

Data Evaluation Report on the Reproductive Effects of AE 0172747 Technical on Mallard Duck (*Anas platyrhynchos*)

PMRA Submission Number {.....}

EPA MRID Number 466955-05

EXECUTIVE SUMMARY

The sub-chronic/one-generation reproductive toxicity of AE 0172747 Technical to 16 pairs per level of 33-week old mallard duck (*Anas platyrhynchos*) was assessed over approximately 8 weeks. AE 0172747 Technical was administered to the birds in the diet at nominal concentrations of 0 (vehicle control), 22, 65, and 185 mg ai/kg dw diet. Mean-measured concentrations were <5 (<LOD, control), 22.4, 65.4, and 198 mg ai/kg diet, respectively. The NOAEC could not be determined (<22.4 mg ai/kg diet) based on statistically-significant reductions in egg production at the lowest treatment level and female body weight gain at all treatment levels. Male body weight gain was significantly reduced at the two highest treatment levels. Food consumption was not reduced from control at any treatment level. These were the only endpoints monitored in this study.

This study deviated significantly from standard methods and appeared to be conducted for supplemental data purposes. Therefore, this study does not satisfy the guideline requirement for a mallard duck (*Anas platyrhynchos*) reproductive toxicity study. Furthermore, because adequate frozen storage stability data were not provided and ancillary factors confounded the ability to assess treatment related effects on egg production, the utility of the data is severely limited.

This study is not scientifically sound, does not satisfy guideline requirements, and is thus classified as INVALID.

Results Synopsis

Test Organism Size/Age (mean Weight): 33-weeks old; 975-1388 g (combined sexes)

NOAEC: <22.4 mg ai/kg diet

LOAEC: 22.4 mg ai/kg diet

Endpoint(s) Affected: body weights of males and females and egg production

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I. MATERIALS AND METHODS

GUIDELINE FOLLOWED: The study protocol was based on procedures outlined in the U.S. EPA *Pesticide Assessment Guidelines*, §71-4; the U.S. EPA Ecological Effects Test Guideline OPPTS No. 850.2300; OECD Guideline No. 206; and ASTM Standard E1062-86. Deviations from OPPTS 850.2300 included:

1. Mortality of the adult birds during acclimation was not reported.
2. The study design differed significantly from guidance. Most notable differences included the lack of a pre-egg-laying exposure period, and failure to monitor numerous required reproductive endpoints (since newly-laid eggs were counted and discarded). **THIS AFFECTS THE VALIDITY OF THE STUDY.**
3. Pen floor size was significantly less (3375 cm²/duck) than recommended (at least 10,000 cm²/duck). As cages were much smaller than recommended, documentation that reproductive parameters and health of birds are not adversely affected should be provided.
4. The actual or expected field residue level was not reported, so it was unknown if the concentration range included this level.
5. It was not reported if the acetone used in preparing the treated feed was allowed to completely evaporate prior to offering.
6. Although adequate ambient 7-day feeder trough stability was demonstrated, frozen storage stability data were not generated. Premix batches were prepared every 3-4 weeks, and stored frozen in plastic bags until needed. **THIS AFFECTS THE VALIDITY OF THE STUDY**
7. Handling the birds for body weight measurements during the egg production phase may have impacted egg production results. Six of the 16 pair in the 22 mg ai/kg diet group appeared to go out of production following the second body weight measurements, and three hens in the 65 mg ai/kg level and two control hens appeared to be similarly impacted. **THIS AFFECTS THE VALIDITY OF THE STUDY.**

COMPLIANCE: Signed and dated GLP, Quality Assurance and Data Confidentiality statements were provided. This study was conducted in compliance with GLP standards as published by the U.S. EPA 40 CFR Part 160 with the following exception: periodic analyses of water and feed for potential contaminants.

A. MATERIALS:

1. Test Material AE 0172747 Technical

Description: Beige powder

Lot No./Batch No. : OP 2250027 / PFI 0215

Purity: 93.9%

Stability of compound

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Stability of compound under test conditions:

Stability was verified at all treatment levels under actual use conditions. Samples were assessed after 7 days of ambient feeder storage during Week 1. Recoveries were 90-100% of initial measured concentrations.

(OECD recommends water solubility, stability in water and light, pKa, Pow, and vapor pressure of test compound)

Storage conditions of test chemicals:

Ambient conditions

Physicochemical properties of AE 0172747 Technical.

| Parameter | Values | Comments |
|--------------------------|--------------|----------|
| Water solubility at 20°C | Not reported | |
| Vapor pressure | Not reported | |
| UV absorption | Not reported | |
| pKa | Not reported | |
| Kow | Not reported | |

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2. Test organism:

Table 1: Test organism.

| Parameter | Details | Remarks |
|--|--|--|
| | | <i>Criteria</i> |
| Species (common and scientific names): | Mallard duck (<i>Anas platyrhynchos</i>) | Birds were from the same hatch, and were phenotypically indistinguishable from wild birds. <i>Recommended species include a wild waterfowl species, preferably the mallard (<i>Anas platyrhynchos</i>) or an upland game species, preferably the northern bobwhite (<i>Colinus virginianus</i>)</i> |
| Age at Study Initiation: | 33 weeks old | It was stated that birds were approaching their first breeding season. <i>Birds approaching their first breeding season should be used.</i> |
| Body Weight: (mean and range) | Males: Overall range (n=64) 975 to 1266 g, with group means of 1113 to 1137 g. Females: Overall range (n=64) of 1003 to 1388 g, with group means of 1133 to 1184 g. | Body weights were recorded at weeks -2, 0, 2, 4, 6, and 8 (study termination). <i>Body weights should be recorded at test initiation and at biweekly intervals up to week eight or up to the onset of egg laying and at termination.</i> |
| Source: | Whistling Wings, Inc. 113 Washington Street Hanover, IL | <i>All birds should be from the same source.</i> |

B. STUDY DESIGN:

1. Experimental Conditions

a. Range-finding study: Test concentrations were selected in consultation with the Sponsor, based upon the results of a mallard reproduction study (Wildlife International Ltd., Project No. 149-194; concurrently-submitted as MRID 466955-05).

b. Definitive Study

Table 2: Experimental Parameters.

| Parameter | Details | Remarks |
|--|---|--|
| | | <i>Criteria</i> |
| Acclimation period: Conditions (same as test or not): | Approx. 12 weeks total Generally the same except for lighting. For the first 7 weeks of acclimation, the ducks were maintained on an 8-hour light/16-hour dark schedule. For the next 3 weeks, lighting was increased to 17 hours light/day to stimulate egg production. For the last 2 weeks of acclimation and during the definitive study, the lighting was increased an additional 15 minutes to further stimulate egg production. | The study author reported that immediately prior to test initiation, all birds were examined for physical injuries and general health, and that birds that did not appear healthy, either due to injury or inability to acclimate to laboratory conditions, or were outside the desired weight range for the test, were excluded from the study. |
| Feeding: | Wildlife International Ltd. Game Bird Ration formulated by Cargill Animal Nutrition (Shippensburg, PA) and tap water were provided <i>ad libitum</i> . | <i>Recommended observation period includes a 2-3 week health observation period prior to selection of birds for treatment. Generally, birds should be healthy without excess mortality. Feeding should be <u>ad libitum</u>, and sickness, injuries or mortality should be noted.</i> |
| Health (any mortality observed): | Mortality not reported. | |

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| Parameter | Details | Remarks |
|---|---|--|
| | | <i>Criteria</i> |
| <p><u>Test duration</u> pre-laying exposure: egg-laying exposure: withdrawal period, if used:</p> | <p>0 weeks 8 weeks N/A</p> | <p>Purposely, egg laying had commenced 2 weeks prior to the start of treatment.</p> <p><u>Recommended pre-laying exposure duration:</u> At least 10 weeks prior to the onset of egg-laying.</p> <p><u>Recommended exposure duration with egg-laying:</u> At least 10 weeks.</p> <p><u>Recommended withdrawal period:</u> If reduced reproduction is evident, a withdrawal period of up to 3 weeks should be added to the test phase.</p> |
| <p><u>Pen (for parental and offspring) size:</u> construction materials: number:</p> | <p>Parents (one pair) were housed in battery cages measuring 75 x 90 x 45 cm high. Offspring – N/A.</p> <p>Vinyl-coated wire mesh.</p> <p>16 parental pens/treatment level.</p> | <p>Pen floor size was significantly less (3375 cm²/duck) than recommended (at least 10,000 cm²/duck). As cages were much smaller than recommended, documentation that reproductive parameters and health of birds are not adversely affected should be provided.</p> <p><u>Pens</u> Pens should have adequate room and be arranged to prevent cross-contamination.</p> <p><u>Materials</u> Recommended materials include nontoxic material and nonbinding material, such as galvanized steel.</p> <p><u>Number</u> At least 5 replicate pens should be used for mallards housed in groups of 7. For other arrangements, at least 12 pens should be used, but considerably more may be used if birds are kept in pairs. Chicks should be housed according to parental grouping.</p> |
| <p>Number of birds per pen (male:female)</p> | <p>2 birds/pen (1 male:1 female)</p> | <p>One male and one female per pen should be used. For quail, one male and two females should be used. For ducks, two males and five females should be used.</p> |

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| Parameter | Details | Remarks |
|--|---|---|
| | | <i>Criteria</i> |
| <u>Number of pens per group/treatment</u> negative control: solvent control: treated: | N/A 16 pens 16 pens/treatment | At least 12-16 pens should be used, but considerably more if birds are kept in pairs. |
| <u>Test concentrations (mg ai/kg diet)</u> nominal: measured: | 0 (vehicle control), 22, 65, and 180 mg ai/kg diet <5 (<LOD, control), 22.4, 65.4, and 198 mg ai/kg diet | Dietary concentrations were adjusted for purity of the test substance. Measured concentrations were determined at all levels during Weeks 1, 3, and 6. Mean-measured concentrations had coefficients of variation of 1.9-4.4% indicating relative precision among the samples. <i>Recommended test concentrations include at least two concentrations other than the control; three or more will provide a better statistical analysis. The highest test concentrations should show a significant effect or be at or above the actual or expected field residue level.</i> |
| Maximum labeled field residue anticipated and source of information: | Not reported | <i>The highest test concentrations should show a significant effect or be at or above the actual or expected field residue level. The source (i.e., maximum label rate in lb ai/A and ppm), label registration no., label date, and site should be cited]</i> |
| Solvent/vehicle, if used type: amount: | Acetone and corn oil Approx. 0.8% (v:w – both) | <i>Recommended solvents include corn oil or other appropriate vehicle not more than 2% of diet by weight</i> |

