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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MAY 17 2012

**MEMORANDUM**

**SUBJECT:** **Guidance for Reviewing Environmental Fate Studies**

**FROM:** Donald Brady, Director
Environmental Fate and Effects Division
Office of Pesticide Programs

**TO:** Environmental Fate and Effects Division
Office of Pesticide Programs

Through issuance of this memorandum, I am providing guidance to the Environmental Fate and Effects Division (EFED) on the review of common environmental fate studies conducted under Office of Chemical Safety and Pollution Prevention (OCSPP) guidelines.[1] EFED reviews the subject studies in support of drinking water exposure and ecological risk assessments. The attached seven study review guides (Attachments 1-7) are intended to help EFED scientists uniformly consider the issues, data, and formatting that are relevant to efficiently review these environmental fate studies. This guidance is effective immediately and supersedes the acceptance criteria for these environmental fate studies provided in the 1989 FIFRA Accelerated Reregistration Phase 3 Technical Guidance and the NAFTA-harmonized environmental fate study DER templates in the interim while the NAFTA-harmonized DER format is renegotiated with the NAFTA partners.

**Attachments**

Attachment 1: Hydrolysis Study Review Guide
Attachment 2: Aqueous Photolysis Study Review Guide
Attachment 3: Soil Photolysis Study Review Guide
Attachment 4: Soil Metabolism Study Review Guide
Attachment 5: Aquatic Metabolism Study Review Guide
Attachment 6: Batch Equilibrium Study Review Guide
Attachment 7: Field Dissipation Study Review Guide

[1] OCSPP guidelines are also referred to as OPPTS guidelines because the guidelines have not been updated following the Office of Prevention, Pesticides, and Toxic Substances' (OPPTS) name change to the Office of Chemical Safety and Pollution Prevention (OCSPP). Therefore, the term 'OPPTS' remains in the guidelines' text.

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

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AND POLLUTION PREVENTION

April 19, 2012

**MEMORANDUM**

**SUBJECT:** **Guidance for Reviewing Environmental Fate Studies**

**FROM:** Greg Orrick, Environmental Scientist
Gabe Rothman, Environmental Scientist
Rochelle Bohaty, Ph.D., Chemist
Katrina White, Ph.D., Biologist
Christopher Koper, Chemist
Robert Miller, Environmental Protection Specialist
Larry Liu, Ph.D., Environmental Scientist

**THROUGH:** Tiffany Dowen, FTT Co-chair
Karen Milians, FTT Co-chair
Mah Shamim, Ph.D., FTT Management Representative

**TO:** Donald Brady, Director
Environmental Fate and Effects Division
Office of Pesticide Programs

This memorandum announces study review guides to aid in the review of common environmental fate studies conducted under Office of Chemical Safety and Pollution Prevention (OCSPP) guidelines.[1] The Environmental Fate and Effects Division (EFED) reviews the subject studies in support of drinking water exposure and ecological risk assessments. The attached seven study review guides (Attachments 1-7) are intended to help EFED scientists uniformly consider the issues, data, and formatting that are relevant to efficiently review these environmental fate studies. This guidance should be effective immediately upon finalization and supersedes the acceptance criteria for these environmental fate studies provided in the 1989 FIFRA Accelerated Reregistration Phase 3 Technical Guidance. These guides also contain study review templates that update the NAFTA-harmonized environmental fate study DER templates. The updated study review templates should be used in the interim while the NAFTA-harmonized DER format is renegotiated with the NAFTA partners.

**Attachments**

Attachment 1: Hydrolysis Study Review Guide

[1] OCSPP guidelines are also referred to as OPPTS guidelines because the guidelines have not been updated following the Office of Prevention, Pesticides, and Toxic Substances' (OPPTS) name change to the Office of Chemical Safety and Pollution Prevention (OCSPP). Therefore, the term 'OPPTS' remains in the guidelines' text.

Attachment 2: Aqueous Photolysis Study Review Guide
Attachment 3: Soil Photolysis Study Review Guide
Attachment 4: Soil Metabolism Study Review Guide
Attachment 5: Aquatic Metabolism Study Review Guide
Attachment 6: Batch Equilibrium Study Review Guide
Attachment 7: Field Dissipation Study Review Guide

# Hydrolysis Study Review Guide

This guide is meant to aid in the review of hydrolyis studies submitted under the Office of Chemical Safety and Pollution Prevention (OCSPP) guideline 835.2120. The hydrolysis study review format is based on the format of the Organisation for Economic Co-operation and Development (OECD) Tier II Summaries (T2S)[1]. Reviewers should add to the T2S format any information, statistical calculations, and formatting that will increase their utility to the Agency under OCSPP guideline 835.2120. In developing study reviews, reviewers should strive to write concisely and to minimize alterations to the T2S format.

Sections I, II, and III of this document provide additional details regarding data, formatting, and issues to consider in developing OCSPP environmental fate study reviews. Section I identifies hydrolysis study data and formatting that do not appear in the OECD T2S format and that should be added to USEPA reviews. Although this guide does not strictly prescribe where and how to present the data, an example study review template is provided in Section II for guidance. In general, the example template should be followed, especially for unilateral reviews (*i.e.*, reviews conducted without the participation of other agencies). However, reviewers may modify the template as needed or disregard it in the case of multilateral reviews (*i.e.*, reviews with other agencies participating) in which an alternative format is agreed upon by the participating agencies. Lastly, a list of review considerations (Section III) is provided to help reviewers focus on critical study issues and to identify any common major or minor deficiencies (*i.e.*, the review considerations update the acceptance criteria for hydrolysis studies provided in the 1989 FIFRA Accelerated Reregistration Phase 3 Technical Guidance (USEPA, 1989)).

## References

U.S. Environmental Protection Agency (USEPA). 1989. FIFRA Accelerated Reregistration, Phase 3 Technical Guidance. Office of the Prevention, Pesticides, and Toxic Substances, Washington, DC. EPA 540/09-90-078.

[1] A Tier II Summary is an OECD format for study reviews prepared by industry. See OECD Guidance Documents for Pesticide Registration at http://www.oecd.org/document/48/0,3746,en_2649_34365_2085104_1_1_1_1,00.html (Accessed Mar. 3, 2011).

## Section I. Data to Include in the Hydrolysis OECD T2S Template

The following information should be added to the hydrolysis T2S template to make it compatible with OCSPP guideline 835.2120 and increase its utility to the Agency:

**First page and Executive Summary**

- The PC code of the test compound and MRID of the study should be provided in the header and on the first page.

- A statement should be included indicating whether the study was conducted in compliance with FIFRA GLP standards (and if not, how not or why not) and whether signed and dated Data Confidentiality, GLP Compliance, Quality Assurance, and Authenticity Certification statements were provided.

- The study classification and a concise statement of any deficiencies that impacted the classification should be provided on the first page of the review.

- A signature line(s) for the final reviewer(s) should be added to the first page of the review. If this is unacceptable for other agencies participating in a multilateral review, then a cover page with the signature line(s) can be attached to each individual review submitted to EFED's files.

- A results synopsis should be added to the Executive Summary to tabulate half-lives, including how they were calculated, as well as a list of transformation products and the maximum amount formed (from individual replicate values, not the mean value) and the interval at which the maximum occurred. Tabulated information should not be summarized in the text of the Executive Summary.

**Materials and Methods**

- The Test Material section should list the names and batch numbers of reference compounds used and provide a small image of the test compound structure with any radiolabeled atoms identified.

- Physicochemical properties of the test compound that are relevant to the study should be listed in the Test Material section. Irrelevant properties should not be listed.

- Initial measured concentrations should be reported in the Experimental Conditions section.

- If samples are stored, storage stability information should be described.

**Results and Discussion**

- The results of any checks on pH, sterility, sorption to vessel walls, or other test conditions should be reported in the Findings section.

- Observed $DT_{50}$ values and indications of how half-lives were calculated (*e.g.*, single first order (SFO)) should be added to the half-life tables in the Findings section.

- The Findings section should indicate whether reviewer-reported half-lives are consistent with study-reported values and observed values.

**Study Deficiencies and Reviewer's Comments**

- The Conclusions section should list any deficiencies with the study and any additional salient information; this section may be renamed "Study Deficiencies and Reviewer's Comments." Results and conclusions contained in the Executive Summary should not be repeated in this section.

**References**

- A References section (Section IV) should be added that lists any literature references other than the study report cited in the study review.

**Attachments**

- A table (*i.e.*, structure table) of the chemical names, SMILES strings, CAS numbers, and structures of the test compound, all identified transformation products, and all reference compounds that were not identified in study samples should be either referenced as a separate, associated document or attached to the study review. Multiple versions of structures to show or not show radiolabeling and multiple versions of chemical names and SMILES strings should not be 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.

  For multilateral reviews, chemical names, SMILES strings, structures, and CAS numbers are captured elsewhere in the Monograph[2]. 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, the Monograph's structure table should be either referenced as a separate, associated document or attached to each individual review.

[2] 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.

- Statistical output files containing calculations (such as statistical analyses and outputs) and graphs that support values reported in the study review should be attached to the review. File names should begin with the same name as that of the individual review. For multilateral reviews, the file naming convention should consistently follow an agreed format.

- A Calculations section should be added that lists equations and defines parameters used to calculate half-lives. This section is currently placed in Attachment III but may be placed in Section I.B.4.

## Section II. Example Hydrolysis Study Review Template

### Hydrolysis of [test compound] at pH [4, 7, and 9, or other values studied]

**Report:** [Provide full citation. Provide the MRID (first) if the review is unilateral.]
**Document No.:** [MRID xxxxxxxx]
**Guideline:** OCSPP 835.2120
[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 835.2120.' 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 how not or why not.]
**Classification:** This study is [provide classification and 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:** [xxxxxx]
**Reviewer:** [Provide final reviewer(s)'s name and title.] **Signature:**
**Date:** [Type date of signature.]

### Executive Summary

The abiotic hydrolysis of [type of radiolabel(s)]-labeled [test compound] at [measured concentration] was investigated in sterile aqueous buffered solutions at pH 4, 7, and 9. A pre-test was conducted in the dark at each pH at 50°C for [5 days or other duration] and was followed by additional tests at each pH conducted at 25°C and at [10°C or other temperature] for [duration]. Duplicate test vessels were collected and analyzed using [methods used (*e.g.*, LSC and HPLC-UV].

**Table 1. Results Synopsis**

| pH | Observed $DT_{50}$ (days) | SFO Half-life [A] (days) | Model Parameters and Statistics | Transformation Products Common Name (maximum %AR [B] observed, associated interval) | |
|---|---|---|---|---|---|
| | | | | Major | Minor |
| 50°C [modify table as needed for other temperatures] | | | | | |
| 4 | [value] | [value] | $C_0$=[#], k=[#], $S_{SFO}$=[#], $r^2$=[#], p=[#] | [name] (#%, # d) | [name] (#%, # d) |
| 7 | [value] | [value] | $C_0$=[#], k=[#], $S_{SFO}$=[#], $r^2$=[#], p=[#] | [name] (#%, # d) | [name] (#%, # d) |
| 9 | [value] | [value] | $C_0$=[#], k=[#], $S_{SFO}$=[#], $r^2$=[#], p=[#] | [name] (#%, # d) | [name] (#%, # d) |

[A] The Single First-Order (SFO) kinetics model is used to describe hydrolytic degradation.
[B] AR means "applied radioactivity."

## I. Material and Methods

### A. Materials:

Provide a small image of the test compound's structure and any radiolabel on the right margin.

1. **Test Material:** [[Type of radiolabel]-labeled[test compound]
   Specific radioactivity: [value] MBq/mg
   Radiochemical purity: [percentage (HPLC, TLC)]
   Chemical purity: [percentage (HPLC)]
   Batch number: [value]
   Solubility in water: [value] mg/L [If pH-dependent, list available values at each study pH.]

2. **Reference Compounds:** [List the common name and batch number of each reference compound. Provide other chemical information in the structure table.]

3. **Buffer:** 0.01 M sterile aqueous buffer solutions were prepared at pH 4 using [compound(s)], pH 7 using [compound(s)], and pH 9 using [compound(s)].

**B. Study Design:** [Tabulation of these data is encouraged as long as the length of this section is not substantially increased.]

1. **Experimental conditions:** The abiotic hydrolysis of [[type of radiolabel(s)]-labeled[test compound] at [measured concentration] was investigated in sterile aqueous buffered solutions at pH 4, 7, and 9. Equipment was sterilized by [method]. A pre-test was conducted in the dark at each pH at 50°C for [5 days or other duration] and was followed by additional tests at each pH conducted at 25°C and at [10°C or other temperature] for [duration]. The tests were performed at a nominal concentration(s) of [value] in sealed [vessel type] test vessels with [trapping method and type of traps, if any] for volatiles. Measured concentrations were [list values]. The cosolvent used ([(concentration) solvent]) was [percentage v/v] of the sample solutions. [If sterility was checked during the study, indicate the method used.]

2. **Sampling:** Duplicate test vessels [volume] were taken for analysis at [list intervals, per system if different] after application. [Report the sampling interval of any checks on pH, temperature, or sterility.]

3. **Analytical procedures:** Samples were analyzed using [LSC] for determination of total radioactivity. [Reversed-phase HPLC with $^{14}$C-flow-through detection techniques and normal phase TLC] were used as primary and confirmatory chromatographic methods for the separation and quantitation of products formed. The limit of detection (LOD) was determined to be [percentage] of the applied radioactivity (%AR), with a limit of quantitation (LOQ) at [percentage]AR).

## II. Results and Discussion

**A. Mass Balance:** Recoveries ranged from [percentage] to [percentage]AR at pH 4, [percentage] to [percentage]AR at pH 7, and [percentage] to [percentage]AR at pH 9. [Indicate whether there was substantial loss of radioactivity by sorption to glassware or volatilization. Indicate whether a substantial amount of radioactivity was unidentified.]

**B. Findings:** The results including total mass balances and distribution of radioactivity are presented in [table(s)]. [Individual replicate values are reported rather than means and standard deviations.] [Indicate the result of any checks on pH, sterility, or other test condition.]

**Table 2. Hydrolysis of [radiolabel-test compound] at pH [value] and [temperature] expressed as percentage of applied radioactivity [Duplicate table as needed for additional pH values, temperatures, and radiolabels.]**

| pH [#], [#]°C | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Sampling Interval (days)** | **[Int. 1]** | **[Int. 1]** | **[Int. 2]** | **[Int. 2]** | **[Int. 3]** | **[Int. 3]** | **[Int. 4]** | **[Int. 4]** | **[Int. 5]** | **[Int. 5]** | **[Int. 6]** | **[Int. 6]** |
| **Replicate Number** | **1** | **2** | **1** | **2** | **1** | **2** | **1** | **2** | **1** | **2** | **1** | **2** |
| [Test compound] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] |
| [Product 1] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] |
| [Product 2] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] |
| Unidentified | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] |
| Volatile organics | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] |
| $CO_2$ | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] |
| Radioactivity at walls of test vessel | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] |
| Mass balance | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] |

n.d. = not detected, n.a. = not analyzed

**Table 3. Hydrolysis kinetics of [radiolabel-test compound] in aqueous buffer solutions [A]**

| pH | Observed $DT_{50}$ (days) | Observed $DT_{90}$ (days) | Calculated Half-life [B] (days) | SFO Model Parameters [B] | SFO Model Statistics |
|---|---|---|---|---|---|
| **50°C** | | | | | |
| 4 | [value] | [value] | [value] | $C_0$=[#], k=[#] | $S_{SFO}$=[#], $r^2$=[#], p=[#] |
| 7 | [value] | [value] | [value] | $C_0$=[#], k=[#] | $S_{SFO}$=[#], $r^2$=[#], p=[#] |
| 9 | [value] | [value] | [value] | $C_0$=[#], k=[#] | $S_{SFO}$=[#], $r^2$=[#], p=[#] |
| **25°C** | | | | | |
| 4 | [value] | [value] | [value] | $C_0$=[#], k=[#] | $S_{SFO}$=[#], $r^2$=[#], p=[#] |
| 7 | [value] | [value] | [value] | $C_0$=[#], k=[#] | $S_{SFO}$=[#], $r^2$=[#], p=[#] |
| 9 | [value] | [value] | [value] | $C_0$=[#], k=[#] | $S_{SFO}$=[#], $r^2$=[#], p=[#] |
| **[10°C or other third temperature]** | | | | | |
| 4 | [value] | [value] | [value] | $C_0$=[#], k=[#] | $S_{SFO}$=[#], $r^2$=[#], p=[#] |
| 7 | [value] | [value] | [value] | $C_0$=[#], k=[#] | $S_{SFO}$=[#], $r^2$=[#], p=[#] |
| 9 | [value] | [value] | [value] | $C_0$=[#], k=[#] | $S_{SFO}$=[#], $r^2$=[#], p=[#] |

[A] Data were obtained from [location of data in study report] and calculations in the attached Excel workbook [name(s) of worksheets, if needed]. See Attachment 3 for calculations.
[B] The Single First-Order (SFO) kinetics model is used to describe hydrolytic degradation.

[Images of kinetics calculation results using the R program may replace **Table 3**. R images should include the model parameters and statistics that are otherwise reported in **Table 3**.]

[Half-lives should be calculated with non-linear regression assuming single first-order (SFO) kinetics and following the NAFTA kinetics guidance (USEPA, 2011). Other half-life calculation methods may be added to the table when needed, such as when degradation is not first-order. Rows may be added for transformation product half-lives and $DT_{50}$s as needed. If multiple experiments were conducted per study condition using test compound with different radiolabel positions, calculate kinetics values for the combined data rather than for specific radiolabel positions.]

[Indicate whether reviewer-reported half-lives are consistent with study-reported values.]

**Table 4. Hydrolytic Products of [Test Compound]**

| pH | Transformation Product(s) | Maximum %AR Observed | Associated Interval | Final %AR Observed | Final Interval |
|---|---|---|---|---|---|
| **50°C [modify table as needed for other temperatures]** | | | | | |
| 4 | [common name] | [#] | [# d] | [#] | [# d] |
| | [common name] | [#] | [# d] | [#] | [# d] |
| 7 | [common name] | [#] | [# d] | [#] | [# d] |
| | [common name] | [#] | [# d] | [#] | [# d] |
| 9 | [common name] | [#] | [# d] | [#] | [# d] |
| | [common name] | [#] | [# d] | [#] | [# d] |

[If applicable, provide a description of the transformation pathway here, including a schematic as Figure 1.]

**[Figure 1. Hydrolysis Pathway of [radiolabel-test compound]]**

## III. Study Deficiencies and Reviewer's Comments

[This section is titled "Conclusions" in the original T2S template.]

[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.]

## IV. References [List any references cited in the review.]

U.S. Environmental Protection Agency (USEPA). 2011. Guidance for Evaluating and Calculating Degradation Kinetics in Environmental Media. (Interim draft document dated Dec. 21, 2011.)

**Attachment 1: Chemical Names and Structures**

[A table (*i.e.*, structure table) of the chemical names, SMILES strings, CAS numbers, and structures of the test compound, all identified transformation products, and all reference compounds that were not identified in study samples should be either referenced as a separate, associated document or attached to the study review. Multiple versions of structures to show or not show radiolabeling and multiple versions of chemical names and SMILES strings should not be 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.

For multilateral reviews, chemical names, SMILES strings, structures, and CAS numbers are captured elsewhere in the Monograph[3]. 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, the Monograph's structure table should be either referenced as a separate, associated document or attached 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.]

Degradate Table.docx

[3] 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.

**Attachment 2: Statistics Spreadsheets and Graphs**

Hydrolysis Study
Review Spreadsheets

[Supporting electronic spreadsheet files should be inserted here; electronic attachment files should be electronically finalized as separate files as well. Electronic attachments should have 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. Electronic attachment files should be compressed into a WinZip file when three or more are prepared for a study review.]

[Hard copies of a study review and any attachment sheets from separate electronic files should be printed and finalized together as one hard copy file.]

[The attached Excel file has two example spreadsheets for mass balance and kinetics calculations.]

**Attachment 3: Calculations**

Calculations were performed by the reviewer using [indicate program(s) used for calculations] and the following equations. [The following equations are anticipated to reflect the NAFTA kinetics guidance as of January, 2012. If these equations are not current, they should be replaced by the applicable equations from current guidance.]

**Single First-Order (SFO) Model**

$$C_t = C_0 e^{-kt} \quad \text{(eq. 1)}$$

where,

$C_t$ = concentration at time t (%)
$C_0$ = initial concentration (%)
e = Euler's number (-)
k = SFO rate constant of decline ($d^{-1}$)
t = time (d)

The SFO equation is solved [with the Excel Solver] by adjusting $C_0$ and $k$ to minimize the objective function ($S_{SFO}$) shown in equation 4.

$DT_{50}$ = natural log (2)/k (eq. 2)

$DT_{90}$ = ln (10)/k (eq. 3)

$$S_{SFO} = \sum (C_{model,t} - C_{d,t})^2 \quad \text{(eq. 4)}$$

where,

$S_{SFO}$ = objective function of SFO model fit ($\%^2$)
n = number of data points (-)
$C_{model,t}$ = modelled value at time corresponding to $C_{d,t}$ (%)
$C_{d,t}$ = experimental concentration at time t (%)

## Section III. Hydrolysis Study Review Considerations

This list of considerations is provided to help reviewers assess the acceptability of hydrolysis studies. This list is not a screen or a checklist and should not be attached to the study reviews. Listed considerations carry unequal weight and should be evaluated using best professional judgment. All information from the study and from similar studies should be considered to determine whether any deficiencies affect the study classification.

» Raw measured data and representative chromatographs were provided.

» The test compound was Technical Grade (TGAI) or a Pure Active Ingredient Radiolabeled (PAIRA) compound.

» The radiopurity and specific activity of the test compound were provided (if radiolabeled).

» Radiolabel positioning was appropriate. For compounds containing ring structures, experiments were conducted separately for each respectively labelled ring structure and test compounds were not radiolabelled on more than one ring structure in each experiment.

» The test compound solubility in water was reported (at each pH tested, if pH-dependent). Also, the concentration of the test compound in each system was below its water solubility or below its solubility in the test solution, if known.

» The study was conducted in darkness.

» If the test compound is susceptible to oxidation, the systems were purged with helium, argon, or nitrogen gas.

» The study was conducted initially at 50°C (unless known to be stable at environmental temperatures). If ≥10% of the test compound hydrolyzed after 5 days at 50°C, the study was conducted at two additional temperatures, including 25°C and a lower temperature preferably, but not less than, 10°C.

» The temperatures were held at ±1°C (the guideline states ±0.5°C).

» The sterility of study equipment, reagents, and chemicals was assured.

» The solutions were buffered.

» The cosolvent (if any) did not exceed 1% (v/v).

» Volatiles, if any, were trapped.

» Sampling intervals were adequate to describe the decline of the test compound and the formation and decline of major transformation products.

» All chromatographic peaks were quantified unless <LOQ.

» Sufficient attempts were made to identify and confirm the identity of all major transformation products and any minor products known or suspected to be of toxicological concern. If attempts failed, unidentified residues were confirmed not to be of concern.

» The study was conducted for at least one half-life or 30 days if one half-life did not pass.

» The material balance was >90% to <110% of the applied radioactivity (AR).

» Appropriate analytical methods were used, with LOQs <2.5% AR for the test compound and major transformation products.

» Limits of detection and quantitation were reported.

» Half-lives were calculated.

# Aqueous Photolysis Study Review Guide

This guide is meant to aid in the review of photodegradation in water studies submitted under the Office of Chemical Safety and Pollution Prevention (OCSPP) guideline 835.2240 and the Organisation for Economic Co-operation and Development (OECD) guideline 316. The aqueous photolysis study review format is based on the format for the OECD Tier II Summaries (T2S)[1]. Reviewers should add to the T2S format any information, statistical calculations, and formating which will increase their utility to the Agency under OCSPP guideline 835.2240. In developing study reviews, reviewers should strive to write concisely and minimize alterations to the T2S format.

