[Fish or Oyster] Bioconcentration Factor (BCF) of [Test Compound]

|  |  |
| --- | --- |
| Report: | [Provide full citation. Provide the MRID (first) if the review is unilateral.] |
| Document No.: | [MRID ######## (for the U.S.)] [PMRA Study No. ####### (for Canada)] |
| Guideline: | OCSPP [850.1710 for oysters or 850.1730 for fish in the U.S.]; DACO [9.4.8 for oysters or 9.5.6 for fish in Canada][If the study was conducted under a different guideline, state ‘Conducted by’ and provide the most relevant guideline(s) the study was conducted under. Then state ‘Reviewed by OCSPP 850.1710’ [‘850.1730’]. If this review is multilateral, also provide the guideline numbers under which participating agencies are reviewing the study.] |
| Statements: | [Indicate whether the study was conducted in compliance with FIFRA GLP standards and whether signed and dated Data Confidentiality, GLP Compliance, Quality Assurance, and Authenticity Certification statements were provided. If the study was not conducted in compliance with FIFRA GLP standards, indicate why or how it deviated.] |
| Classification: | This study is [provide classification and a very concise statement of any deficiencies that impacted the classification]. [If multiple classification terminologies are needed for multilateral reviews, list or tabulate them.] |
| PC Code: | [######] |
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| Reviewer: | [Provide final reviewer(s)’s name] | Signature: |
|  | [Title] | Date: [Type date of signature.] |

**Executive Summary**

The bioconcentration and depuration of [location(s) of radiolabel(s)-14C]-[test compound] in [common name of test species] was investigated in a [type of test system, *e.g.*, continuous flow-through or renewal] system. The [fish or oysters] were continuously exposed at nominal low and high dose concentrations of [##] µg/L and [##] µg/L, respectively, for [##] days at [##]°C. Concentrations in [fish or oysters], [reached or did not reach] a plateau after [##] days of exposure. The [fish or oysters] were then transferred to [flowing or renewed] untreated water after [##] days of study initiation to depurate for [##] days. [##] treated replicate tanks, [##] control tanks, and [##] solvent control tanks per concentration were tested.

[If bioconcentration factors (BCFs) were corrected for TOC in the water, then state it.] BCFs appeared to be [dependent or independent] of the water concentration. The [test compound] was a maximum of [##]% of the total residue recovered (TRR) at day [##] of exposure in the [fish or oyster] tissue for the high [or low] dose exposure samples. [No or [##]] transformation products were identified in the water and subsequently in the [fish or oyster] tissue (**Table 11**). Metabolism of [test compound] [occurred or did not occur] in the [fish or oyster] tissue as shown by the presence of [no or [##]] tissue metabolites in the [fish or oyster] tissue that were not present in the water (**Table 11**). A synopsis of the study results is provided in **Table 1** and **Table 2**.

| Table 1. [Test substance] [Fish/Oyster] Kinetic Parameters [report only the ones required] |
| --- |
| Type of exposure | Continuous flow-through or renewal |
| Time to steady state | [##] days |
| Uptake rate constant *k*1 | [##]±[C.I.] L·Kg-1·day-1 |
| Depuration rate constant *k*2 | [##]±[C.I.] days-1 |
| Growth rate constant *k*G | [##]±[C.I.] days-1 [usually required only for the fish BCF studies conducted for extended periods of time, *e.g.*, above 28 days] |
| Metabolism rate constant *k*M | [##]±[C.I.] days-1 [usually required only for the fish BCF studies where there is considerable tissue metabolism] |
| Fecal egestion rate constant *k*E | 0 days-1 (considered negligible in BCF studies) |
| *k*T = *k*2 + *k*M + *k*G + *k*E | [##]±[C.I.] days-1 |
| Depuration half-life | Low dose: [##]±[C.I.] days | High dose: [##]±[C.I.] days |
| Amount depurated | [##]% TRR after [##] days for the [low or high] dose samples |
| *k*T is the total elimination rate constant. Data obtained from pages [##] of the study report. Rate constants were calculated using the equations in Attachment I, Table I-1. |