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| Parameter | Details | Remarks |
|---|--|--|
| | | <i>Criteria</i> |
| Was detailed description and nutrient analysis of the basal diet provided? (Yes/No) | Yes. The basal ration contained at least 27% protein and 2.5% fat, and no more than 5% fiber. The diet was supplemented with limestone, to increase the calcium level to approximately 3%. | <i>A commercial breeder feed or an equivalent that is appropriate for the test species is recommended.</i> |
| Preparation of test diet | <p>The appropriate amount of test material was dissolved in acetone and corn oil using a magnetic stir plate, and quantitatively transferred to a bowl containing a portion of basal feed. The contents of the bowl were mixed on a Hobart mixer for approximately 15 minutes. The remainder of the basal ration was added, and the contents mixed for an additional 10 minutes. Premixes were prepared every 3-4 weeks, and if not used immediately after mixing, they were stored frozen in plastic bags.</p> <p>As needed, the appropriate premix was combined with additional basal ration and limestone and mixed in a Patterson-Kelly Twin Shell Blender for approximately 20 minutes.</p> | <p>It was not reported if the acetone (175 ml per premix) was allowed to completely evaporate prior to offering.</p> <p><i>A premixed diet containing the test substance should be mechanically mixed with basal diet. If an evaporative vehicle is used, it should be completely evaporated prior to feeding.</i></p> |
| Indicate whether stability and homogeneity of test material in diet determined (Yes/No) | Yes | |
| Were concentrations in diet verified by chemical analysis? | Yes | |

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| Parameter | Details | Remarks |
|---|--|--|
| | | Criteria |
| Did chemical analysis confirm that diet was stable and homogeneous? | Yes, for ambient 7-day feeder storage. Frozen storage stability data were not generated (premix batches were prepared every 3 to 4 weeks and were stored frozen until needed). Yes | Stability was assessed in treated feed prepared at all treatment levels after 7 days of ambient feeder storage during Week 1. Recoveries averaged 100, 100, and 90% of initial concentrations for the 22, 65, and 185 mg ai/kg diet levels, respectively. Homogeneity was assessed in treated feed prepared on Day 0 of Week 1 at the 22 mg ai/kg diet level. Six samples per level were collected: one sample per side from the top, middle, and bottom of the batch. The calculated coefficients of variation (CV=RSD) was 2.86%. |
| Feeding and husbandry | Feeding and husbandry conditions appeared to be adequate, given guideline recommendations. | |
| <u>Test conditions (pre-laying)</u> temperature: relative humidity: photoperiod: | 20.2 ± 0.5 °C 37 ± 11% 8 hr light/day during 7-week acclimation; 17 hr light/day during 3-week pre-egg laying period; 17.25 hr light/day during 2-week pre-treatment egg-laying period and treatment period. | Temperature and humidity were for the adult room during the entire study. The air handling system provided up to 15 room air volumes every hours. Light intensity averaged approximately 244 lux (or 23 foot candles). ----- <i>Recommended temperature: about 21 °C (70 °F)</i> <i>Recommended relative humidity: about 55%</i> <i>Recommended lighting</i> <i>First 8 weeks: 7 h per day.</i> <i>Thereafter: 16-17 h per day.</i> <i>At least 6 foot-candles are recommended at bird level.</i> |

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| Parameter | Details | Remarks |
|--|--------------|---|
| | | Criteria |
| Egg Collection and Incubation | | |
| <u>Egg collection and storage</u> collection interval: storage temperature: storage humidity: | Daily N/A | Eggs were discarded following counting. <i>Eggs should be collected daily; recommended egg storage temperature is approximately 16 °C (61 °F); recommended humidity is approximately 65%. Recommended collection interval: daily</i> |
| Were eggs candled for cracks prior to setting for incubation? | N/A | <i>Eggs should be candled on day 0</i> |
| Were eggs set weekly? | N/A | |
| When candling was done for fertility? | N/A | <i>Quail: approx. day 11 Ducks: approx. day 14</i> |
| When the eggs were transferred to the hatcher? | N/A | <i>Bobwhite: usually day 21 Mallard: usually day 23</i> |
| <u>Hatching conditions</u> temperature: humidity: photoperiod: | N/A | <i>Recommended temperature is 39 °C (102 °F) Recommended humidity is 70%</i> |
| Day the hatched eggs were removed and counted | N/A | <i>Eggs for bobwhite should be removed on day 24; for mallard on day 27</i> |
| Were egg shells washed and dried for at least 48 hrs before measuring? | N/A | |

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| Parameter | Details | Remarks |
|---|-----------|---|
| | | Criteria |
| <u>Egg shell thickness</u> no. of eggs used: intervals: mode of measurement: | N/A | Newly hatched eggs should be collected at least once every two weeks. Thickness of the shell plus membrane should be measured to the nearest 0.01 mm with 3 - 4 measurements per shell. |
| Reference chemical, if used | None used | |

2. Observations:

Table 3: Observations.

| Parameter | Details | Remarks |
|--|---|--|
| Parameters measured | | |
| <u>Parental</u> (mortality, body weight, mean feed consumption) | - mortality - body weight - food consumption - signs of toxicity - necropsy | All adult birds were subjected to gross necropsy. |
| <u>Egg collection and subsequent development</u> (no. of eggs laid, no. of eggs cracked, shell thickness, no. of eggs set, no. of viable embryos, no. of live 3 week embryos, no. hatched, no. of 14-day survivors, average weight of 14-d old survivors, mortality, gross pathology, others) | - eggs laid | <i>Recommended endpoints measured include:</i> <ul style="list-style-type: none"> • Eggs laid/pen • Eggs cracked/pen • Eggs set/pen • Viable embryos/pen • Live 3-week embryos/pen • Normal hatchlings/pen • 14-day-old survivors/pen • 14-day-old survivors/pen • Weights of 14-day-old survivors (mean per pen) • Egg shell thickness • Food consumption (mean per pen) • Initial and final body weight (mean per pen) |
| Indicate if the test material was regurgitated | No indications of dietary regurgitation. | |

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| Parameter | Details | Remarks |
|--|--|---|
| Observation intervals (for various parameters) | Parental mortality and signs of toxicity were recorded once daily. Parental body weights were recorded at weeks -2 (beginning of the pre-treatment egg laying period), 0 (test initiation), 2, 4, 6, and 8 (adult termination). Parental food consumption was measured weekly throughout the test. | <i>Body weights and food consumption should be measured at least biweekly</i> |
| Were raw data included? | Yes | |

II. RESULTS AND DISCUSSION:

A. MORTALITY:

No mortalities were observed in the control, 63, or 185 mg ai/kg diet groups. However, one incidental mortality occurred in the 22 mg ai/kg diet group. The single mortality was a female (pen 334) that was found dead during Week 2 without having exhibited prior clinical signs of toxicity. Necropsy revealed lesions on the right foot, cloudy air sacs, a firm, pale, and mottled liver, clear yellow fluid in the abdominal cavity, a regressing ovary, and cystic follicles of the reproductive tract. Necropsy of the pen-mate revealed small testes, but was otherwise unremarkable. This mortality was not considered to be related to treatment, and the NOAEC for adult mortality was 185 mg ai/kg diet.

Table 4: Effect of AE 0172747 Technical on Mortality of Mallard Duck.

| Treatment (mg ai/kg diet) Mean-measured (and Nominal) Concentrations | Observation Period | | | | | |
|---|--------------------|--------------------|------------------|--------------------|------------------|--------------------|
| | Week 2 | | Week 4 | | Week 8 | |
| | No. Dead Male | No. Dead Female | No. Dead Male | No. Dead Female | No. Dead Male | No. Dead Female |
| Control | 0 | 0 | 0 | 0 | 0 | 0 |
| 22.4 (22) | 0 | 1 | 0 | 1 | 0 | 1 |
| 65.4 (65) | 0 | 0 | 0 | 0 | 0 | 0 |
| 198 (185) | 0 | 0 | 0 | 0 | 0 | 0 |

B. REPRODUCTIVE AND OTHER ENDPOINTS:

Abnormal Effects/Behavior: No overt signs of toxicity were observed at any treatment level. Incidental clinical observations included those normally associated with injuries and pen wear; effects included feather loss and molting, food and head lesions, and occasional lameness. The NOAEC for clinical signs of toxicity was 185 mg ai/kg diet.

Food Consumption: No apparent treatment-related effects on feed consumption were observed at any treatment level. Although there was a statistically-significant increase (of 126% of control value) in feed consumption during

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Week 4 at the 65 mg ai/kg diet level, the difference was slight, and was neither concentration responsive nor consistent. The NOAEC for feed consumption was 250 mg ai/kg diet.

Body Weight: Slight, but statistically-significant reductions in body weights were observed in drakes from all treatment levels at Week 2, and continued throughout the study at the 185 mg ai/kg diet level. As body weights of drakes from the 22 and 65 mg ai/kg diet levels were similar to controls after Week 2 (indicating effect was transitory), only changes at the 185 mg ai/kg diet level were considered treatment-related. In hens, statistically-significant reductions in body weights were observed at Weeks 6 and 8; however, the reductions were partially reflective of the reproductive condition and/or incidental injury noted at study termination (see reproductive effects below). The subsequent NOAEC for adult body weight was 65 mg ai/kg diet.

Necropsy: There were no macroscopic findings at necropsy that were considered related to treatment.

Reproductive Effects: A treatment-related reduction in egg production was observed during the first 2 weeks of exposure at the 185 mg ai/kg diet level compared to the controls; the difference was statistically-significant at Week 1 ($p < 0.05$). During the first 2 weeks of treatment, controls produced 95-100 eggs/week compared to 69 eggs/weeks from hens at the 185 mg ai/kg diet level. Weekly egg production increased during the third week to 80 eggs/week, which was comparable to control production (85 eggs/week). No statistically-significant differences from controls were observed on egg production at the 65 mg ai/kg diet level. At the 22 mg ai/kg diet level, egg production values appeared to have been impacted by handling stress during weight measurements. Six of the 16 pairs at this level appeared to go out of production (defined as at least 2 consecutive weeks of no eggs laid) following the second body weight measurement, and the difference in egg production was statistically-reduced from the control (42 versus 85 eggs/week) during Week 3 (42 versus 85 eggs/week) and overall (457 versus 707 total eggs laid). Three hens in the 65 mg ai/kg diet level and two hens in the control group appeared to be similarly impacted. The NOAEC for egg production was 65 mg ai/kg diet.