Sections I, II, and III of this document provide additional details regarding formatting, data, and issues to consider in developing OCSPP environmental fate study reviews. Section I identifies aqueous photolysis data and formatting that do not appear in the OECD T2S format and that should be added to USEPA reviews. Although this guide does not strictly prescribe where and how to present the data, an example study review template is provided in Section II for guidance. In general, the example template should be followed, especially for unilateral reviews (*i.e.*, reviews conducted without the participation of other agencies). However, reviewers may modify the templates as needed or disregard it in the case of multilateral reviews (*i.e.*, reviews with other agencies participating) in which an alternative format is agreed upon by the participating agencies. Lastly, a list of review considerations (Section III) is provided to help reviewers focus on critical study issues and to identify any common major or minor deficiencies (*i.e.*, the review considerations update the acceptance criteria for aqueous photolysis studies provided in the 1989 FIFRA Accelerated Reregistration Phase 3 Technical Guidance (USEPA, 1989)).

## References

Organisation for Economic Co-operation and Development (OECD). 2008. Test No. 316: Phototransformation of Chemicals in Water – Direct Photolysis, OECD Guidelines for the Testing of Chemicals, Section 3: Degradation and Accumulation, OECD Publishing. DOI: 10.1787/9789264067585-en

U.S. Environmental Protection Agency (USEPA). 1989. FIFRA Accelerated Reregistration, Phase 3 Technical Guidance. Office of the Prevention, Pesticides, and Toxic Substances, Washington, DC. EPA 540/09-90-078.

[1] A Tier II Summary is an OECD format for study reviews prepared by industry. See OECD Guidance Documents for Pesticide Registration at http://www.oecd.org/document/48/0,3746,en_2649_34365_2085104_1_1_1_1,00.html (Accessed Mar. 3, 2011).

## Section I. Data to Include in the Aqueous Photolysis OECD T2S Template

The following information should be added to the aqueous photolysis T2S template to make it compatible with OCSPP guideline 835.2240 and increase its utility to the Agency:

**First page**

- The PC code of the test compound and MRID of the study should be provided in the header and on the first page.

- A statement should be included indicating whether the study was conducted in compliance with FIFRA GLP standards (and if not, how not or why not) and whether signed and dated Data Confidentiality, GLP Compliance, Quality Assurance, and Authenticity Certification statements were provided.

- The study classification and a concise statement of any deficiencies that impacted the classification should be provided on the first page of the review.

- A signature line(s) for the final reviewer(s) should be added to the first page of the review. If this is unacceptable for other agencies participating in a multilateral review, then a cover page with the signature line(s) can be attached to each individual review submitted to EFED's files.

- A results synopsis should be added to the Executive Summary to tabulate half-lives, including how they were calculated, as well as a list of transformation products and the maximum amount formed (from individual replicate values, not the mean value) and the interval at which the maximum occurred. Tabulated information should not be summarized in the text of the Executive Summary.

**Materials and Methods**

- The Test Material section should list the names and batch numbers of reference compounds used and provide a small image of the test compound structure with any radiolabeled atoms identified.

- Physicochemical properties of the test compound that are relevant to the study should be listed in the Test Material section. Irrelevant properties should not be listed.

- Initial measured concentrations should be reported in the Experimental Conditions section.

- If samples are stored storage stability information should be described.

**Results and Discussion**

- The results of any checks on pH, sterility, sorption to vessel walls, or other test conditions should be reported in the Findings section.

- Observed $DT_{50}$ values and indications of how half-lives were calculated (*e.g.*, single first order (SFO)) should be added to the half-life tables in the Findings section.

- The Findings section should indicate whether reviewer-reported half-lives are consistent with study-reported values and observed values.

**Study Deficiencies and Reviewer's Comments**

- The Conclusions section should list any deficiencies with the study and any additional salient information; this section may be renamed "Study Deficiencies and Reviewer's Comments." Results and conclusions contained in the Executive Summary are not repeated in this section in order to reduce redundancy.

**References**

- A References section (Section III) should be added that lists any literature references other than the study report cited in the study review.

**Attachments**

- A table (*i.e.*, structure table) of the chemical names, SMILES strings, CAS numbers, and structures of the test compound, all identified transformation products, and all reference compounds that were not identified in study samples should be either referenced as a separate, associated document or attached to the study review. Multiple versions of structures to show or not show radiolabeling and multiple versions of chemical names and SMILES strings should not be 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.

  For multilateral reviews, chemical names, SMILES strings, structures, and CAS numbers are captured elsewhere in the Monograph[2]. 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, the Monograph's structure table should be either referenced as a separate, associated document or attached to each individual review.

[2] 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.

- Statistical output files containing calculations (such as statistical analyses and outputs) and graphs that support values reported in the study review should be attached to the review. File names should begin with the same name as that of the individual review. For multilateral reviews, the file naming convention should consistently follow an agreed format.

- A Calculations section should be added that lists equations and defines parameters used to calculate half-lives. This section is currently placed in Attachment III but may be placed in Section I.B.3.

## Section II. Example Aqueous Photolysis Study Review Template

**Aqueous Photolysis of [test compound]**

| | |
|---|---|
| **Report:** | [Provide full citation. Provide the MRID (first) if the review is unilateral.] |
| **Document No.:** | [MRID xxxxxxxx] |
| **Guideline:** | OCSPP 835.2240<br>[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 835.2410.' 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 how not or why not.] |
| **Classification:** | This study is [provide classification and 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:** | [xxxxxx] |
| **Reviewer:** | [Provide final reviewer(s)'s name and title.] **Signature:**<br>**Date:** [Type date of signature.] |

**Executive Summary**

In an aqueous photolysis study, the phototransformation of [[type of radiolabel(s)]-labeled[test compound] was investigated in [sterile aqueous buffered solutions at pH # (buffer used)] at [x] ± [x] °C using [light source] for a period of [x] days (equivalent to [x] days natural summer sunlight at 40 °N). Test and control soil samples were treated at [test concentration] mg a.i./kg, which is equivalent to a field application rate of [#] g a.i./ha ([#] lbs a.i./a). A control experiment was conducted under the same experimental conditions except the control samples were kept in the dark (absence of light). Duplicate samples were collected and analyzed using [methods used (*e.g.*, LSC and HPLC-UV].

The phototransformation profile of [test compound] was [similar/different] for both irradiated and control samples indicating. [Add a brief sentence to explain the pattern of degradation. If the phototransformation is not first order, additional discussion is needed.] The overall mass balance for the study ranged from [# to #]. The test system [was/was not] adequate to trap both organic and inorganic volatile compounds. $CO_2$ accounted for up to [x]% of applied radioactivity. Other volatile compounds accounted for [#]% of the applied radioactivity. Major phototransformation products included [x], [y], and [z]. The observed $DT_{50}$ for the phototransformation of [test compound] was [#] days. The calculated dark control-adjusted $DT_{50}$ for the phototransformation of [test compound] under summer sun at 40 °N latitude was [#] days. More information on the phototransformation of [test compound] is provided in **Table 1**. [If the environmentally relevant

half-life cannot be calculated, include a brief summary of why it cannot be calculated. Include a brief description of how the estimated and observed $DT_{50}$ values compare and state the best fit model used.]

The duration of the experiment was [not adequate/adequate] to observe the formation and decline of the transformation products. [If a natural water source was used, explain the relevance and usefulness of the data.] The calculated $DT_{50}$ values for the major transformation product(s) [name(s) here] ranged from [#] to [#] days, respectively.[3]

**Table 1. Results Synopsis: Aqueous Phototransformation of [Test Compound]**

| Compound Name | Observed $DT_{50}$ (hours/days) | Observed $DT_{90}$ (hours/days) | SFO Half-life [A] (hours/days) | Model Parameters and Statistics | Adjusted Half-life (days) [B] | Phototransformation Products (Common Name (maximum %AR [C] observed, associated interval)) | |
|---|---|---|---|---|---|---|---|
| | | | | | | Major | Minor Identified |
| **Irradiated: [buffer or natural water, pH #, # °C]** | | | | | | | |
| **Parent [test compound]** | [#] | [#] | [#] | $C_0$=[#], k=[#], $S_{SFO}$=[#], $r^2$=[#], p=[#] | [#] | [name] (# %, # days) | [name] (# %, # days) |
| **[Transformation product]*** | [#] | [#] | [#] | $C_0$=[#], k=[#], $S_{SFO}$=[#], $r^2$=[#], p=[#] | [#] | [name] (# %, # days) | [name] (# %, # days) |

[A] The Single First-Order (SFO) kinetics model is used to describe abiotic photolytic degradation.
[B] Dark control-adjusted and adjusted to a 12-hour/day photoperiod at 40 °N latitude.
[C] AR means "applied radioactivity."
[If the experiment permits half-life calculations for phototransformation products, include the information in this table.]

[3] [Calculate the half-life values for transformation products based on the maximum amount of the transformation product observed and its decline over at least four sampling intervals. Simultaneous formation and decline of the transformation product was not accounted for in the calculation or discuss how it was taken into account.]

## I. Material and Methods

### A. Materials:

Provide a small image of the test compound's structure and any radiolabel on the right margin.

1. **Test Material:** [[Type of radiolabel]-labeled[test compound]
   Specific radioactivity: [value; units]
   Radiochemical purity: [percentage (HPLC, TLC)]
   Chemical purity: [percentage (HPLC)]
   Batch number: [value]
   Solubility in water: [value] mg/L [If pH-dependent, list available values at each study pH.]

2. **Reference Compounds:** [List the common name and batch number of each reference compound. Provide other chemical information in the structure table.]

3. **Test Media:** [Describe buffered solutions of natural water used in experiments]

**Table 2. Physicochemical Properties of [media] used in photolysis study**

| Property | Reported Value |
|---|---|
| pH | [#] |
| Electrical Conductivity (µS/cm) | [#] |
| Total Carbon (mg/L) | [#] |
| Total Inorganic Carbon (mg/L) | [#] |
| Total Suspended Solids (mg/L) | [#] |
| Nitrate-Nitrogen (mg/L) | [#] |
| Ammonium-Nitrogen (mg/L) | [#] |
| Alkalinity as $HCO^-_3$ (mg/L) | [#] |
| Total Magnesium (mg/L) | [#] |
| Total Calcium (mg/L) | [#] |
| Total Iron (mg/L) | [#] |
| Total Dissolved Iron (mg/L) | [#] |
| Ferric Ion Concentration (mg/L) | [#] |
| Ferrous Ion Concentration (mg/L) | [#] |

### B. Study Design:

1. **Experimental Conditions:**

[If molar absorptivity was investigated and reported in the study report include the methods used and reference the tiered experimental design.]

**Table 3. Experimental Design**

| Parameter | Description |
|---|---|
| Nature of light source | |
| Emission wavelength | |

| | | |
|---|---|---|
| spectrum | | |
| Nominal light intensity | | |
| Filters used | | |
| Relationship to natural sunlight | | |
| Method used to determine relations between light source and summer sunlight (*e.g.*, 40 °N) | | |
| Duration of the test | | |
| Solution volume | | |
| Sterilization method | | |
| Test concentration (µg ai/L) | | |
| Control conditions | | |
| Number of replicates | Irradiated | |
| | Darkness | |
| Test apparatus | Irradiated | |
| | Darkness | |
| Traps | Organics | |
| | $CO_2$ | |
| Test material application | Solvent | |
| | Test solution volume used/ treatment | |
| | Application method | |
| | Evaporation of application solvent | |
| Indication of test material adsorbing to walls of test apparatus | | |
| Experimental conditions | Temperature (°C) | |
| | Continuous irradiation | |
| | Moisture content | |
| | Moisture maintenance method | |
| | Continuous darkness (Yes/No): | |

| | |
|---|---|
| Sample storage before analysis | |

**2. Description of Analytical Procedures:**

Samples were analyzed using [LSC] for determination of total radioactivity. [Reversed-phase HPLC with $^{14}C$-flow-through detection techniques and normal phase TLC] were used as primary and confirmatory chromatographic methods for the separation and quantitation of products formed. The limit of detection (LOD) was determined to be [percentage] of the applied radioactivity (%AR), with a limit of quantitation (LOQ) at [percentage]AR.

## II. Results and Discussion

[If molar absorptivity was investigated and reported in the study report, include the results of the study here referencing the tiered experimental design.]

**A. Data:**

**Table 4. Aqueous Photodegradation of [radiolabel-test compound] expressed as percentage of applied radioactivity** [Add to the table as needed for additional media such as natural water. The results including total mass balances and distribution of radioactivity are presented as individual replicate values rather than means and standard deviations.]

| | **Percent of Applied Radioactivity** | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Sampling Interval (hours)** | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] |
| **Replicate** | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] |
| **Component** | **Irradiated [media, pH #, # °C]** | | | | | | | | | | | | | |
| [Test compound] | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| [Degradate 1] | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| [Degradate 2] | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Unidentified | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Volatiles | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| $^{14}CO_2$ | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Mass Balance** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Sampling Interval (hours)** | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] |
| **Replicate** | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] |
| **Component** | **Control (Dark)[media, pH #, # °C]** | | | | | | | | | | | | | |
| [Test compound] | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| [Degradate 1] | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| [Degradate 2] | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Unidentified | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Volatiles | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| $^{14}CO_2$ | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Mass Balance** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

Data obtained from [Table #, pp. #] of the study report.
Total Characterized Residues is the sum of identified and unidentified extractable residues and volatilized compounds.
n.d. = not detected, n.a. = not analyzed

**B. Mass Balance:**

Recoveries ranged from [percentage] to [percentage]AR for the irradiated experiment and [percentage] to [percentage]AR for the control experiment. [Indicate whether there was substantial loss of radioactivity by sorption to glassware or volatilization. Indicate whether a substantial amount of radioactivity was unidentified.]

**C. Volatilization:**

Volatiles [were/were not] trapped. The level of $CO_2$ evolved was [#]%.[Add information regarding additional volatile chemical as need.]

**D. Transformation of Test Compound:**

Degradation of [radiolabel-test compound] in water was [gradual, rapid, or some other characterization]. The $DT_{50}$ ranged from [x] to [x] as highlighted in **Table 5**. [Indicate the software used to determine model parameters. Indicate whether reviewer-reported half-lives are consistent with study-reported values and the relationship between calculated and observed values. If multiple experiments were conducted per study condition such as using two different test compounds (*i.e.*, different radiolabels), calculate kinetic values for combined data. Discuss any abnormalities observed in the data.]

[Images of kinetics calculation results using the R program may replace most of **Table 5** (dark-control adjusted half-lives and environmental half-lives would still need to be reported). R images should include the model parameters and statistics that are otherwise reported in **Table 5**.]

**Table 5. Aqueous Phototransformation of [Test Compound] [A]**

| Compound Name | Observed $DT_{50}$ (hours/days) | Observed $DT_{90}$ (hours/days) | Calculated Half-life [B] (days) | SFO Model Parameters [B] | SFO Model Statistics | Dark Control Adjusted Half-life (days) [C] | Environmental Half-life (days) [C] |
|---|---|---|---|---|---|---|---|
| **Parent [test compound]** | [#] | [#] | [#] | $C_0$=[#], k=[#] | $S_{SFO}$=[#], $r^2$=[#], p=[#] | [#] | [#] |
| **Control: Parent [test compound]** | [#] | [#] | [#] | $C_0$=[#], k=[#] | $S_{SFO}$=[#], $r^2$=[#], p=[#] | | |
| **Degradate [compound]*** | [#] | [#] | [#] | $C_0$=[#], k=[#] | $S_{SFO}$=[#], $r^2$=[#], p=[#] | [#] | [#] |
| **Control: Degradate [compound]*** | [#] | [#] | [#] | $C_0$=[#], k=[#] | $S_{SFO}$=[#], $r^2$=[#], p=[#] | | |

[A] Data were obtained from [location of data in study report] and calculations in the attached Excel workbook [name(s) of worksheets, if needed]. See Attachment 3 for calculations.

[B] The Single First-Order (SFO) kinetics model is used to describe abiotic photolytic degradation.

[C] Half-life value was adjusted to a 12-hour/day photoperiod under summer sun at 40 °N latitude).

[Half-lives should be calculated with non-linear regression assuming single first-order (SFO) kinetics and following the NAFTA kinetics guidance (USEPA, 2011). Other half-life calculation methods may be added to the table when needed, such as when degradation is not first-order. Rows may be added for transformation product half-lives and $DT_{50}$s as needed. If multiple experiments were conducted per study condition using test compound with different radiolabel positions, calculate kinetics values for the combined data rather than for specific radiolabeled positions.]

[Briefly summarize the transformation products per system in **Table 6**. If transformation product decline is observed over four time intervals, calculate a half-life and discuss the pattern of decline. Based on the control experiment, discuss which transformation products are the likely result of phototransformation as compared to other degradation processes.]

**Table 6. Transformation Products of [Test Compound] in Water**

| | Transformation Product(s) | Maximum %AR Observed | Associated Interval | Final %AR Observed | Final Interval |
|---|---|---|---|---|---|
| **Irradiated Samples** | [common name] | [#] | [# d] | [#] | [# d] |
| | [common name] | [#] | [# d] | [#] | [# d] |
| **Controls** | [common name] | [#] | [# d] | [#] | [# d] |
| | [common name] | [#] | [# d] | [#] | [# d] |

[If applicable, provide a description of the transformation pathway here, including a schematic as Figure 1.]

**[Figure 1. Aqueous Phototransformation Pathway of [radiolabel-test compound]]**

**E. Findings:**

[Include the result of any checks on pH, sterility, or other test condition. Don't repeat information in the executive summary. If no additional information is needed refer to the Executive Summary]

## III. Study Deficiencies and Reviewer's Comments

[This section is titled "Conclusions" in the original T2S template.]

[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.]

## IV. References [List any references cited in the review.]

U.S. Environmental Protection Agency (USEPA). 2011. Guidance for Evaluating and Calculating Degradation Kinetics in Environmental Media. (Interim draft document dated Dec. 21, 2011.)

**Attachment 1: Chemical Names and Structures**

[A table (*i.e.*, structure table) of the chemical names, SMILES strings, CAS numbers, and structures of the test compound, all identified transformation products, and all reference compounds that were not identified in study samples should be either referenced as a separate, associated document or attached to the study review. Multiple versions of structures to show or not show radiolabeling and multiple versions of chemical names and SMILES strings should not be 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.

For multilateral reviews, chemical names, SMILES strings, structures, and CAS numbers are captured elsewhere in the Monograph[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, the Monograph's structure table should be either referenced as a separate, associated document or attached 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.]

Degradate Table.docx

[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.

**Attachment 2: Statistics Spreadsheets and Graphs**

Aqueous Photolysis
Study Review Tables

[Supporting electronic spreadsheet files should be inserted here (electronic attachment files should be electronically finalized as separate files as well). Electronic attachments should have 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. Electronic attachment files should be compressed into a WinZip file when three or more are prepared for a study review.]

[Hard copies of a study review and any attachment sheets from separate electronic files should be printed and finalized together as one hard copy file.]

**Attachment 3: Calculations**

Calculations were performed by the reviewer using [indicate program(s) used for calculations] and the following equations. [The following equations are anticipated to reflect the NAFTA kinetics guidance as of January 2012. If these equations are not current, they should be replaced by the applicable equations from current guidance.]

**Single First-Order (SFO) Model**

$$C_t = C_0 e^{-kt} \quad \text{(eq. 1)}$$

where,

$C_t$ = concentration at time t (%)
$C_0$ = initial concentration (%)
e = Euler's number (-)
k = SFO rate constant of decline ($d^{-1}$)
t = time (d)

The SFO equation is solved [with the Excel Solver] by adjusting $C_0$ and $k$ to minimize the objective function ($S_{SFO}$) shown in equation 4.

$DT_{50}$ = natural log (2)/k (eq. 2)

$DT_{90}$ = ln (10)/k (eq. 3)

$$S_{SFO} = \sum(C_{model,t} - C_{d,t})^2 \quad \text{(eq. 4)}$$

where,

$S_{SFO}$ = objective function of SFO model fit ($\%^2$)
n = number of data points (-)
$C_{model,t}$ = modelled value at time corresponding to $C_{d,t}$ (%)
$C_{d,t}$ = experimental concentration at time t (%)

## Section III. Aqueous Photolysis Study Review Considerations

This list of considerations is provided to help reviewers assess the acceptability of aqueous photolysis studies. This list is not a screen or a checklist and should not be attached to the study reviews. Listed considerations carry unequal weight and should be evaluated using best professional judgment. All information from the study and from similar studies should be considered to determine whether any deficiencies affect the study classification.

» Raw measured data and representative chromatographs were provided.

» The test compound was Technical Grade (TGAI) or a Pure Active Ingredient Radiolabeled (PAIRA) compound.

» The radio purity and specific activity of the test compound was provided (if radiolabeled).

» Radiolabel positioning was appropriate. For compounds containing ring structures, experiments were conducted separately for each respectively labelled ring structure and test compounds were not radiolabelled on more than one ring structure in each experiment.

» The test compound solubility in water was reported (at each pH tested, if pH-dependent). And the concentration of the test compound in each system was below its water solubility or below its solubility in the test solution, if known.

» The control was conducted in darkness.

» The test was conducted at a pH that minimizes hydrolysis.

» The study was conducted in darkness.

» The artificial light source (if used) was appropriate and wavelengths >290 and <800 nm were filtered out.

» A comparison of the light source (artificial or natural) to summer sunlight at 40°N latitude was provided. If sunlight was used, a record of the intensity of incident sunlight, time of exposure, and other major variables that affect incident light such as latitude, time of year, and atmospheric cover was provided. If artificial light was used, the nature of the source, intensity, wavelength, distribution, and time of exposure, and the relationship of the light intensity employed to that of natural sunlight was reported.

» The temperatures were held at 25 ± 1°C.

» If the test compound is susceptible to oxidation, the systems were purged with helium, argon, or nitrogen gas.

» The sterility of study equipment, reagents, and chemicals was assured.

» The solutions were buffered.

» The cosolvent (if any) did not exceed 1% (v/v).

» Volatiles, if any, were trapped. Traps were appropriate to capture $CO_2$ as well as organic volatiles. The identity of $CO_2$ as well as other volatiles was confirmed.

» Sampling intervals (at least four) were adequate to describe the decline of the test compound and the formation and decline of major transformation products. Duplicate samples were removed at each interval. At least one observation was made after one-half of the test substance was degraded or 30 days, whichever comes first.

» All chromatographic peaks were quantified unless <LOQ.

» Sufficient and reasonable attempts were made to identify and confirm the identity of all major transformation products and any minor products known or suspected to be of toxicological concern. If attempts failed, unidentified residues were confirmed not to be of concern.

» The study was conducted for at least one half-life or 30 days if one half-life did not pass.

» The material balance was >90% to <110% of the applied radioactivity (AR).

» Limits of detection and quantitation were reported.

» Appropriate analytical methods were used with suitable LOQs for the test compound and major transformation products.

» Half-lives were calculated including a dark-control-adjusted half-life (that is adjusted to a 12-hour/day photoperiod if artificial light was used) for summer at 40°N latitude.

» If molar absorptivity was investigated and reported in the study report as part of a Tier 1 analysis, include the information in the study review.

» If quantum yields along with theoretical half-lives by season results are reported as part of a Tier 2 analysis, include this information in the study review.

# Soil Photolysis Study Review Guide

This guide was developed to aid in the review of soil photolysis studies submitted under the Office of Chemical Safety and Pollution Prevention (OCSPP) guideline 835.2410. The soil photolysis study review format is based on the format for the Organisation for Economic Co-operation and Development (OECD) Tier II Summaries (T2S)[1]. Reviewers should add to the T2S format any information, statistical calculations, and formating that will increase their utility to the Agency under OCSPP guideline 835.2410. In developing the study reviews, reviewers should strive to write concisely and to minimize alterations to the T2S format.

Sections I, II, and III of this document provide additional details regarding formatting, data, and issues to consider in developing OCSPP environmental fate study reviews. Section I identifies soil photolysis data and review formatting that does not appear in the OECD T2S format and that should be added to USEPA reviews. Although this guide does not strictly prescribe where and how to present the data, an example study review template is provided in Section II for guidance. In general, the example template should be followed, especially for unilateral reviews (*i.e.*, reviews conducted without the participation of other agencies). However, reviewers may modify the template as needed or disregard it in the case of multilateral reviews (*i.e.*, reviews with other agencies participating) in which an alternative format is agreed upon by the participating agencies. Lastly, a list of review considerations (Section III) is provided to help reviewers focus on critical study issues and to identify any common major or minor deficiencies (*i.e.*, the review considerations update the acceptance criteria for soil photolysis studies provided in the 1989 FIFRA Accelerated Reregistration Phase 3 Technical Guidance (USEPA, 1989)).