| **Table 2. [Test substance] [Fish/Oyster] Bioconcentration Factors** [report the ones required] |
| --- |
| **Concentration:** | **[##] µg a.i./L** | **[##] µg a.i./L** |
| Tissue: | Edible | Non-edible | Whole | Edible | Non-edible | Whole |
| BCFSS (L·Kg-1)\* | [##]±[S.D.] | [##]±[S.D.] | [##]±[S.D.] | [##]±[S.D.] | [##]±[S.D.] | [##]±[S.D.] |
| BCFK (L·Kg-1)\* | [##]±[C.I.] | [##]±[C.I.] | [##]±[C.I.] | [##]±[C.I.] | [##]±[C.I.] | [##]±[C.I.] |
| BCFKG (L·Kg-1)\* | [##]±[C.I.] | [##]±[C.I.] | [##]±[C.I.] | [##]±[C.I.] | [##]±[C.I.] | [##]±[C.I.] |
| L (%) | [##] | [##] | [##] | [##] | [##] | [##] |
| BCFSS, L (L·Kg-1)\* | [##]±[S.D.] | [##]±[S.D.] | [##]±[S.D.] | [##]±[S.D.] | [##]±[S.D.] | [##]±[S.D.] |
| BCFK, L (L·Kg-1)\* | [##] | [##] | [##] | [##] | [##] | [##] |
| BCFKG, L (L·Kg-1)\* | [##] | [##] | [##] | [##] | [##] | [##] |
| **\*** Units for BCFs: L/Kg wet weight tissue; units for lipid normalized BCFs are L/Kg lipid.Data were obtained from pages [##] of the study report. BCFSS, BCFK and BCFKG are the steady state, kinetic and growth corrected kinetic BCF; L is the lipid content which was determined at [##] days of exposure. BCFs were calculated using the equations in Attachment I, **Table I-1**. |

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| [Notes to the reviewer: For the BCFs and kinetic constants, provide the confidence limits or standard deviations, where available, in **Table 1** and **Table 2**. BCF values are calculated from the concentration of test substance (instead of the total radioactivity), unless evidence is provided that the test material does not degrade. For further guidance on the correction for TOC in the dilution water, which is typically required when the log KOW >4 and TOC is high, see the KABAM manual (**Equation *A*2** of Appendix A, which is from Arnot and Gobas, 2004) [[1]](#footnote-1). The oyster BCF guideline does not recommend calculation of *k*G, BCFKG or BCFKG L. For fish, BCFKG is needed only for extended studies. BCFL and BCFKG may or may not be available for individual tissues in the fish BCF study. For OCSPP BCF studies, *k*E (rate constant for fecal egestion) is not usually measured and is assumed to be negligible. Be careful throughout the review to distinguish transformation products in the organisms from those in the water.] |

1. **Study Design**
2. **Preliminary Tests**

[Describe any preliminary tests performed such as a range finding, solubility or toxicity test.]

****

1. **Materials**

| **Table 3. Materials** |
| --- |
| **Test material** | [Type of label]-radiolabeled [test compound]. Radiolabel position(s) [was/ was not/ were/were not] appropriate for this study. |
| Specific radioactivity | [##] MBq/mg |
| Radiochemical purity | [##]% [HPLC or specify method of determining purity] |
| Chemical purity | [##]% [HPLC, GC/MS or specify method of determining purity] |
| Batch number or ID | [xxxxxx] |
| Solubility in water | [##] mg/L [If pH-dependent, list available value at study pH; also list the solubility in saltwater if available and relevant (*e.g.*, for an oyster BCF study or for a fish BCF study conducted with a saltwater species).] |
| Hydrolysis half-life at pH 7 | [##] days [provide other hydrolysis half-lives and/or aqueous photolysis half-life, if relevant] |
| pKa | [##] [provide when appropriate] |
| **Other** | [Provide a brief description of any other issues that might have been encountered in the study or any other physicochemical or environmental fate parameters that may have affected the results. Describe detected impurities in the water.] |
| Data obtained from pages [##] of the study report. |

