**Attachment J**

**Avian Data Evaluation Record (DER) Template**

**March 2024**

***Part A: Overview***

**I. Test Information**

**Chemical name:**

CAS name: CAS Number:

Purity: Storage conditions:

Solubility in Water (units):

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Controlled Experiment** |  | **Field Study/Observation** | (*Place X by One*) |
|  | (*manipulated*) |  | (*not manipulated*) |  |

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Primary Reviewer:** |  | **Date:** |  |  |  | **EPA** |  | **Contractor** | (*Place X by One*) |
| **Secondary Reviewer:** |  | **Date:** |  |  |  | **EPA** |  | **Contractor** | (*Place X by One*) |
| (*At least one reviewer should be from EPA for sensitive taxa*) | | | | | | | | | |

**Citation**: *Indicate: author(s), year, study title, journal, volume, and pages*.

(e.g., Heinz, G. H. 1979. Methylmercury: reproductive and behavioral effects on three generations of mallard ducks. J. Wildl. Manage. 43(2): 394 – 401.)

**Companion Papers:** *Identify any companion papers associated with this paper using the citation format above.*

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Were other DERs completed for Companion Papers?** |  |  | **Yes** |  |  | **No** | (*If yes, list file names of DERs below*) |

**Study Classification for Aquatic Life Criteria Development:** *Place X by One Based on Highest Use*

|  |  |
| --- | --- |
|  | Acceptable for Quantitative Use |
|  | Acceptable for Qualitative Use |
|  | Not Acceptable for Use/Unused |

**General Notes:** *Provide any necessary details regarding the study’s use classification for all pertinent endpoints, including non-apical endpoints within the study (e.g., note all study classifications for each endpoint if the use varies)*

**Major Deficiencies (note any stated exclusions)**: *Check all that apply. Checking any of* t*hese items make the study “****Not Acceptable for Use****”*

|  |  |  |  |
| --- | --- | --- | --- |
|  | Mixture (for controlled experiments only) |  | No Controls (for controlled experiments only) |
|  | Excessive Control Mortality (dependent on test type and species) | | |
|  | Diet not adequately characterized |  | Bioaccumulation: steady state not reached |
|  | Dermal or Injection Exposure Pathway |  |  |
|  | Review paper or previously published without modification | | |
|  | Other: *(if an, list here)* | | |

POTENTIAL CHEMICAL MIXTURES:*Describe any potential chemicals mixtures as characterized by study authors (including any confirmation of chemical mixtures).*

***General Notes:***

**Minor Deficiencies:** *List and describe any minor deficiencies or other concerns with test. These items may make the study “****Acceptable for Qualitative Use****”* **(exceptions may apply as noted)**

DESCRIPTION OF UNMEASURED TEST CONCENTRATIONS: *Describe concerns with unmeasured test concentrations and the influence of the study classification.*

DESCRIPTION OF CONCERNS WITH DILUTION WATER: *Describe concerns with characterization of and/or deficiencies with dilution water (e.g., uncharacterized stream or lake water, potential presence of unknown containments, high organic content, extreme hardness, pH, etc).*

***For Field Studies/Observations****: A field study/observation may be considered “****Acceptable for Quantitative Use****” if it consisted of a range of exposure concentrations and the observed effects are justifiably contributed to a single chemical exposure*

|  |  |
| --- | --- |
|  | Mixture (observed effects not justifiably contributed to single chemical exposure) |
|  | Uncharacterized Reference Sites/Conditions |

POTENTIAL CHEMICAL MIXTURES PRESENT AT SITE: *Describe any potential chemicals mixtures present at the site as characterized by study authors (including any confirmation of chemicals present at study site).*

EXPOSURE VARIABILITY ACROSS STUDY SITE(S): *Describe any exposure variability across study site(s) as characterized by study authors (i.e., description of study design with reference and contaminated sites).*

***General Notes:***

**Reviewer’s Comments:** *Provide additional comments that do not appear under other sections of the template*.

**ABSTRACT**: *Copy and paste abstract from publication*.

**SUMMARY***: Fill out for the most sensitive endpoint (apical and/or non-apical) and modify as needed. If study is classified as “Not Acceptable for Use” DO NOT complete summary tables.*