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Table 5: Reproductive and Other Parameters (nominal concentrations; study author-reported).

| Parameter | Control | 22 mg ai/kg | 65 mg ai/kg | 185 mg ai/kg | NOAEC/ LOAEC |
|---|--|-------------|-------------|--------------|-------------------------------|
| Eggs laid/pen | Not reported | | | | N/A |
| Eggs laid/hen/day | 0.79 | 0.53* | 0.68 | 0.75 | 65 mg ai/kg 185 mg ai/kg |
| Eggs cracked | N/A | | | | N/A |
| Eggs set | N/A | | | | N/A |
| Shell thickness (mm ± SD) | N/A | | | | N/A |
| Viable embryos | N/A | | | | N/A |
| Live 3-week embryos | N/A | | | | N/A |
| No. of hatchlings/hen | N/A | | | | N/A |
| No. of normal hatchlings | N/A | | | | N/A |
| Hatchling weight (g ± SD) | N/A | | | | N/A |
| 14-day old survivors | N/A | | | | N/A |
| 14-day old survivors weight (g ± SD) | N/A | | | | N/A |
| Mean food consumption (g/bird/day) ^(a) | 186 | 195 | 214 | 201 | 185 mg ai/kg >185 mg ai/kg |
| Weight (g) of parent females at test initiation: | 1173 | 1133 | 1184 | 1159 | 185 mg ai/kg |
| at test termination: | 1157 | 1048** | 1097 | 1120 | >185 mg ai/kg |
| Weight (g) of parent males at test initiation: | 1137 | 1117 | 1115 | 1113 | 65 mg ai/kg |
| at test termination: | 1213 | 1174 | 1134 | 1119* | 185 mg ai/kg |
| Gross pathology | No treatment-related abnormalities observed. | | | | 185 mg ai/kg >185 mg ai/kg |

N/A = Not statistically-analyzed.

^(a) Reviewer-calculated from weekly data.

* Statistically different from the control at p<0.05.

** Statistically different from the control at p<0.01.

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C. REPORTED STATISTICS:

The following variables were statistically analyzed: adult body weight, adult feed consumption, and eggs laid. Each of the treatment groups was compared to the control group using an analysis of variance (ANOVA) followed by Dunnett's Multiple Comparison Procedure. Sample units were the individual pens within each experimental group, except adult body weights, where the sample unit was the individual bird. Nominal concentrations were used for all estimations.

D. VERIFICATION OF STATISTICAL RESULTS:

Statistical Method: Analysis was conducted using "chicks.sas" (Ver. 3; March 2002), a SAS program provided by EFED/OPP/USEPA. Data for all endpoints were examined graphically using box plots to determine if they exhibited a dose-dependent response, which was ultimately used to select the multiple comparison test to detect LOAEC and NOAEC. Data for each endpoint were tested to determine if their distributions were normal and if their variances were homogeneous using Shapiro-Wilk's and Levene's tests, respectively. Data that satisfied these assumptions were subjected to Dunnett's and William's tests and data that did not satisfy these assumptions were subjected to the non-parametric MannWhitney-U (with a Bonferroni adjustment) and Jonckheere's tests. Data for dead birds were excluded from the analyses. See Appendix I for output of reviewer's statistical verification and graphs for affected endpoints to support any reviewer-generated conclusions that may differ from those reported in the study.

NOAEC: <22.4 mg ai/kg

LOAEC: 22.4 mg ai/kg

Most Sensitive Endpoint(s): eggs laid and female weight gain

Table 6: Reproductive and Other Parameters (mean-measured concentrations; reviewer-reported).

| Parameter | Control | 22.4 mg ai/kg | 65.4 mg ai/kg | 198 mg ai/kg | NOAEC/ LOAEC |
|---------------------------------|---------|---------------|---------------|--------------|---------------------------------|
| Eggs laid/pen | 44.2 | 28.6* | 38.1 | 42.0 | <22.4 mg ai/kg 22.4 mg ai/kg |
| Eggs cracked/pen | N/A | N/A | N/A | N/A | N/A |
| Eggs not cracked/eggs laid (%) | N/A | N/A | N/A | N/A | N/A |
| Eggs set/pen | N/A | N/A | N/A | N/A | N/A |
| Shell thickness | N/A | N/A | N/A | N/A | N/A |
| Eggs set/eggs laid (%) | N/A | N/A | N/A | N/A | N/A |
| Viable embryos/pen | N/A | N/A | N/A | N/A | N/A |
| Viable embryos/eggs set (%) | N/A | N/A | N/A | N/A | N/A |
| Live embryos/pen | N/A | N/A | N/A | N/A | N/A |
| Live embryos/viable embryos (%) | N/A | N/A | N/A | N/A | N/A |
| No. of hatchlings/pen | N/A | N/A | N/A | N/A | N/A |

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| | | | | | |
|--|-------|--------|--------|--------|---------------------------------|
| No. of hatchlings/eggs laid (%) | N/A | N/A | N/A | N/A | N/A |
| No. of hatchlings/eggs set (%) | N/A | N/A | N/A | N/A | N/A |
| No. of hatchlings/live embryos (%) | N/A | N/A | N/A | N/A | N/A |
| Hatchling survival/pen | N/A | N/A | N/A | N/A | N/A |
| Hatchling survival/eggs set (%) | N/A | N/A | N/A | N/A | N/A |
| Hatchling survival/no. of hatchlings (%) | N/A | N/A | N/A | N/A | N/A |
| Hatchling weight (g) | N/A | N/A | N/A | N/A | N/A |
| Survivor weight (g) | N/A | N/A | N/A | N/A | N/A |
| Mean food consumption (g/bird/day) | 186.1 | 195.3 | 214.1 | 201.1 | 198 mg ai/kg >198 mg ai/kg |
| Male weight gain (g) | 75.8 | 53.5 | 19.3* | 6.3* | 22.4 mg ai/kg 65.4 mg ai/kg |
| Female weight gain (g) | -15.8 | -76.4* | -87.4* | -39.3* | <22.4 mg ai/kg 22.4 mg ai/kg |

* Statistically different from the control at $p < 0.05$.

E. STUDY DEFICIENCIES:

Treated premixes were prepared every 3 to 4 weeks and were stored frozen in plastic bags until needed; however, frozen storage stability data were not provided. This deficiency affects the scientific soundness of this study. In addition, notable deficiencies from OPPTS 850.2300 guideline included: the study methods deviated significantly from standard procedures (e.g., no pre-egg laying treatment period, 8-week duration, failure to incubate collected eggs and therefore measure numerous reproductive endpoints); pen floor size was significantly less (3375 cm²/duck) than recommended (at least 10,000 cm²/duck), and documentation that reproductive parameters and health of birds are not adversely affected were not provided; and handling of the birds for body weight measurements during the egg production phase may have adversely affected egg production. Other noted deviations from guidance were not considered significant by the reviewer.

F. REVIEWERS COMMENTS:

Results of the reviewer's statistical verification differed slightly from the study authors'. Both detected a statistically significant reduction in egg production at the lowest treatment level; however, the study author dismissed this effect because it was confounded by the adverse impact of handling adult birds during the egg production phase. Similarly, the study authors and reviewer detected significant reductions in male and female weight gain, but arrived at different conclusions for the NOAEC values. The study author dismissed reductions in male weight gain at the 65.4 mg ai/kg treatment level because they were reportedly transitory and dismissed reductions in female weight gain at all treatment levels because they were associated with reproductive condition and incidental injuries. The reviewer's toxicity values are reported in the Executive Summary and Conclusions sections.

Data Evaluation Report on the Reproductive Effects of AE 0172747 Technical on Mallard Duck (*Anas platyrhynchos*)

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Although not specified in the report, this study appeared to have been conducted to provide supplemental data to further support and/or define the NOAEC and LOAEC values that were obtained from the standard avian reproduction study conducted using mallard ducks (concurrently-submitted MRID 466955-05).

Based on mean body weights and food consumption, the overall estimated daily dietary dose was calculated as 3.9, 12.5, and 33.5 mg ai/kg bw/day for the nominal 22, 65, and 185 mg ai/kg diet levels, respectively.

Matrix blanks were fortified at 10 or 200 mg ai/kg diet and analyzed concurrently with sample analysis. Recoveries ranged from 100-109% for all samples (mean range of 102-107%). Sample concentrations were not corrected for mean procedural recoveries.

Samples were analyzed by HPLC/UV. The analytical LOD and LOQ were 5 and 10 mg ai/kg diet, respectively.

In-life dates were December 21, 2004 to February 16, 2005.

G. CONCLUSIONS:

This study is not scientifically sound and is thus INVALID. Adequate freezer storage stability data were not provided. In addition, this study does not fulfill guideline requirements because it deviated significantly from standard methods and appeared instead to be for supplemental data purposes, the ducks were maintained in cages significantly smaller than recommended, and handling of the birds during the study for body weight measurements appeared to have adversely affected egg production. This study does not fulfill the guideline requirement for an avian reproduction study.

NOAEC: <22.4 mg ai/kg diet

LOAEC: 22.4 mg ai/kg diet

Endpoint(s) Affected: body weights of males and females and egg production

Data Evaluation Report on the Reproductive Effects of AE 0172747 Technical on Mallard Duck (*Anas platyrhynchos*)

PMRA Submission Number {.....}

EPA MRID Number 466955-05

III. REFERENCES:

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Data Evaluation Report on the Reproductive Effects of AE 0172747 Technical on Mallard Duck (*Anas platyrhynchos*)
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APPENDIX I. OUTPUT OF REVIEWER'S STATISTICAL VERIFICATION:

Mallard repro, Bayer AE0172747, MRID 466955-06

PRINTOUT OF RAW DATA

| Obs | TRT | EL | EC | ENC_EL | ES | ES_EL | VE | VE_ES | LE | LE_VE | NH | NH_EL |
|-----|-------|----|----|--------|----|-------|----|-------|----|-------|----|-------|
| 1 | Ctrl | 53 | . | . | . | . | . | . | . | . | . | . |
| 2 | Ctrl | 51 | . | . | . | . | . | . | . | . | . | . |
| 3 | Ctrl | 56 | . | . | . | . | . | . | . | . | . | . |
| 4 | Ctrl | 40 | . | . | . | . | . | . | . | . | . | . |
| 5 | Ctrl | 46 | . | . | . | . | . | . | . | . | . | . |
| 6 | Ctrl | 54 | . | . | . | . | . | . | . | . | . | . |
| 7 | Ctrl | 50 | . | . | . | . | . | . | . | . | . | . |
| 8 | Ctrl | 12 | . | . | . | . | . | . | . | . | . | . |
| 9 | Ctrl | 43 | . | . | . | . | . | . | . | . | . | . |
| 10 | Ctrl | 55 | . | . | . | . | . | . | . | . | . | . |
| 11 | Ctrl | 5 | . | . | . | . | . | . | . | . | . | . |
| 12 | Ctrl | 31 | . | . | . | . | . | . | . | . | . | . |
| 13 | Ctrl | 54 | . | . | . | . | . | . | . | . | . | . |
| 14 | Ctrl | 55 | . | . | . | . | . | . | . | . | . | . |
| 15 | Ctrl | 58 | . | . | . | . | . | . | . | . | . | . |
| 16 | Ctrl | 44 | . | . | . | . | . | . | . | . | . | . |
| 17 | Dose1 | 7 | . | . | . | . | . | . | . | . | . | . |
| 18 | Dose1 | 10 | . | . | . | . | . | . | . | . | . | . |
| 19 | Dose1 | 54 | . | . | . | . | . | . | . | . | . | . |
| 20 | Dose1 | 25 | . | . | . | . | . | . | . | . | . | . |
| 21 | Dose1 | 53 | . | . | . | . | . | . | . | . | . | . |
| 22 | Dose1 | 10 | . | . | . | . | . | . | . | . | . | . |
| 23 | Dose1 | 27 | . | . | . | . | . | . | . | . | . | . |
| 24 | Dose1 | 56 | . | . | . | . | . | . | . | . | . | . |
| 25 | Dose1 | 12 | . | . | . | . | . | . | . | . | . | . |
| 26 | Dose1 | 50 | . | . | . | . | . | . | . | . | . | . |

Data Evaluation Report on the Reproductive Effects of AE 0172747 Technical on Mallard Duck (*Anas platyrhynchos*)

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EPA MRID Number 466955-05

| | | | | | | | | | | | | |
|----|-------|----|---|---|---|---|---|---|---|---|---|---|
| 55 | Dose3 | 37 | . | . | . | . | . | . | . | . | . | . |
| 56 | Dose3 | 57 | . | . | . | . | . | . | . | . | . | . |
| 57 | Dose3 | 33 | . | . | . | . | . | . | . | . | . | . |
| 58 | Dose3 | 38 | . | . | . | . | . | . | . | . | . | . |
| 59 | Dose3 | 40 | . | . | . | . | . | . | . | . | . | . |
| 60 | Dose3 | 52 | . | . | . | . | . | . | . | . | . | . |
| 61 | Dose3 | 46 | . | . | . | . | . | . | . | . | . | . |
| 62 | Dose3 | 49 | . | . | . | . | . | . | . | . | . | . |
| 63 | Dose3 | 31 | . | . | . | . | . | . | . | . | . | . |
| 64 | Dose3 | 56 | . | . | . | . | . | . | . | . | . | . |

Mallard repro, Bayer AE0172747, MRID 466955-06

PRINTOUT OF RAW DATA (continued)

| Obs | TRT | NH_LE | HS | HS_ES | HS_NH | THICK | HATWT | SURVWT | FOOD | WTGAINM | |
|-----|-------|-------|----|-------|-------|-------|-------|--------|------|---------|------|
| 1 | Ctrl | . | . | . | . | . | . | . | 174 | 13 | -25 |
| 2 | Ctrl | . | . | . | . | . | . | . | 281 | 50 | -63 |
| 3 | Ctrl | . | . | . | . | . | . | . | 151 | 42 | -131 |
| 4 | Ctrl | . | . | . | . | . | . | . | 198 | 48 | 43 |
| 5 | Ctrl | . | . | . | . | . | . | . | 156 | 181 | -66 |
| 6 | Ctrl | . | . | . | . | . | . | . | 197 | 90 | -23 |
| 7 | Ctrl | . | . | . | . | . | . | . | 207 | 33 | 47 |
| 8 | Ctrl | . | . | . | . | . | . | . | 158 | 199 | -90 |
| 9 | Ctrl | . | . | . | . | . | . | . | 228 | 75 | 5 |
| 10 | Ctrl | . | . | . | . | . | . | . | 229 | 22 | -29 |
| 11 | Ctrl | . | . | . | . | . | . | . | 154 | 81 | -2 |
| 12 | Ctrl | . | . | . | . | . | . | . | 144 | 107 | 109 |
| 13 | Ctrl | . | . | . | . | . | . | . | 136 | 67 | 29 |
| 14 | Ctrl | . | . | . | . | . | . | . | 214 | 67 | 19 |
| 15 | Ctrl | . | . | . | . | . | . | . | 193 | 97 | -45 |
| 16 | Ctrl | . | . | . | . | . | . | . | 157 | 41 | -31 |
| 17 | Dose1 | . | . | . | . | . | . | . | 200 | 121 | -121 |
| 18 | Dose1 | . | . | . | . | . | . | . | 197 | 111 | -41 |
| 19 | Dose1 | . | . | . | . | . | . | . | 272 | 1 | -115 |
| 20 | Dose1 | . | . | . | . | . | . | . | 216 | 45 | 50 |
| 21 | Dose1 | . | . | . | . | . | . | . | 281 | 102 | -92 |
| 22 | Dose1 | . | . | . | . | . | . | . | 229 | 134 | -95 |
| 23 | Dose1 | . | . | . | . | . | . | . | 143 | -98 | -42 |
| 24 | Dose1 | . | . | . | . | . | . | . | 187 | 62 | -27 |
| 25 | Dose1 | . | . | . | . | . | . | . | 190 | 83 | -155 |
| 26 | Dose1 | . | . | . | . | . | . | . | 177 | 55 | -74 |
| 27 | Dose1 | . | . | . | . | . | . | . | 202 | 54 | -115 |
| 28 | Dose1 | . | . | . | . | . | . | . | 183 | 32 | -36 |
| 29 | Dose1 | . | . | . | . | . | . | . | 153 | 134 | -63 |
| 30 | Dose1 | . | . | . | . | . | . | . | 162 | 38 | -110 |
| 31 | Dose1 | . | . | . | . | . | . | . | 187 | -72 | -110 |
| 32 | Dose1 | . | . | . | . | . | . | . | 145 | . | . |
| 33 | Dose2 | . | . | . | . | . | . | . | 346 | 36 | -106 |

Data Evaluation Report on the Reproductive Effects of AE 0172747 Technical on Mallard Duck (*Anas platyrhynchos*)

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| | | | | | | | | | | |
|----|-------|---|---|---|---|---|---|-----|-----|------|
| 34 | Dose2 | . | . | . | . | . | . | 143 | 56 | 12 |
| 35 | Dose2 | . | . | . | . | . | . | 194 | -83 | -185 |
| 36 | Dose2 | . | . | . | . | . | . | 142 | 80 | -36 |
| 37 | Dose2 | . | . | . | . | . | . | 157 | 64 | -3 |
| 38 | Dose2 | . | . | . | . | . | . | 289 | -6 | 86 |
| 39 | Dose2 | . | . | . | . | . | . | 205 | 62 | -148 |
| 40 | Dose2 | . | . | . | . | . | . | 194 | -47 | -81 |
| 41 | Dose2 | . | . | . | . | . | . | 143 | 106 | -196 |
| 42 | Dose2 | . | . | . | . | . | . | 228 | -4 | -174 |
| 43 | Dose2 | . | . | . | . | . | . | 224 | -5 | -2 |
| 44 | Dose2 | . | . | . | . | . | . | 225 | 23 | -155 |
| 45 | Dose2 | . | . | . | . | . | . | 236 | 22 | -169 |
| 46 | Dose2 | . | . | . | . | . | . | 176 | -6 | -4 |
| 47 | Dose2 | . | . | . | . | . | . | 310 | 0 | -127 |
| 48 | Dose2 | . | . | . | . | . | . | 213 | 10 | -110 |
| 49 | Dose3 | . | . | . | . | . | . | 185 | -7 | -169 |
| 50 | Dose3 | . | . | . | . | . | . | 141 | 0 | -31 |
| 51 | Dose3 | . | . | . | . | . | . | 203 | -4 | -95 |
| 52 | Dose3 | . | . | . | . | . | . | 211 | 15 | -64 |
| 53 | Dose3 | . | . | . | . | . | . | 222 | -71 | 44 |
| 54 | Dose3 | . | . | . | . | . | . | 212 | 17 | -47 |
| 55 | Dose3 | . | . | . | . | . | . | 137 | 94 | 57 |
| 56 | Dose3 | . | . | . | . | . | . | 153 | 21 | -27 |
| 57 | Dose3 | . | . | . | . | . | . | 171 | -23 | 29 |
| 58 | Dose3 | . | . | . | . | . | . | 251 | 135 | -56 |
| 59 | Dose3 | . | . | . | . | . | . | 160 | -60 | 87 |
| 60 | Dose3 | . | . | . | . | . | . | 241 | 12 | -125 |
| 61 | Dose3 | . | . | . | . | . | . | 250 | -20 | -51 |
| 62 | Dose3 | . | . | . | . | . | . | 222 | -75 | -58 |
| 63 | Dose3 | . | . | . | . | . | . | 257 | 26 | -129 |
| 64 | Dose3 | . | . | . | . | . | . | 202 | 40 | 6 |

Data Evaluation Report on the Reproductive Effects of AE 0172747 Technical on Mallard Duck (*Anas platyrhynchos*)

PMRA Submission Number {.....}

EPA MRID Number 466955-05

Mallard repro, Bayer AE0172747, MRID 466955-06
ANALYSIS RESULTS FOR VARIABLE EL (Eggs Laid)

TESTS OF ASSUMPTIONS FOR PARAMETRIC ANALYSIS

Shapiro-Wilks test for Normality of Residuals -- alpha-level=0.01

Levenes test for homogeneity of variance (absolute residuals) -- alpha-level=0.05

Use parametric analyses if neither test rejected, otherwise non-parametric analyses.

| Shapiro-Wilks Test Stat | Shapiro-Wilks P-value | Levenes Test Stat | Levenes P-value | Conclusion |
|-------------------------|-----------------------|-------------------|-----------------|--------------------|
| 0.969 | 0.106 | 3.671 | 0.017 | USE NON-PARAMETRIC |