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| **Table 4. Water Solutions** |
| **Water** | [Brief description of the dilution water and its source, *e.g.*, filtered ([##] µm) well water, dechlorinated tap water, natural seawater, from [source], *etc.*] |
| Temperature | Mean [##]±[##]°C; range [##]-[##]°C [report frequency of measurements] |
| Flow rate | [##] mL per [##] hr or [##] L/hr [report frequency of measurements] |
| Dissolved oxygen concentration | [##] to [##] mg/L; dissolved oxygen was maintained at ≥[##]% saturation (method) [report frequency of measurements] |
| pH | [##] to [##] (method) [report frequency of measurements] |
| Total organic carbon | [##] to [##] mg carbon/L [report frequency of measurements] |
| Dissolved organic carbon | [##] to [##] mg carbon/L [report frequency of measurements] |
| Particulate matter | [##] to [##] mg/L [report frequency of measurements] |
| Hardness | [##] to [##] mg/L as CaCO3 [report frequency of measurements] |
| Alkalinity | [##] to [##] mEq/L [report frequency of measurements] |
| Salinity | [##] to [##] ppt [report frequency of measurements; report salinity only for tests performed with estuarine/marine fish or with oysters] |
| **Test concentrations** | Nominal low dose: [##] mg/L | Nominal high dose: [##] mg/L  |
| Range | Low dose: [##]-[##] mg/L | High dose: [##]-[##] mg/L |
| Stock solution | [Indicate how the stock solution was prepared.] |
| Water solution | [Indicate how the water was prepared.] |
| **Vehicle/Concentration** | [name of vehicle used] at [##] mL/L |
| Surfactants | A surfactant or dispersant [was or was not] used in the preparation of a stock or water solution. [Identify the surfactant if used.] |
| **Loading rates** | [##], [##] and [##] g fish/L/day [or [##], [##] and [##] oysters/L/hour], for the low dose samples, high dose samples, and control, respectively. The loading rate [was or was not] compliant with the [Fish or Oyster] BCF guideline requirement. |
| **Other** | [Describe any other issues that might have been encountered in the study.] |
| Data obtained from pages [##] of the study report. |

| **Table 5. Testing System** |
| --- |
| **Test type** | [For example, continuous flow-through or renewal], [##] volume additions per day, [[##] flow rate for flow-through test.] The type of test system [was or was not] compliant with the [Fish or Oyster] BCF guideline requirements. |
| **Test chambers** | [Provide a description of the aquaria, volume, *e.g.*, [##]-L; material, *e.g.*, glass or stainless steel; and shape, *e.g.*, rectangular chambers. Indicate the dimensions of each aquarium.] All test vessels and compartments [had or did not have] the same dimensions and water volumes. |
| Number of aquaria | [##] treated aquaria, [##] control, and [##] solvent (vehicle) control. |
| Randomization | Treatments [were or were not] randomly assigned to individual test vessel locations and individual test organisms [were or were not] randomly assigned to test vessels. |
| Aeration | Aeration [was or was not] used [If aeration was used, describe in brief; note that aeration is not recommended.] |
| **Light source** | [xxxx] |
| Intensity of light | [##] to [##] [unit (*e.g.*, ft-c or lux)] |
| Photoperiod | [##] hours of light:[##] hours dark |
| **Other** | [Describe any other issues that might have been encountered in the study.] |
| Data obtained from pages [##] of the study report. |

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| **Table 6. Test Organisms** |
| **Test organism** | [Provide the common name of the species.] |
| Species | [Provide the *Scientific name* of the species.] |
| Weight [or Valve height] | Mean [##]±[##] g; range [##] to [##] g [For oyster BCF: Substitute for valve height range in mm.] [For fish BCF: the registrant may have provided the length in lieu of the weight (note that the guidance recommends measuring both). If this is the case, report the length and the registrant’s justification for not reporting the weight of the test organisms.] |
| Size | [For fish BCF: The smallest fish [was or was not] smaller than ⅔ the weight of the largest. For oyster BCF: The organisms [were or were not] within the recommended range of 30-50 mm in valve height and the standard deviation was less than 20% of the mean.] |
| Age/Life Stage | [xxxx]/[xxxx] [For fish BCF: It is recommended to use fish of the same year-class; if the fish were not juveniles, provide a justification for using older fish] |
| Source | [xxxx] ][It is recommended that all fish or oysters proceed from the same source.] |
| EC10, EC50, IC10, IC50,or LC50 | [##] µg/L [Provide the appropriate values from guideline studies and citation (*e.g.*, MRID [########]) or from preliminary experiments conducted and reported in this study.] |
| Acclimation period | [##] days [A holding period of at least 14 days for fish BCF, and 12 days for oyster BCF, is recommended] |
| Diet | [For example, for fish BCF: Test organisms were fed approximately [##]% of the fish body weight per day. Uneaten food and feces was siphoned [##] minutes after being fed. Or for oyster BCF: Feeding regime was continuous via delivery of dilution water (*e.g.*, natural unsterilized and unfiltered seawater, or supplemented artificial seawater).] |
| Treatment for disease | [No or [xxxx]] treatment for disease was conducted through the acclimation or testing periods. |
| Mortality for the treated samples | [##] ([##]%) for the treated samples at the low dose concentration; [##] ([##]%) for the treated samples at the high dose concentration. |
| Mortality for the controls | [##] ([##]%) for the vehicle (solvent) control; [##] ([##]%) for the control. |
| Frequency of observations | Mortality observations were conducted [frequency] for treated and control samples. [Mortality should be recorded at least daily] |
| Other observations | [Report any other observations such as spawning, any evidence of adverse effects, and lack of feeding, such that chemical uptake and/or depuration were likely impacted.] |
| **Other** | [Describe any other issues that might have been encountered in the study.] |
| Data obtained from pages [##] of the study report. |