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Species (lifestage)** | **Duration** | **Exposure Mediaa** | **Measured–M; Unmeasured–U;**  **Form Measuredb** | **Chemical Form Exposure** | **WW / DW / FWWc** | **Moisture Content (%)** | **Test Endpoint and Effectd** | **Reported Effect Concentration**  **(µg/g or ppm)** | **Verified Effect Concentratione**  **(units)** | **Classification** |
|  |  |  |  |  |  |  |  |  |  | Quantitative / Qualitative |

a Diet, tissue type, etc.

b In addition, note if maternal transfer (MT)

c WW=wet weight, DW=dry weight, FWW=fresh wet weight.

d Where Test Endpoint = ECx, NOEC, LOEC, MATC, etc., and Effect = growth, survival, reproduction, etc.

e Verification following completion of Part C of the DER

**II. Results** *Provide results as reported in the publication (including supplemental materials). Include screen shots of tables and/or figures reporting results from the article following tabulated data table in each associated results section for all studies*. *Complete tabulated data tables for all studies for studies marked “****Acceptable for Quantitative Use”*** *and* ***“Acceptable for Qualitative Use****”*.

**Test Condition Parameters**: *If only general summary data of test condition parameters is provided by study authors (i.e., no specific details of test condition parameters on a treatment level is provided), summarize any information regarding test condition parameters under General Notes below.*

**General Notes:**

**Table A.II.1. Measured Test Condition Parameters.**

Dissolved oxygen, temperature, pH and [other parameters (hardness, salinity, DOC)] in test solutions during the *[X]*-day exposure of *[test organism]* to *[concentration of treatment(s)]* of *[test substance]* under *[static renewal/flow-through]* conditions.

|  |  |  |  |
| --- | --- | --- | --- |
| **Parameter** | **Treatment** | **Mean** | **Range** |
| **Photoperiod** | *[1]* |  |  |
| *[2]* |  |  |
| *j* |  |  |
| *j* |  |  |
| **Temperature (̊C)** | *[1]* |  |  |
| *[2]* |  |  |
| *j* |  |  |
| *j* |  |  |
| **Humidity**  **(%)** | *[1]* |  |  |
| *[2]* |  |  |
| *j* |  |  |
| *j* |  |  |
| **Other (e.g., ventilation, lighting)** | *[1]* |  |  |
| *[2]* |  |  |
| *j* |  |  |
| *j* |  |  |

**Chemical Concentrations**: *Summarize the concentration verification data from test solutions/media. Expand table to include each measured concentration data for each media type (i.e., muscle, liver, blood, etc.).*

**General Notes:** *Provide any necessary detail regarding the measured concentrations, including any identified cause for substantial differences between nominal and measured concentrations, if samples were collected on separate days (and if so provide details), and any potential cross contamination.*

**Table A.II.2. Measured (and Nominal) Chemical Concentrations in Test Solutions/Media.**

[Analytical Method] verification of test and control concentrations during an [X]-day exposure of [test organism] to [test substance] under [static renewal/flow-through] conditions.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Treatment** | **Nominal Concentration (units)** | **[Mean] Measured Concentration (units)** | **Number of Samples** | **Non-Detecta** | **Number of Samples Below Non-Detect** | **[Standard Deviation or Standard Error]** | **Range** |
| *Control* |  |  |  |  |  |  |  |
| [1] |  |  |  |  |  |  |  |
| [2] |  |  |  |  |  |  |  |
| [3] |  |  |  |  |  |  |  |
| [4] |  |  |  |  |  |  |  |
| [5] |  |  |  |  |  |  |  |
| [6] |  |  |  |  |  |  |  |
| *J* |  |  |  |  |  |  |  |

aNon-Detect : 0 = measured and detected; 1=measured and not detected; if not measured or reported enter as such

**Mortality**: *Briefly summarize mortality results (if any).*

**General Notes:** *Comment on concentrations response relations and slope of response if provided. Compare mortality with control treatment and/or the reference chemical.*