**

BASIC SUMMARY STATISTICS

| Level | N | Mean | StdDev | StdErr | Coef of Var | 95% Conf.Interval | |
|-------|----|-------|--------|--------|-------------|-------------------|-------|
| Ctrl | 16 | 44.19 | 15.67 | 3.92 | 35.46 | 35.84, | 52.54 |
| Dose1 | 16 | 28.56 | 17.55 | 4.39 | 61.43 | 19.21, | 37.91 |
| Dose2 | 16 | 38.13 | 18.47 | 4.62 | 48.44 | 28.28, | 47.97 |
| Dose3 | 16 | 42.00 | 8.61 | 2.15 | 20.50 | 37.41, | 46.59 |

| Level | Median | Min | Max | %of Control (means) | |
|-------|--------|-------|-------|---------------------|-------|
| Ctrl | 50.50 | 5.00 | 58.00 | . | . |
| Dose1 | 26.00 | 7.00 | 56.00 | 64.64 | 35.36 |
| Dose2 | 46.00 | 1.00 | 56.00 | 86.28 | 13.72 |
| Dose3 | 40.00 | 31.00 | 57.00 | 95.05 | 4.95 |

**

NON-PARAMETRIC ANALYSES - use alpha-level=0.05 for all tests

Kruskal-Wallis test - equality among treatment groups

| Degrees of Freedom | TestStat | P-value |
|--------------------|----------|---------|
| 3 | 7.70 | 0.053 |

MannWhit(Bon) - testing each trt median signif. less than control

Jonckheere - test assumes dose-response relationship, testing negative trend

| Level | Median | MannWhit(Bon adjust)p-value | Jonckheere p-value |
|-------|--------|-----------------------------|--------------------|
| Ctrl | 50.50 | . | . |
| Dose1 | 26.00 | 0.037 | 0.009 |
| Dose2 | 46.00 | 0.635 | 0.189 |
| Dose3 | 40.00 | 0.259 | 0.398 |

SUMMARY

MannWhit (Bonf adjust)
Jonckheere

NOEC

<lowest dose
Dose3

LOEC

Dose1
>highest dose

Data Evaluation Report on the Reproductive Effects of AE 0172747 Technical on Mallard Duck (*Anas platyrhynchos*)

PMRA Submission Number {.....}

EPA MRID Number 466955-05

Mallard repro, Bayer AE0172747, MRID 466955-06
 ANALYSIS RESULTS FOR VARIABLE NEG_EC (Eggs Cracked)

TESTS OF ASSUMPTIONS FOR PARAMETRIC ANALYSIS

Shapiro-Wilks test for Normality of Residuals -- alpha-level=0.01
 Levenes test for homogeneity of variance(absolute residuals) -- alpha-level=0.05

Use parametric analyses if neither test rejected, otherwise non-parametric analyses.

| Shapiro-Wilks Test Stat | Shapiro-Wilks P-value | Levenes Test Stat | Levenes P-value | Conclusion |
|-------------------------|-----------------------|-------------------|-----------------|------------------|
| . | . | . | . | NO DATA FOR TEST |

 **

BASIC SUMMARY STATISTICS

| Level | N | Mean | StdDev | StdErr | Coef of Var | 95% Conf.Interval |
|-------|---|------|--------|--------|-------------|-------------------|
| Ctrl | 0 | . | . | . | . | ./. |
| Dose1 | 0 | . | . | . | . | ./. |
| Dose2 | 0 | . | . | . | . | ./. |
| Dose3 | 0 | . | . | . | . | ./. |

| Level | Median | Min | Max | %of Control (means) |
|-------|--------|-----|-----|---------------------|
| Ctrl | . | . | . | . |
| Dose1 | . | . | . | . |
| Dose2 | . | . | . | . |
| Dose3 | . | . | . | . |

Mallard repro, Bayer AE0172747, MRID 466955-06
 ANALYSIS RESULTS FOR VARIABLE ENC_EL ((EL-EC)/EL (%))

TESTS OF ASSUMPTIONS FOR PARAMETRIC ANALYSIS

Shapiro-Wilks test for Normality of Residuals -- alpha-level=0.01
 Levenes test for homogeneity of variance(absolute residuals) -- alpha-level=0.05

Use parametric analyses if neither test rejected, otherwise non-parametric analyses.

| Shapiro-Wilks Test Stat | Shapiro-Wilks P-value | Levenes Test Stat | Levenes P-value | Conclusion |
|-------------------------|-----------------------|-------------------|-----------------|------------------|
| . | . | . | . | NO DATA FOR TEST |

 **

BASIC SUMMARY STATISTICS

| Level | N | Mean | StdDev | StdErr | Coef of Var | 95% Conf.Interval |
|-------|---|------|--------|--------|-------------|-------------------|
| Ctrl | 0 | . | . | . | . | ./. |
| Dose1 | 0 | . | . | . | . | ./. |
| Dose2 | 0 | . | . | . | . | ./. |
| Dose3 | 0 | . | . | . | . | ./. |

| Level | Median | Min | Max | %of Control (means) |
|-------|--------|-----|-----|---------------------|
| Ctrl | . | . | . | . |
| Dose1 | . | . | . | . |
| Dose2 | . | . | . | . |
| Dose3 | . | . | . | . |

Data Evaluation Report on the Reproductive Effects of AE 0172747 Technical on Mallard Duck (*Anas platyrhynchos*)

PMRA Submission Number {.....}

EPA MRID Number 466955-05

Mallard repro, Bayer AE0172747, MRID 466955-06
 ANALYSIS RESULTS FOR VARIABLE ES (Eggs Set)

TESTS OF ASSUMPTIONS FOR PARAMETRIC ANALYSIS

Shapiro-Wilks test for Normality of Residuals -- alpha-level=0.01

Levenes test for homogeneity of variance(absolute residuals) -- alpha-level=0.05

Use parametric analyses if neither test rejected, otherwise non-parametric analyses.

| Shapiro-Wilks Test Stat | Shapiro-Wilks P-value | Levenes Test Stat | Levenes P-value | Conclusion |
|-------------------------|-----------------------|-------------------|-----------------|------------------|
| . | . | . | . | NO DATA FOR TEST |

 **

BASIC SUMMARY STATISTICS

| Level | N | Mean | StdDev | StdErr | Coef of Var | 95% Conf.Interval |
|-------|---|------|--------|--------|-------------|-------------------|
| Ctrl | 0 | . | . | . | . | . / . |
| Dose1 | 0 | . | . | . | . | . / . |
| Dose2 | 0 | . | . | . | . | . / . |
| Dose3 | 0 | . | . | . | . | . / . |

| Level | Median | Min | Max | %of Control(means) |
|-------|--------|-----|-----|--------------------|
| Ctrl | . | . | . | . |
| Dose1 | . | . | . | . |
| Dose2 | . | . | . | . |
| Dose3 | . | . | . | . |

Mallard repro, Bayer AE0172747, MRID 466955-06
 ANALYSIS RESULTS FOR VARIABLE ES_EL (EggsSet/EggsLaid (%))

TESTS OF ASSUMPTIONS FOR PARAMETRIC ANALYSIS

Shapiro-Wilks test for Normality of Residuals -- alpha-level=0.01

Levenes test for homogeneity of variance(absolute residuals) -- alpha-level=0.05

Use parametric analyses if neither test rejected, otherwise non-parametric analyses.

| Shapiro-Wilks Test Stat | Shapiro-Wilks P-value | Levenes Test Stat | Levenes P-value | Conclusion |
|-------------------------|-----------------------|-------------------|-----------------|------------------|
| . | . | . | . | NO DATA FOR TEST |

 **

BASIC SUMMARY STATISTICS

| Level | N | Mean | StdDev | StdErr | Coef of Var | 95% Conf.Interval |
|-------|---|------|--------|--------|-------------|-------------------|
| Ctrl | 0 | . | . | . | . | . / . |
| Dose1 | 0 | . | . | . | . | . / . |
| Dose2 | 0 | . | . | . | . | . / . |
| Dose3 | 0 | . | . | . | . | . / . |

| Level | Median | Min | Max | %of Control(means) |
|-------|--------|-----|-----|--------------------|
| Ctrl | . | . | . | . |
| Dose1 | . | . | . | . |
| Dose2 | . | . | . | . |

Data Evaluation Report on the Reproductive Effects of AE 0172747 Technical on Mallard Duck (*Anas platyrhynchos*)

PMRA Submission Number {.....}

EPA MRID Number 466955-05

Dose3

Mallard repro, Bayer AE0172747, MRID 466955-06
 ANALYSIS RESULTS FOR VARIABLE VE (Viable Embryo(d14))

TESTS OF ASSUMPTIONS FOR PARAMETRIC ANALYSIS

Shapiro-Wilks test for Normality of Residuals -- alpha-level=0.01
 Levenes test for homogeneity of variance(absolute residuals) -- alpha-level=0.05

Use parametric analyses if neither test rejected, otherwise non-parametric analyses.

| Shapiro-Wilks Test Stat | Shapiro-Wilks P-value | Levenes Test Stat | Levenes P-value | Conclusion |
|-------------------------|-----------------------|-------------------|-----------------|------------------|
| . | . | . | . | NO DATA FOR TEST |

 **

BASIC SUMMARY STATISTICS

| Level | N | Mean | StdDev | StdErr | Coef of Var | 95% Conf.Interval |
|-------|---|------|--------|--------|-------------|-------------------|
| Ctrl | 0 | . | . | . | . | . / . |
| Dose1 | 0 | . | . | . | . | . / . |
| Dose2 | 0 | . | . | . | . | . / . |
| Dose3 | 0 | . | . | . | . | . / . |

| Level | Median | Min | Max | %of Control (means) |
|--------------------|--------|-----|-----|---------------------|
| %Reduction (means) | | | | |
| Ctrl | . | . | . | . |
| Dose1 | . | . | . | . |
| Dose2 | . | . | . | . |
| Dose3 | . | . | . | . |

Mallard repro, Bayer AE0172747, MRID 466955-06
 ANALYSIS RESULTS FOR VARIABLE VE_ES (ViableEmbryo/EggsSet (%))

TESTS OF ASSUMPTIONS FOR PARAMETRIC ANALYSIS

Shapiro-Wilks test for Normality of Residuals -- alpha-level=0.01
 Levenes test for homogeneity of variance(absolute residuals) -- alpha-level=0.05

Use parametric analyses if neither test rejected, otherwise non-parametric analyses.

| Shapiro-Wilks Test Stat | Shapiro-Wilks P-value | Levenes Test Stat | Levenes P-value | Conclusion |
|-------------------------|-----------------------|-------------------|-----------------|------------------|
| . | . | . | . | NO DATA FOR TEST |