1. **Sampling and Analysis**
2. **Water**

|  |
| --- |
| Table 7. Water Sampling and Analysis |
| Number of replicates sampled | [Duplicate for fish BCF or triplicate for oyster BCF] treated and control water samples were taken from each tank at each sampling interval. [See also Table 5 (Testing System) for number of aquaria.] |
| Sampling intervals | At days -[##] and -[##], after 0, [##], [##], [##], [##], and [##] days of exposure, and after 0, [##], [##], [##], and [##] days of depuration. Water samples [were or were not] collected before feeding and at the same time that fish were collected. Initial water samples [were/were not] collected prior to the addition of fish/oyster to the test chamber. |
| Solvent (vehicle) sampling | Solvent (vehicle) control samples were taken at 0, [##], and [##] days. |
| Sample volume | [##] mL |
| Sample collection method | Samples were collected from each tank using [test equipment, *e.g.*, a volumetric pipette]. |
| Analysis | Aliquots ([##] mL) were analyzed [*e.g.*, for total radioactivity using LSC, or appropriate analytical method]. |
| LOD / LOQ for LSC in water | [##] μg/L / [##] μg/L [report results for low dose and high dose samples if they are different], equivalent to [##]% / [##]% of the TRR. |
| Additional analysis | [On days [##] and [##] of exposure, additional water samples ([##] samples, volume [##] L) were collected from each test aquarium and tested for [test compound] and [transformation products]. The analysis was performed [provide a synopsis of the analytical method].] |
| LOD / LOQ for parent compound in water | [##]μg/L/[##] μg/L (report results for low dose and high dose samples if they are different). Equivalent to [##]% / [##]% of the TRR. |
| LOD / LOQ for transformation products | [##]μg/L/[##] μg/L (report results for low dose and high dose samples if they are different). Equivalent to [##]% / [##]% of the TRR. |
| Raw data | Raw measured data and representative chromatographs [were or were not] provided. |
| Other | [Describe any other issues that might have been encountered in the study.] |
| Data obtained from pages [##] of the study report. |

1. **[Fish or Oyster] Tissue**

| Table 8. [Fish or Oyster] Sampling and Tissue Analysis |
| --- |
| Number of [fish or oysters] sampled at each interval | [##] for treated samples, [##] for solvent controls, and [##] for the control tank. [Note: usually 4 replicates are taken, for each test interval, except for the last exposure interval, when 6 replicates are taken. Additional replicates may be taken for lipid determination if it is not possible to measure it from the same fish or oysters tested.] |
| Pooling | Samples [were or were not] pooled. [If samples were pooled, describe.] |
| Sampling intervals | At 0, [##], [##], [##], [##], and [##] days of exposure, and after 0, [##], [##], [##], and [##] days of depuration |
| Sample handling | The [fish or oysters] were sacrificed, [for fish BCF weighted and measured or for oyster BCF valve height was measured], [for fish BCF add: and separated into fillet (edible tissue) and viscera (non-edible tissue)]. |
| Methods of extraction and cleanup | Aliquots (*ca*. [##]-[##] g) were [methods, *e.g.*, dried overnight, extracted with [solvent], samples [cleaned up] using [method]] and [additional methods, [*e.g.*, combusted] prior to [method, *e.g.*, LSC] analysis. [Combustion or method] efficiency was [##]%.] |
| Analytical methods | Samples of days [##], [##] and [##] were further analyzed for parent compound and transformation products [or metabolites] using [method, *e.g.*, HPLC, GC/MS] analysis. [HPLC] extraction efficiency was [##]%. A reasonable attempt [was or was not] made to extract the test compound and its transformation products and/or metabolites from the tissue tested. [If a reasonable attempt was not made to extract the samples, refer to the Study Deficiencies (Section IV) for further details.] |
| LOD / LOQ for LSC analysis in [fish/oyster] tissue | [##]% of the TRR / [##]% of the TRR (report results for low dose and high dose samples if they are different). |
| LOD / LOQ for parent compound in [fish/ oyster] tissue | [##]μg/Kg or [##]% of the TRR /[##] μg/Kg or equivalent to [##]% of the TRR (report results for low dose and high dose samples if they are different). |
| LOD / LOQ for transformation products in [fish/oyster] tissue | [##]μg/Kg or [##]% of the TRR /[##] μg/Kg or equivalent to [##]% of the TRR (report results for low dose and high dose samples if they are different). |
| Raw data | Raw measured data and representative chromatographs [were or were not] provided. |
| Other | [Describe any other issues that might have been encountered in the study.] |
| Data obtained from pages [##] of the study report. |