**Table A.II.3.** **Mean Percent [Mortality or Survival].**

Mean percent mortality [or number of immobilized] or survival of [test organism] exposed to [test substance] for [test duration] under [static/renewal/flow-through] conditions. Superscript(s) used to identify the values reported to be significantly different from control as p value of [0.05/ or any other provided by authors].

|  |  |  |  |
| --- | --- | --- | --- |
| **Treatment** | **[Mean % Mortality]** | **Sample Size** | **[Standard Deviation or Standard Error]** |
| *Control* |  |  |  |
| [1] |  |  |  |
| [2] |  |  |  |
| [3] |  |  |  |
| [4] |  |  |  |
| [5] |  |  |  |
| [6] |  |  |  |
| [LCx] |  | | |
| NOEC |  | | |
| LOEC |  | | |

a Use superscript(s) to identify the values reported to be significantly different from control.

**Growth**: *Briefly summarize growth results (if any).*

**General Notes:** *Comment on concentrations response relations and slope of response if provided. Compare growth endpoints with control treatment and/or the reference chemical.*

**Table A.II.4. Mean [Growth].**

Mean growth [length and/or weight] of [test organism] exposed to [test substance] for [test duration] under [static/renewal/flow-through] conditions. Superscript(s) used to identify the values reported to be significantly different from control as p value of [0.05/ or any other provided by authors].

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Treatment** | **Mean Growth**  **[Adult/Offspring]**  **[Weight]**  **(units)** | **Sample Size** | **[Standard Deviation or Standard Error]** | **Mean Growth**  **[Adult/Offspring]**  **[Length]**  **(units)** | **Sample Size** | **[Standard Deviation or Standard Error]** | **Mean Percent Change in [Length/ Biomass]** | **Sample Size** | **[Standard Deviation or Standard Error]** |
| *Control* |  |  |  |  |  |  |  |  |  |
| [1] |  |  |  |  |  |  |  |  |  |
| [2] |  |  |  |  |  |  |  |  |  |
| [3] |  |  |  |  |  |  |  |  |  |
| [4] |  |  |  |  |  |  |  |  |  |
| [5] |  |  |  |  |  |  |  |  |  |
| [6] |  |  |  |  |  |  |  |  |  |
| *j* |  |  |  |  |  |  |  |  |  |
| [ECx] |  | | |  | | |  | | |
| NOEC |  | | |  | | |  | | |
| LOEC |  | | |  | | |  | | |

a Use superscript(s) to identify the values reported to be significantly different from control.

**Reproductive**: *Briefly summarize reproduction endpoint results (if any). For multi-generational studies, copy and paste* Table A.II.5 *below for each generation with reproductive effects data.*

**General Notes:** *Comment on concentrations response relations and slope of response if provided. Compare reproduction endpoints with control treatment and/or the reference chemical.*

**Table A.II.5. Mean [Reproductive] Effect.**

Mean [reproductive] effects for [generation] of [test organism] exposed to [test substance] for [test duration] under [static/renewal/flow-through] conditions. Superscript(s) used to identify the values reported to be significantly different from control as p value of [0.05/ or any other provided by authors].

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Treatment**  **(units)** | **[Mean Number of Clutches]** | **Sample Size** | **[Standard Deviation or Standard Error]** | **[Mean Clutch Size]** | **Sample Size** | **[Standard Deviation or Standard Error]** | **[Mean Number of Hatchlings]** | **Sample Size** | **[Standard Deviation or Standard Error]** | **[Mean Number of Fledglings]** | **Sample Size** | **[Standard Deviation or Standard Error]** |
| *Control* |  |  |  |  |  |  |  |  |  |  |  |  |
| [1] |  |  |  |  |  |  |  |  |  |  |  |  |
| [2] |  |  |  |  |  |  |  |  |  |  |  |  |
| [3] |  |  |  |  |  |  |  |  |  |  |  |  |
| [4] |  |  |  |  |  |  |  |  |  |  |  |  |
| [5] |  |  |  |  |  |  |  |  |  |  |  |  |
| [6] |  |  |  |  |  |  |  |  |  |  |  |  |
| *j* |  |  |  |  |  |  |  |  |  |  |  |  |
| [ECx] |  | | |  | | |  | | |  | | |
| NOEC |  | | |  | | |  | | |  | | |
| LOEC |  | | |  | | |  | | |  | | |

a Use superscript(s) to identify the values reported to be significantly different from control.