**References**

U.S. Environmental Protection Agency (USEPA). 1989. FIFRA Accelerated Reregistration, Phase 3 Technical Guidance. Office of the Prevention, Pesticides, and Toxic Substances, Washington, DC. EPA 540/09-90-078.

[1] A Tier II Summary is an OECD format for study reviews prepared by industry. See OECD Guidance Documents for Pesticide Registration at http://www.oecd.org/document/48/0,3746,en_2649_34365_2085104_1_1_1_1,00.html (Accessed August 17, 2011).

## Section I. Data to Include in the Soil Photolysis OECD T2S Template

The following information should be added to the soil photolysis T2S template to make it compatible with OCSPP guideline 835.2410 and increase its utility to the Agency:

**First Page and Executive Summary**

- The PC code of the test compound and MRID of the study should be provided in the header and on the first page.

- A statement should be included indicating whether the study was conducted in compliance with FIFRA GLP standards (and if not, how not or why not) and whether signed and dated Data Confidentiality, GLP Compliance, Quality Assurance, and Authenticity Certification statements were provided.

- The study classification and a concise statement of any deficiencies that impacted the classification should be provided on the first page of the review.

- A signature line(s) for the final reviewer(s) should be added to the first page of the review. If this is unacceptable for other agencies participating in a multilateral review, then a cover page with the signature line(s) can be attached to each individual review submitted to EFED's files.

- A results synopsis should be added to the Executive Summary to tabulate half-lives, including how they were calculated, as well as a list of transformation products and the maximum amount formed (from individual replicate values, not the mean value) and the interval at which the maximum occurred. Tabulated information should not be summarized in the text of the Executive Summary.

**Materials and Methods**

- The Test Material section should list the names and batch numbers of reference compounds used and provide a small image of the test compound structure with any radiolabeled atoms identified.

- Physicochemical properties of the test compound that are relevant to the study should be listed in the Test Material section. Irrelevant properties should not be listed.

- Initial measured concentrations should be reported in the Experimental Conditions section.

- If samples are stored, storage stability information should be described.

**Results and Discussion**

- The results of any checks on pH, sterility, sorption to vessel walls, or other test conditions should be reported in the Findings section.

- Observed $DT_{50}$ values and indications of how half-lives were calculated (*e.g.*, single first order (SFO)) should be added to the half-life tables in the Findings section.

- The Findings section should indicate whether reviewer-reported half-lives are consistent with study-reported values and observed values.

**Study Deficiencies and Reviewer's Comments**

- The Conclusions section should list any deficiencies with the study and any additional salient information; this section may be renamed "Study Deficiencies and Reviewer's Comments." Results and conclusions contained in the Executive Summary should not be repeated in this section.

**References**

- A References section (Section III) should be added which lists any literature references other than the study report cited in the study review.

**Attachments**

- A table (*i.e.*, structure table) of the chemical names, SMILES strings, CAS numbers, and structures of the test compound, all identified transformation products, and all reference compounds that were not identified in study samples should be either referenced as a separate, associated document or attached to the study review. Multiple versions of structures to show or not show radiolabeling and multiple versions of chemical names and SMILES strings should not be 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.

  For multilateral reviews, chemical names, SMILES strings, structures, and CAS numbers are captured elsewhere in the Monograph[2]. 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, the Monograph's structure table should be either referenced as a separate, associated document or attached to each individual review.

[2] 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.

- Statistical output files containing calculations (such as statistical analyses and outputs) and graphs that support values reported in the study review should be attached to the review. File names should begin with the same name as that of the individual review. For multilateral reviews, the file naming convention should consistently follow an agreed format.

- A Calculations section should be added that lists equations and defines parameters used to calculate half-lives. This section is currently placed in Attachment III but may be placed in Section I.B.3.

## Section II. Example Soil Photolysis Study Review Template

**Soil Photolysis of [test compound]**

| | |
|---|---|
| **Report:** | [Provide full citation. Provide the MRID (first) if the review is unilateral.] |
| **Document No.:** | [MRID xxxxxxxx] |
| **Guideline:** | OCSPP 835.2410<br>[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 835.2410.' 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 how not or why not.] |
| **Classification:** | This study is [provide classification and 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:** | [xxxxxx] |
| **Reviewer:** | [Provide final reviewer(s)'s name and title.] **Signature:**<br>**Date:** [Type date of signature.] |

**Executive Summary**

In a soil photolysis study, the phototransformation of [[type of radiolabel(s)]-labeled[test compound] was investigated on [soil] under aerobic conditions at [x] ± [x] °C using [light source] for a period of [x] days (equivalent to [x] days natural summer sunlight at 40 °N). The soil used [was/was not] one of the soils used in the aerobic soil metabolism study and [is/is not] representative of an intended use-site. Test and control soil samples were treated at [test concentration] mg a.i./kg, which is equivalent to a field application rate of [#] g a.i./ha ([#] lbs a.i./a).[3] The control samples were subjected to the same experimental conditions as the test samples except the control samples were kept in the dark (absence of light). Duplicate samples were collected and analyzed using [methods used (*e.g.*, LSC and HPLC-UV].

The degradation profile of [test compound] was [similar/different] for both irradiated and control samples indicating. [Add a brief sentence to explain the pattern of degradation]. The overall mass balance for the study ranged from [# to #]. The test system [was/was not] adequate to trap both organic and inorganic volatile compounds. $CO_2$ accounted for up to [x]% of applied radioactivity. Other volatile compounds accounted for [#]% of the applied radioactivity. Major phototransformation products included [x], [y] and [z]. Other identified transformation products included [x], [y] and [z]. The observed $DT_{50}$ for the phototransformation of [test compound] was

[3] [Explain how the application rate was calculated.]

[#] days. The calculated dark control-adjusted $DT_{50}$ for the phototransformation of [test compound] under summer sun at 40 °N latitude was [#] days as highlighted in **Table 1**. [If the environmentally relevant half-life cannot be calculated include a brief summary of why it cannot be calculated. Include a brief description of how the estimated and observed $DT_{50}$ values compare. And state the best fit model used].

The duration of the experiment was [not adequate/adequate] to see the formation and decline of the transformation products. The calculated $DT_{50}$ values for the major transformation product(s) [name(s) here] ranged from [#] to [#] days, respectively.[4]

[4] [Calculate the half-life values for transformation products based on the maximum amount of the transformation product observed and its decline over at least four sampling intervals. Simultaneous formation and decline of the transformation product was not accounted for in the calculation or discuss how it was taken into account.]

**Table 1. Results Synopsis: Phototransformation of [Test Compound] on Soil**

| Compound Name | Observed $DT_{50}$ (hours/days) | Observed $DT_{90}$ (hours/days) | Calculated Half-life (method) | Model Parameters and Statistics | Environmental Half-life (days) [A] | Phototransformation Products (Common Name (maximum %AR [B] observed, associated interval)) | |
|---|---|---|---|---|---|---|---|
| | | | | | | Major | Minor Identified |
| **Irradiated: [Soil Name, Soil Texture, Taxonomy # °C, Moisture Content]** | | | | | | | |
| **Parent [test compound]** | [#] | [#] | [#] | [values] | **[#]** | [name] (# %, # days) | [name] (# %, # days) |
| **[Transformation product]*** | [#] | [#] | [#] | [values] | **[#]** | [name] (# %, # days) | [name] (# %, # days) |

[A] Dark control-adjusted and adjusted to a 12-hour/day photoperiod at 40 °N latitude.
[B] AR means "applied radioactivity."
[If the experiment permits half-life calculations for phototransformation products, include the information in this table.]

## I. Material and Methods

### A. Materials:

Provide a small image of the test compound's structure and any radiolabel on the right margin.

1. **Test Material:** [[Type of radiolabel]-labeled[test compound]
   Specific radioactivity: [value; units]
   Radiochemical purity: [percentage (HPLC, TLC)]
   Chemical purity: [percentage (HPLC)]
   Batch number: [value]
   Solubility in water: [value] mg/L [If pH-dependent, list available values at each study pH]

2. **Reference Compounds:** [List the common name and batch number of each reference compound. Provide other chemical information in the structure table.]

3. **Soil:**

**Table 2. Soil(s) Collection, Storage and Properties**

| Property | Value |
|---|---|
| Geographic location | |
| Pesticide use history at the collection site | |
| Collection date | |
| Collection procedures | |
| Sampling depth | |
| Storage conditions | |
| Storage duration | |
| Soil preparation | |
| Soil texture (USDA[5]): | |
| % Sand | |
| % Silt | |
| % Clay | |
| pH (1:1 soil:water or other) [method] | |
| Organic carbon (%) [method] | |
| Organic matter (%) [method] | |
| CEC (meq/100 g) [method] | |

[5] U.S. Department of Agriculture

| Property | Value |
|---|---|
| Soil Moisture Content (units): | |
| At 0.1 bar (pF 2.0) | |
| At 1/3 bar (pF 2.5) | |
| Bulk density (g/cm$^3$) | |
| Microbial biomass (units): | |
| At initiation | |
| At termination | |
| Soil taxonomic classification | |

Data obtained from page [#] of the study report.
[The method used to measure pH, organic carbon, organic matter, and CEC should be reported, if available, since the values of these soil properties are method dependent.]

**B. Study Design:**

**1. Experimental Conditions:**

**Table 3. Experimental Design**

| Parameter | | Description |
|---|---|---|
| Nature of light source | | |
| Emission wavelength spectrum | | |
| Nominal light intensity | | |
| Filters used | | |
| Relationship to natural sunlight | | |
| Method used to determine relations between light source and summer sunlight (*e.g.*, 40 °N) | | |
| Duration of the test | | |
| Soil condition | | |
| Soil sample weight | | |
| Test concentration (mg ai/kg soil (dry weight)) | | |
| Field Equivalent Application Rate (lb a.i./a) | | |
| Control conditions | | |
| Number of replicates | Irradiated | |
| | Darkness | |
| Test apparatus | Irradiated | |
| | Darkness | |

| Parameter | | Description |
|---|---|---|
| Traps | Organics | |
| | $CO_2$ | |
| Test material application | Solvent | |
| | Test solution volume used/ treatment | |
| | Application method | |
| | Evaporation of application solvent | |
| Indication of test material adsorbing to walls of test apparatus | | |
| Experimental conditions | Temperature (°C) | |
| | Continuous irradiation | |
| | Moisture content | |
| | Moisture maintenance method | |
| | Continuous darkness (Yes/No): | |
| Sample storage before analysis | | |

**2. Description of Analytical Procedures:**

Samples were analyzed using [LSC] for determination of total radioactivity. [Reversed-phase HPLC with $^{14}C$-flow-through detection techniques and normal phase TLC] were used as primary and confirmatory chromatographic methods for the separation and quantification of products formed. The limit of detection (LOD) was determined to be [percentage] of the applied radioactivity (%AR), with a limit of quantitation (LOQ) at [percentage]AR.

## II. Results and Discussion

### A. Data:

**Table 4. Photodegradation of [radiolabel-test compound] in soil expressed as percentage of applied radioactivity** [Add to the table as needed for additional soils. The results including total mass balances and distribution of radioactivity are presented as individual replicate values rather than means and standard deviations.]

| | **Percent of Applied Radioactivity** | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Sampling Interval (hours)** | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] |
| **Replicate Number** | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] |
| **Component** | **Irradiated [Soil Name, Soil Texture, Taxonomy # °C, Moisture Content]** | | | | | | | | | | | | | |
| [Test compound] | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| [Degradate 1] | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| [Degradate 2] | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Unidentified | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Volatiles | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| $^{14}CO_2$ | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Total Recovery** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Unextracted Residues | | | | | | | | | | | | | | |
| **Mass Balance** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Sampling Interval (hours)** | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] |
| **Replicate Number** | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] |
| **Component** | **Control (Dark) [Soil Name, Soil Texture, Taxonomy # °C, Moisture Content]** | | | | | | | | | | | | | |
| [Test compound] | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| [Degradate 1] | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| [Degradate 2] | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Unidentified | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Volatiles | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| $^{14}CO_2$ | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Total Recovery** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Unextracted Residues | | | | | | | | | | | | | | |
| **Mass Balance** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

Data obtained from [Table #, pp. #] of the study report.
Total Characterized Residues is the sum of identified and unidentified extractable residues and volatilized compounds.
n.d. = not detected, n.a. = not analyzed

### B. Mass Balance:

The total recoveries and distribution of radioactivity from each soil are shown in **Table 4**. Recoveries ranged from [percentage] to [percentage]AR. [Indicate whether there was substantial loss of radioactivity by sorption to glassware or volatilization. Also mention if the mass balance meets guideline criteria.]

#### 1. Bound and Extractable Residues:

In irradiated samples unextracted residues comprised [#]% of the applied radioactivity. A [reasonable/unreasonable] attempt was made to extract soil residues. [If a reasonable attempt was made to extract all radioactivity, discuss the likelihood unextracted residues are bound residues]. Unidentified residues accounted for [#]% of the applied radioactivity. If there is a large amount of unidentified radioactivity mention it here.]

### C. Volatilization:

Volatiles [were/were not] trapped. The level of $CO_2$ evolved was [#]%. [Add information regarding additional volatile chemical as need.]

### D. Transformation of Test Compound:

Degradation of [radiolabel-test compound] on soil was [gradual, rapid, or some other characterization]. The $DT_{50}$ ranged from [x] to [x] as highlighted in **Table 5** (calculated half-lives and model parameters for the best fit kinetics models are in bold). [Indicate the software used to determine model parameters. Indicate whether reviewer-reported half-lives are consistent with study-reported values and the relationship between calculated and observed values. If multiple experiments were conducted per study condition such as using two different test compounds (*i.e.*, different radiolabels), calculate kinetic values for combined data. Discuss any abnormalities observed in the data.]

[Images of kinetics calculation results using the R program may replace most of **Table 5** (dark-control adjusted half-lives and environmental half-lives would still need to be reported). R images should include the model parameters and statistics that are otherwise reported in **Table 5**.]

**Table 5. Phototransformation of [Test Compound] on Soil [A, B]**

| Compound Name | Observed $DT_{50}$ (hours/days) | Observed $DT_{90}$ (hours/days) | Calculated Half-life (days) | Kinetics Model [C] | Model Parameters | Model Statistics | Dark Control Adjusted Half-life (days) [D] | Environmental Half-life (days) [D] |
|---|---|---|---|---|---|---|---|---|
| **Parent [test compound]** | [#] | [#] | [#] | SFO | $C_0$=[#], k=[#] | $S_{SFO}$=[#], $r^2$=[#], p=[#] | [#] | [#] |
| | | | [#] | IORE | $C_0$=[#], k=[#], n=[#] | $S_{IORE}$=[#], $S_C$=[#], $r^2$=[#], p=[#] | | |
| | | | [#] | DFOP [if applicable] | $C_0$=[#], g=[#], $k_1$=[#], $k_2$=[#], | $S_{DFOP}$=[#], $r^2$=[#], p=[#] | | |
| **Control: Parent [test compound]** | [#] | [#] | [#] | SFO | $C_0$=[#], k=[#] | $S_{SFO}$=[#], $r^2$=[#], p=[#] | | |
| | | | [#] | IORE | $C_0$=[#], k=[#], n=[#] | $S_{IORE}$=[#], $S_C$=[#], $r^2$=[#], p=[#] | | |
| | | | [#] | DFOP [if applicable] | $C_0$=[#], g=[#], $k_1$=[#], $k_2$=[#], | $S_{DFOP}$=[#], $r^2$=[#], p=[#] | | |
| **Degradate [compound]*** | [#] | [#] | [#] | SFO | $C_0$=[#], k=[#] | $S_{SFO}$=[#], $r^2$=[#], p=[#] | [#] | [#] |
| | | | [#] | IORE | $C_0$=[#], k=[#], n=[#] | $S_{IORE}$=[#], $S_C$=[#], $r^2$=[#], p=[#] | | |
| | | | [#] | DFOP [if applicable] | $C_0$=[#], g=[#], $k_1$=[#], $k_2$=[#], | $S_{DFOP}$=[#], $r^2$=[#], p=[#] | | |
| **Control: Degradate [compound]*** | [#] | [#] | [#] | SFO | $C_0$=[#], k=[#] | $S_{SFO}$=[#], $r^2$=[#], p=[#] | | |
| | | | [#] | IORE | $C_0$=[#], k=[#], n=[#] | $S_{IORE}$=[#], $S_C$=[#], $r^2$=[#], p=[#] | | |
| | | | [#] | DFOP [if applicable] | $C_0$=[#], g=[#], $k_1$=[#], $k_2$=[#], | $S_{DFOP}$=[#], $r^2$=[#], p=[#] | | |

[A] Data were obtained from [location of data in study report] and calculations in the attached Excel workbook [name(s) of worksheets, if needed]. See Attachment 3 for calculations.

[B] Calculated half-lives and model parameters for the best fit kinetics models, in accordance with the NAFTA kinetics guidance (USEPA, 2011), are in bold.

[C] Kinetics models: Single First-Order (SFO); Double First-Order in Parallel (DFOP), and Indeterminate Order Rate Equation (IORE).

[D] Half-life value for the best fit kinetics model was adjusted to a 12-hour/day photoperiod under summer sun at 40 °N latitude.

[Rows may be added for transformation product half-lives and $DT_{50}$s as needed. Half-lives should be calculated following the NAFTA kinetics guidance (USEPA, 2011). If multiple experiments were conducted per study condition using test compound with different radiolabeled positions, calculate kinetics values for the combined data rather than for specific radiolabeled positions.]

[Briefly summarize the transformation products per system in **Table 6**. If transformation product decline is observed over four time intervals, calculate a half-life and discuss the pattern of decline. Based on the control experiment, discuss which transformation products are the likely the result of phototransformation as compared to other degradation processes.]

**Table 6. Transformation Products of [Test Compound] in Soil**

| | Transformation Product(s) | Maximum %AR Observed | Associated Interval | Final %AR Observed | Final Interval |
|---|---|---|---|---|---|
| **Irradiated Samples** | [common name] | [#] | [# d] | [#] | [# d] |
| | [common name] | [#] | [# d] | [#] | [# d] |
| **Controls** | [common name] | [#] | [# d] | [#] | [# d] |
| | [common name] | [#] | [# d] | [#] | [# d] |

[If applicable, provide a description of the transformation pathway here, including a schematic as Figure 1.]

**[Figure 1. Phototransformation Pathway of [radiolabel-test compound] in Soil]**

## III. Study Deficiencies and Reviewer's Comments

[This section is titled "Conclusions" in the original T2S template.]

[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.]

## IV. References [List any references cited in the review.]

U.S. Environmental Protection Agency (USEPA). 2011. Guidance for Evaluating and Calculating Degradation Kinetics in Environmental Media. (Interim draft document dated Dec. 21, 2011.)

**Attachment 1: Chemical Names and Structures**

[A table (*i.e.*, structure table) of the chemical names, SMILES strings, CAS numbers, and structures of the test compound, all identified transformation products, and all reference compounds that were not identified in study samples should be either referenced as a separate, associated document or attached to the study review. Multiple versions of structures to show or not show radiolabeling and multiple versions of chemical names and SMILES strings should not be 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.

For multilateral reviews, chemical names, SMILES strings, structures, and CAS numbers are captured elsewhere in the Monograph[6]. 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, the Monograph's structure table should be either referenced as a separate, associated document or attached 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.]

Degradate Table.docx

[6] 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.

**Attachment 2: Statistics Spreadsheets and Graphs**

Soil Photolysis Study
Review Tables 1-12-1

[Supporting electronic spreadsheet files should be inserted here (electronic attachment files should be electronically finalized as separate files as well). Electronic attachments should have 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. Electronic attachment files should be compressed into a WinZip file when three or more are prepared for a study review.]

[Hard copies of a study review and any attachment sheets from separate electronic files should be printed and finalized together as one hard copy file.]

**Attachment 3: Calculations**

Calculations were performed by the reviewer using [indicate program(s) used for calculations] and the following equations. [The following equations are anticipated to reflect the NAFTA kinetics guidance as of January, 2012. If these equations are not current, they should be replaced by the applicable equations from current guidance.]

**Single First-Order (SFO) Model**

$$C_t = C_0 e^{-kt} \quad \text{(eq. 1)}$$

where,

$C_t$ = concentration at time t (%)
$C_0$ = initial concentration (%)
e = Euler's number (-)
k = SFO rate constant of decline ($d^{-1}$)
t = time (d)

The SFO equation is solved [with the Excel Solver] by adjusting $C_0$ and $k$ to minimize the objective function ($S_{SFO}$) shown in equation 9.

$DT_{50}$ = natural log (2)/k (eq. 2)

$DT_{90}$ = ln (10)/k (eq. 3)

**Indeterminate Order Rate Equation (IORE) Model**

$$C_t = \left[C_0^{(1-N)} - (1-N)k_{IORE}t\right]^{\left(\frac{1}{1-N}\right)} \quad \text{(eq. 4)}$$

where,

N = order of decline rate (-)
$k_{IORE}$ = IORE rate constant of decline ($d^{-1}$)

This equation is solved [with the Excel Solver] by adjusting $C_0$, $k_{IORE}$, and $N$ to minimize the objective function for IORE ($S_{IORE}$) (See equation 9). Half-lives for the IORE model are calculated using equation 5, which represents a first-order half-life that passes through the $DT_{90}$ of the IORE model. (Traditional $DT_{50}$ and $DT_{90}$ values for the IORE model can be calculated using equations 6 and 7.)

$$t_{IORE} = \frac{\log(2)}{\log(10)} \frac{C_0^{1-N}(1-0.1^{(1-N)})}{(1-N)k_{IORE}} \quad \text{(eq. 5)}$$

$$DT_{50} = \frac{(C_0/2)^{(1-N)} - C_0^{(1-N)}}{k(N-1)} \quad \text{(eq. 6)}$$

$$DT_{90} = \frac{(C_0/10)^{(1-N)} - C_0^{(1-N)}}{k(N-1)} \quad \text{(eq. 7)}$$

**Double First-Order in Parallel (DFOP) Model**

$$C_t = C_0 g^{-k_1 t} + C_0(1-g)^{-k_2 t} \quad \text{(eq. 8)}$$

where,

g = the fraction of $C_0$ applied to compartment 1 (-)
$k_1$ = rate constant for compartment 1 ($d^{-1}$)
$k_2$ = rate constant for compartment 2 ($d^{-1}$)

If $C_0 \times g$ is set equal to $a$ and $C_0(1-g)$ is set equal to $c$, then the equation can be solved [with the Excel Solver] for $a$, $c$, $k_1$, and $k_2$ by minimizing the objective function ($S_{DFOP}$) as described in equation 9.

$DT_{50}$ and $DT_{90}$ values can be calculated using equations 2 and 3, with $k_1$ or $k_2$ in place of k.

**Objective Function:** SFO, IORE, and DFOP are solved by minimizing the objective function ($S_{SFO}$, $S_{IORE}$, or $S_{DFOP}$).

$$S_{SFO}, S_{IORE}, \text{or } S_{DFOP} = \sum(C_{model,t} - C_{d,t})^2 \quad \text{(eq. 9)}$$

where,

$S_{SFO}$ , $S_{IORE}$, or $S_{DFOP}$ = objective function of kinetics model fit ($\%^2$)
n = number of data points (-)
$C_{model,t}$ = modelled value at time corresponding to $C_{d,t}$ (%)
$C_{d,t}$ = experimental concentration at time t (%)

**Critical Value to Determine Whether SFO is an Adequate Kinetics Model**

If $S_{SFO}$ is less than $S_C$, the SFO model is adequate to describe kinetics. If not, the faster of $t_{IORE}$ or the DFOP $DT_{50}$ for compartment 2 should be used.

$$S_c = S_{IORE}\left(1 + \frac{p}{n-p}F(\alpha, p, n-p)\right) \quad \text{(eq. 10)}$$

where,

$S_c$ = the critical value that defines the confidence contours ($\%^2$)
p = number of parameters (3 in this case)
$\alpha$ = the confidence level (0.50 in this case)
$F(\alpha, p, n-p)$ = F distribution with $\alpha$ level of confidence and degrees of freedom p and n-p

## Section III. Soil Photolysis Study Review Considerations

This list of considerations is provided to help reviewers assess the acceptability of soil photolysis studies. This list is not a screen or a checklist and should not be attached to the study reviews. Listed considerations carry unequal weight and should be evaluated using best professional judgment. All information from the study and from similar studies should be considered to determine whether any deficiencies affect the study classification.