 **

BASIC SUMMARY STATISTICS

| Level | N | Mean | StdDev | StdErr | Coef of Var | 95% Conf.Interval |
|-------|---|------|--------|--------|-------------|-------------------|
| Ctrl | 0 | . | . | . | . | . / . |
| Dose1 | 0 | . | . | . | . | . / . |
| Dose2 | 0 | . | . | . | . | . / . |
| Dose3 | 0 | . | . | . | . | . / . |

| Level | Median | Min | Max | %of Control (means) |
|--------------------|--------|-----|-----|---------------------|
| %Reduction (means) | | | | |
| Ctrl | . | . | . | . |
| Dose1 | . | . | . | . |

Data Evaluation Report on the Reproductive Effects of AE 0172747 Technical on Mallard Duck (*Anas platyrhynchos*)

PMRA Submission Number {.....}

EPA MRID Number 466955-05

Dose2
 Dose3

Mallard repro, Bayer AE0172747, MRID 466955-06
 ANALYSIS RESULTS FOR VARIABLE LE (Live Embryo(d21))

TESTS OF ASSUMPTIONS FOR PARAMETRIC ANALYSIS
 Shapiro-Wilks test for Normality of Residuals -- alpha-level=0.01
 Levenes test for homogeneity of variance(absolute residuals) -- alpha-level=0.05
 Use parametric analyses if neither test rejected, otherwise non-parametric analyses.

| Shapiro-Wilks Test Stat | Shapiro-Wilks P-value | Levenes Test Stat | Levenes P-value | Conclusion |
|-------------------------|-----------------------|-------------------|-----------------|------------------|
| . | . | . | . | NO DATA FOR TEST |

 **

BASIC SUMMARY STATISTICS

| Level | N | Mean | StdDev | StdErr | Coef of Var | 95% Conf.Interval |
|-------|---|------|--------|--------|-------------|-------------------|
| Ctrl | 0 | . | . | . | . | . / . |
| Dose1 | 0 | . | . | . | . | . / . |
| Dose2 | 0 | . | . | . | . | . / . |
| Dose3 | 0 | . | . | . | . | . / . |

| Level | Median | Min | Max | %of Control(means) |
|-------|--------|-----|-----|--------------------|
| Ctrl | . | . | . | . |
| Dose1 | . | . | . | . |
| Dose2 | . | . | . | . |
| Dose3 | . | . | . | . |

Mallard repro, Bayer AE0172747, MRID 466955-06
 ANALYSIS RESULTS FOR VARIABLE LE_VE (LiveEmbryo/ViableEmbryo (%))

TESTS OF ASSUMPTIONS FOR PARAMETRIC ANALYSIS
 Shapiro-Wilks test for Normality of Residuals -- alpha-level=0.01
 Levenes test for homogeneity of variance(absolute residuals) -- alpha-level=0.05
 Use parametric analyses if neither test rejected, otherwise non-parametric analyses.

| Shapiro-Wilks Test Stat | Shapiro-Wilks P-value | Levenes Test Stat | Levenes P-value | Conclusion |
|-------------------------|-----------------------|-------------------|-----------------|------------------|
| . | . | . | . | NO DATA FOR TEST |

 **

BASIC SUMMARY STATISTICS

| Level | N | Mean | StdDev | StdErr | Coef of Var | 95% Conf.Interval |
|-------|---|------|--------|--------|-------------|-------------------|
| Ctrl | 0 | . | . | . | . | . / . |
| Dose1 | 0 | . | . | . | . | . / . |
| Dose2 | 0 | . | . | . | . | . / . |
| Dose3 | 0 | . | . | . | . | . / . |

| Level | Median | Min | Max | %of Control(means) |
|-------|--------|-----|-----|--------------------|
| Ctrl | . | . | . | . |

Data Evaluation Report on the Reproductive Effects of AE 0172747 Technical on Mallard Duck (*Anas platyrhynchos*)

PMRA Submission Number {.....}

EPA MRID Number 466955-05

Dose1
 Dose2
 Dose3

Mallard repro, Bayer AE0172747, MRID 466955-06
 ANALYSIS RESULTS FOR VARIABLE NH (Number Hatched)

TESTS OF ASSUMPTIONS FOR PARAMETRIC ANALYSIS
 Shapiro-Wilks test for Normality of Residuals -- alpha-level=0.01
 Levenes test for homogeneity of variance(absolute residuals) -- alpha-level=0.05
 Use parametric analyses if neither test rejected, otherwise non-parametric analyses.

| Shapiro-Wilks Test Stat | Shapiro-Wilks P-value | Levenes Test Stat | Levenes P-value | Conclusion |
|-------------------------|-----------------------|-------------------|-----------------|------------------|
| . | . | . | . | NO DATA FOR TEST |

 **

BASIC SUMMARY STATISTICS

| Level | N | Mean | StdDev | StdErr | Coef of Var | 95% Conf.Interval |
|-------|---|------|--------|--------|-------------|-------------------|
| Ctrl | 0 | . | . | . | . | . / . |
| Dose1 | 0 | . | . | . | . | . / . |
| Dose2 | 0 | . | . | . | . | . / . |
| Dose3 | 0 | . | . | . | . | . / . |

| Level | Median | Min | Max | %of Control(means) |
|-------|--------|-----|-----|--------------------|
| Ctrl | . | . | . | . |
| Dose1 | . | . | . | . |
| Dose2 | . | . | . | . |
| Dose3 | . | . | . | . |

Mallard repro, Bayer AE0172747, MRID 466955-06
 ANALYSIS RESULTS FOR VARIABLE NH_EL (NumberHatched/EggsLaid (%))

TESTS OF ASSUMPTIONS FOR PARAMETRIC ANALYSIS
 Shapiro-Wilks test for Normality of Residuals -- alpha-level=0.01
 Levenes test for homogeneity of variance(absolute residuals) -- alpha-level=0.05
 Use parametric analyses if neither test rejected, otherwise non-parametric analyses.

| Shapiro-Wilks Test Stat | Shapiro-Wilks P-value | Levenes Test Stat | Levenes P-value | Conclusion |
|-------------------------|-----------------------|-------------------|-----------------|------------------|
| . | . | . | . | NO DATA FOR TEST |

 **

BASIC SUMMARY STATISTICS

| Level | N | Mean | StdDev | StdErr | Coef of Var | 95% Conf.Interval |
|-------|---|------|--------|--------|-------------|-------------------|
| Ctrl | 0 | . | . | . | . | . / . |
| Dose1 | 0 | . | . | . | . | . / . |
| Dose2 | 0 | . | . | . | . | . / . |
| Dose3 | 0 | . | . | . | . | . / . |

| Level | Median | Min | Max | %of Control(means) |
|-------|--------|-----|-----|--------------------|
| Ctrl | . | . | . | . |
| Dose1 | . | . | . | . |
| Dose2 | . | . | . | . |
| Dose3 | . | . | . | . |

Data Evaluation Report on the Reproductive Effects of AE 0172747 Technical on Mallard Duck (*Anas platyrhynchos*)

PMRA Submission Number {.....}

EPA MRID Number 466955-05

```

Ctrl      .      .      .      .      .
Dose1     .      .      .      .      .
Dose2     .      .      .      .      .
Dose3     .      .      .      .      .
    
```

Mallard repro, Bayer AE0172747, MRID 466955-06
 ANALYSIS RESULTS FOR VARIABLE NH_ES (NumberHatched/EggsSet (%))

TESTS OF ASSUMPTIONS FOR PARAMETRIC ANALYSIS
 Shapiro-Wilks test for Normality of Residuals -- alpha-level=0.01
 Levenes test for homogeneity of variance(absolute residuals) -- alpha-level=0.05
 Use parametric analyses if neither test rejected, otherwise non-parametric analyses.

| Shapiro-Wilks Test Stat | Shapiro-Wilks P-value | Levenes Test Stat | Levenes P-value | Conclusion |
|-------------------------|-----------------------|-------------------|-----------------|------------------|
| . | . | . | . | NO DATA FOR TEST |

 **

BASIC SUMMARY STATISTICS

| Level | N | Mean | StdDev | StdErr | Coef of Var | 95% Conf.Interval |
|-------|---|------|--------|--------|-------------|-------------------|
| Ctrl | 0 | . | . | . | . | . / . |
| Dose1 | 0 | . | . | . | . | . / . |
| Dose2 | 0 | . | . | . | . | . / . |
| Dose3 | 0 | . | . | . | . | . / . |

| Level | Median | Min | Max | %of Control(means) |
|-------|--------|-----|-----|--------------------|
| Ctrl | . | . | . | . |
| Dose1 | . | . | . | . |
| Dose2 | . | . | . | . |
| Dose3 | . | . | . | . |

Mallard repro, Bayer AE0172747, MRID 466955-06
 ANALYSIS RESULTS FOR VARIABLE NH_LE (NumberHatched/LiveEmbryo (%))

TESTS OF ASSUMPTIONS FOR PARAMETRIC ANALYSIS
 Shapiro-Wilks test for Normality of Residuals -- alpha-level=0.01
 Levenes test for homogeneity of variance(absolute residuals) -- alpha-level=0.05
 Use parametric analyses if neither test rejected, otherwise non-parametric analyses.

| Shapiro-Wilks Test Stat | Shapiro-Wilks P-value | Levenes Test Stat | Levenes P-value | Conclusion |
|-------------------------|-----------------------|-------------------|-----------------|------------------|
| . | . | . | . | NO DATA FOR TEST |

 **

BASIC SUMMARY STATISTICS

| Level | N | Mean | StdDev | StdErr | Coef of Var | 95% Conf.Interval |
|-------|---|------|--------|--------|-------------|-------------------|
| Ctrl | 0 | . | . | . | . | . / . |
| Dose1 | 0 | . | . | . | . | . / . |
| Dose2 | 0 | . | . | . | . | . / . |
| Dose3 | 0 | . | . | . | . | . / . |

Data Evaluation Report on the Reproductive Effects of AE 0172747 Technical on Mallard Duck (*Anas platyrhynchos*)

PMRA Submission Number {.....}

EPA MRID Number 466955-05

| Level | Median | Min | Max | %of Control(means) |
|-------------------|--------|-----|-----|--------------------|
| %Reduction(means) | | | | |
| Ctrl | . | . | . | . |
| Dose1 | . | . | . | . |
| Dose2 | . | . | . | . |
| Dose3 | . | . | . | . |

Mallard repro, Bayer AE0172747, MRID 466955-06
 ANALYSIS RESULTS FOR VARIABLE HS (Hatching Survival(d14))

TESTS OF ASSUMPTIONS FOR PARAMETRIC ANALYSIS
 Shapiro-Wilks test for Normality of Residuals -- alpha-level=0.01
 Levenes test for homogeneity of variance(absolute residuals) -- alpha-level=0.05
 Use parametric analyses if neither test rejected, otherwise non-parametric analyses.