b Per EPA’s Ecological Effects Test Guidelines - OCSPP 850.2300: Avian Reproduction Test, the following general requirements apply to controls.

(ii) For a satisfactory test, the following values for response variables in controls should be met or at least approached at test termination. There is likely to be a problem with test procedures or conditions that should be investigated and corrected when these values are not met.

(A) **Eggs lai**d - Normal values for both northern bobwhite and mallards are 29 to 61 eggs per hen for a 10 week egg laying period.

(B) **Eggs cracked** - Normal values for northern bobwhite are 0 to 7.0% of eggs laid. Normal values for mallards are 0 to 4.0% of eggs laid.

(C) **Fertility (viable embryos)** - Normal fertility values for northern bobwhite and mallards are 80 to 100% of eggs set.

(D) **Live 18-d or 21-d northern bobwhite and mallard embryos, respectively (as a percentage of viable embryos**) - Normal values for northern bobwhite are 97 to 100%. Normal values for mallards are 94 to 100%.

(E) **Hatchability (percentage of 18-d or 21-d northern bobwhite and mallard embryos, respectively that hatch**) - Normal values for northern bobwhite are 85 to 100%. Normal values for mallards are 52 to 100%.

(F) **Percentage of eggs set that hatch** - Normal values for northern bobwhite are 71 to 95%. Normal values for mallards are 44 to 92%.

(G) **14-day-old survivors of eggs hatched** - Normal values for northern bobwhite are 77 to 100%. Normal values for mallards are 94 to 100%.

(H) **Eggshell thickness** - Normal average values for northern bobwhite are 0.20 to 0.24 mm. Normal values for mallards are 0.316 to 0.372 mm.

**Sublethal Toxicity Endpoints**: *Include other sublethal effect(s), including behavioral abnormalities or other signs of toxicity, if any. Copy Table A.II.6 as needed to provide details for each sublethal effect observed.*

**General Notes:** *Briefly summarize observed sublethal effects otherwise not captured in the results table(s) below.*

**Table A.II.6. Mean [Sublethal] Effect.**

*Mean [*Sublethal effect*, (e.g., behavioral abnormalities, etc.)]* in *[test organism]* during [test duration (*acute/chronic*)] exposure to *[test substance]* under *[static/renewal/flow-through]* conditions. Superscript(s) used to identify the values reported to be significantly different from control as p value of [0.05/ or any other provided by authors].

|  |  |  |  |
| --- | --- | --- | --- |
| **Treatment** | **[Mean Sublethal Response]**  **(units)** | **Sample Size** | **[Standard Deviation or Standard Error]** |
| *Control* |  |  |  |
| [1] |  |  |  |
| [2] |  |  |  |
| [3] |  |  |  |
| [4] |  |  |  |
| [5] |  |  |  |
| [6] |  |  |  |
| *j* |  |  |  |
| [ECx] |  | | |
| NOEC |  | | |
| LOEC |  | | |

a Use superscript(s) to identify the values reported to be significantly different from control