» Raw measured data and representative chromatographs were provided.

» The test compound was Technical Grade (TGAI) or a Pure Active Ingredient Radiolabeled (PAIRA) compound.

» The radiopurity and specific activity of the test compound was provided (if radiolabeled).

» Radiolabeled positioning was appropriate. For compounds containing ring structures, experiments were conducted separately for each respectively labelled ring structure and test compounds were not radiolabelled on more than one ring structure in each experiment.

» The control was conducted in darkness.

» The artificial light source (if used) was appropriate and wavelengths >290 and <800 nm were filtered out.

» One of the soils (*e.g.*, sandy loam, silt loam, or other soil appropriate to the application site) specified in OCSPP 835.4100 (aerobic soil metabolism study) was used.

» A comparison of the light source (artificial or natural) to summer sunlight at 40°N latitude was provided. If sunlight was used, a record of the intensity of incident sunlight, time of exposure, and other major variables that affect incident light such as latitude, time of year, and atmospheric cover was provided. If artificial light was used, the nature of the source, intensity, wavelength, distribution, and time of exposure, and the relationship of the light intensity employed to that of natural sunlight was reported.

» The temperatures were held at ±2°C (the guideline states ±1°C) between 18 and 30°C.

» Sampling intervals (at least four) were adequate to describe the decline of the test compound and the formation and decline of major transformation products. Duplicate samples were removed at each interval. At least one observation was made after one-half of the test substance was degraded or 30 days, whichever comes first.

» The application rate was representative of the intended use.

» All chromatographic peaks were quantified unless <LOQ.

» Volatiles, if any, were trapped. Traps were appropriate to capture $CO_2$ as well as organic volatiles. The identity of $CO_2$ as well as other volatiles was confirmed.

» Limits of detection and quantification were reported.

» A reasonable attempt was made – perhaps with a polar and multiple mild non-polar solvent systems – to extract the test compound and its transformation products.

- » Sufficient and reasonable attempts were made to identify and confirm the identity of all major transformation products and any minor products known or suspected to be of toxicological concern. If attempts failed, unidentified residues were confirmed not to be of concern.
- » The study was conducted for at least one half-life or 30 days if one half-life did not pass.
- » The material balance was reasonable (90% - 110%) for labeled chemicals and 70% - 120% for non-labeled chemicals.
- » Appropriate analytical methods were used with suitable LOQs for the test compound and major transformation products.
- » The soil was not sterile and its target moisture content was reported and adequately maintained during the course of the experiment.
- » The soil was completely characterized, using the USDA or World Reference Based for Soil Resources classification system. If a foreign soil(s) was/were used, the soil(s) was/were adequately compared with domestic (U.S.) soils.
- » The soil was sieved using a 2 mm screen. If a larger screen was used, the study included a rational for its use.
- » Half-lives were calculated. This included a dark-control-adjusted half-life, which was adjusted to a 12-hour/day photoperiod if artificial light was used, for summer at 40°N latitude.

# Aerobic and Anaerobic Soil Metabolism Study Review Guide

This guide was developed to aid in the review of aerobic and anaerobic soil metabolism (hereafter referred to as "soil metabolism") studies submitted under the Office of Chemical Safety and Pollution Prevention (OCSPP) guidelines 835.4100 (aerobic) and 835.4200 (anaerobic) and the Organisation for Economic Co-operation and Development (OECD) guideline 307 (OECD, 2002). The soil metabolism study review format is based on the format for OECD Tier II Summaries (T2S)[1]. Reviewers should add to the T2S format any information, statistical calculations, and formatting that will increase their utility to the Agency under OCSPP guidelines 835.4100 and 835.4200. In developing study reviews, reviewers should strive to write concisely and to minimize alterations to the T2S format.

Sections I, II, and III of this document provide additional details regarding data, formatting, and issues to consider in developing OCSPP environmental fate study reviews. Section I identifies soil metabolism data and formatting that does not appear in the OECD T2S format and that should be added to USEPA reviews. Although this guide does not strictly prescribe where and how to present the data, an example study review template is provided in Section II for guidance. In general, the example template should be followed, especially for unilateral reviews (*i.e.*, reviews conducted without the participation of other agencies). However, reviewers may modify the template as needed or disregard it in the case of multilateral reviews (*i.e.*, reviews with other agencies participating) in which an alternative format is agreed upon by the participating agencies. Lastly, a list of review considerations (Section III) is provided to help reviewers focus on critical study issues and to identify any common major or minor deficiencies (*i.e.*, the review considerations update the acceptance criteria for soil metabolism studies provided in the 1989 FIFRA Accelerated Reregistration Phase 3 Technical Guidance (USEPA, 1989)).

**References**

Organisation for Economic Co-operation and Development (OECD). 2002. Test No. 307: Aerobic and Anaerobic Transformation in Soil. OECD Guidelines for the Testing of Chemicals, Section 3: Degradation and Accumulation, OECD Publishing. DOI: 10.1787/9789264070509-en

U.S. Environmental Protection Agency (USEPA). 1989. FIFRA Accelerated Reregistration, Phase 3 Technical Guidance. Office of the Prevention, Pesticides, and Toxic Substances, Washington, DC. EPA 540/09-90-078.

[1] A Tier II Summary is an OECD format for study reviews prepared by industry. See OECD Guidance Documents for Pesticide Registration at http://www.oecd.org/document/48/0,3746,en_2649_34365_2085104_1_1_1_1,00.html (Accessed August 17, 2011).

## Section I. Data to Include in the Soil Metabolism OECD T2S Template

The following information should be added to the soil metabolism T2S template to make it compatible with OCSPP guidelines 835.4100 and 835.4200 and increase its utility to the Agency:

**First Page and Executive Summary**

- The PC code of the test compound and MRID of the study should be provided in the header and on the first page.

- A statement should be included indicating whether the study was conducted in compliance with FIFRA GLP standards (and if not, how not or why not) and whether signed and dated Data Confidentiality, GLP Compliance, Quality Assurance, and Authenticity Certification statements were provided.

- The study classification and a concise statement of any deficiencies that impacted the classification should be provided on the first page of the review.

- A signature line(s) for the final reviewer(s) should be added to the first page of the review. If this is unacceptable for other agencies participating in a multilateral review, then a cover page with the signature line(s) can be attached to each individual review submitted to EFED's files.

- A results synopsis should be added to the Executive Summary to tabulate half-lives, including how they were calculated, as well as a list of transformation products and the maximum amount formed and the interval at which the maximum occurred. Tabulated information should not be summarized in the text of the Executive Summary.

**Materials and Methods**

- The Test Material section should list the names and batch numbers of reference compounds used and provide a small image of the test compound structure with any radiolabeled atoms identified.

- Physicochemical properties of the test compound that are relevant to the study should be listed in the Test Material section. Irrelevant properties should not be listed.

- Initial measured concentrations should be reported in the Experimental Conditions section.

- If samples are stored, storage stability information should be described.

**Results and Discussion**

- The results of any checks on aerobic or anaerobic conditions, redox conditions, pH, sterility, sorption to vessel walls, or other test conditions that may affect the acceptability of the study should be reported in the Findings section.

- Observed $DT_{50}$ values and indications of how half-lives were calculated (*e.g.*, SFO, DFOP, IORE) should be added to the half-life tables in the Findings section.

- The Findings section should indicate whether reviewer-reported half-lives are consistent with study-reported values and observed values.

**Study Deficiencies and Reviewer's Comments**

- The Conclusions section should list any deficiencies with the study and any additional salient information; this section may be renamed "Study Deficiencies and Reviewer's Comments." Results and conclusions contained in the Executive Summary should not be repeated in this section.

**References**

- A References section (Section IV) should be added that lists any literature references other than the study report cited in the study review.

**Attachments**

- A table (*i.e.*, structure table) of the chemical names, SMILES strings, CAS numbers, and structures of the test compound, all identified transformation products, and all reference compounds that were not identified in study samples should be either referenced as a separate, associated document or attached to the study review. Multiple versions of structures to show or not show radiolabeling and multiple versions of chemical names and SMILES strings should not be 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.

  For multilateral reviews, chemical names, SMILES strings, structures, and CAS numbers are captured elsewhere in the Monograph[2]. 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, the Monograph's structure table should be either referenced as a separate, associated document or attached to each individual review.

[2] 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.

- Statistical output files containing calculations (such as statistical analyses and outputs) and graphs that support values reported in the study review should be attached to the review. File names should begin with the same name as that of the individual review. For multilateral reviews, the file naming convention should consistently follow an agreed format.

- A Calculations section should be added that lists equations and defines parameters used to calculate half-lives. This section is currently placed in Attachment III but may be placed in Section I.B.4.

## Section II. Example Soil Metabolism Study Review Template

### Aerobic (or Anaerobic) Degradation in Soil of [test compound]

| | |
|---|---|
| **Report:** | [Provide full citation. Provide the MRID (first) if the review is unilateral.] |
| **Document No.:** | [MRID ########] |
| **Guideline:** | [OCSPP 835.4100 (aerobic) or OCSPP 835.4200 (anaerobic)] [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 835.####.' If this review is multilateral, also provide the guideline numbers under which participating agencies are reviewing the study.] |
| **Compliance:** | [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 how not or why not.] |
| **Classification:** | This study is [provide classification and 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:** | [######] |
| **Reviewer:** | [Provide final reviewer(s)'s name and title.] **Signature:** **Date:** [Type date of signature.] |

### Executive Summary

The [aerobic or anaerobic] transformation of [type of radiolabel]-labeled [test compound] was studied in [number of] soils for [duration] days in a closed system in darkness at [temperature] °C, pH [value] and [value] soil moisture content at 1/3 bar. The soils were treated at [test concentration] mg a.i./kg, which was equivalent to a field application rate of [value] kg a.i./ha. [Indicate whether anaerobic conditions were maintained in the soil.] Microbial biomass determinations indicated the soils [were or were not] viable at study initiation and termination.

For [soil x], the overall mass balance for the study averaged [value]% of the applied radioactivity (%AR), ranging from [value to value]%AR. For [soil y], the overall mass balance averaged [value]%AR, ranging from [value to value]%AR.

Observed $DT_{50}$ values, calculated half-lives based on the harmonized NAFTA kinetics guidance (USEPA, 2011), and information on transformation products are listed in **Table 1**. [Describe whether a reasonable effort was made to maximize recovery of residues. If not, describe whether transformation kinetics calculations were performed for test compound plus unextracted residues as well as for test compound alone.] The amount of extracted radioactivity declined from [value]%AR at study initiation to [value]%AR at day [number]. Unextracted radioactivity increased to [value]%AR at day [number]. The total evolved $CO_2$ and other volatile compounds amounted to [value]%AR and [value]%AR, respectively.

**Table 1. Results Synopsis: [Aerobic or Anaerobic] Soil Metabolism of [Test Compound]**

| Compound Name | Observed $DT_{50}$ (days) | Calculated Half-life (days) Method | Model Parameters and Statistics | Transformation Products Common Name (maximum %AR[A] observed, associated interval) | |
|---|---|---|---|---|---|
| | | | | Major | Minor |
| [Soil Location] [USDA Soil Series] [Soil Texture] [# °C, pH #] | [value] | [value] [method] | [values] | [name] (# %, # days) | [name] (# %, # days) |
| [Soil Location] [USDA Soil Series] [Soil Texture] [# °C, pH #] | [value] | [value] [method] | [values] | [name] (# %, # days) | [name] (# %, # days) |
| [Soil Location] [USDA Soil Series] [Soil Texture] [# °C, pH #] | [value] | [value] [method] | [values] | [name] (# %, # days) | [name] (# %, # days) |
| [Soil Location] [USDA Soil Series] [Soil Texture] [# °C, pH #] | [value] | [value] [method] | [values] | [name] (# %, # days) | [name] (# %, # days) |

[A] AR means "applied radioactivity."

[Model parameters include model variables; model statistics include Sc values, correlation coefficients, and p values.]

[Half-lives and model parameters should be reported for the best fit kinetics model in accordance with the NAFTA kinetics guidance (USEPA, 2011). If multiple experiments were conducted per study condition using test compound with different radiolabel positions, calculate kinetics values for the combined data rather than for specific radiolabel positions.]

## I. Materials and Methods

### A. Materials:

Provide a small image of the test compound's structure and any radiolabel on the right margin.

1. **Test Material:** [[Type of radiolabel]-labeled[test compound]
   Specific radioactivity: [value] [units]
   Radiochemical purity: [percentage [HPLC or TLC]
   Chemical purity: [percentage (HPLC)]
   Batch number: [value]
   Solubility in water: [value] mg/L at [value] °C
   [If pH-dependent, list available values at each pH and temperature]

2. **Reference Compounds:** The following standards were used in the analysis.

**Table 2. Reference Compounds**

| Applicant's Code Name | Chemical Name | Purity (%) | Lot No. |
|---|---|---|---|
| [code name] | [chemical name] | [#] | [#] |
| [code name] | [chemical name] | [#] | [#] |
| [code name] | [chemical name] | [#] | [#] |

Data were obtained from [page number] of the study report.
[Provide other chemical information in the structure table.]

3. **Soil:** Soil collection and characterization are summarized in **Table 3** and **Table 4**, respectively. [Characterize any unique properties of soil collection or storage conditions].

**Table 3. Description of Soil Collection and Storage**

| Description | [Soil Series #1] | [Soil Series #2] | [Soil Series #3] | [Soil Series #4] |
|---|---|---|---|---|
| Geographic location | | | | |
| Soil series | | | | |
| Pesticide use history at the collection site | | | | |
| Collection date | | | | |
| Collection procedures | | | | |
| Sampling depth | | | | |
| Storage temperature | | | | |
| Storage length | | | | |
| Soil preparation | | | | |

Data were obtained from page [#] of the study report.

**Table 4. Properties of the Soils**

| Property: | [Soil Series #1] | [Soil Series #2] | [Soil Series #3] | [Soil Series #4] |
|---|---|---|---|---|
| Soil Texture (USDA): | | | | |
| % Sand | | | | |
| % Silt | | | | |
| % Clay | | | | |
| pH (solution) [method] | | | | |
| Organic carbon (%) [method] | | | | |
| Organic matter (%) [method] | | | | |
| Cation Exchange Capacity (meq/100 g) [method] | | | | |
| $CaCO_3$ equivalence (%) | | | | |
| Soil Moisture Content (units): | | | | |
| At 0.1 bar (pF 2.0) | | | | |
| At 1/3 bar (pF 2.5) | | | | |
| Bulk density ($g/cm^3$) | | | | |
| Microbial Biomass (units): | | | | |
| At initiation | | | | |
| During study | | | | |
| At termination | | | | |
| Soil taxonomic classification (USDA or other) [*i.e.*, soil order] | | | | |

Data obtained from page [#] of the study report.
[The method used to measure pH, organic carbon, organic matter, and CEC should be reported, if available, since the values of these soil properties are method dependent.]

## B. Study Design:

1. **Experimental Conditions:** (Summarized in **Table 5**.) [Characterize any unique details of experiential conditions.]

**Table 5. Experimental Design**

| **Experimental Design** | **Details** |
|---|---|
| Duration of the test (days) | |
| Soil condition: (Air dried/fresh) | |
| Soil (g/replicate) | |
| Application rates: | |
| Nominal | |
| Actual | |
| Control conditions (if used) | |
| Number of Replicates: | |

| | |
|---|---|
| Controls ( if used) | |
| Treatment | |
| Test Apparatus: | |
| Type/material/volume | |
| Details of traps for $CO_2$ and organic volatiles ( if any) | |
| If no traps were used, is the system closed/open? | |
| Identity and concentration of co-solvent | |
| Test Material: | |
| Volume of the test solution used/treatment | |
| Application method | |
| Is the co-solvent evaporated? | |
| Any indication of the test material adsorbing to the walls of the test apparatus? | |
| Experimental Conditions: | |
| Temperature (°C) | |
| Continuous darkness | |
| Moisture content | |
| Moisture maintenance method | |
| Other details (if any) | |

Data obtained from pages [#] of the study report.

2. **Sampling During Study Period:** (Details summarized in **Table 6**. Describe any unique characteristics of sampling during study period, if any.)

**Table 6. Sampling During Study Period**

| Criteria | Details |
|---|---|
| Sampling intervals (units) | |
| Sampling method | |
| Method of collection of $CO_2$ and organic volatile compounds | |
| Sampling Intervals/Times for: | |
| Sterility check ( if sterile controls are used) | |
| Moisture content | |
| Redox potential, other | |
| Sample storage before analysis | |
| Other observations ( if any) | |

Data obtained from pages [#] of the study report.

## 3. Analytical Procedures:

**Extraction Methods:** [Briefly describe the extraction method. An example follows. Be sure to describe the effectiveness of the soil extraction process. Solvent selection should be sufficiently robust to ensure extraction of bound residues.]

Soil samples were extracted [# of extractions] with [solvent system] (%:%, v:v) by [extraction method] for [#] minutes per extraction ([report page reference]). After each extraction, the mixtures were centrifuged and the supernatant decanted. Extracts were combined, diluted with [solvent], and pH adjusted [pH value] using [dilution solvent]. Aliquots of the combined extracts were analyzed for total radioactivity using [analytical method].

Aliquots of the combined extracts were concentrated under a stream of [gas] in a waterbath, diluted with [dilution solvent] and filtered (# µm). Aliquots of the concentrated solutions were analyzed by [analytical method].

**Determination of Unextracted Residues:**

Portions ([# x # g]) of the extracted soils were air-dried, ground with a mortar and pestle, then analyzed for total radioactivity by [analytical method] followed by combustion ([report page reference]). In addition, portions of the [termination day] extracted soils were further analyzed to determine the concentrations of fulvic acid, humic acid, and humin ([report page reference]). The extracted soils were extracted with [extraction solvent], then centrifuged. The soil pellet was combusted to quantify the soil humin fraction. The supernatant was adjusted to pH [value] then centrifuged. The resulting supernatant (fulvic acid) and precipitate (humic acid) were analyzed using [analytical method].

**Determination of Volatile Compounds:**

Aliquots ([# x # mL]) of the volatile trapping solutions were analyzed for total radioactivity using [analytical method] ([report page reference]). The presence of $CO_2$ in the KOH trapping solution was confirmed by precipitation with saturated barium chloride ([report page reference]).

**Total Radioactivity Measurement:**

Total $^{14}C$ residues were determined by summing the concentrations of residues measured in the soil extracts, extracted soil and volatile trapping solutions ([report page number]).

**Derivatization Method:** [Describe derivatization method, if employed.].

**Identification and Quantification of Parent Compound:**

Aliquots of the soil extracts were analyzed using [analytical method (i.e., HPLC)] under the following conditions: [describe instrument, column, mobile phase, gradient, and UV (# nm) and radiochemical detection ([report page number]). Radiolabeled [parent compound] was identified by comparison to the retention time of an unlabeled reference standard (purity [%], retention

time (Rt) ([# to #] minutes) that was co-chromatographed with the samples ([report page number]). Column recovery determined prior to analysis of the definitive samples was [#] % ([report page number]). In addition, the identification of [parent compound] was confirmed by [analytical method (*i.e.*, LC-MS/MS)] with electrospray ionization in the positive mode ([report page number]).

**Detection Limits (LOD, LOQ) for the Parent Compound:**

The limit of detection (LOD) was determined to be [percentage] of the applied radioactivity (%AR), with a limit of quantitation (LOQ) at [percentage] AR.

**Detection Limits (LOD, LOQ) for the Transformation Products:**

The LOD and LOQ were the same as parent ([report page number]).

## II. Results and Discussion

### A. Data:

Study results including total mass balances and distribution of radioactivity are presented in **Table 7**. [Indicate the results of any checks on aerobic or anaerobic conditions and viability of test soils. If applicable, report redox conditions.]

### B. Mass Balance:

The mass balance and distribution of radioactivity from each soil are shown in **Table 7**. Recoveries ranged from [percentage] to [percentage] of the applied radioactivity (%AR). Unidentified residues accounted for [percentage]AR. [If there is a large amount of unidentified radioactivity, mention it here. Indicate whether there was substantial loss of radioactivity by sorption to glassware or volatilization. Also mention if the mass balance meets guideline criteria.]

### C. Bound and Extractable Residues:

The amount of extractable radioactivity declined from [percentage]AR at time zero to [percentage]AR at day [number] for [test compound]. Unextracted radioactivity increased to [percentage]AR at day [number]. [If unextracted residues were >10% of the applied, discuss whether the sediment extraction procedures were reasonable and whether the unextracted residues may include available residues.]

### D. Volatilization:

Volatiles [were/were not] trapped. Volatile radioactivity, identified as evolved $^{14}CO_2$ represented [percentage]AR at day [number] for [test compound]. [Add information regarding additional volatile chemicals as needed.]

**Table 7. Transformation of [test compound], Expressed as a Percentage of Applied Radioactivity in [Soil Series]**

| Sampling Interval (days) | Interval # | | Interval # | | Interval # | | Interval # | | Interval # | | Interval # | | Interval # | | Interval # | | Interval # | | Interval # | | Interval # | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Replicate Number** | **1** | **2** | **1** | **2** | **1** | **2** | **1** | **2** | **1** | **2** | **1** | **2** | **1** | **2** | **1** | **2** | **1** | **2** | **1** | **2** | **1** | **2** |
| [Parent compound] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] |
| [Transformation product #1] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] |
| [Transformation product #2] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] |
| [Others] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] |
| Extracted residues | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] |
| Unextracted residues | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] |
| $CO_2$ | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] |
| Volatile organics | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] |
| Mass balance | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] |

[Repeat this table as needed for additional soils. Note that individual replicate values are tabulated rather than means and standard deviations.]

## E. Transformation of Test Compound:

Degradation of [radiolabel-test compound] on soil was [gradual, rapid, or some other characterization]. The calculated half-life ranged from [x] to [x] days, as tabulated in **Table 8** (calculated half-lives and model parameters for the best fit kinetics models are in bold). [Indicate the software used to determine model parameters. Indicate whether reviewer-reported half-lives are consistent with study-reported values and the relationship between calculated and observed values. Discuss any abnormalities observed in the data.]

[Images of kinetics calculation results using the R program may replace **Table 8**. R images should include the model parameters and statistics that are otherwise reported in **Table 8**.]

**Table 8. Transformation Kinetics of [Test Compound] in Soil [A, B]**

| | Observed $DT_{50}$ (days) | Observed $DT_{90}$ (days) | Calculated Half-life (days) | Kinetics Model [C] | Model Parameters | Model Statistics |
|---|---|---|---|---|---|---|
| [Soil Location] [USDA Soil Series] [Soil Texture] [# °C, pH #] | [#] | [#] | [#] | SFO | $C_0$=[#], k=[#] | $S_{SFO}$=[#], $r^2$=[#], p=[#] |
| | | | [#] | IORE | $C_0$=[#], k=[#], n=[#] | $S_{IORE}$=[#], $S_C$=[#], $r^2$=[#], p=[#] |
| | | | [#] | DFOP [if applicable] | $C_0$=[#], g=[#], $k_1$=[#], $k_2$=[#], | $S_{DFOP}$=[#], $r^2$=[#], p=[#] |
| [Soil Location] [USDA Soil Series] [Soil Texture] [# °C, pH #] | [#] | [#] | [#] | SFO | $C_0$=[#], k=[#] | $S_{SFO}$=[#], $r^2$=[#], p=[#] |
| | | | [#] | IORE | $C_0$=[#], k=[#], n=[#] | $S_{IORE}$=[#], $S_C$=[#], $r^2$=[#], p=[#] |
| | | | [#] | DFOP [if applicable] | $C_0$=[#], g=[#], $k_1$=[#], $k_2$=[#], | $S_{DFOP}$=[#], $r^2$=[#], p=[#] |

[A] Data were obtained from [location of data in study report] and calculations in the attached Excel workbook [name(s) of worksheets, if needed]. See Attachment 3 for calculations.

[B] Calculated half-lives and model parameters for the best fit kinetics models, in accordance with the NAFTA kinetics guidance (USEPA, 2011), are in bold.