| Shapiro-Wilks Test Stat | Shapiro-Wilks P-value | Levenes Test Stat | Levenes P-value | Conclusion |
|-------------------------|-----------------------|-------------------|-----------------|------------------|
| . | . | . | . | NO DATA FOR TEST |

 **

BASIC SUMMARY STATISTICS

| Level | N | Mean | StdDev | StdErr | Coef of Var | 95% Conf.Interval |
|-------|---|------|--------|--------|-------------|-------------------|
| Ctrl | 0 | . | . | . | . | . / . |
| Dose1 | 0 | . | . | . | . | . / . |
| Dose2 | 0 | . | . | . | . | . / . |
| Dose3 | 0 | . | . | . | . | . / . |

| Level | Median | Min | Max | %of Control(means) |
|-------------------|--------|-----|-----|--------------------|
| %Reduction(means) | | | | |
| Ctrl | . | . | . | . |
| Dose1 | . | . | . | . |
| Dose2 | . | . | . | . |
| Dose3 | . | . | . | . |

Mallard repro, Bayer AE0172747, MRID 466955-06
 ANALYSIS RESULTS FOR VARIABLE HS_ES (HatchingSurvival/EggsSet (%))

TESTS OF ASSUMPTIONS FOR PARAMETRIC ANALYSIS
 Shapiro-Wilks test for Normality of Residuals -- alpha-level=0.01
 Levenes test for homogeneity of variance(absolute residuals) -- alpha-level=0.05
 Use parametric analyses if neither test rejected, otherwise non-parametric analyses.

| Shapiro-Wilks Test Stat | Shapiro-Wilks P-value | Levenes Test Stat | Levenes P-value | Conclusion |
|-------------------------|-----------------------|-------------------|-----------------|------------------|
| . | . | . | . | NO DATA FOR TEST |

 **

BASIC SUMMARY STATISTICS

| Level | N | Mean | StdDev | StdErr | Coef of Var | 95% Conf.Interval |
|-------|---|------|--------|--------|-------------|-------------------|
| Ctrl | 0 | . | . | . | . | . / . |
| Dose1 | 0 | . | . | . | . | . / . |
| Dose2 | 0 | . | . | . | . | . / . |
| Dose3 | 0 | . | . | . | . | . / . |

Data Evaluation Report on the Reproductive Effects of AE 0172747 Technical on Mallard Duck (*Anas platyrhynchos*)

PMRA Submission Number {.....}

EPA MRID Number 466955-05

| Level | Median | Min | Max | %of Control (means) |
|--------------------|--------|-----|-----|---------------------|
| %Reduction (means) | | | | |
| Ctrl | . | . | . | . |
| Dose1 | . | . | . | . |
| Dose2 | . | . | . | . |
| Dose3 | . | . | . | . |

Mallard repro, Bayer AE0172747, MRID 466955-06

ANALYSIS RESULTS FOR VARIABLE HS_NH (HatchingSurvival/NumberHatched (%))

TESTS OF ASSUMPTIONS FOR PARAMETRIC ANALYSIS

Shapiro-Wilks test for Normality of Residuals -- alpha-level=0.01

Levenes test for homogeneity of variance (absolute residuals) -- alpha-level=0.05

Use parametric analyses if neither test rejected, otherwise non-parametric analyses.

| Shapiro-Wilks Test Stat | Shapiro-Wilks P-value | Levenes Test Stat | Levenes P-value | Conclusion |
|-------------------------|-----------------------|-------------------|-----------------|------------------|
| . | . | . | . | NO DATA FOR TEST |

**

BASIC SUMMARY STATISTICS

| Level | N. | Mean | StdDev | StdErr | Coef of Var | 95% Conf.Interval |
|-------|----|------|--------|--------|-------------|-------------------|
| Ctrl | 0 | . | . | . | . | . / . |
| Dose1 | 0 | . | . | . | . | . / . |
| Dose2 | 0 | . | . | . | . | . / . |
| Dose3 | 0 | . | . | . | . | . / . |

| Level | Median | Min | Max | %of Control (means) |
|--------------------|--------|-----|-----|---------------------|
| %Reduction (means) | | | | |
| Ctrl | . | . | . | . |
| Dose1 | . | . | . | . |
| Dose2 | . | . | . | . |
| Dose3 | . | . | . | . |

Mallard repro, Bayer AE0172747, MRID 466955-06

ANALYSIS RESULTS FOR VARIABLE THICK (Eggshell thickness)

TESTS OF ASSUMPTIONS FOR PARAMETRIC ANALYSIS

Shapiro-Wilks test for Normality of Residuals -- alpha-level=0.01

Levenes test for homogeneity of variance (absolute residuals) -- alpha-level=0.05

Use parametric analyses if neither test rejected, otherwise non-parametric analyses.

| Shapiro-Wilks Test Stat | Shapiro-Wilks P-value | Levenes Test Stat | Levenes P-value | Conclusion |
|-------------------------|-----------------------|-------------------|-----------------|------------------|
| . | . | . | . | NO DATA FOR TEST |

**

BASIC SUMMARY STATISTICS

| Level | N | Mean | StdDev | StdErr | Coef of Var | 95% Conf.Interval |
|-------|---|------|--------|--------|-------------|-------------------|
| Ctrl | 0 | . | . | . | . | . / . |
| Dose1 | 0 | . | . | . | . | . / . |
| Dose2 | 0 | . | . | . | . | . / . |

Data Evaluation Report on the Reproductive Effects of AE 0172747 Technical on Mallard Duck (*Anas platyrhynchos*)

PMRA Submission Number {.....}

EPA MRID Number 466955-05

| Level | Median | Min | Max | %of Control (means) |
|-------|--------|-----|-----|---------------------|
| Dose3 | 0 | . | . | . |
| Ctrl | . | . | . | . |
| Dose1 | . | . | . | . |
| Dose2 | . | . | . | . |
| Dose3 | . | . | . | . |

Mallard repro, Bayer AE0172747, MRID 466955-06
 ANALYSIS RESULTS FOR VARIABLE HATWT (Hatchling Weight)

TESTS OF ASSUMPTIONS FOR PARAMETRIC ANALYSIS
 Shapiro-Wilks test for Normality of Residuals -- alpha-level=0.01
 Levenes test for homogeneity of variance (absolute residuals) -- alpha-level=0.05
 Use parametric analyses if neither test rejected, otherwise non-parametric analyses.

| Shapiro-Wilks Test Stat | Shapiro-Wilks P-value | Levenes Test Stat | Levenes P-value | Conclusion |
|-------------------------|-----------------------|-------------------|-----------------|------------------|
| . | . | . | . | NO DATA FOR TEST |

 **

BASIC SUMMARY STATISTICS

| Level | N | Mean | StdDev | StdErr | Coef of Var | 95% Conf.Interval |
|-------|---|------|--------|--------|-------------|-------------------|
| Ctrl | 0 | . | . | . | . | . |
| Dose1 | 0 | . | . | . | . | . |
| Dose2 | 0 | . | . | . | . | . |
| Dose3 | 0 | . | . | . | . | . |

| Level | Median | Min | Max | %of Control (means) |
|-------|--------|-----|-----|---------------------|
| Ctrl | . | . | . | . |
| Dose1 | . | . | . | . |
| Dose2 | . | . | . | . |
| Dose3 | . | . | . | . |

Mallard repro, Bayer AE0172747, MRID 466955-06
 ANALYSIS RESULTS FOR VARIABLE SURVWT (Survivor Wt (d14))

TESTS OF ASSUMPTIONS FOR PARAMETRIC ANALYSIS
 Shapiro-Wilks test for Normality of Residuals -- alpha-level=0.01
 Levenes test for homogeneity of variance (absolute residuals) -- alpha-level=0.05
 Use parametric analyses if neither test rejected, otherwise non-parametric analyses.

| Shapiro-Wilks Test Stat | Shapiro-Wilks P-value | Levenes Test Stat | Levenes P-value | Conclusion |
|-------------------------|-----------------------|-------------------|-----------------|------------------|
| . | . | . | . | NO DATA FOR TEST |

 **

BASIC SUMMARY STATISTICS

| Level | N | Mean | StdDev | StdErr | Coef of Var | 95% Conf.Interval |
|-------|---|------|--------|--------|-------------|-------------------|
| Ctrl | 0 | . | . | . | . | . |
| Dose1 | 0 | . | . | . | . | . |

Data Evaluation Report on the Reproductive Effects of AE 0172747 Technical on Mallard Duck (*Anas platyrhynchos*)

PMRA Submission Number {.....}

EPA MRID Number 466955-05

| | | | | | | | |
|--------------------|--------|-----|-----|---------------------|---|---|---|
| Dose2 | 0 | . | . | . | . | . | . |
| Dose3 | 0 | . | . | . | . | . | . |
| Level | Median | Min | Max | %of Control (means) | | | |
| %Reduction (means) | | | | | | | |
| Ctrl | . | . | . | . | . | . | . |
| Dose1 | . | . | . | . | . | . | . |
| Dose2 | . | . | . | . | . | . | . |
| Dose3 | . | . | . | . | . | . | . |

Data Evaluation Report on the Reproductive Effects of AE 0172747 Technical on Mallard Duck (*Anas platyrhynchos*)

PMRA Submission Number {.....}

EPA MRJD Number 466955-05

Mallard repro, Bayer AE0172747, MRID 466955-06
 ANALYSIS RESULTS FOR VARIABLE FOOD (Food Consumption)

TESTS OF ASSUMPTIONS FOR PARAMETRIC ANALYSIS

Shapiro-Wilks test for Normality of Residuals -- alpha-level=0.01
 Levenes test for homogeneity of variance(absolute residuals) -- alpha-level=0.05

Use parametric analyses if neither test rejected, otherwise non-parametric analyses.

| Shapiro-Wilks Test Stat | Shapiro-Wilks P-value | Levenes Test Stat | Levenes P-value | Conclusion |
|-------------------------|-----------------------|-------------------|-----------------|----------------------|
| 0.965 | 0.066 | 1.060 | 0.373 | USE PARAMETRIC TESTS |