**Reported Statistics**: *Copy and paste statistical section from publication.*

***Part B: Detailed Review***

**I. Materials and Methods**

**Protocol/Guidance Followed**: *Indicate if provided by authors.*

**Deviations from Protocol**: *If authors report any deviations from the protocol noted above indicate here.*

**Study Design and Methods:** *Copy and paste methods section from publication.*

**TEST ORGANISM**: *Provide information under Details and any relevant or related information or clarifications in Remarks.*

| **Parameter** | **Details** | **Remarks** |
| --- | --- | --- |
| **Species:**  Useful sites include:   * <https://www.itis.gov/> * <https://www.fws.gov/endangered/> * <https://www.fisheries.noaa.gov/find-species> | Common Name:  Scientific Name:  Order Name:  Family Name: | |  |  | | --- | --- | | North American species? |  | | Surrogate for North American Taxon? |  | | Is this species Threatened or Endangered? |  | | *(Place X if applicable)* |  | |
| **Strain/Source:**   * May be laboratory-reared or purchased from a breeder [1-3] * All birds should be from the same source and breeding population [1-3] * Test birds should be phenotypically indistinguishable (except for size) from wild stock [1-3] |  |  |
| **Age at Study Initiation:**   * Acute test: Young adults of both sexes, not mated, at least 16 weeks old [1] * Dietary test: Not too old to be able to avoid eating (e.g., mallard – 5 days old, bobwhite quail – 10-14 days old [2]) * Reproduction test: approaching first breeding season, at least 16 weeks old, all within 1 month age [3] |  |  |
| **Was body weight or length recorded at test initiation and/or at regular intervals?**   * For field observations, was body weight measured in a consistent manner (e.g., during blood sample collection) | |  |  |  |  | | --- | --- | --- | --- | |  | Yes |  | No | |  |
| **Was body weight or length recorded at regular intervals?** | |  |  |  |  |  | | --- | --- | --- | --- | --- | |  | Yes |  |  | No |   *If yes, describe regular intervals:* |  |

**STUDY PARAMETERS:** *Provide information under Details and any relevant information of deficiencies in Remarks. Complete for both Controlled Experiments and Field Studies/Observations*

| *For Both Controlled Experiments and Field Observations* | **Parameter** | **Details** | **Remarks** |
| --- | --- | --- | --- |
| **Number of Replicates per Treatment Group:**   * Acute and Dietary tests: 1-2 per treatment level [1,2] * Reproductive test: 16 per treatment level [3] | Control(s): |  |
| Treatment(s): |
| **Number of Birds per Replicate/Test Condition:**   * Acute and Dietary tests: at least 10 per treatment level (equal numbers from each sex) [1,2] * Reproductive test: one pair (1 M, 1 F) [3] |  |  |
| **Body Condition:**   * Birds should be healthy without excess mortality [1-3] * Deformed, abnormal, sick, of injured birds should not be used [1-3] * Birds used in a previous test, or offspring of birds used in a test treatment group, should not be used [3] | Good: |  |
| Poor: |  |
| Number of individuals excluded from analysis: |
| **Exposure Pathway:**   * Should be dietary exposure [3] |  |  |
| **Exposure Duration:** |  |  |
| **Exposure Time:** | |  |  | | --- | --- | |  | Breeding | |  | Non-breeding | |  | Year round | |  |
| **Observation Intervals:**   * No specific guidance on number of observation intervals for changes in survival, deformities, behavior, etc. of study organisms during a test.   Should be an appropriate number of observations over the study to ensure test conditions are being properly maintained [4] |  |  |
| **Test Concentrations (remember units):**  *Recommended test concentrations include at least two concentrations other than the control; three or more will provide a better statistical analysis.* | Nominal: |  |
| Measured: |
| Media measured in: |
| **What analytic methods were used to measure test concentrations?** |  |  |
| **What was the recovery of the test material?** |  |  |
| **What was the reporting limit of the analytical method used to measure the test concentrations?** |  |  |
| **Were standards used as part of the analytical method?** |  |  |

**EGG COLLECTION AND INCUBATION (*if applicable*):**

| *For Both Controlled Experiments and Field Observations* | **Parameter** | **Details** | **Remarks** |
| --- | --- | --- | --- |
| **Collection Interval:**   * Recommend daily [3] |  |  |
| **Egg Storage Conditions:**   * Temperature recommend 13-16ºC (55-61ºF) [3] * Relative humidity recommend 55-80% [3] | Temperature: |  |
| Relative humidity: |  |
| **Were eggs candled for cracks prior to setting for incubation?** | |  |  |  |  | | --- | --- | --- | --- | |  | Yes |  | No | |  |
| **Were eggs set weekly?** | |  |  |  |  | | --- | --- | --- | --- | |  | Yes |  | No | |  |
| **When was candling done to check for fertility?** |  |  |
| **When were eggs transferred to the hatcher?** |  |  |
| **Hatching Conditions:**   * Temperature recommend 37.5-39ºC (100-102ºF) [2,3] * Relative humidity recommend ~70% [2,3] | Temperature: |  |
| Relative humidity: |
| **What day was hatched eggs removed and counted?**  *(e.g., removed on day 27)* |  |  |