[C] Kinetics models: Single First-Order (SFO); Double First-Order in Parallel (DFOP), and Indeterminate Order Rate Equation (IORE).

[Rows may be added for transformation product half-lives and $DT_{50}$s as needed. Half-lives should be calculated following the NAFTA kinetics guidance (USEPA, 2011). If multiple experiments were conducted per study condition using test compound with different radiolabel positions, calculate kinetics values for the combined data rather than for specific radiolabel positions.]

[Briefly summarize the transformation products per system in **Table 9**. If transformation product decline is observed over four time intervals, calculate a half-life and discuss the pattern of decline.]

**Table 9. Transformation Products of [Test Compound] in Soil**

| | Transformation Product(s) | Maximum %AR Observed | Associated Interval | Final %AR Observed | Final Interval |
|---|---|---|---|---|---|
| [Soil Location]<br>[USDA Soil Series]<br>[Soil Texture]<br>[# °C, pH #] | [common name] | [#] | [# d] | [#] | [# d] |
| | [common name] | [#] | [# d] | [#] | [# d] |
| [Soil Location]<br>[USDA Soil Series]<br>[Soil Texture]<br>[# °C, pH #] | [common name] | [#] | [# d] | [#] | [# d] |
| | [common name] | [#] | [# d] | [#] | [# d] |

[If applicable, provide a description of the transformation pathway here, including a schematic as Figure 1.]

**[Figure 1. Aerobic/Anaerobic Soil Degradation Pathway of [radiolabel-test compound]]**

## III. Study Deficiencies and Reviewer's Comments

[This section is titled "Conclusions" in the original T2S template.]

[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.]

## IV. References [List any references cited in the review.]

U.S. Environmental Protection Agency (USEPA). 2011. Guidance for Evaluating and Calculating Degradation Kinetics in Environmental Media. (Interim draft document dated Dec. 21, 2011.)

**Attachment 1: Chemical Names and Structures**

[A table (*i.e.*, structure table) of the chemical names, SMILES strings, CAS numbers, and structures of the test compound, all identified transformation products, and all reference compounds that were not identified in study samples should be either referenced as a separate, associated document or attached to the study review. Multiple versions of structures to show or not show radiolabeling and multiple versions of chemical names and SMILES strings should not be 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.

For multilateral reviews, chemical names, SMILES strings, structures, and CAS numbers are captured elsewhere in the Monograph[3]. 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, the Monograph's structure table should be either referenced as a separate, associated document or attached 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.]

Degradate Table.docx

[3] 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.

**Attachment 2: Statistics Spreadsheets and Graphs**

Soil Metabolism
Study Review Spread

[Supporting electronic spreadsheet files should be inserted here (electronic attachment files should be electronically finalized as separate files as well). Electronic attachments should have 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. Electronic attachment files should be compressed into a WinZip file when three or more are prepared for a study review.]

[Hard copies of a study review and any attachment sheets from separate electronic files should be printed and finalized together as one hard copy file.]

[The attached Excel file has three example spreadsheets for pe + pH (for anaerobic studies), mass balance, and kinetics calculations.]

**Attachment 3: Calculations**

Calculations were performed by the reviewer using [indicate program(s) used for calculations] and the following equations. [The following equations are anticipated to reflect the NAFTA kinetics guidance as of January, 2012. If these equations are not current, they should be replaced by the applicable equations from current guidance.]

**Single First-Order (SFO) Model**

$$C_t = C_0 e^{-kt} \quad \text{(eq. 1)}$$

where,

$C_t$ = concentration at time t (%)
$C_0$ = initial concentration (%)
e = Euler's number (-)
k = SFO rate constant of decline ($d^{-1}$)
t = time (d)

The SFO equation is solved [with the Excel Solver] by adjusting $C_0$ and $k$ to minimize the objective function ($S_{SFO}$) shown in equation 9.

$DT_{50}$ = natural log (2)/k (eq. 2)

$DT_{90}$ = ln (10)/k (eq. 3)

**Indeterminate Order Rate Equation (IORE) Model**

$$C_t = \left[C_0^{(1-N)} - (1-N)k_{IORE}t\right]^{\left(\frac{1}{1-N}\right)} \quad \text{(eq. 4)}$$

where,

N = order of decline rate (-)
$k_{IORE}$ = IORE rate constant of decline ($d^{-1}$)

This equation is solved [with the Excel Solver] by adjusting $C_0$, $k_{IORE}$, and $N$ to minimize the objective function for IORE ($S_{IORE}$) (See equation 9). Half-lives for the IORE model are calculated using equation 5, which represents a first-order half-life that passes through the $DT_{90}$ of the IORE model. (Traditional $DT_{50}$ and $DT_{90}$ values for the IORE model can be calculated using equations 6 and 7.)

$$t_{IORE} = \frac{\log(2)}{\log(10)} \frac{C_0^{1-N}(1-0.1^{(1-N)})}{(1-N)k_{IORE}} \quad \text{(eq. 5)}$$

$$DT_{50} = \frac{(C_0/2)^{(1-N)} - C_0^{(1-N)}}{k(N-1)} \quad \text{(eq. 6)}$$

$$DT_{90} = \frac{(C_0/10)^{(1-N)} - C_0^{(1-N)}}{k(N-1)} \quad \text{(eq. 7)}$$

**Double First-Order in Parallel (DFOP) Model**

$$C_t = C_0 g^{-k_1 t} + C_0(1-g)^{-k_2 t} \quad \text{(eq. 8)}$$

where,

g = the fraction of $C_0$ applied to compartment 1 (-)
$k_1$ = rate constant for compartment 1 ($d^{-1}$)
$k_2$ = rate constant for compartment 2 ($d^{-1}$)

If $C_0 \times g$ is set equal to $a$ and $C_0(1-g)$ is set equal to $c$, then the equation can be solved [with the Excel Solver] for $a$, $c$, $k_1$, and $k_2$ by minimizing the objective function ($S_{DFOP}$) as described in equation 9.

$DT_{50}$ and $DT_{90}$ values can be calculated using equations 2 and 3, with $k_1$ or $k_2$ in place of k.

**Objective Function:** SFO, IORE, and DFOP are solved by minimizing the objective function ($S_{SFO}$, $S_{IORE}$, or $S_{DFOP}$).

$$S_{SFO}, S_{IORE}, \text{ or } S_{DFOP} = \sum(C_{model,t} - C_{d,t})^2 \quad \text{(eq. 9)}$$

where,

$S_{SFO}$ , $S_{IORE}$, or $S_{DFOP}$ = objective function of kinetics model fit ($\%^2$)
n = number of data points (-)
$C_{model,t}$ = modelled value at time corresponding to $C_{d,t}$ (%)
$C_{d,t}$ = experimental concentration at time t (%)

**Critical Value to Determine Whether SFO is an Adequate Kinetics Model**

If $S_{SFO}$ is less than $S_C$, the SFO model is adequate to describe kinetics. If not, the faster of $t_{IORE}$ or the DFOP $DT_{50}$ for compartment 2 should be used.

$$S_c = S_{IORE}\left(1 + \frac{p}{n-p}F(\alpha, p, n-p)\right) \quad \text{(eq. 10)}$$

where,

$S_c$ = the critical value that defines the confidence contours ($\%^2$)
p = number of parameters (3 in this case)
$\alpha$ = the confidence level (0.50 in this case)
$F(\alpha, p, n-p)$ = F distribution with $\alpha$ level of confidence and degrees of freedom p and n-p

## Section III. Soil Metabolism Study Review Considerations

This list of considerations is provided to help reviewers assess the acceptability of soil metabolism studies. This list is not a screen or a checklist and should not be attached to the study reviews. Listed considerations carry unequal weight and should be evaluated using best professional judgment. All information from the study and from similar studies should be considered to determine whether any deficiencies affect the study classification.

» The test substance was the Technical Grade (TGAI) or a Pure Active Ingredient Radiolabeled (PAIRA). Known impurities or contaminants in the test material were reported.

» The radiopurity and specific activity of the test compound were provided (if radiolabeled).

» Radiolabel positioning was appropriate. For compounds containing ring structures, experiments were conducted separately for each respectively labelled ring structure, and test compounds were not radiolabeled on more than one ring structure in each experiment.

» Soils were completely characterized, including the USDA or WRB (World Reference Base) taxonomy.

» Foreign soils, if any, were adequately compared with domestic (U.S.) soils.

» The four soils were representative of intended use areas, with varying organic carbon content, pH, clay content, and microbial biomass.

» Soil moisture was maintained at approximately 75% of 1/3 bar or pF 2.0 – 2.5 during the aging process.

» Soils were not sieved using a screen smaller than 2 mm.

» The soils were incubated at a constant temperature representative of the climate conditions where use will occur. For example, a temperature of 20±2°C was used if the chemical may be used in temperate climates (including Great Britain, Europe, northern Asia, North America, and northern Mexico). For chemicals applied in colder climates, additional soil samples were incubated at a lower temperature (*e.g.*, 10±2°C). Other temperatures may be appropriate for other use locations.

» The study was conducted in darkness.

» Sampling intervals were adequate over the duration of the study.

» Duplicate incubation flasks were removed at each sampling interval.

» The material balance was reasonable (90% - 110%) for labeled chemicals and 70% - 120% for non-labeled chemicals.

» Repeatability of the analytical method and uniformity of the application procedure were verified by analyzing duplicate sediment samples immediately after the addition of test substance and by analyzing duplicate sediment extract samples.

» The study was conducted until patterns of decline of parent and patterns of formation and decline of transformation products were established or for no more than one year. If this criterion was met and at least 5% $CO_2$ was formed, then the study may have been terminated after 120 days or after at least 90% of the test substance was transformed.

» Detection and quantitation limits were reported.

A reasonable attempt was made, perhaps with a polar and multiple mild non-polar solvent systems, to extract the test compound and its transformation products from the soil.

» A reasonable attempt was made to identify the parent and all transformation products.

» Half-life ($DT_{50}$) and $DT_{90}$ for the test substance and, where appropriate, major transformation products were reported.

» Appropriate analytical methods were provided.

» pH, dissolved oxygen concentration and redox potential were reported initially, during and at the end of the study.

**Review Considerations for Anaerobic Studies**

» Treated soil was aged for one $DT_{50}$ or 30 days, whichever is shorter, prior to initiation of anaerobic conditions.

» pH, dissolved oxygen concentration and redox potential were reported for study initiation, termination, and at each sampling interval.

» The dissolved oxygen content found to be negligible, using best professional judgment.

» Values of pe plus pH were reduced to and held less than 12 in the flood water (pe is calculated with standard redox potentials).

» If the standard hydrogen electrode was not used to measure redox potentials, then measured redox potential values were reported as well as standard redox potential values (corrected for the difference in electrode potential).

# Aerobic and Anaerobic Aquatic Metabolism Study Review Guide

This guide is meant to aid in the review of aerobic and anaerobic aquatic metabolism (hereafter referred to as "aquatic metabolism") studies submitted under the Office of Chemical Safety and Pollution Prevention (OCSPP) guidelines 835.4300 (aerobic) and 835.4400 (anaerobic) and the Organisation for Economic Co-operation and Development (OECD) guideline 308 (OECD, 2002). The aquatic metabolism study review format is based on the format for OECD Tier II Summaries (T2S)[1]. Reviewers should add to the T2S format any information, statistical calculations, and formatting that will increase their utility to the Agency under OCSPP guidelines 835.4300 and 835.4400. In developing study reviews, reviewers should strive to write concisely and to minimize alterations to the T2S format.

Sections I, II, and III of this document provide additional details regarding formatting, data, and issues to consider in developing OCSPP environmental fate study reviews. Section I identifies aquatic metabolism data and formatting that do not appear in the OECD T2S format and that should be added to USEPA reviews. Although this guide does not strictly prescribe where and how to present the data, an example study review template is provided in Section II for guidance. In general, the example template should be followed, especially for unilateral reviews (*i.e.*, reviews conducted without the participation of other agencies). However, reviewers may modify the template as needed or disregard it in the case of multilateral reviews (*i.e.*, reviews with other agencies participating) in which an alternative format is agreed upon by the participating agencies. Lastly, a list of considerations (Section III) is provided to help reviewers focus on critical study issues and to identify any common major or minor deficiencies (*i.e.*, the considerations update the acceptance criteria for aquatic studies provided in the 1989 FIFRA Accelerated Reregistration Phase 3 Technical Guidance (USEPA, 1989).

**References**

Organisation for Economic Co-operation and Development (OECD). 2002. Test No. 308: Aerobic and Anaerobic Transformation in Aquatic Sediment Systems. OECD Guideline for the Testing of Chemicals, Section 3: Degradation and Accumulation, OECD Publishing. DOI: 10.1787/9789264070509-en

U.S. Environmental Protection Agency (USEPA). 1989. FIFRA Accelerated Reregistration, Phase 3 Technical Guidance. Office of the Prevention, Pesticides, and Toxic Substances, Washington, DC. EPA 540/09-90-078.

[1] A Tier II Summary is an OECD format for study reviews prepared by industry. See OECD Guidance Documents for Pesticide Registration at http://www.oecd.org/document/48/0,3746,en_2649_34365_2085104_1_1_1_1,00.html (Accessed June 20, 2011).

## Section I. Data to Include in the Aquatic Metabolism OECD T2S Template

The following information should be added to the aquatic metabolism T2S template to make it compatible with OCSPP guidelines 835.4300 and 835.4400 and increase its utility to the Agency:

**First Page and Executive Summary**

- The PC code of the test compound and MRID of the study should be provided in the header and on the first page.

- A statement should be included indicating whether the study was conducted in compliance with FIFRA GLP standards (and if not, how not or why not) and whether signed and dated Data Confidentiality, GLP Compliance, Quality Assurance, and Authenticity Certification statements were provided.

- The study classification and a concise statement of any deficiencies that impacted the classification should be provided on the first page of the review.

- A signature line(s) for the final reviewer(s) should be added to the first page of the review. If this is unacceptable for other agencies participating in a multilateral review, then a cover page with the signature line(s) can be attached to each individual review submitted to EFED's files.

- A results synopsis should be added to the Executive Summary to tabulate half-lives, including how they were calculated, as well as a list of transformation products and the maximum amount formed and interval at which the maximum occurred. Tabulated information should not be summarized in the text of the Executive Summary.

**Materials and Methods**

- The Test Material section should list the names and batch numbers of reference compounds used and provide a small image of the test compound structure with any radiolabeled atoms identified.

- Physicochemical properties of the test compound that are relevant to the study should be listed in the Test Material section. Irrelevant properties should not be listed.

- Initial measured concentrations should be reported in the Experimental Conditions section.

- If samples are stored, storage stability information should be described.

**Results and Discussion**

- The results of any checks on aerobic or anaerobic conditions, redox conditions, pH, sterility, sorption to vessel walls, or other test conditions that may affect the acceptability of the study should be reported in the Findings section.

- Observed $DT_{50}$ values and indications of how half-lives were calculated [*e.g.*, single first order (SFO)] should be added to the half-life tables in the Findings section.

- The Findings section should indicate whether reviewer-reported half-lives are consistent with study-reported values and observed values.

**Study Deficiencies and Reviewer's Comments**

- The Conclusions section should list any deficiencies with the study and any additional salient information; this section may be renamed "Study Deficiencies and Reviewer's Comments." Results and conclusions contained in the Executive Summary are not repeated in this section.

**References**

- A References section (Section IV) should be added that lists any literature references other than the study report cited in the study review.

**Attachments**

- A table (*i.e.*, structure table) of the chemical names, SMILES strings, CAS numbers, and structures of the test compound, all identified transformation products, and all reference compounds that were not identified in study samples should be either referenced as a separate, associated document or attached to the study review. Multiple versions of structures to show or not show radiolabeling and multiple versions of chemical names and SMILES strings should not be 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.

  For multilateral reviews, chemical names, SMILES strings, structures, and CAS numbers are captured elsewhere in the Monograph[2]. 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, the Monograph's structure table should be either referenced as a separate, associated document or attached to each individual review.

[2] 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.

- Statistical output files containing calculations (such as statistical analyses and outputs) and graphs that support values reported in the study review should be attached to the review. File names should begin with the same name as that of the individual review. For multilateral reviews, the file naming convention should consistently follow an agreed format.

- A Calculations section should be added that lists equations and defines parameters used to calculate half-lives. This section is currently placed in Attachment III but may be placed in Section I.B.4.

## Section II. Example Aquatic Metabolism Study Review Template

### Aerobic (or Anaerobic) Degradation in Aquatic Systems

| | |
|---|---|
| **Report:** | [Provide full citation. Provide the MRID (first) if the review is unilateral.] |
| **Document No.:** | [MRID ########] |
| **Guideline:** | [OCSPP 835.4300 (aerobic) or OCSPP 835.4400 (anaerobic)] [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 835.####.' 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 how not or why not.] |
| **Classification:** | This study is [provide classification and concise statement of any deficiencies that impacted the classification]. [If multiple classification terminologies are needed for multilateral reviews, list or tabulate them.] |
| **PC Code:** | [######] |
| **Reviewer:** | [Provide final reviewer(s)'s name and title.] **Signature:** **Date:** [Type date of signature.] |

### Executive Summary

The [aerobic or anaerobic] transformation of [type of radiolabel]-labeled [test compound] was studied in [number of] $H_2O$:sediment systems for [duration] days in a closed system in darkness at [temperature] °C, water column pH [value], sediment pH [value] with a total organic carbon of [value] mg/L. [Indicate whether anaerobic conditions were maintained in sediment.] Microbial biomass determinations indicated the water sediment systems [were or were not] viable at study initiation and termination.

Overall mass balances for [system x and y] averaged [value]% of the applied radioactivity (%AR) and [value]%AR, respectively, ranging from [value to value]%AR. In the water column [test compound] ranged from [value]% at day 0 to [value]% at [value] days, while in sediment [test compound] ranged from [value]% at day 0 to [value]% at [value] days.

Observed $DT_{50}$ values, calculated half-lives based on the harmonized NAFTA kinetics guidance (USEPA, 2011), and information on transformation products are listed in **Table 1**. [Describe whether a reasonable effort was made to maximize recovery of residues in sediment. If not, describe whether transformation kinetics calculations were performed for test compound plus unextracted residues as well as for test compound alone.] The amount of extracted radioactivity declined from [value]%AR at study initiation to [value]%AR at day [number]. Unextracted radioactivity increased to [value]%AR at day [number]. The total evolved $CO_2$ and other volatile compounds amounted to [value]%AR and [value]%AR, respectively.

**Table 1. Results Synopsis: [Aerobic or Anaerobic] Aquatic Metabolism of [Test Compound] in the Total System**

| Total System | Observed $DT_{50}$ (days) | Calculated Half-life (days) Method | Model Parameters and Statistics | Transformation Products Common Name (maximum %AR [A] observed, associated interval) | |
|---|---|---|---|---|---|
| | | | | Major | Minor |
| [$H_2O$:Sediment System , # °C, pH #] | [value] | [value] [method] | [value] | [name] (# %, # days) | [name] (# %, # days) |
| [$H_2O$:Sediment System , # °C, pH #] | [value] | [value] [method] | [value] | [name] (# %, # days) | [name] (# %, # days) |

[A] AR means "applied radioactivity"
[Model parameters include model variables; model statistics include Sc values, correlation coefficients, and p values.]
[Half-lives and model parameters should be reported for the best fit kinetics model in accordance with the NAFTA kinetics guidance (USEPA, 2011). If multiple experiments were conducted per study condition using test compound with different radiolabel positions, calculate kinetics values for the combined data rather than for specific radiolabel positions.]

## I. Materials and Methods

### A. Materials:

Provide a small image of the test compound's structure and any radiolabel on the right margin.

1. **Test Material:** [Type of radiolabel]-labeled[test compound]
   Specific radioactivity: [value] units
   Radiochemical purity: [percentage [HPLC or TLC]
   Chemical purity: [percentage (HPLC)]
   Batch number: [value]
   Solubility in water: [value] mg/L at [value] °C [If pH-dependent, list available values at each pH and temperature]

2. **Reference Compounds:** The following compounds were used in the analysis.

**Table 2. Reference Compounds**

| Applicant's Code Name | Chemical Name | Purity (%) | Lot No. |
|---|---|---|---|
| [code name] | [chemical name] | [#] | [#] |
| [code name] | [chemical name] | [#] | [#] |
| [code name] | [chemical name] | [#] | [#] |

Data were obtained from [page number] of the study report.
[Provide other chemical information in the structure table.]

3. **Water-sediment:** [Characterize any unique properties of water and sediment collection or storage conditions]. Water and sediment collection and characterization are summarized in **Table 3** and **Table 4**, respectively.

**Table 3. Water:Sediment Collection and Storage**

| **Description** | | **Water:Sediment System** |
|---|---|---|
| Geographic location | | |
| Pesticide use history at the collection site | | |
| Collection procedures | Water: | |
| | Sediment: | |
| Storage temperature | | |
| Storage length | | |
| Preparation | Water: | |
| | Sediment: | |

Data obtained from page [#] of the study report.
[Repeat this table as needed for additional $H_2O$:sediment systems.]

**Table 4. Parameters for Characterization of Water:Sediment Samples**

| **Parameter (unit)** | **Field Sampling/Post Handling** | **Stage of Test Procedure** | | |
|---|---|---|---|---|
| | | **Prior to Test** | **During Test** | **End of Test** |
| **Water** | | | | |
| Temperature (°C) | [#] | | | |
| pH | [#] | [#] | [#] | [#] |
| TOC (mg/L) | | [#] | [#] | [#] |
| $O_2$ concentration (mg/L) | [#] | [#] | [#] | [#] |
| Standard redox potential (mV) | | [#] | [#] | [#] |
| **Sediment** | | | | |
| Sampling Depth (cm) | [range] | | | |
| pH | [#] | [#] | [#] | [#] |
| Particle Size Distribution | [%] sand (2000-50 µm)<br>[%] silt (50-2 µm)<br>[%] clay (<2 µm) | | | |
| TOC (mg/L) | | [#] | | [#] |
| Microbial biomass (mg $CO_2$/hr/kg dry wt.) | | [#] | | [#] |
| Standard redox potential (mV) | | [#] | [#] | [#] |

[Repeat this table as needed for additional water:sediment systems. Indicate the use of any non-standard sampling instruments or methods. Standard redox potential values should be reported. If the standard hydrogen electrode was not used to measure redox potentials, then measured redox potential values should be corrected for the difference in electrode potential to produce standard values.]

## B. Study Design:

1. **Experimental Conditions:** [Describe any unique characteristics of the study design, if any.] **Table 5** summarizes the experimental conditions.

**Table 5. Experimental Design**

| Experimental Design | Details |
|---|---|
| Duration of the test | [#] days |
| Water: | |
| Type and size of filter used | |
| Amount of sediment and water per treatment: | |
| Water | [#] mL ([#] mL associated with sediment, plus [#] mL added) |
| Sediment | [#] g dry wt. ([#] g wet wt., [#] mL) |
| Water/sediment ratio | [#] mL: [#] g dry weight |
| Application rates: | |
| Nominal | [#] mg a.i./L |
| Actual | [#] mg a.i./L |
| Number of replicates: | |
| Control, if used | |
| Treated | |
| Test apparatus: | |
| Type/ material/volume | |
| Details of traps for $CO_2$ and organic volatile, if any | |
| If no traps were used, is the system closed? | |
| Identity and final concentration (based on water volume) of co-solvent | [#] ([#] µL/[#] mL) |
| Test material application method: | |
| Volume of the test solution used/treatment | |
| Application method (*i.e.*;, mixed/not mixed) | |
| Any indication of the test material adsorbing to the walls of the test apparatus? | |
| Microbial biomass/population of control units: | |
| Water | |
| Sediment | [#] mg $CO_2$/hr/kg dry wt. |
| Microbial biomass/population of treated: | |
| Water | |
| Sediment | [#] mg $CO_2$/hr/kg dry wt. |
| Experimental conditions: | |
| Temperature | [#] °C |
| Continuous darkness (yes/no) | |
| Other details, (if any) | |

[Repeat this table as needed for additional water:sediment systems.]

2. **Sampling during Study Period:** [Describe any unique characteristics of sampling during study period, if any.] **Table 6** summarizes sampling during the study period.

