68 |
| Average Hatch Weight (g) | 7.1 | 7.1 | 7.0 | 6.8* |
| Average 14-Day Old Survivors Weight (g) | 23 | 24 | 23 | 24 |
| Adult Bodyweight (grams per bird) | | | | |
| Females (at termination) | 223 | 226 | 228 | 231 |
| Males (at termination) | 207 | 210 | 207 | 201 |
| Mean Eggshell Thickness | .21 | .21 | .21 | .21 |
| Mean Egg Weight | 10.5 | 10.6 | 10.5 | 10.2 |
| Average Feed Consumption (grams per bird) | | | | |
| Pre-egg-production Period | 18 | 18 | 18 | 16* ^t |
| Egg Production Period | 19 | 20 | 20 | 18* ^t |

* P<0.05

^t Author did not distinguish which period was characterized by a significant difference between groups.

ONE LINER SHEET

Shaughnessey No. _____

Study/Species/Lab
Accession # _____

Chemical
% Active

Chemical Name Technical Amitraz

Chemical Class _____

Page _____ of _____

Results

Reviewer/
Date _____

Validation
Status _____

Avian Reproduction
Species: Bobwhite quail

97.5

Lab: Huntingdon Res. Ctr
Project #: TOX 87220
AC #: 408403-01
408403-02

| Group | Dose (ppm) | Affected Parameters(1) | Mort.(%) | % CHE Inh. |
|--------------------------|------------|--|----------|------------|
| Control | 0 | none | 10 | N/A |
| Treatment I | 10 | none | 2.5 | N/A |
| Treatment II | 40 | embryonic death (2) | 5 | N/A |
| Treatment III | 160 | embryonic death (2) & chick hatching weight | 2.5 | N/A |
| Study Duration: 25 weeks | | | | |

Lincer/
12/8/88 Supplemental

- (1) All groups displayed high % of cracked eggs (EC/EL); 20-22% range.
(2) According to author's statistics but not Big Bird.

EL

CHEMICAL: amitraz

TOTAL NUMBER OF LEVELS 4
NUMBER OF CONTROL REPLICATES: 20
CONTROL MEAN: 53.7
TOTAL NUMBER OF REPLICATES: 80
MEAN SQUARE ERROR: 428.224
ERROR DEGREES OF FREEDOM: 76
V1 used for this calculation: 3
V2 used for this calculation: 60
PHI value used for calculation of D 1.7

MEAN 1
61.10
NUMBER OF REPLICATES: 20

MEAN 2
53.70
NUMBER OF REPLICATES: 20

MEAN 3
53.60
NUMBER OF REPLICATES: 20

MEAN 4
48.70
NUMBER OF REPLICATES: 20

GRAND MEAN: 54.275
=====

Calculated PHI value for the Power Test .9570596

PERCENT CHANGE DETECTION LIMIT = 41.4324

CHEMICAL: amitraz

TOTAL NUMBER OF LEVELS 4
NUMBER OF CONTROL REPLICATES: 20
CONTROL MEAN: 38.75
TOTAL NUMBER OF REPLICATES: 80
MEAN SQUARE ERROR: 308.512
ERROR DEGREES OF FREEDOM: 76
V1 used for this calculation: 3
V2 used for this calculation: 60
PHI value used for calculation of D 1.7

MEAN 1
45.05
NUMBER OF REPLICATES: 20

MEAN 2
39.50
NUMBER OF REPLICATES: 20

MEAN 3
38.75
NUMBER OF REPLICATES: 20

MEAN 4
35.80
NUMBER OF REPLICATES: 20

GRAND MEAN: 39.775
=====

Calculated PHI value for the Power Test .8516431

PERCENT CHANGE DETECTION LIMIT = 48.73526

NH

CHEMICAL: amitraz

TOTAL NUMBER OF LEVELS 4
NUMBER OF CONTROL REPLICATES: 20
CONTROL MEAN: 32.15
TOTAL NUMBER OF REPLICATES: 80
MEAN SQUARE ERROR: 300.513
ERROR DEGREES OF FREEDOM: 76
V1 used for this calculation: 3
V2 used for this calculation: 60
PHI value used for calculation of D 1.7

MEAN 1
38.95
NUMBER OF REPLICATES: 20

MEAN 2
32.15
NUMBER OF REPLICATES: 20

MEAN 3
31.85
NUMBER OF REPLICATES: 20

MEAN 4
31.45
NUMBER OF REPLICATES: 20

GRAND MEAN: 33.6
=====

Calculated PHI value for the Power Test .799421

PERCENT CHANGE DETECTION LIMIT = 57.97351

VE

CHEMICAL: amitraz

TOTAL NUMBER OF LEVELS 4
NUMBER OF CONTROL REPLICATES: 20
CONTROL MEAN: 34.95
TOTAL NUMBER OF REPLICATES: 80
MEAN SQUARE ERROR: 321.641
ERROR DEGREES OF FREEDOM: 76
V1 used for this calculation: 3
V2 used for this calculation: 60
PHI value used for calculation of D 1.7

MEAN 1
41.60
NUMBER OF REPLICATES: 20

MEAN 2
34.95
NUMBER OF REPLICATES: 20

MEAN 3
34.90
NUMBER OF REPLICATES: 20

MEAN 4
34.20
NUMBER OF REPLICATES: 20

GRAND MEAN: 36.4125

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Calculated PHI value for the Power Test .7504895

PERCENT CHANGE DETECTION LIMIT = 55.17184

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amitraz

CHEMICAL:

TOTAL NUMBER OF LEVELS 4
NUMBER OF CONTROL REPLICATES: 20
CONTROL MEAN: 34.9
TOTAL NUMBER OF REPLICATES: 80
MEAN SQUARE ERROR: 319.731
ERROR DEGREES OF FREEDOM: 76
V1 used for this calculation: 3
V2 used for this calculation: 60
PHI value used for calculation of D 1.7

MEAN 1
41.10
NUMBER OF REPLICATES: 20

MEAN 2
34.90
NUMBER OF REPLICATES: 20

MEAN 3
34.50
NUMBER OF REPLICATES: 20

MEAN 4
34.05
NUMBER OF REPLICATES: 20

GRAND MEAN: 36.1375

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Calculated PHI value for the Power Test .720512

PERCENT CHANGE DETECTION LIMIT = 55.08659