1. **Lipid Determination**

[Briefly describe the method used for lipid determination. Provide citations for methods where applicable in **Section V**.]

1. **Supplementary Studies**

[Briefly describe any other supplementary studies and their results if any.]

1. **Analytical Results**
2. **Findings**

Based on a log KOW = [##] for [test substance] at pH [##], bioconcentration was expected to plateau after [##] days of exposure. Steady state [was or was not] operationally achieved after [##] days of exposure, since after [##] consecutive measurements [minimum 3 measurements], separated by [##] days [usually 2-7 days], a plot of [test substance] concentration in whole fish on a wet weight basis (C*f*), against time [became or did not become] nearly parallel to the time axis. They were within ±20% of each other [if after 3 measurements the concentration is still increasing, an additional intervals are recommended to document steady state; furthermore, when samples are pooled, 4 consecutive measurements are the minimum required to document steady state] (**Table 9** and **Figure 1**).

| **Table 9. [Test Substance] [Fish or Oyster] Residue Analysis (Exposure Phase)** |
| --- |
| **Days** | **Exposure** |
| **0** | **[##]** | **[##]** | **[##]** | **[##]** | **[##]** |
| **Water TWA*C* (µg/L)** | [##] | [##] | [##] | [##] | [##] | [##] |
| **C*f* (µg/kg wet wt)** | [##]±[##] | [##]±[##] | [##]±[##] | [##]±[##] | [##]±[##] | [##]±[##] |
| %TRR | [##]±[##] | [##]±[##] | [##]±[##] | [##]±[##] | [##]±[##] | [##]±[##] |
| BCF (L·Kg wet wt-1) | [##] | [##] | [##] | [##] | [##] | [##] |
| Data obtained from pages [##] of the study report. TWA*C*=time weighted average concentration; C*f* [or C*o*] is the [test substance concentration] in whole fish [or oyster] on a wet weight basis. TRR=total residue recovered. TWA*C* is calculated according to equation in **Table I-1** of Attachment I. |

[If bioconcentration factors (BCFs) were corrected for total organic carbon (TOC) in the water, then state it. If the water analysis is based on LSC as opposed to individual residue analysis due to test substance’s persistence, provide results of analyses for transformation products for representative samples, and proof that the levels of parent compound were reasonably related to the total radioactive residues in the water (*e.g.*, [TLC, HPLC, GC/MS] analysis showed that [14C]-[test substance] accounted for ≥[##]% of the TRR and no additional individual residue analyses were conducted in the water samples.) [Provide a description of any transformation products or impurities in the water.] A summary of kinetic parameters and bioconcentration factors is provided in Table 1 and Table 2, respectively, of the Executive Summary.

The period of depuration and sampling intervals [were or were not] adequate to determine a depuration rate constant and a depuration half-life for the parent compound. After [##] days of depuration, [##]% of the TRR and [##]% of the parent compound remained in the fish tissue (Table 10 and Figure 1).

| **Table 10. [Test Substance] [Fish or Oyster] Residue Analysis (Depuration Phase)** |
| --- |
| **Days of depuration** | **Depuration** |
| **0** | **[##]** | **[##]** | **[##]** | **[##]** |
| **C*f* (µg/kg wet wt)** | [##]±[##] | [##]±[##] | [##]±[##] | [##]±[##] | [##]±[##] |
| %TRR | [##]±[##] | [##]±[##] | [##]±[##] | [##]±[##] | [##]±[##] |
| Data obtained from pages [##] of the study report. [C*f* or C*o*] is the [test substance] concentration in [whole fish or oyster] on a wet weight basis. TRR=total residue recovered. |