**CONTROLLED EXPERIMENT STUDY PARAMETERS:** *Provide information under Details and any relevant information of deficiencies in Remarks. Complete for Controlled Experiments only.*

| *For Controlled Experiments Only* | **Parameter** | **Details** | **Remarks** |
| --- | --- | --- | --- |
| **Acclimation Period:**   * Recommend at least 2 weeks [1,3] * Dietary test: 3 days – mallard, 7 days – bobwhite quail [2] * Acute test: Should not be if mortality during acclimation >5% (lab, breeder) or 10% (wild) [1] * Dietary test: Should not be used if >5% mortality during acclimation * Reproduction test: Should not be used if >3% dead or debilitated during acclimation [3] |  |  |
| **Acclimation followed published guidance?**  *Describe, if any* | |  |  |  |  | | --- | --- | --- | --- | |  | Yes |  | No | |  |
| **Food Type:**   * Recommend commercial feed or nutritional equivalent [1-3] |  |  |
| **Test Chemical Solubility in Water:**   * List units and conditions (e.g., 0.01% at 20ºC) |  |  |
| **Solvent/vehicle Type:**   * Recommended solvents include (acetone, methylene chloride, table grade corn oil, propylene glycol, gum arabic) [3] * Should not comprise more than 2% of diet by weight [3] * Should be completely evaporated before feeding [3] * Equivalent amount should be added to control diets [3] |  |  |
| **Negative Control:** | |  |  |  |  | | --- | --- | --- | --- | |  | Yes |  | No | |  |
| **Reference Toxicant Testing:** | |  |  |  |  | | --- | --- | --- | --- | |  | Yes |  | No |   *If Yes, identify substance:* |  |
| **Other Control:** *If any (e.g. solvent control)* |  |  |
| **Describe preparation of test diet:** |  |  |
| **Were concentrations in diet verified by chemical analysis?** | |  |  |  |  | | --- | --- | --- | --- | |  | Yes |  | No | |  |
| **Indicate whether stability and homogeneity of test material in diet determined:** | |  |  |  |  | | --- | --- | --- | --- | |  | Yes |  | No | |  |
| **Indicate if the test material was regurgitated/avoided:** | |  |  |  |  | | --- | --- | --- | --- | |  | Yes |  | No | |  |
| **Pen Size:**   * Acute test: At least 75 in.2 / bird (quail) or 150 in.2 / bird (mallard) surface area [1]   + Should be at least 9.5 in. height (quail) or 12.5 in. height (mallard) [1] * Dietary test: At least 50 in.2 / bird (quail) or 100 in.2 / bird (mallard) surface area, and pens should be arranged to prevent cross contamination [2] * Reproductive test: should be of sufficient size to prevent stress, and pens should be arranged to prevent cross-contamination [3] * Outdoor pens should only be used during breeding season.[3] |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Parameter** | **Details** | **Remarks** |
| *For Controlled Experiments Only* | **Number of Birds per Pen:**   * Acute and Dietary tests: at least 10 per pen (equal numbers from each sex) [1,2] * Reproductive test: one pair (1 M, 1 F) [3] | Male: |  |
| Female: |
| **Number of Pens per Group/Treatment:**   * Acute and Dietary tests: 1 or 2 per treatment 1,2] * Reproductive test: 16 per treatment level [3] | Control: |  |
| Treatment: |
| **Test Conditions:**   * Recommended temperature:   + Adults:     - 15-27ºC (59-81ºF) [1]     - 15-30ºC (59-86ºF) [3]   + Hatchlings:     - 22-38˚C (72-100ºF) [2]     - 22-35˚C (72-95ºF) [1,3] * Relative humidity recommend 45-70% [1-3] | Temperature: |  |
| Relative humidity: |
| Photoperiod: |
| **Feeding:**   * Should be administered *ad libitum* throughout the study [1-3] |  |  |
| **Lighting:**   * All pens should receive equal illumination [1-3] * Acute and Dietary tests: indoor lighting recommended [1,2]   + Incandescent of fluorescent acceptable [1,2]   + 14 Light: 10 Dark photoperiod recommended for most species [1,2]     - Should be adjusted as appropriate for test species [1]   + Light intensity not specified [1,2] * Reproductive test.   + Should be full spectrum simulating daylight (avoid shorter wavelength “cool-white” fluorescent) [3]   + Photoperiod should be acceptable for the test and species [3]   + Recommended illumination (10-65 lux) [3]   + Outdoor lighting acceptable but not recommended [3] |  |  |