**Table 6. Sampling during Study Period**

| Parameter | Details |
|---|---|
| Sampling intervals (duration) | |
| Sampling method | |
| Method of collection of $CO_2$ and organic volatile compounds | |
| **Sampling Intervals/Times** | |
| Redox potential in water layer | |
| Dissolved oxygen in water layer | |
| pH in water layer | |
| Redox potential in sediment | |
| pH in sediment | |
| Other details, if any | |

[Repeat this table as needed for additional $H_2O$:sediment systems. Indicate the use of any non-standard sampling instruments or methods.]

3. **Analytical Procedures:** [Briefly describe the extraction method. An example follows.]

**Separation of the Water and Sediment:** The water layer was decanted and centrifuged (speed, interval), then triplicate aliquots ([#] mL) were analyzed for total radioactivity by LSC (report page number). Resulting solids were combined with the respective sediment sample.

**Extraction/Clean Up/Concentration Methods:** Water layer samples were analyzed directly by TLC (described below, report page number).

Sediment was transferred to a centrifuge beaker and extracted [value] times with [solvent] via [method] (*e.g.*, shaker) at speed ([value] rpm) for [duration]; extraction solvent volumes were [value] mL. Extract and sediment were separated by centrifugation [speed], [interval] (if reported); after which, the extract was decanted and filtered ([brand name] filter), and pore/mesh size (if reported). Extracts were combined and [#] of replicate aliquots ([value] mL) were analyzed for total radioactivity by [analytical method]. Aliquots of the extracts were analyzed directly by [analytical method].

Reflux extraction. Extracted sediment ([#] g) was further refluxed ([apparatus], [duration] boiling, [#] [duration] rinsing) and extracted with acetonitrile:water ([#]:[#], v:v, [#] mL; report page number). Duplicate aliquots ([#] mL) were analyzed for total radioactivity by LSC.

Aliquots of the acetonitrile (ambient) and reflux extracts were analyzed directly by TLC without concentration (report page number).

**Total $^{14}C$ Measurement:** Total $^{14}C$ residues were determined by summing the concentrations of residues measured in the water layers, sediment extracts, extracted sediment, filter papers and volatile trapping materials (report page numbers).

**Determination of Unextracted Residues:** Aliquots of acetonitrile-extracted sediment were air-dried, then homogenized (homogenizing equipment, report page number). Triplicate aliquots (*ca.* [#] g) were analyzed for total radioactivity by LSC following combustion.

**Determination of Volatile Residues:** Polyurethane foam plugs were extracted with ethyl acetate ([#] mL, report page number). Duplicate aliquots ([#] mL) of the extract were analyzed for total radioactivity by LSC.

To recover radioactivity (presumably, $^{14}CO_2$) from the (substance, *i.e.*, soda lime), [value] % ( substance, *i.e.*, HCl) ([value] mL) was applied [method] to the (substance, *i.e.*, soda lime), ([value] g) with agitation via[method]. Released $^{14}CO_2$ was purged (nitrogen, flow rate, if reported, *ca.* [duration] minutes) through ice-cooled [apparatus] (ratio if specified, [value] mL scintillation cocktail and quantified by LSC. Any dissolved $^{14}CO_2$ in the water layer samples ([value] mL) and [$^{14}$C]carbonates in the (duration)-day sediment samples ([value] g) were similarly recovered.

**Total Radioactivity Measurement:** Total $^{14}$C residues were determined by summing the concentrations of residues measured in the water layers, sediment extracts, extracted sediment, filter papers and volatile trapping materials ([report page number]).

**Derivatization Method:** [Describe derivatization method, if employed.]

**Identification and Quantification of Parent Compound:** Aliquots of the water layer ([#] µL) and sediment extract (aliquot volume. if reported) samples were analyzed using one-dimensional TLC on normal-phase plates (*i.e.*, silica gel) developed with methylene chloride:acetonitrile:acetic acid ([#]:[#]:[#], v:v:v, SS1; report page number). Following development, areas of radioactivity were detected and quantified using a (analyzer product name and number) Analyzer in conjunction with (software name) software (report page number)). Parent [$^{14}$C][parent compound] was identified by co-chromatography with unlabeled reference standard visualized under UV light ([#] nm).

Identification of parent was confirmed in selected samples using one-dimensional TLC on reverse-phase plates (*i.e.*, silica gel ) developed with acetonitrile: [#] M sodium chloride: trifluoroacetic acid ([#]:[#]:[#], v:v:v, SS2; report page number). Following development, areas of radioactivity were detected, quantified and identified as described above (report page number).

**Identification and Quantification of Transformation Products:** Transformation products were separated, quantified and identified using TLC as described for the parent compound (report page number).

**Detection Limits (LOD, LOQ) for the Parent Compound:** The limit of detection (LOD) was determined to be [%] of the applied radioactivity (%AR), with a limit of quantitation (LOQ) at [%]AR.

**Detection Limits (LOD, LOQ) for the Transformation Products:** For [method] analyses, the limit of quantitation (LOQ) was reported as *ca.* [value] % of the applied radioactivity, corresponding to *ca.* [value] µg/kg for parent and transformation products (report page number).

## II. Results and Discussion

### A. Data:

Study results, including total mass balances and distribution of radioactivity, are presented in **Table 7**. [Indicate the results of any checks on aerobic or anaerobic conditions and viability of test soils. If applicable, report redox conditions.]

### B. Mass Balance:

In [system x], recoveries ranged from [percentage] to [percentage] of the applied radioactivity (%AR). In the water column [test compound] ranged from [value]% at day 0 to [value]% at [value] days, while in sediment [test compound] ranged from [value]% at day 0 to [value]% at [value] days. In [system y], recoveries ranged from [percentage] to [percentage]AR. In the water column, [test compound] ranged from [value]% at day 0 to [value]% at [value] days, while in sediment [test compound] ranged from [value]% at day 0 to [value]% at [value] days. [If there is a large amount of unidentified radioactivity, mention it here. Indicate whether there was substantial loss of radioactivity by sorption to glassware or volatilization. Also mention if the mass balance meets guideline criteria.]

### C. Bound and Extractable Residues:

The amount of extractable radioactivity declined from [percentage]AR at time zero to [percentage]AR at day [number] for [test compound]. Unextracted radioactivity increased to [percentage]AR at day [number]. [If unextracted residues were >10% of the applied, discuss whether the sediment extraction procedures were reasonable and whether the unextracted residues may include available residues.]

### D. Volatilization:

Volatiles [were/were not] trapped. Volatile radioactivity, identified as evolved $^{14}CO_2$, represented [percentage]AR at day [number] for [test compound]. [Add information regarding additional volatile chemicals as needed.]

**Table 7. Transformation of [test compound] in [water:sediment system], Expressed as a Percentage of Applied Radioactivity**

| Sampling Interval (days) | Interval # | | Interval # | | Interval # | | Interval # | | Interval # | | Interval # | | Interval # | | Interval # | | Interval # | | Interval # | | Interval # | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Replicate Number** | **1** | **2** | **1** | **2** | **1** | **2** | **1** | **2** | **1** | **2** | **1** | **2** | **1** | **2** | **1** | **2** | **1** | **2** | **1** | **2** | **1** | **2** |
| [Parent compound] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] |
| [Transformation product #1] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] |
| [Transformation product #2] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] |
| [Others] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] |
| Extracted residues | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] |
| Unextracted residues | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] |
| $CO_2$ | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] |
| Volatile organics | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] |
| Mass balance | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] |

[Repeat this table as needed for additional water:sediment systems. Note that individual replicate values are tabulated rather than means and standard deviations.]

## E. Transformation of Test Compound:

Degradation of [radiolabel-test compound] in sediment was [gradual, rapid, or some other characterization]. The calculated half-life ranged from [x] to [x] days, as tabulated in **Table 8** (calculated half-lives and model parameters for the best fit kinetics models are in bold). [Indicate the software used to determine model parameters. Indicate whether reviewer-reported half-lives are consistent with study-reported values and the relationship between calculated and observed values. Discuss any abnormalities observed in the data.]

[Images of kinetics calculation results using the R program may replace **Table 8**. R images should include the model parameters and statistics that are otherwise reported in **Table 8**.]

**Table 8. Transformation Kinetics of [Test Compound] in Total Aquatic Systems [A, B]**

| | Observed $DT_{50}$ (days) | Observed $DT_{90}$ (days) | Calculated Half-life (days) | Kinetics Model [C] | Model Parameters | Model Statistics |
|---|---|---|---|---|---|---|
| [$H_2O$:Sediment System , #°C, pH #] | [#] | [#] | [#] | SFO | $C_0$=[#], k=[#] | $S_{SFO}$=[#], $r^2$=[#], p=[#] |
| | | | [#] | IORE | $C_0$=[#], k=[#], n=[#] | $S_{IORE}$=[#], $S_C$=[#], $r^2$=[#], p=[#] |
| | | | [#] | DFOP [if applicable] | $C_0$=[#], g=[#], $k_1$=[#], $k_2$=[#], | $S_{DFOP}$=[#], $r^2$=[#], p=[#] |
| [$H_2O$:Sediment System , #°C, pH #] | [#] | [#] | [#] | SFO | $C_0$=[#], k=[#] | $S_{SFO}$=[#], $r^2$=[#], p=[#] |
| | | | [#] | IORE | $C_0$=[#], k=[#], n=[#] | $S_{IORE}$=[#], $S_C$=[#], $r^2$=[#], p=[#] |
| | | | [#] | DFOP [if applicable] | $C_0$=[#], g=[#], $k_1$=[#], $k_2$=[#], | $S_{DFOP}$=[#], $r^2$=[#], p=[#] |

[A] Data were obtained from [location of data in study report] and calculations in the attached Excel workbook [name(s) of worksheets, if needed]. See Attachment 3 for calculations.
[B] Calculated half-lives and model parameters for the best fit kinetics models, in accordance with the NAFTA kinetics guidance (USEPA, 2011), are in bold.
[C] Kinetics models: Single First-Order (SFO); Double First-Order in Parallel (DFOP), and Indeterminate Order Rate Equation (IORE).

[Rows may be added for transformation product half-lives and $DT_{50}$s as needed. Half-lives should be calculated following the NAFTA kinetics guidance (USEPA, 2011). If multiple experiments were conducted per study condition using a test compound with different radiolabel positions, calculate kinetics values for the combined data rather than for specific radiolabel positions.]

[Briefly summarize the transformation products per system in **Table 9**. If transformation product decline is observed over four time intervals, calculate a half-life and discuss the pattern of decline.]

**Table 9. Transformation Products of [Test Compound] in Total Aquatic Systems**

| | Transformation Product(s) | Maximum %AR Observed | Associated Interval | Final %AR Observed | Final Interval |
|---|---|---|---|---|---|
| [$H_2O$:Sediment System , #°C, pH #] | [common name] | [#] | [# d] | [#] | [# d] |
| | [common name] | [#] | [# d] | [#] | [# d] |
| [$H_2O$:Sediment System , #°C, pH #] | [common name] | [#] | [# d] | [#] | [# d] |
| | [common name] | [#] | [# d] | [#] | [# d] |

[If applicable, provide a description of the transformation pathway here, including a schematic as Figure 1.]

**[Figure 1. Aerobic/Anaerobic Aquatic Degradation Pathway of [radiolabel-test compound]]**

## III. Study Deficiencies and Reviewer's Comments

[This section is titled "Conclusions" in the original T2S template.]

[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.]

## IV. References [List any references cited in the review.]

U.S. Environmental Protection Agency (USEPA). 2011. Guidance for Evaluating and Calculating Degradation Kinetics in Environmental Media. (Interim draft document dated Dec. 21, 2011.)

**Attachment 1: Chemical Names and Structures**

[A table (*i.e.*, structure table) of the chemical names, SMILES strings, CAS numbers, and structures of the test compound, all identified transformation products, and all reference compounds that were not identified in study samples should be either referenced as a separate, associated document or attached to the study review. Multiple versions of structures to show or not show radiolabeling and multiple versions of chemical names and SMILES strings should not be 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.

For multilateral reviews, chemical names, SMILES strings, structures, and CAS numbers are captured elsewhere in the Monograph[3]. 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, the Monograph's structure table should be either referenced as a separate, associated document or attached 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.]

Degradate Table.docx

[3] 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.

**Attachment 2: Statistics Spreadsheets and Graphs**

Aquatic Metabolism
Study Review Spread

[Supporting electronic spreadsheet files should be inserted here (electronic attachment files should be electronically finalized as separate files as well). Electronic attachments should have 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. Electronic attachment files should be compressed into a WinZip file when three or more are prepared for a study review.]

[Hard copies of a study review and any attachment sheets from separate electronic files should be printed and finalized together as one hard copy file.]

[The attached Excel file has three example spreadsheets for pe + pH, mass balance, and kinetics calculations.]

**Attachment 3: Calculations**

Calculations were performed by the reviewer using [indicate program(s) used for calculations] and the following equations. [The following equations are anticipated to reflect the NAFTA kinetics guidance as of January, 2012. If these equations are not current, they should be replaced by the applicable equations from current guidance.]

**Single First-Order (SFO) Model**

$$C_t = C_0 e^{-kt} \quad \text{(eq. 1)}$$

where,

$C_t$ = concentration at time t (%)
$C_0$ = initial concentration (%)
e = Euler's number (-)
k = SFO rate constant of decline ($d^{-1}$)
t = time (d)

The SFO equation is solved [with the Excel Solver] by adjusting $C_0$ and $k$ to minimize the objective function ($S_{SFO}$) shown in equation 9.

$DT_{50}$ = natural log (2)/k (eq. 2)

$DT_{90}$ = ln (10)/k (eq. 3)

**Indeterminate Order Rate Equation (IORE) Model**

$$C_t = \left[C_0^{(1-N)} - (1-N)k_{IORE}t\right]^{\left(\frac{1}{1-N}\right)} \quad \text{(eq. 4)}$$

where,

N = order of decline rate (-)
$k_{IORE}$ = IORE rate constant of decline ($d^{-1}$)

This equation is solved [with the Excel Solver] by adjusting $C_0$, $k_{IORE}$, and $N$ to minimize the objective function for IORE ($S_{IORE}$) (See equation 9). Half-lives for the IORE model are calculated using equation 5, which represents a first-order half-life that passes through the $DT_{90}$ of the IORE model. (Traditional $DT_{50}$ and $DT_{90}$ values for the IORE model can be calculated using equations 6 and 7.)

$$t_{IORE} = \frac{\log(2)}{\log(10)} \frac{C_0^{1-N}\left(1-0.1^{(1-N)}\right)}{(1-N)k_{IORE}} \quad \text{(eq. 5)}$$

$$DT_{50} = \frac{(C_0/2)^{(1-N)} - C_0^{(1-N)}}{k(N-1)} \quad \text{(eq. 6)}$$

$$DT_{90} = \frac{(C_0/10)^{(1-N)} - C_0^{(1-N)}}{k(N-1)} \quad \text{(eq. 7)}$$

**Double First-Order in Parallel (DFOP) Model**

$$C_t = C_0 g^{-k_1 t} + C_0(1-g)^{-k_2 t} \quad \text{(eq. 8)}$$

where,

g = the fraction of $C_0$ applied to compartment 1 (-)
$k_1$ = rate constant for compartment 1 ($d^{-1}$)
$k_2$ = rate constant for compartment 2 ($d^{-1}$)

If $C_0 \times g$ is set equal to $a$ and $C_0(1-g)$ is set equal to $c$, then the equation can be solved [with the Excel Solver] for $a$, $c$, $k_1$, and $k_2$ by minimizing the objective function ($S_{DFOP}$) as described in equation 9.

$DT_{50}$ and $DT_{90}$ values can be calculated using equations 2 and 3, with $k_1$ or $k_2$ in place of k.

**Objective Function:** SFO, IORE, and DFOP are solved by minimizing the objective function ($S_{SFO}$, $S_{IORE}$, or $S_{DFOP}$).

$$S_{SFO}, S_{IORE}, \text{ or } S_{DFOP} = \sum(C_{model,t} - C_{d,t})^2 \quad \text{(eq. 9)}$$

where,

$S_{SFO}$ , $S_{IORE}$, or $S_{DFOP}$ = objective function of kinetics model fit ($\%^2$)
n = number of data points (-)
$C_{model,t}$ = modelled value at time corresponding to $C_{d,t}$ (%)
$C_{d,t}$ = experimental concentration at time t (%)

**Critical Value to Determine Whether SFO is an Adequate Kinetics Model**

If $S_{SFO}$ is less than $S_C$, the SFO model is adequate to describe kinetics. If not, the faster of $t_{IORE}$ or the DFOP $DT_{50}$ for compartment 2 should be used.

$$S_c = S_{IORE}\left(1 + \frac{p}{n-p}F(\alpha, p, n-p)\right) \quad \text{(eq. 10)}$$

where,

$S_c$ = the critical value that defines the confidence contours ($\%^2$)
p = number of parameters (3 in this case)
α = the confidence level (0.50 in this case)
F(α, p, n-p) = F distribution with α level of confidence and degrees of freedom p and n-p

## Section III. Aquatic Metabolism Study Review Considerations

This list of considerations is provided to help reviewers assess the acceptability of aquatic metabolism studies. This list is not a screen or a checklist and should not be attached to the study reviews. Listed considerations carry unequal weight and should be evaluated using best professional judgment. All information from the study and from similar studies should be considered to determine whether any deficiencies affect the study classification.

» Test substance was the Technical Grade (TGAI) or a Pure Active Ingredient Radiolabeled (PAIRA). Known impurities or contaminants in the test material were reported.

» The radiopurity and specific activity of the test compound were provided (if radiolabeled).

» Radiolabel positioning was appropriate. For compounds containing ring structures, experiments were conducted separately for each respectively labeled ring structure, and test compounds were not radiolabeled on more than one ring structure in each experiment.

» The maximum length of the study was one year.

» Aerobic or aquatic conditions were assured and maintained throughout the test.

» The study was conducted in darkness.

» Application rate was consistent with the sensitivity of the analytical method so that degradates could be identified.

» Reported experimental temperature was held constant between 10 and 30°C (± 1 °C).

» Sampling intervals were adequate over the duration of the study.

» The material balance was reasonable (>90% - <110%) for labeled chemicals and 70-110% for non-labeled chemicals.

» Repeatability of the analytical method and uniformity of the application procedure were verified by analyzing duplicate sediment samples immediately after the addition of test substance and by analyzing duplicate sediment extract samples.

» The study was conducted until patterns of decline of parent and patterns of formation and decline of transformation products were established or for no more than one year. If this criterion was met and at least 5% $CO_2$ was formed, then the study may have been terminated after 120 days or after at least 90% of the test substance was transformed.

» Detection and quantitation limits were reported.

» A reasonable attempt was made to identify the parent and all transformation products.

» A reasonable attempt was made, perhaps with a polar and multiple mild non-polar solvent systems, to extract the test compound and its transformation products from the sediment.

» Half-life ($DT_{50}$) and $DT_{90}$ for the test substance and, where appropriate, major transformation products were reported.

» Appropriate analytical methods were provided.

» pH, dissolved oxygen concentration and redox potential were reported initially, during, and at the end of the study.

**Review Considerations for Anaerobic Studies**

» The dissolved oxygen content was negligible, using best professional judgment.

» Values of pe plus pH were reduced to and held less than 12 in the flood water (pe is calculated with standard redox potentials).

» If the standard hydrogen electrode was not used to measure redox potentials, then measured redox potential values were reported as well as standard redox potential values (corrected for the difference in electrode potential).

# Adsorption/Desorption (Batch Equilibrium) Study Review Guide

This guide is meant to aid in the review of adsorption/desorption (specifically, batch equilibrium) studies submitted under the Office of Chemical Safety and Pollution Prevention (OCSPP) guideline 835.1230. The batch equilibrium study review format is based on the format for the Organisation for Economic Co-operation and Development (OECD) Tier II Summaries (T2S)[1]. Reviewers should add to the T2S format any information, statistical calculations, and formatting which will increase their utility to the Agency under OCSPP guideline 835.1230. In developing study reviews, reviewers should strive to write concisely and to minimize alterations to the T2S format.

Sections I, II, and III of this document provide additional details regarding formatting, data, and issues to consider in developing OCSPP environmental fate study reviews. Section I identifies batch equilibrium data and formatting that do not appear in the OECD T2S format and that should be added to USEPA reviews. Although this guide does not strictly prescribe where and how to present the data, an example study review template is provided in Section II for guidance. In general, the example template should be followed, especially for unilateral reviews (*i.e.*, reviews conducted without the participation of other agencies). However, reviewers may modify the template as needed or disregard it in the case of multilateral reviews (*i.e.*, reviews with other agencies participating) in which an alternative format is agreed upon by the participating agencies. Lastly, a list of review considerations (Section III) is provided to help reviewers focus on critical study issues and to identify any common major or minor deficiencies (*i.e.*, the review considerations update the acceptance criteria for batch equilibrium studies provided in the 1989 FIFRA Accelerated Reregistration Phase 3 Technical Guidance (USEPA, 1989)).

## References

U.S. Environmental Protection Agency (USEPA). 1989. FIFRA Accelerated Reregistration, Phase 3 Technical Guidance. Office of the Prevention, Pesticides, and Toxic Substances, Washington, DC. EPA 540/09-90-078.

[1] A Tier II Summary is an OECD format for study reviews prepared by industry. See OECD Guidance Documents for Pesticide Registration at http://www.oecd.org/document/48/0,3746,en_2649_34365_2085104_1_1_1_1,00.html (Accessed Mar. 3, 2011).

## Section I. Data to Include in the Batch Equilibrium OECD T2S Template

The following information should be added to the batch equilibrium T2S template to make the study review compatible with OCSPP guideline 835.1230 and increase its utility to the Agency:

**First Page and Executive Summary**

- The PC code of the test compound and MRID of the study should be provided in the header and on the first page.
- A statement should be included indicating whether the study was conducted in compliance with FIFRA GLP standards (and if not, how not or why not) and whether signed and dated Data Confidentiality, GLP Compliance, Quality Assurance, and Authenticity Certification statements were provided.
- The study classification and a concise statement of any deficiencies that impacted the classification should be provided on the first page of the review.
- A signature line(s) for the final reviewer(s) should be added to the first page of the review. If this is unacceptable for other agencies participating in a multilateral review, then a cover page with the signature line(s) can be attached to each individual review submitted to EFED's files.
- A results synopsis should be added to the Executive Summary to tabulate sorption coefficients, including how they were calculated. Tabulated information should not be summarized in the text of the Executive Summary.
- The coefficient of variation of regressed $K_d$, $K_{OC}$, $K_F$, and $K_{FOC}$ values should be reported.

**Materials and Methods**

- The Test Material section should list the names and batch numbers of reference compounds used and provide a small image of the test compound structure with any radiolabeled atoms identified.
- Physicochemical properties of the test compound that are relevant to the study should be listed in the Test Material section. Irrelevant properties should not be listed.
- The analytical method used to measure the test material and any transformation products in water and soil/sediment should be described, as should the method(s) used to determine the identity of the test material and any transformation products. The analytical method limits of detection (LOD) and quantitation (LOQ) should also be reported.
- The method used to measure the amount of organic carbon in the soils and sediments should be described.

- If samples are stored, storage stability information should be described.

**Results and Discussion**

- The results of any checks on verification of pH, sterility, sorption to vessel walls, or other test conditions should be reported in the Findings section.

- The Findings section should indicate whether reviewer-reported sorption coefficients are consistent with study-reported values.

- $K_d$ should be regressed by percent organic carbon. If organic carbon is important in understanding sorption for the compound, regress the $K_{OC}$ values to pH, percent clay, and cation exchange capacity (CEC). Otherwise, regress the $K_d$ values with pH, percent clay, and CEC. Data plots of $K_d$ or $K_{OC}$ (as appropriate) versus each of these properties should be reported along with the results of the linear regression (slope, squared correlation coefficient ($r^2$), and the significance p-value). If the compound has a pKa, note how the association state of the chemical may have influenced or confounded the correlations.

- The range of equilibrium concentrations associated with a particular sorption coefficient should be reported, as this is the range of concentrations where the sorption coefficient is valid. It is needed to ensure that the solubility of the test compound was not approached and that sorption was measured over an appropriate range of equilibrium concentrations.