A plot of C*f* vs. time is shown in Figure 1 [example plot]:



Figure 1. Concentration of [test substance] in whole fish (C*f*, µg/Kg) vs. time (days)

1. **Bioconcentration of Transformation Products and/or Metabolites**

[If the BCFSS is ≥500 and transformation products or metabolites exceed 10% TRR, then they are identified. Furthermore, any compound of toxicological concern is also measured, regardless of the percent of the TRR. Use this section and the sample Table 11 to report this data.]

| **Table 11. Concentration in [Fish or Oyster] of [Test Substance] and Transformation Products** |
| --- |
| Tissue | [Edible, Non-edible or Whole Fish or Oyster Tissue, as applicable] |
| Name | Max. Conc.(µg/g) | Interval(days) | Maximum% of TRR | Max. Conc. After Depuration (µg/g)\*\* | % of TRR AfterDepuration\*\* |
| [Test substance] | [##] | [##] | [##] | [##] | [##] |
| [Compound #1] | [##] | [##] | [##] | [##] | [##] |
| [Compound #2] | [##] | [##] | [##] | [##] | [##] |
| [Compound #3] | [##] | [##] | [##] | [##] | [##] |
| NERs | N/A | [##] | [##] | N/A | [##] |
| Data obtained from pages [##] of the study report. TRR = total residues recovered; NERs = non-extracted residues. **\*\***Value was measured after [##] days of depuration. |

Maximum unextracted (or non-extracted) residues (NERs) were [##]% TRR. [If unextracted residues were ≥10% TRR, then indicate whether the extraction effort was exhaustive. Further discussion may be placed in the **Study Deficiencies** section below.]

1. **Study Deficiencies and Reviewer’s Comments**

[List any deficiencies with the study and any additional salient information. Results and conclusions contained in the Executive Summary are not repeated in this section.]

1. **References**

[Self explanatory]

Attachment 1: Equations

| Table I-1. Equations |
| --- |
| **Box I-1A. Calculation of *k*1 and *k*2** |
| ln C*f dep*= ln C*f* 0 – (*k*2) (t*dep*)*k2* is derived from the slope of ln C*f dep* vs. t*dep*;[C is the concentration of the test substance in [“*f*” fish (“*o*” oyster), or “*w*” water]; t is the time for “*up*” uptake or “*dep*” depuration. C*f* 0 is the concentration in fish at the time 0 (zero) when depuration starts. *k*1 and *k*2 are the uptake and depuration rate constants, respectively.] |
| **Box I-1B. Calculation of *k*G** |
| Calculation of the growth rate constant, *k*G (required for fish BCF studies conducted for extended periods of time, *e.g.*, exposure and depuration above 28 days): Plot the natural logarithm of each individual fish weight (*e.g.*, kg) against time (days) or the natural logarithm of each fish length (*e.g.*, mm) against time (day) when the weight is not available. The slope of the line is *k*G, the growth rate constant (days-1). Use all individual fish available in this calculation (control, and two test concentrations). See OCSPP 850.1730 for further guidance. |
| **Box I-1C. Calculation of *k*M** |
| Calculation of the metabolism rate constant, *k*M (required for fish BCF studies when there is considerable metabolism): The metabolism rate constant (*k*M) may be calculated using one of the methods described in Appendix H of the KABAM user’s manual (Methods for Estimating Metabolism Rate Constant (*k*M))[[2]](#footnote-2). For further guidance, see the manual and Arnot *et al.*, 2008, along with the supplementary materials for the article.[[3]](#footnote-3) |
| **Box I-1D. Calculation of BCFSS, BCFK and BCFKG** |
| BCFSS = Steady state bioconcentration factor = Mean BCF over the time period when steady state is achieved or BCFSS = C*f*, SS/C*w* (for derivation of C*w*, the time weighted average concentration, see the equations in the **Box I-1F**)BCFK = Kinetic bioconcentration factor = *k*1/*k2*BCFKG = Growth corrected bioconcentration factor = *k*1/(*k*2 – *k*G) (assuming that *k*T = *k*2 + *k*G and *k*M and *k*E, the fecal egestion rate constant, are negligible) |
|  |
| **Box I-1E. Lipid Normalization** |
| L is the lipid content in fish [or oyster] tissue (unitless or percent).C*f*, L = lipid normalized concentration in fish [or “*o*” oyster if appropriate] = C*f*/LBCFL = lipid normalized BCF = C*f*, L/C*w* = BCF/LBCFSS, L = lipid normalized steady state BCF = BCFSS/LBCFK, L = lipid normalized kinetic BCF = BCFK/LBCFKG, L = lipid normalized growth corrected kinetic BCF = BCFKG/L |
| **Box I-1F. Calculation of Time Weighted Average Concentration** |
| TWA*C* = time weighted average water concentration, calculated after [##] days of exposure: Where the carried weight *wi* is the period of time (tj – tj-1) or the number of hours or days at the concentration *xi*; and *xi* is the average concentration [(Cj + Cj-1)/2]. |