**Study Design/Methods Classification:** *(Place X by One Based on Overall Study Design/Methods Classification)*

***Provide details of Major or Minor Deficiencies/Concerns with Study Design in Associated Sections of Part A: Overview***

*This classification should be taken into consideration for the overall study classification for aquatic life criteria development in Part A.*

|  |  |
| --- | --- |
|  | Study Design Acceptable for Quantitative Use |
|  | Study Design Acceptable for Qualitative Use |
|  | Study Design Not Acceptable for Use |

**Additional Notes:** *Provide additional considerations for the classification of study use based on the study design.*

**Clarifying Questions for Study Authors and the Other Pertinent Information/Notes from Discussion:** *Provide clarifying questions for study authors.*

**OBSERVATIONS:** *Provide information under Details and any relevant information in Remarks. This information should be consistent with the Results Section in Part A.*

| **Parameter** | **Details** | **Remarks** |
| --- | --- | --- |
| **Parental:**  *(e.g., mortality, body weight, mean feed consumption )* [1-3] | *List parameters:* |  |
| **Reproductive Success:**  *(e.g., eggs laid/pen, nestlings produced, juvenile body weight)* [3] | *List parameters:* |  |
| **Was control survival acceptable?**   * Unacceptable if >10% control birds dead or moribund [1-3] | |  |  |  |  | | --- | --- | --- | --- | |  | Yes |  | No |   Control survival (%): |  |
| **Were individuals excluded from the analysis?** | |  |  |  |  | | --- | --- | --- | --- | |  | Yes |  | No |   *If yes, describe justification provided:* |  |
| **Was test condition parameters acceptable?**  ***(see notes under Reproductive Effects of Results Section for test validity considerations) [1-3]*** | |  |  |  |  | | --- | --- | --- | --- | |  | Yes |  | No | |  |
| **Availability of concentration-response data:** |  |  |
| * Were treatment level concentration-response data included in study publication (can be from tables, graphs, or supplemental materials)?   *specify endpoints in remarks* | |  |  |  |  | | --- | --- | --- | --- | |  | Yes |  | No | |  |
| * Were replicate level concentration-response data included in study publication (can be from tables, graphs, or supplemental materials)?   *specify endpoints in remarks* | |  |  |  |  | | --- | --- | --- | --- | |  | Yes |  | No | |  |
| * If treatment and/or replicate level concentration-response data were included, how was data presented? *(check all that apply)* | |  |  | | --- | --- | |  | Tables | |  | Graphs | |  | Supplemental Files | |  |
| * Were concentration-response data estimated from graphs study publication or supplemental materials? | |  |  |  |  | | --- | --- | --- | --- | |  | Yes |  | No |   *If yes, indicate software used:* |  |
| * Should additional concentration-response data be requested from study authors? | |  |  |  |  | | --- | --- | --- | --- | |  | Yes |  | No |   Requested by:  Request date:  Date additional data received: |  |
| *If concentration-response data are available, complete* ***Verification of Statistical Results (Part C)*** *for sensitive species*. |  |  |