 **

BASIC SUMMARY STATISTICS

| Level | N | Mean | StdDev | StdErr | Coef of Var | 95% Conf.Interval |
|-------|----|--------|--------|--------|-------------|-------------------|
| Ctrl | 16 | 186.06 | 39.46 | 9.87 | 21.21 | 165.03, 207.09 |
| Dose1 | 16 | 195.25 | 39.73 | 9.93 | 20.35 | 174.08, 216.42 |
| Dose2 | 16 | 214.06 | 60.00 | 15.00 | 28.03 | 182.09, 246.04 |
| Dose3 | 16 | 201.13 | 39.65 | 9.91 | 19.71 | 180.00, 222.25 |

| Level | Median | Min | Max | %of Control (means) |
|-------|--------|--------|--------|---------------------|
| Ctrl | 183.50 | 136.00 | 281.00 | . |
| Dose1 | 188.50 | 143.00 | 281.00 | 104.94 |
| Dose2 | 209.00 | 142.00 | 346.00 | 115.05 |
| Dose3 | 207.00 | 137.00 | 257.00 | 108.10 |

 **

PARAMETRIC ANALYSES - use alpha-level=0.05 for all tests

Analysis of Variance (ANOVA) - overall F-test

| Numerator df | Denominator df | F-stat | P-value |
|--------------|----------------|--------|---------|
| 3 | 60 | 1.06 | 0.373 |

Dunnett - testing each trt mean signif. less than control
 Williams - test assumes dose-response relationship, testing negative trend
 Tukey - two-sided tests, all possible comparisons, not used for NOEC or LOEC

| Level | Mean | Dunnett p-value | Isotonic mean | Williams p-value | Tukey p-values |
|-------|--------|-----------------|---------------|------------------|-------------------------|
| | | | | | Dose1 Dose2 Dose3 Dose4 |
| Dose5 | | | | | |
| Ctrl | 186.06 | . | 199.13 | . | . |
| Dose1 | 195.25 | . | 199.13 | 0.865 | . |
| Dose2 | 214.06 | . | 199.13 | 0.891 | . |
| Dose3 | 201.13 | . | 199.13 | 0.904 | . |

SUMMARY

| Dunnett | NOEC | LOEC |
|----------|--------------|---------------|
| Williams | <lowest dose | Dose1 |
| | Dose3 | >highest dose |

Data Evaluation Report on the Reproductive Effects of AE 0172747 Technical on Mallard Duck (*Anas platyrhynchos*)

PMRA Submission Number {.....}

EPA MRID Number 466955-05

Mallard repro, Bayer AE0172747, MRID 466955-06
 ANALYSIS RESULTS FOR VARIABLE WTGAINM (Male wt gain)

TESTS OF ASSUMPTIONS FOR PARAMETRIC ANALYSIS

Shapiro-Wilks test for Normality of Residuals -- alpha-level=0.01
 Levenes test for homogeneity of variance (absolute residuals) -- alpha-level=0.05

Use parametric analyses if neither test rejected, otherwise non-parametric analyses.

| Shapiro-Wilks Test Stat | Shapiro-Wilks P-value | Levenes Test Stat | Levenes P-value | Conclusion |
|-------------------------|-----------------------|-------------------|-----------------|----------------------|
| 0.981 | 0.448 | 0.426 | 0.735 | USE PARAMETRIC TESTS |

 **

BASIC SUMMARY STATISTICS

| Level | N | Mean | StdDev | StdErr | Coef of Var | 95% Conf.Interval | |
|-------|----|-------|--------|--------|-------------|-------------------|--------|
| Ctrl | 16 | 75.81 | 51.97 | 12.99 | 68.55 | 48.12, | 103.51 |
| Dose1 | 15 | 53.47 | 68.84 | 17.78 | 128.76 | 15.34, | 91.59 |
| Dose2 | 16 | 19.25 | 47.89 | 11.97 | 248.78 | -6.27, | 44.77 |
| Dose3 | 16 | 6.25 | 54.82 | 13.70 | 877.05 | -22.96, | 35.46 |

| Level | Median | Min | Max | %of Control (means) | |
|-------|--------|--------|--------|---------------------|-------|
| Ctrl | 67.00 | 13.00 | 199.00 | . | . |
| Dose1 | 55.00 | -98.00 | 134.00 | 70.52 | 29.48 |
| Dose2 | 16.00 | -83.00 | 106.00 | 25.39 | 74.61 |
| Dose3 | 6.00 | -75.00 | 135.00 | 8.24 | 91.76 |

 **

PARAMETRIC ANALYSES - use alpha-level=0.05 for all tests

Analysis of Variance (ANOVA) - overall F-test

| Numerator df | Denominator df | F-stat | P-value |
|--------------|----------------|--------|---------|
| 3 | 59 | 5.09 | 0.003 |

Dunnett - testing each trt mean signif. less than control
 Williams - test assumes dose-response relationship, testing negative trend
 Tukey - two-sided tests, all possible comparisons, not used for NOEC or LOEC

| Level | Mean | Dunnett p-value | Isotonic mean | Williams p-value | Tukey p-values | | | |
|-------|-------|-----------------|---------------|------------------|----------------|-------|-------|-------|
| | | | | | Dose1 | Dose2 | Dose3 | Dose4 |
| Dose5 | | | | | | | | |
| Ctrl | 75.81 | . | 75.81 | . | . | . | . | . |
| Dose1 | 53.47 | . | 53.47 | 0.163 | . | . | . | . |
| Dose2 | 19.25 | . | 19.25 | 0.003 | . | . | . | . |
| Dose3 | 6.25 | . | 6.25 | <.001 | . | . | . | . |

SUMMARY

| | NOEC | LOEC |
|----------|--------------|-------|
| Dunnett | <lowest dose | Dose1 |
| Williams | Dose1 | Dose2 |

Data Evaluation Report on the Reproductive Effects of AE 0172747 Technical on Mallard Duck (*Anas platyrhynchos*)
 PMRA Submission Number {.....} EPA MRID Number 466955-05

Mallard repro, Bayer AE0172747, MRID 466955-06
 ANALYSIS RESULTS FOR VARIABLE WTGAINF (Female wt gain)

TESTS OF ASSUMPTIONS FOR PARAMETRIC ANALYSIS

Shapiro-Wilks test for Normality of Residuals -- alpha-level=0.01
 Levenes test for homogeneity of variance(absolute residuals) -- alpha-level=0.05

Use parametric analyses if neither test rejected, otherwise non-parametric analyses.

| Shapiro-Wilks Test Stat | Shapiro-Wilks P-value | Levenes Test Stat | Levenes P-value | Conclusion |
|-------------------------|-----------------------|-------------------|-----------------|----------------------|
| 0.983 | 0.542 | 2.309 | 0.086 | USE PARAMETRIC TESTS |

 **

BASIC SUMMARY STATISTICS

| Level | N | Mean | StdDev | StdErr | Coef of Var | 95% Conf. Interval |
|-------|----|--------|--------|--------|-------------|--------------------|
| Ctrl | 16 | -15.81 | 58.73 | 14.68 | -371.41 | -47.11, 15.48 |
| Dose1 | 15 | -76.40 | 51.18 | 13.21 | -66.98 | -104.74, -48.06 |
| Dose2 | 16 | -87.38 | 85.69 | 21.42 | -98.07 | -133.04, -41.71 |
| Dose3 | 16 | -39.31 | 71.11 | 17.78 | -180.89 | -77.20, -1.42 |

| Level | Median | Min | Max | % of Control (means) |
|-------|---------|---------|--------|----------------------|
| Ctrl | -24.00 | -131.00 | 109.00 | . |
| Dose1 | -92.00 | -155.00 | 50.00 | 483.16 |
| Dose2 | -108.00 | -196.00 | 86.00 | 552.57 |
| Dose3 | -49.00 | -169.00 | 87.00 | 248.62 |

 **

PARAMETRIC ANALYSES - use alpha-level=0.05 for all tests

Analysis of Variance (ANOVA) - overall F-test

| Numerator df | Denominator df | F-stat | P-value |
|--------------|----------------|--------|---------|
| 3 | 59 | 3.74 | 0.016 |

Dunnnett - testing each trt mean signif. less than control
 Williams - test assumes dose-response relationship, testing negative trend
 Tukey - two-sided tests, all possible comparisons, not used for NOEC or LOEC

| Level | Mean | Dunnnett p-value | Isotonic mean | Williams p-value | Dose1 | Dose2 | Tukey p-values Dose3 | Dose4 |
|-------|--------|------------------|---------------|------------------|-------|-------|----------------------|-------|
| Dose5 | | | | | | | | |
| Ctrl | -15.81 | . | -15.81 | . | . | . | . | . |
| Dose1 | -76.40 | . | -67.51 | 0.022 | . | . | . | . |
| Dose2 | -87.38 | . | -67.51 | 0.021 | . | . | . | . |
| Dose3 | -39.31 | . | -67.51 | 0.022 | . | . | . | . |

| SUMMARY | NOEC | LOEC |
|----------|--------------|-------|
| Dunnnett | <lowest dose | Dose1 |
| Williams | <lowest dose | Dose1 |

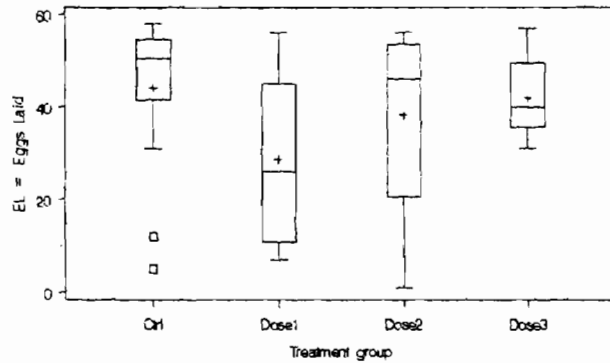
Data Evaluation Report on the Reproductive Effects of AE 0172747 Technical on Mallard Duck (*Anas platyrhynchos*)

PMRA Submission Number {.....}

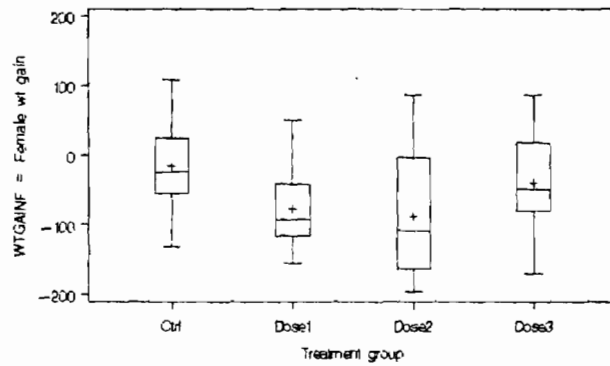
EPA MRID Number 466955-05

Box Plots:

Mallard repro, Bayer AE0172747, MRID 466955-06



Mallard repro, Bayer AE0172747, MRID 466955-06



Mallard repro, Bayer AE0172747, MRID 466955-06