**Attachment 2: Chemical Names and Structures**

[Attach a table (*i.e.*, structure table) of the chemical names, SMILES strings, CAS numbers, and structures of the analytes (*i.e.*, the test compound, identified transformation products, and reference compounds that were not identified in study samples) or refer to this table if it exists in a separate, associated document. Multiple versions of chemical names and SMILES strings are not included in the table. Sources of data need not be included. However, formatting the structure table in conformance with the guidance for tabulating transformation product data for EFED ROCKS memoranda is recommended. This formatting includes table columns for MRIDs and associated study data such as maximum and final concentrations of transformation products and their intervals. At a minimum, repeat the table below for the analytes.

For multilateral reviews, chemical names, SMILES strings, structures, and CAS numbers are captured elsewhere in the Monograph.[[4]](#footnote-4) Therefore these data are not attached to each study review within the Monograph. When the Monograph is split into individual reviews in EFED’s files, however, either reference the Monograph’s structure table as a separate, associated document or attach it to each individual review.]

[Sample structure table with the minimum information needed.]

|  |
| --- |
| **[Common name] [list other common names] [if the same common name is used in different studies for different compounds, provide in parentheses the MRID associated with the common name for this compound]** |
|  |  |
| IUPAC Name: | [Provide one IUPAC name.] |
| CAS Name: | [Provide one CAS name.] |
| CAS Number: | [Provide if available.] |
| SMILES String: | [Provide one SMILES string.] |
|  |
| [Paste structure here.] |
|  |
|  |

[Sample EFED ROCKS memorandum format for structure tables.]



Attachment 3: Statistics Spreadsheets and Graphs

[Insert supporting electronic spreadsheet files here (electronic attachment files are electronically finalized as separate files as well). Name electronic attachments the same file name as the Microsoft Word study review file with the addition of “Calc” for Excel workbooks and WinZip files, the addition of “Data” for Adobe Acrobat and Document Imaging files, and the addition of brief descriptors as appropriate for SigmaPlot Notebooks. Compress electronic attachment files into a WinZip file when three or more are prepared for a study review.]

[If the PestDF Tool is used, include the output files (note that PestDF is intended to describe degradation, while the process described in this study is depuration, which is assumed to follow single first order (SFO) kinetics). Output images can be pasted to the study review (as done in the example below), to the Excel spreadsheet, or attached as individual files with appropriate file names and extensions (*e.g.*, JPEG).]

[Print hard copies of the study review and any attachment sheets from separate electronic files to produce one hard copy file for finalization.]

[Example plot for the same data set shown in Figure 1 above (choose SFO kinetics, t1/2=1.75 days):]



1. Arnot, J.A. and F.A.P.C. Gobas. 2004. A food web bioaccumulation model for organic chemicals in aquatic ecosystems. Environmental Toxicology and Chemistry, 23 (10): 2343-2355. [↑](#footnote-ref-1)
2. <http://www.epa.gov/oppefed1/models/water/kabam/kabam_user_guide.html> [↑](#footnote-ref-2)
3. Arnot, J.A., D. Mackay, M. Bonnell. 2008. Estimating metabolic biotransformation rates in fish from laboratory data. *Environ. Toxicol. Chem.* 27 (2), 2008, pp. 341–351. [↑](#footnote-ref-3)
4. A Monograph is a collection of multiple study reviews and data summaries prepared by government agencies into a single document that follows an OECD format. Typically, Tier II Summaries prepared by industry are updated by government agencies based on agency-review and then placed within the Monograph. [↑](#footnote-ref-4)