**Study Deficiencies and Reviewer's Comments**

- The Conclusions section should list any deficiencies with the study and any additional salient information; this section may be renamed "Study Deficiencies and Reviewer's Comments." Results and conclusions contained in the Executive Summary should not be repeated in this section.

**References**

- A References section should be added that lists any literature references other than the study report cited in the study review.

**Attachments**

- A table (*i.e.*, structure table) of the chemical names, SMILES strings, CAS numbers, and structures of the test compound, all identified transformation products, and all reference compounds that were not identified in study samples should be either referenced as a separate, associated document or attached to the study review. Multiple versions of structures to show or not show radiolabeling and multiple versions of chemical names and SMILES strings should not be 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.

For multilateral reviews, chemical names, SMILES strings, structures, and CAS numbers are captured elsewhere in the Monograph[2]. 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, the Monograph's structure table should be either referenced as a separate, associated document or attached to each individual review.

- Statistical output files containing calculations (such as statistical analyses and outputs) and graphs that support values reported in the study review should be attached to the review. File names should begin with the same name as that of the individual review. For multilateral reviews, the file naming convention should consistently follow an agreed format.

- A Calculations section should be added that lists equations and defines parameters used to calculate study results such as sorption coefficients. This section is currently placed in Attachment III but may be placed in Section I.B.3.

[2] 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.

## Section II. Example Batch Equilibrium Study Review Template

**Adsorption and desorption of [test compound] in [number] soils [or sediments]**

| | |
|---|---|
| **Report:** | [Provide full citation. Provide the MRID (first) if the review is unilateral.] |
| **Document No.:** | [MRID xxxxxxxx] |
| **Guideline:** | OCSPP 835.1230 [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 835.1230.' 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 how not or why not.] |
| **Classification:** | This study is [provide classification and 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:** | [xxxxxx] |
| **Reviewer:** | [Provide final reviewer(s)'s name and title.] **Signature:** **Date:** [Type date of signature.] |

**Executive Summary**

In a batch equilibrium study, [identify number of soils/sediments and origin and range of pH, *e.g.*, one U.S. soil and two European soils (pH range of 5.2 - 7.3)] were used to measure sorption coefficients of [type of radiolabel(s)]-labeled [test compound] at [temperature±degree of variation]. Determined Freundlich Adsorption Coefficient ($K_F$) values ranged from [value] to [value] (mean $K_F$=[value]); $K_{FOC}$ values ranged from [value] to [value] (mean $K_{FOC}$= [value]).[3] The Freundlich Desorption Coefficients ($K_{F\text{-}des}$) for desorption were [greater than/similar to] ([provide range, mean $K_F$ =[value]]) those obtained for the initial sorption measurement and a total of [percentage] the amount initially sorbed was desorbed. [Discuss implications of results, *e.g.*, is sorption reversible?] Freundlich exponents corresponding to $K_F$ values ranged from [provide range] indicating that sorption [was/was not] linear, *i.e.* the sorption coefficient [was/was not] independent of the test item concentration. Adsorption coefficients ($K_d$) ranged from [value] to [value and units] and organic carbon normalized adsorption coefficients ($K_{OC}$) ranged from [report range of values and units]. **Table [number]** summarizes the adsorption coefficients measured in the study. **Table [number]** summarizes the desorption coefficients measured in the study. [Report coefficients of variation for $K_d$, $K_{OC}$, $K_F$ and $K_{FOC}$ values and

[3] Sorption is a generic term that applies to absorption, adsorption, and desorption processes. Adsorption refers to sorption onto a two-dimensional surface; absorption refers to sorption into a three dimensional matrix. Both types of sorption occur in soils and sediments. Desorption refers to a sorbate becoming desorbed from a sorbent. Desorption distribution coefficients are measured by removing solution from a sorption experiment and adding fresh solution, so that all material measured in solution will be the desorbed material. The guideline uses the term adsorption in place of sorption and refers to the initial measurement of sorption.

discuss which would be a better predictor of sorption across soils. Discuss whether the concentration range examined was appropriate.]

The mass balance at the end of the study ranged from [value] to [value] percent. It was verified that equilibrium was achieved in test systems, and the study was carried out for [duration]. Sorption to test vessel walls [was/was not] observed [if there was sorption to vessel walls, describe how the loss to vessel walls was handled in calculations of sorption coefficients].

**Results Synopsis:**

**Table 1. Summary of Adsorption/Desorption Results [A]**

| Soil (% OC, pH) | Regressed $K_d$ (L/kg-soil) | | | Range of $K_d$ (L/kg-soil) | Regressed $K_{OC}$ (L/kg-OC) | $K_F$ ((L/kg-soil)$^{-1/n}$) | | | 1/n | $K_{FOC}$ (L/kg-OC)$^{-1/n}$) | Ceq Range (mg/L) |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | Value±SE | $r^2$ | p-value | | Value±SE | Value±SE | $r^2$ | p-value | Value±SE | Value±SE | |
| **Adsorption** | | | | | | | | | | | |
| Soil (%OC, pH) | ± | | | - | ± | ± | | | ± | ± | - |
| Soil (%OC, pH) | ± | | | - | ± | ± | | | ± | ± | - |
| Soil (%OC, pH) | ± | | | - | ± | ± | | | ± | ± | - |
| Soil (%OC, pH) | ± | | | - | ± | ± | | | ± | ± | - |
| Soil (%OC, pH) | ± | | | - | ± | ± | | | ± | ± | - |
| **Desorption** | | | | | | | | | | | |
| Soil (%OC, pH) | ± | | | - | ± | ± | | | ± | ± | - |
| Soil (%OC, pH) | ± | | | - | ± | ± | | | ± | ± | - |
| Soil (%OC, pH) | ± | | | - | ± | ± | | | ± | ± | - |
| Soil (%OC, pH) | ± | | | - | ± | ± | | | ± | ± | - |
| Soil (%OC, pH) | ± | | | - | ± | ± | | | ± | ± | - |

Abbreviations: SE = standard error of regression; NR = not reported; NA = not applicable.

[A] Data were obtained from [location of data in study report] and data and results are in the attached [Excel workbook or sigma plot file] [name(s) of worksheets, if needed]. See Attachment 3 for equations used for calculations.

## I. Material and Methods

### A. Materials:

Provide a small image of the test compound's structure and any radiolabel on the right margin.

1. **Test Material:** [[Type of radiolabel]-labeled[test compound]
   Specific radioactivity: [value] MBq/mg
   Radiochemical purity: [percentage (HPLC, TLC)]
   Chemical purity: [percentage (HPLC)]
   Batch number: [value]
   Solubility in water: [value] mg/L at [#]°C [If pH-dependent, list available values at each study pH.]
   pKa: [value]

2. **Reference Compounds:** [List the common name and batch number of each reference compound. Provide other chemical information in the structure table.]

3. **Soils/Sediment:** The study was conducted with [number] different soil types ([number of European soils and number of U.S. soils]) and [number] of sediments ([number of European soils and number of U.S. sediments]). These soils were collected from the top [depth of soil layer in cm] layer in fields that had not been treated with a pesticide for at least [number] of years. Air dried soils were stored at ambient temperatures for [number] weeks prior to experimentation. A summary of the physical and chemical properties of the soils is provided in Table [identify table] [include USDA Soil Taxonomy and/or World Resources Base (WRB) soil classification]. [Indicate whether the soil is representative of use sites.]

**Table 2. Description of Soil/Sediment**

| Soil Name<br>Origin | | | | | |
|---|---|---|---|---|---|
| USDA<br>Textural Class | | | | | |
| % Sand | | | | | |
| % Silt | | | | | |
| % Clay | | | | | |
| %OC[1] | | | | | |
| CEC[2] | | | | | |
| pH[3] | | | | | |
| % moisture<br>(1/3 bar) | | | | | |
| Soil Taxonomy | | | | | |

[1] %OM/1.72 = %OC. [Specify method used to measure OC.]
[2] [Specify method used to measure CEC.]
[3] Measured in a xx:xx soil water suspension. [Specify method used to measure pH.]

**B. Study design:** [Tabulation of these data is encouraged as long as the length of this section is not substantially increased.]

1. **Experimental conditions:**
[Describe the preliminary studies conducted to determine the soil:solution ratio, equilibration period, sorption of test compound to the test vessels, stability of the test compound under test conditions, *etc.*]

Stock solutions of [type of radiolabel(s) test compound] in [solvent] were prepared and aliquots added to portions of 0.01 M $CaCL_2$ solution to give a concentration range of [range of initial concentrations] mg/L, ensuring that the concentration of [solvent] in aqueous solution did not exceed 0.1 % by volume. The appropriate solution to soil ratio was determined in preliminary testing at [ratio; *e.g.*, 2 : 1 (*circa* 10 % sorption)]. Portions of test solution [volume] were shaken at [temperature] with samples of test soil ([value] g dry weight) for a [duration] equilibration period in darkness. Duplicate test systems were performed at each test concentration. Following centrifugation (x rpm for y minutes), the supernatant was decanted and aliquots were prepared for radioassay. Blank controls (solution +soil/sediment without test substance) were subject to the same test procedures to identify interfering compounds or contaminated soils/sediment. Blank controls (solution + test substance without soil/sediment) were subject to the same test procedures to assess potential sorption to glass test vessels and potential of loss due to instability. Following the sorption phase, fresh 0.01 M aqueous $CaCL_2$ [volume] was added to each test vessel, equilibrated for [duration] at [temperature], solutions and soils separated, quantified and subject to a further desorption phase. Soil extracts from the highest concentration tested were further extracted by shaking twice with [number] ml [solvent]. The extracts were used to assess the degree of degradation of [test compound] during equilibration. Results [were/were not] corrected for the degradation observed.

[Describe soil collection and preparation, including sieve size and sterilization technique (if used).]

[Indicate other studies supporting the chemical registration that use the same soil.]

2. **Analytical procedures:** Radioactivity was determined by Liquid Scintillation Counting (LSC), and both aqueous supernatants and soil extracts obtained after equilibration were analyzed by [identify method of analysis] of the highest test concentration [identify concentration] samples. [Identify methods used to confirm chemical identity] were used to confirm the identity and concentrations of the parent and degradation products detected. The limit of detection (LOD) for [test substance and any metabolites] was [value(s)] µg as/g soil. The limit of quantification (LOQ) for [test substance and any metabolites] was [value(s)] µg/g soil.

## II. Results and Discussion

**A. Mass Balance:** Recovery of radioactivity in aqueous supernatant and soil extracts on [describe when balance was taken and what extracts were used] ranged from [range of values] of the applied amount. Recoveries following desorption ranged from [range of values]. [Indicate

whether there was substantial loss of radioactivity by sorption to glassware or volatilization. Indicate whether unidentified radioactivity occurred at levels that would impact study results.]

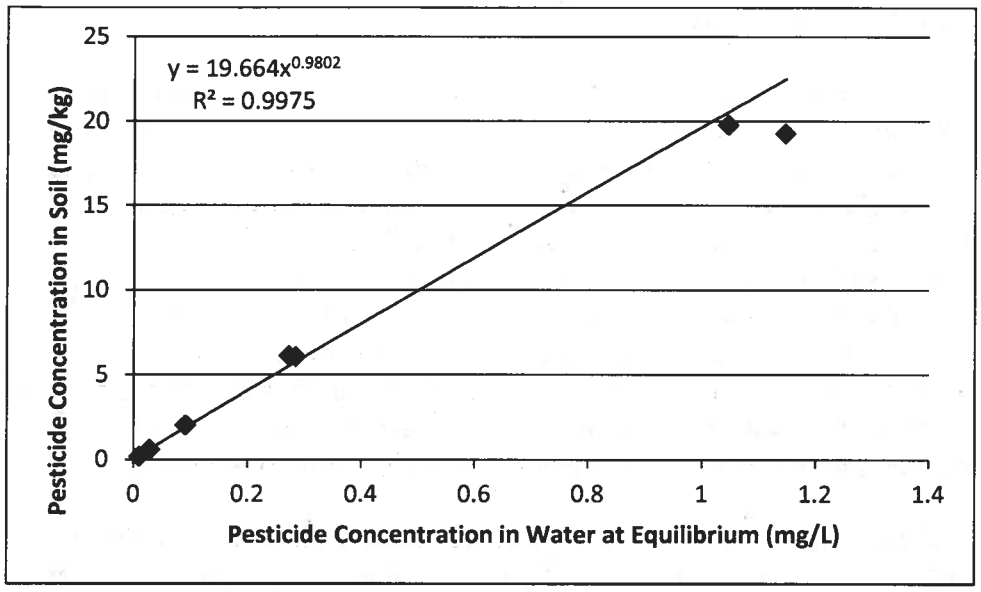
**B. Transformation of Parent Compound:** During the [duration] equilibration period, [test substance] was degraded to varying degrees depending on the soil/sediment. The major degradation product(s) was [metabolite X], which represented [range of values] % of the applied radioactivity in the soil extracts and [range of values] % in the aqueous supernatant. Each of the other degradation products accounted for <[value]% of the applied radioactivity.

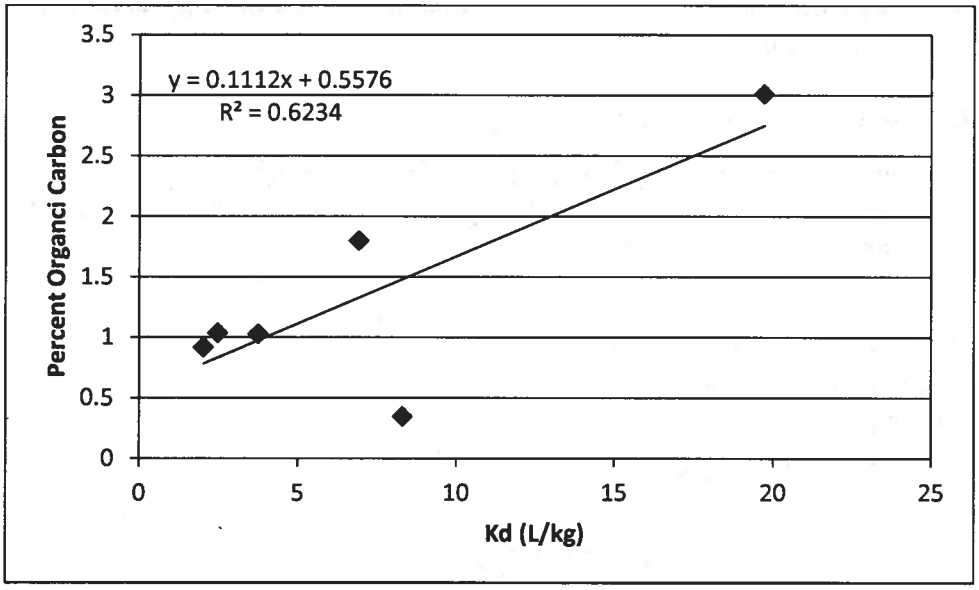
**C. Findings:**

[Reported values were calculated using [identify program used to calculate coefficient] and the equations and methods discussed in the calculations section. Refer to tabulated adsorption and desorption coefficients. Discuss whether isotherms are linear or nonlinear. Report the range of adsorption and desorption coefficients. Regress $K_d$ by percent organic carbon, CEC, and percent clay. Report the $r^2$ and p-value for the regressions in a table. Include the graphs in the study review (see example below). Calculate coefficients of variation (*e.g.*, standard deviation divided by the mean) across soils for $K_d$, $K_{OC}$, $K_F$ and $K_{FOC}$. If the coefficient of variation (CV) for $K_{FOC}$ is less than the CV for $K_F$, then $K_{FOC}$ is a better predictor of sorption across soils. Discuss whether evidence indicates that organic carbon, CEC, and pH influence sorption. Note whether the relationships were confounded by factors such as pH and pKa, factors not being held constant across soils, *etc.* Compare the range of desorption coefficients with the range of adsorption coefficients for the same soil/sediment. Provide the range of percentages of the amount of sorbed that was desorbed. Provide the range of equilibrium concentrations in water and discuss whether the ranges were appropriate. Discuss whether sorption to the walls of the test system or instability of test compound influenced the results. Report the pH of the equilibrium solution. If the compound has a pKa and may be present in multiple association states, discuss whether sorption coefficients were measured over a range of environmentally relevant pH values and how pH may have influenced the results.]

[Indicate whether reviewer-reported sorption coefficients are consistent with study-reported values.]

[Include graphs of Ceq versus Cs for each isotherm. An example graph is provided below, as well as an example graph for $K_d$ versus percent organic carbon.]




## III. Study Deficiencies and Reviewer's Comments

[This section is titled "Conclusions" in the original T2S template.]

[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.]

## IV. References

[List any references cited in the review.]

**Attachment 1: Chemical Names and Structures**

[A table (*i.e.*, structure table) of the chemical names, SMILES strings, CAS numbers, and structures of the test compound, identified transformation products, and reference compounds that were not identified in study samples should be either referenced as a separate, associated document or attached to the study review. Multiple versions of structures to show or not show radiolabeling and multiple versions of chemical names and SMILES strings should not be 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 test compound, identified transformation products, and reference compounds not identified in the study samples.

For multilateral reviews, chemical names, SMILES strings, structures, and CAS numbers are captured elsewhere in the Monograph. 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, the Monograph's structure table should be either referenced as a separate, associated document or attached 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.]

Degradate Table.docx

**Attachment 2: Statistics Spreadsheets and Graphs**

[Supporting electronic spreadsheet files should be inserted here (electronic attachment files should be electronically finalized as separate files as well). Electronic attachments should have 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. Electronic attachment files should be compressed into a WinZip file when three or more are prepared for a study review.]

[Hard copies of a study review and any attachment sheets from separate electronic files should be printed and finalized together as one hard copy file.]

**Attachment 3: Calculations**

Calculations were performed by the reviewer using [indicate program(s) used for calculations] and the following equations.

Ceq range is the range of [test substance] concentrations in water at equilibrium.
Cs is the concentration of [test substance] sorbed to soil or sediment at equilibrium.

$K_d$ –Distribution Coefficient for Adsorption = $C_s/C_{eq}$ (eq 1)

- Regressed $K_d$ is calculated using linear regression of Cs versus Ceq with a forced zero intercept over the range of measured Ceq for each soil/sediment.
- Range of $K_d$ reflects the range of each $K_d$ measured at a specific concentration in a soil/sediment

$K_{OC}$ - Organic Carbon Normalized Adsorption Coefficient = regressed $K_d$ *100/% OC (eq 2)

Standard Error (SE) of $K_{OC}$= $K_d$ SE *100/%OC (eq 3)

$K_F$ - Freundlich Adsorption Coefficient and the Freundlich exponent (1/n) were calculated using nonlinear regression of $C_s = K_F \times Ceq^{1/n}$. Cs should be expressed in mg/kg and Ceq should be expressed in mg/L in the regression. (eq 4)

$K_{FOC}$ –Organic Carbon Normalized Adsorption Coefficient = $K_F$*100/%OC (eq 5)

Standard Error (SE) of $K_{FOC}$= $K_F$ SE *100/%OC (eq 6)

$K_{DES}$ –Apparent Desorption Coefficient = $C_s/C_{eq}$ where $C_s$ and $C_{eq}$ are measured after an initial sorption measurement and the soil/sediment is placed in a new solution and allowed to equilibrate, so that any material in solution desorbed from the soil/sediment. (eq 7)

- Regressed $K_{DES}$ is calculated using linear regression of Cs versus Ceq over the range of Ceq measured with a forced zero intercept for each soil/sediment.
- Range of $K_{DES}$ reflects the range of each $K_{DES}$ measured at a specific concentration in a soil/sediment

$K_{OC\text{-}DES}$ - Organic Carbon Normalized Apparent Desorption Coefficient = regressed $K_{DES}$ *100/% OC (eq 8)

Standard Error of $Koc_{\text{-}DES}$ = $K_{DES}$ SE* 100/%OC (eq 9)

$K_{F\text{-}DES}$ - Freundlich Desorption Coefficient and the Freundlich Desorption exponent (1/n) were calculated using nonlinear regression of $C_s = K_{F\text{-}DES} \times Ceq^{1/n}$ (eq 10)

$K_{FOC\text{-}DES}$ - Organic Carbon Normalized Freundlich Desorption Coefficient= $K_{F\text{-}DES}$*100/%OC (eq 11)

Standard Error of $K_{FOC\text{-}DES}$ = $K_F$ SE *100/%OC (eq 12)

## Section III. Batch Equilibrium Study Review Considerations

This list of review considerations is provided to help reviewers assess the acceptability of batch equilibrium studies. This list is not a screen or a checklist and should not be attached to the study reviews. Listed considerations carry unequal weight and should be evaluated using best professional judgment. All information from the study and from similar studies should be considered to determine whether any deficiencies affect the study classification.

**Test Material**

» The test compound was Technical Grade (TGAI) or a Pure Active Ingredient Radiolabeled (PAIRA) compound.

» The radiopurity and specific activity of the test compound was provided (if radiolabeled).

» The test compound solubility in water was reported (at each pH tested, if pH-dependent). The concentration of the test compound in each system was below its water solubility or below its solubility in the test solution, if known.

» The test compound pKa value(s), if any, was reported. If the pKa value is in the range of environmental pH values, indicate whether the study pH values were adequate to evaluate the mobility of the compound in soils over the range of environmentally relevant pH values, including above the compound's pKa.

**Analytical Method**

» Raw measured data and representative chromatographs were provided.

» Appropriate analytical methods were provided.

» All chromatographic peaks were quantified unless <LOQ.

» Limits of detection and quantitation were reported.

**Soils/Sediments**

» At least 5 soils/sediments that are representative of agricultural use areas where the pesticide will be applied were examined. For pesticides applied to terrestrial environments, generally 5 soils and a sediment test (if the substance may be found in the aquatic environment) should be examined.

» One soil had %OM less than 1%.

» Soils were completely characterized (pH, moisture capacity, percent organic matter, bulk density, CEC, textural composition (percent sand, silt, and clay) using the USDA classification system. Foreign soils (if any) were adequately compared with domestic (USA) soils via WRB taxonomy.

» Roots and rocks were removed from soil, and it was homogenised. Soils were not sieved using a screen smaller than 2 mm.

» Soil/sediment was collected from the A horizon.

» Soil/sediment was not autoclaved.

**Other**

» If the chemical is not stable to photolysis, the study was conducted in the darkness.

» The study was conducted at laboratory ambient temperature and, if possible, at a constant temperature between 20-25°C.

» There were a minimum of 5 concentrations analyzed for each soil/sediment covering at least two orders of magnitude. These concentrations should be at least two orders of magnitude higher than detection limits and should not exceed half of the compound's solubility limit.

» The cosolvent (if any) did not exceed 0.1% (v/v) in test solution. Preferably, no cosolvents were used.

» 0.01 N Ca++ from a $CaCl_2$ solution was used.

» Centrifugation or a filtration procedure separated 0.2 μm and larger particles from solution.

» Appropriate soil:solution ratios were used.

» Two control samples with only the test substance in 0.01 M $CaCl_2$ solution (no soil) were subjected to precisely the same steps as the test systems in order to check the stability of the test substance in $CaCl_2$ solution and its possible adsorption on the test vessel surfaces.

» Two blank samples per soil with the same amount of soil and total volume of 50 mL 0.01 M $CaCl_2$ solution (without test substance) were subjected to the same test procedures as the test system. This serves as a background control during the analysis to detect interfering compounds or contaminated soils.

» Duplicate test systems were included for each concentration.

» Initial concentration did not exceed solubility of test substance.

» Concentrations in both water and soil/sediment were measured if very weak or strong sorption yielded very low concentrations in water or soil, or if measured $K_d$ values were below 0.3 mL/g. Concentrations in both water and soil/sediment were measured, if the test compound was not stable (parent made up less than 90% of radioactivity) during the time scale of the experiment or sorption to vessel walls or filters occurred.

» The material balance was reasonable.

» Adequate time was allowed for complete equilibration.

» Potential for loss of volatile compounds was accounted for.

» $K_d$, $K_F$, 1/n, $K_{OC}$, and $K_{DES}$ were reported.

# Field Dissipation Study Review Guide

This guide is meant to aid in the review of field dissipation studies (*i.e.*, terrestrial, aquatic, or forestry) submitted under the Office of Chemical Safety and Pollution Prevention (OCSPP) guidelines 835.6100, 835.6200, and 835.6300, respectively. The field dissipation study review format is based on the format for Organisation for Economic Co-operation and Development (OECD) Tier II Summaries (T2S)[1]. Reviewers should add to the T2S format any information, statistical calculations, and formatting which will increase the usefulness to the Agency under OCSPP guidelines. In developing study reviews, reviewers should strive to write concisely and to minimize alterations to the T2S format.