***Part C: Statistical Verification of Results***

**I. Statistical Verification Information:** *Report the statistical methods (e.g., R, EPA TRAP, BMDS, other) used to verify the reported study or test results for the five (5) most sensitive genera and sensitive apical endpoints (including for tests where such estimates were not provided). If values for the LC50, LT50 and NOEC are greater than the highest test concentration, use the “>” symbol.*

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Primary Reviewer:** |  | **Date:** |  |  |  | **EPA** |  | **Contractor** | (*Place X by One*) |
| **Secondary Reviewer:** |  | **Date:** |  |  |  | **EPA** |  | **Contractor** | (*Place X by One*) |
| (*At least one reviewer should be from EPA for sensitive taxa*) | | | | | | | | | |

**Endpoint(s) Verified:**

**Additional Calculated Endpoint(s):**

**Statistical Method (e.g., TRAP, BMDS, R, other):**

**Fitted Model:**

**II. Toxicity Values:** *Include confidence intervals (CI) if applicable. 95% CI unless otherwise noted.*

|  |  |
| --- | --- |
| **NOEC:** |  |
| **LOEC:** |  |
| **MATC:** |  |
|  |  |
| **EC5:** |  |
| **EC10:** |  |
| **EC20:** |  |
| **EC50 or LC50:** |  |

**Dose-Response Curve Classification:** *(Place X by One)*

*This classification should be taken into consideration for the overall study classification for aquatic life criteria development in Part A*

|  |  |
| --- | --- |
|  | Dose-Response Curve Acceptable for Quantitative Use |
|  | Dose-Response Curve Acceptable for Qualitative Use |
|  | Dose-Response Curve Not Acceptable for Use |

**Summary of Statistical Verification:** *Provide summary of methods used in statistical verification.*

**Additional Notes:**

**Attachments:**

1. *Provide attachments to ensure all data used in Part C are captured, whether from study results reported in the publication and/or from additional data requested from study authors*
   * *Data from study results of the publication should be reported in Results section of Part A*
   * *Additional data provided upon request from study authors should be reported in Table C.II.1 below and original correspondence with study authors should be included as attachments*
2. *Model assessment output (including all model figures, tables, and fit metrics)*
3. *Statistical code used for curve fitting*

**III. Attachments:** *Include all attachments listed above after the table below.*

**Additional Data Used in Response-Curve**: *Provide all data used to fit dose-response curve not captured in Results section of DER above in Part A, rows as needed. First row in italicized text is an example.*

**Table C.II.1 Additional Da****ta Used in Dose-Response Curve.**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Curve ID** | **Species** | **Endpoint** | **Treatment** | **Replicate** | **[Standard Deviation or Standard Error]** | **# of Survivors** | **Na** | **ka** | **na** | **Response** | **Response Unit** | **Conc** | **Conc units** |
| *Alchronic1* | *Ceriodaphnia dubia* | *# of young/female* | *0* | *6* |  |  | *10* | *10* | *1* | *18* | *count* | *0.03* | *mg/L* |
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a N = number of individuals per treatment; k = number of replicates per treatment level; n = number of individuals per replicate

**III. Attachments:** *Include model assessment output (including all model figures, tables, and fit metrics) here*

***Part D: References to Test Guidance***

1. U.S. EPA. 2012a. OCSPP 850.2300: Avian acute oral toxicity test. Ecological effects test guidelines. Office of Chemical Safety and Pollution Prevention. EPA 712-C-025. January 2012
2. U.S. EPA. 2012b. OCSPP 850.2300: Avian dietary toxicity test. Ecological effects test guidelines. Office of Chemical Safety and Pollution Prevention. EPA 712-C-024. January 2012
3. U.S. EPA. 2012c. OCSPP 850.2300: Avian reproduction test. Ecological effects test guidelines. Office of Chemical Safety and Pollution Prevention. EPA 712-C-023. January 2012
4. American Public Health Association (APHA). 2012. Standard methods for the examination of water and wastewater. Part 8000 - Toxicity. APHA. Washington, DC.