Sections I, II, and III of this document provide additionals details regarding formatting, data, and issues to consider in developing OCSPP environmental fate study reviews. Section I identifies field dissipation data and formatting that do not appear in the OECD T2S format and should be added to USEPA reviews. Although this guide does not strictly prescribe where and how to present the data, an example study review template is provided in Section II for guidance. In general, the example template should be followed, especially for unilateral reviews (*i.e.*, reviews conducted without the participation of other agencies). However, reviewers may modify it as needed or disregard it in the case of multilateral reviews (*i.e.*, reviews with other agencies participating) in which an alternative format is agreed upon by the participating agencies. Lastly, a list of study review considerations (Section III) is provided to help reviewers focus on critical study issues and to identify any common major or minor deficiencies (*i.e.*, the review considerations update the acceptance criteria for field dissipation studies provided in the 1989 FIFRA Accelerated Reregistration Phase 3 Technical Guidance (USEPA, 1989)).

**References**

USEPA. 1989. FIFRA Accelerated Reregistration, Phase 3 Technical Guidance. Office of the Prevention, Pesticides, and Toxic Substances, Washington, DC. EPA 540/09-90-078.

[1] A Tier II Summary is an OECD format for study reviews prepared by industry. See OECD Guidance Documents for Pesticide Registration at http://www.oecd.org/document/48/0,3746,en_2649_34365_2085104_1_1_1_1,00.html (Accessed Mar. 3, 2011).

## Section I. Data to Include in the Field Dissipation OECD T2S Template

The following information should be added to the field dissipation T2S template to make it compatible with OCSPP guidelines 835.6100, 835.6200, and 835.6300 and increase its utility to the Agency:

**First Page and Executive Summary**

- The PC code of the test compound and the MRID of the study or studies should be provided in the header and on the first page.

- A statement should be included indicating whether the study was conducted in compliance with FIFRA GLP standards (and if not, how not or why not) and whether signed and dated Data Confidentiality, GLP Compliance, Quality Assurance, and Authenticity Certification statements were provided.

- The study classification and a concise statement of any deficiencies that impacted the classification should be provided on the first page of the review.

- A signature line(s) for the final reviewer(s) should be added to the first page of the review. If this is unacceptable for other agencies participating in a multilateral review, then a cover page with the signature line(s) can be attached to each individual review submitted to EFED's files.

- A results synopsis should be added to the Executive Summary to tabulate half-lives, including how they were calculated, as well as a list of the transformation products, including the maximum amount formed (from individual replicate values, not the mean value) and the interval at which the maximum occurred. Tabulated information should not be summarized in the text of the Executive Summary.

**Materials and Methods**

- The Test Material section should list the names and batch numbers of reference compounds used and provide a small image of the test compound structure.

- Physicochemical properties of the test compound that are relevant to the study should be listed in the Test Material section (Section I.A.1). Irrelevant properties should not be listed.

- The parameters of latitude, longitude, eco region, and weather characterization should be specified in the site description table (Table 2).

- Notes on irrigation practices should be specified in the experiment design table (Table 3).

- A soil sampling information table (*e.g.*, Table 4) should be included.

- If samples are stored, a description of storage stability should be included.

**Results and Discussion**

- Verification of pH, sterility, sorption to vessel walls, or other test conditions should be reported in the Findings section.

- Observed $DT_{50}$ values and indications of how half-lives were calculated [*e.g.*, single first order (SFO)] should be added to the half-life tables in the Findings section.

- Mass accounting information (*e.g.*, constituents in different compartments) should be included in Section II.C with a brief description of parsing of mass by dissipation pathway (*i.e.*, soil residues, volatiles, residues of run off water and sediment, and residues taken up by plants). Appendix 1 should be included as needed, showing tables of mass accounting of soil residues, volatiles, residues of run off water and sediment, and residues taken up by plants.

**Study Deficiencies and Reviewer's Comments**

- The Conclusions section (Section III) should list any deficiencies with the study and any additional salient information; the section may be renamed "Study Deficiencies and Reviewer's Comments." Results and conclusions contained in the Executive Summary are not repeated in this section.

**References**

- A References section (Section IV) should be added that lists any literature references other than the study report cited in the study review.

**Attachments**

- A table (*i.e.*, structure table) of the chemical names, SMILES strings, CAS numbers, and structures of the test compound, all identified transformation products, and all reference compounds that were not identified in study samples should be either referenced as a separate, associated document or attached to the study review. Multiple versions of structures to show or not show radiolabeling and multiple versions of chemical names and SMILES strings should not be 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.

  For multilateral reviews, chemical names, SMILES strings, structures, and CAS numbers are captured elsewhere in the Monograph[2]. Therefore these data are not attached to each

[2] 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

study review within the Monograph. When the Monograph is split into individual reviews in EFED's files, however, the Monograph's structure table should be either referenced as a separate, associated document or attached to each individual review.

- Statistical output files containing calculations (such as statistical analyses and outputs) and graphs that support values reported in the study review should be attached to the review. File names should begin with the same name as that of the individual review (*i.e.*, PC code, MRID, and guideline number separated by spaces). However, for multilateral reviews, file naming convention should consistently follow an agreed format.

- A Calculations section should be added that lists equations and defines parameters used to calculate half-lives. This section is currently placed in Attachment III but may be placed in Section I.G.

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government agencies based on agency-review and then placed within the Monograph.

## Section II. Example Field Dissipation Study Review Template

**Field Dissipation of [test compound]**

| | |
|---|---|
| **Report:** | [Provide full citation] |
| **Document No.:** | [MRID xxxxxxxx] |
| **Guideline:** | OCSPP [guideline number]<br>[If the study was conducted under a different guideline than it is being reviewed under, state 'Conducted by' and provide the most relevant guideline(s) the study was conducted under. Then state 'Reviewed by OCSPP [guideline number].' 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 how not or why not.] |
| **Classification:** | This study is [provide classification and 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:** | [xxxxxx] |
| **Reviewer:** | [Provide final reviewer(s)'s name and title.] **Signature:** **Date:** [Type date of signature.] |

**Executive Summary**

**[Modify the Executive Summary as needed, incorporating the following critical elements and level of detail.]**

Dissipation of [test material] under [Country] field conditions was examined in [bare plots or cropped plots] at [number] site(s) in [location(s), state(s), province(s)]. The site(s) where the studies were conducted were at [locations]. The experiment(s) in [site(s)] was/were conducted for [number] days. The nominal application rate[s] in [site(s)] were [value] lbs. a.i./A. The treated plots were [value] m apart, and the control plot was [value] m away from the treated plot. [Provide details if cropped plots are used.]

Under field conditions at Site 1, [test material] had a dissipation half-life value of ___day(s), and a DT90 value of ___day(s). At the end of the ___day period, the total carryover of residues of [test material] was ___ % of the measured applied amount. The major route(s) of dissipation of [test material] under field conditions at [each Site] was/were [leaching, transformation, volatilization, plant uptake, *etc.*].

[FOR EFED SCIENTISTS: The TFD study report should present a conceptual model of dissipation, identifying which routes of dissipation are important. EFED scientists should include

a description of whether or not this can be verified in laboratory studies by considering the sum of dissipation rates from abiotic and biotic degradation studies given as:

$K_{field} = \Sigma ( k_{metabolism} + k_{photolysis} + k_{volatilization} + k_{runoff} + k_{leaching} + \ldots . k_x)$.

Ideally, the field rate of dissipation would be equal to the sum of the important dissipation rates identified from the laboratory fate studies. To determine whether the field study result is consistent with the conceptual model proposed rate, the EFED scientist should calculate the rate of dissipation from the original compartment (*e.g.*, the top X inch(es) of soil) using the latest guidance on degradation kinetics. This field rate should be compared to the sum of the rates from the laboratory fate studies for important processes in the conceptual model. Adsorption and desorption properties of the test substance from batch equilibrium studies should also be considered in characterizing the field dissipation from the test plot.]

**Table 1. Dissipation Synopsis**

| Test System | Major Dissipation Route | Maximum Concentrations (lb/A) in Media (cm soil, ft water, or cm air), at Time Period (days after application) |
|---|---|---|
| [Soil Location]<br>[USGS Soil Series]<br>[Soil Texture]<br>[pH #] | [Biodegradation] | [list concentrations, depths/heights in media, and time periods of measurement for all measured constituents] |
| [Soil Location]<br>[USGS Soil Series]<br>[Soil Texture]<br>[pH #] | [Biodegradation] | [list concentrations, depths/heights in media, and time periods of measurement for all measured constituents] |

**Table 2. Results Synopsis**

| | Observed Total Field $DT_{50}$ (days) | Calculated Total Field Dissipation Half-life (days) Method | Model Parameters and Statistics | Transformation Products Common Name (maximum % of nominal application, associated interval) |
|---|---|---|---|---|
| [Soil Location]<br>[USGS Soil Series]<br>[Soil Texture]<br>[pH #] | [value] | [value]<br>[method] | [values] | [name] (#%, # d) |
| [Soil Location]<br>[USGS Soil Series]<br>[Soil Texture]<br>[pH #] | [value] | [value]<br>[method] | [values] | [name] (#%, # d) |

[Add on to tables as necessary for different locations, plots, or applications. Model parameters include model variables, Sc values, and correlation coefficients.]

## I. Materials and Methods

### A. Materials:

1. **Test Material:** Product Name:
Formulation Type (e.g., liquid or granular):
CAS #:
Storage stability: [Indicate the time period that the test material was stable as well as the percentage degradation over this period of time.]

Provide (a) small image(s) of the test compound(s) in the right margin.

2. **Storage Conditions:** [Indicate if the test material was frozen, refrigerated, and/or maintained in the dark for [#] days.]

### B. Test Sites:

The site description is provided in **Table 3**.

**Table 3. Site Description**

| **Parameter** | | **Value** | | | | |
|---|---|---|---|---|---|---|
| **Site 1:** [Description (location/ soil series)] | | | | | | |
| Geographic Coordinates | Latitude | | | | | |
| | Longitude | | | | | |
| | County | | | | | |
| | Province/State | | | | | |
| | Country | | | | | |
| Hydrologic setting - Location within watershed | | | | | | |
| Slope/Gradient | | | | | | |
| Depth to Ground Water Table (m) | | | | | | |
| Distance from weather station used for climatic measurements | | | | | | |
| Indicate whether the meteorological conditions before starting or during the study were within 30 year normal levels (Yes/No). If no, provide details. | | | | | | |
| Field Surface (e.g. bare soil, trees, or crops) | | | | | | |
| Other Details, if any | | | | | | |
| Property | | Depth (cm) | | | | |
| | | 0 | 15-30 | 30-45 | x-y | y-z |
| Textural classification | | | | | | |
| % sand | | | | | | |
| % silt | | | | | | |
| % clay | | | | | | |
| pH (1:1 soil:water or other) | | | | | | |
| Total organic carbon (%) | | | | | | |
| CEC (meq/100 g) | | | | | | |
| AEC (meq/100 g) | | | | | | |
| Bulk density (g/cm3) | | | | | | |

| Parameter | Value | | | | |
|---|---|---|---|---|---|
| Soil Moisture at 0.1 bar (%) | | | | | |
| Soil Moisture at 1/3 bar (%) | | | | | |
| Taxonomic classification (e.g., ferro-humic podzol) | | | | | |
| Others | | | | | |
| Site Usage | Previous Year | | 2 years previous | | 3 years previous |
| Crops Grown | | | | | |
| Pesticides Used | | | | | |
| Fertilizers Used | | | | | |
| Cultivation Methods | | | | | |
| Comments | | | | | |

[Add to table as necessary for different locations or plots.]

## C. Experimental Design:

Specifications on the design for the field dissipation study are shown in **Table 4**.

**Table 4. Study Design**

| Details | | Site 1 | Site n |
|---|---|---|---|
| Pesticides used during study [a.i., % a.i., and product]:<br><br>name of product/a.i concentration:<br>amount applied:<br>application method: | | | |
| Amount applied (lbs. a.i./A) | | | |
| Number of applications | | | |
| Maximum single labelled application rate ? (yes/no) | | | |
| Application method | | | |
| Application Dates(s) (dd mm yyyy) | | | |
| Duration of study | | | |
| Control used (Yes/No) | | | |
| No. of replications | Controls | | |
| | Treatments | | |
| Plot size (L x W m) | Control | | |
| | Treatment | | |
| Distance between control plot and treated plot | | | |
| Distance between treated plots | | | |
| Type of spray equipment, if used | | | |

| Details | | Site 1 | Site n |
|---|---|---|---|
| Total volume of spray solution applied/plot or total amount broadcasted/plot | | | |
| Identification and volume of carrier (e.g., water), if used | | | |
| Name and concentration of co-solvents, adjuvants, and/or surfactants, if used | | | |
| Indicate whether the following was submitted:<br><br>Hourly/Daily/Monthly Precipitation<br>Daily/Monthly average minimum and maximum air temperature<br>Daily/Monthly average minimum and maximum air temperature<br>Average annual frost-free periods | | | |
| Indicate whether the pan evaporation data were submitted | | | |
| Meteorological conditions during application | Cloud cover | | |
| | Temperature (°F) | | |
| | Humidity | | |
| Indicate if any extreme climatic events occurred during the study (e.g., drought, heavy rainfall, flooding, storm, etc.) | | | |
| Supplemental irrigation used (Yes/No)<br><br>If yes, provide the following details:<br><br>No. of irrigation:<br>Interval between irrigation:<br>Amount of water added each time:<br>Method of irrigation: | | | |
| Indicate whether water received through rainfall + irrigation equals the 30-year average rainfall (Yes/No) | | | |
| Were the application rates verified? | | | |
| Were field spikes used? | | | |
| Were good agricultural practices followed (Yes or No) | | | |
| If cropped plots were used, provide the following details:<br><br>Plant - Common name/variety:<br>Details of planting:<br>Crop maintenance (e.g., fertilizers used): | | | |

| Details | Site 1 | Site n |
|---|---|---|
| Was volatilization included in the study? (Yes/No) | | |
| Was leaching included in the study? (Yes/No) | | |
| Was runoff included in the study? (Yes/No) | | |
| Was plant uptake or canopy monitoring included in the study? (Yes/No) | | |

**D. Sampling:**

Specifications on the methods used for the field dissipation study are shown in **Table 5.**

**Table 5. Sampling**

| Details | Site 1 | Site n |
|---|---|---|
| Method of sampling (random or systematic) | | |
| Sampling intervals | | |
| Method of collection (e.g., soil cores) | | |
| Sampling depths or heights | | |
| Number of cores collected per plot | | |
| Number of segments per core (if applicable) | | |
| Length of soil segments (if applicable) | | |
| Core diameter (Provide details if more than one width) (if applicable) | | |
| Method of sample processing, if any | | |
| Shipping time to Storage Facility (hours) | | |
| Storage conditions | | |
| Storage length (days) | | |

[Include only applicable information in similar tables for air, plant, runoff water, or water body sampling, if applicable]

**E. Analytical Procedures:**

Briefly describe the analytical methodology for the analyses of soil, plant, air, runoff water, and water body samples (provide references for the environmental chemistry method(s) and independent laboratory validation(s)):

- Number of soil samples or samples from appropriate media (air, plants, runoff water, or water bodies) analyzed per treatment or composite sample:
- Extraction and clean up of soil, air, plant, runoff water, or water body samples:

- Identification and quantification of parent compound (briefly describe HPLC/GC/TLC/MS conditions, *e.g.*, column, mobile phase, detector, etc.):
- Identification and quantification of transformation products (briefly describe HPLC/GC/TLC/MS conditions, *e.g.*, column, mobile phase, detector, etc.):
- Detection limits (LOD, LOQ) for the parent compound in soil, air, plant, runoff water, or water bodies (indicate the criteria/reference, if provided):
- Detection limits (LOD, LOQ) for the transformation products in soil, air, plant, runoff water, or water bodies (indicate the criteria/reference, if provided):

**F. Verification of the Extraction Method and Storage Stability:**

**1. Spike Recoveries:**

[Most/All] field spike recoveries are within the acceptable range with overall recoveries between [x and y percent]. The exceptions include field spikes extracted during [period] with an average percent recovery of [x percent ± y percent] at the fortification level of [<c1 mg/kg, c1 mg/kg – c2 mg/kg, or c2 mg/kg>]. [Repeat for additional unacceptable field spike extractions (less than 70 percent or greater than 120 percent)].

[Spike recoveries for all products applied in the field should be reported. Also apply above similar information regarding travel spikes and laboratory spikes according to available data.]

**2. Storage Stability Study:**

[Provide the study MRID and a brief description of the storage conditions of samples after collection and the longest duration of storage for each media analyzed. Indicate the stability of the residues based on the submitted storage stability study(ies) for each media (provide a reference(s)) and whether the storage stability study duration(s) was/were sufficient to evaluate the longest field study storage duration(s). State whether corrections were made to account for any instability.]

[Note: Details of the storage stability study can be discussed in a separate study review.]

## II. Results and Discussion

**A. Application Verification:**

Briefly describe the application verification methods used, *e.g.*, petri dish, saturation pads, spray tank analysis, *etc.*

Recoveries achieved on extraction and analysis of application monitors was in the range [xx to xy %]. Recovery achieved on analysis of field spiked samples was [xx %].

## B. Findings:

Concentrations of constituents measured in the [#] module of the [soil, aquatic, forestry] field dissipation study are shown in **Table 6**.

[Table 6 below shows an example based on a soil profile module of the field dissipation study. Tables for other modules of the field dissipation study should be included as appropriate. These tables are available in the Excel files attached in Attachment 2.]

[Note: If a volatility module is included, a separate study review should be developed to address this study.]

**Table 6. Concentration of [Test compound] in Soil, Expressed as mg/kg**

| Sampling Intervals (days) | | Concentration (mg/kg) | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | # | # | # | # | # | # | # | # |
| Replicate | | # | # | # | # | # | # | # | # |
| **Site 1:** [Description (location/ soil series)] | | | | | | | | | |
| [Parent Compound] | 0 -15 cm | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] |
| | depth 2 | n.a. | n.a. | [#] | [#] | [#] | [#] | [#] | [#] |
| | depth n | n.a. | n.a. | [#] | [#] | n.d. | n.d. | n.d. | n.d. |
| [Transformation Product 1] | 0 -15 cm | n.a. | n.a. | [#] | [#] | [#] | [#] | n.d. | n.d. |
| | depth 2 | n.a. | n.a. | [#] | [#] | [#] | [#] | n.d. | n.d. |
| | depth n | n.a. | n.a. | [#] | [#] | [#] | [#] | n.d. | n.d. |
| [Transformation Product n] | 0 -15 cm | n.a. | n.a. | [#] | [#] | [#] | n.d. | n.d. | n.d. |
| | depth 2 | n.a. | n.a. | [#] | [#] | [#] | n.d. | n.d. | n.d. |
| | depth n | n.a. | n.a. | [#] | [#] | [#] | n.d. | n.d. | n.d. |

n.d. = not detected n.a. = not analyzed (LOD = x mg/kg)

[Add on to table as necessary for different locations, plots, or applications.]

[For multiple applications, time for sampling intervals should be referenced from the beginning of the specific application being reported (*i.e.*, NOT from the beginning of the first or last application for all applications).]

## C. Dissipation of Test Compound:

Dissipation of [test compound] on soil was [gradual, rapid, or some other characterization] in the field. The $DT_{50}$ ranged from [x] to [x] as tabulated in **Table 7** (calculated half-lives and model parameters for the best fit kinetics models are in bold). [Field dissipation half-lives for the whole field including the total soil profile should be determined. Indicate the software used to

determine model parameters. Indicate whether reviewer-reported half-lives are consistent with study-reported values and the relationship between calculated and observed values. Discuss any abnormalities observed in the data.]

[Images of kinetics calculation results using the R program may replace **Table 7**. R images should include the model parameters and statistics that are otherwise reported in **Table 7**.]

**Table 7. Transformation Kinetics of [Test Compound] in the Field [A, B]**

| | Observed $DT_{50}$ (days) | Observed $DT_{90}$ (days) | Calculated Half-life (days) | Kinetics Model [C] | Model Parameters | Model Statistics |
|---|---|---|---|---|---|---|
| [Location 1] [USGS Soil Series] [Soil Texture] [# °C, pH #] | [#] | [#] | [#] | SFO | $C_0$=[#], k=[#] | $S_{SFO}$=[#], $r^2$=[#], p=[#] |
| | | | [#] | IORE | $C_0$=[#], k=[#], n=[#] | $S_{IORE}$=[#], $S_C$=[#], $r^2$=[#], p=[#] |
| | | | [#] | DFOP [if applicable] | $C_0$=[#], g=[#], $k_1$=[#], $k_2$=[#], | $S_{DFOP}$=[#], $r^2$=[#], p=[#] |
| [Location n] [USGS Soil Series] [Soil Texture] [# °C, pH #] | [#] | [#] | [#] | SFO | $C_0$=[#], k=[#] | $S_{SFO}$=[#], $r^2$=[#], p=[#] |
| | | | [#] | IORE | $C_0$=[#], k=[#], n=[#] | $S_{IORE}$=[#], $S_C$=[#], $r^2$=[#], p=[#] |
| | | | [#] | DFOP [if applicable] | $C_0$=[#], g=[#], $k_1$=[#], $k_2$=[#], | $S_{DFOP}$=[#], $r^2$=[#], p=[#] |

[A] Data were obtained from [location of data in study report] and calculations in the attached Excel workbook [name(s) of worksheets, if needed]. See Attachment 3 for calculations.
[B] Calculated half-lives and model parameters for the best fit kinetics models, in accordance with the NAFTA kinetics guidance (USEPA, 2011), are in bold.
[C] Kinetics models: Single First-Order (SFO); Double First-Order in Parallel (DFOP), and Indeterminate Order Rate Equation (IORE).
[Rows may be added for transformation product half-lives and $DT_{50}$s as needed. Half-lives should be calculated following the NAFTA kinetics guidance (USEPA, 2011).]

[Add information as necessary for additional sites, plots, or applications.]

[Briefly summarize the transformation products per system in **Table 8**. If transformation product decline is observed over four time intervals, calculate a half-life and discuss the pattern of decline.]

**Table 8. Transformation Products of [Test Compound] in the Field**

| | Transformation Product(s) | Maximum %AR Observed | Associated Interval | Final %AR Observed | Final Interval |
|---|---|---|---|---|---|
| [Location] [USGS Soil Series] [Soil Texture] [# °C, pH #] | [common name] | [#] | [# d] | [#] | [# d] |
| | [common name] | [#] | [# d] | [#] | [# d] |
| [Location] [USGS Soil Series] [Soil Texture] [# °C, pH #] | [common name] | [#] | [# d] | [#] | [# d] |
| | [common name] | [#] | [# d] | [#] | [# d] |

## D. Mass Accounting:

[State whether a reasonable attempt to quantify the mass accounting of various dissipation pathways was demonstrated considering the number of dissipation pathways quantified, levels of residue extracted, and existing validated methods. Provide a summary of the mass accounting of dissipation pathways in **Table 9**. Insert tables showing detailed calculations for each dissipation pathway contribution by depth and sampling period electronically and in **Appendix 2**.]

***[Note: The purpose of this section is to identify the most significant routes of dissipation. This section is NOT intended to verify whether material balance is acceptable since a field dissipation study is an open system. Only the major dissipation pathways identified in the conceptual model in the study report should be included in the study review.]***

[All of the percent ranges of the mass accounting over the study duration attempted for any of the dissipation pathways in the table below should be referenced with the nominal application rate].

[Add information as necessary for additional sites, plots, or applications.]

**Table 9. Summary of Mass Accounting for Dissipation Pathways [A]**

| Field Study Module | Percentage of Applied Mass at Time 0 (%) | Maximum Percentage of Applied Mass (%) and Time After Application (days) | Percentage of Applied Mass at Study Termination (%) and Time After Application (days) |
|---|---|---|---|
| Soil Profile | [# %] | [# %]<br>[# days] | [# %]<br>[# days] |
| Volatilization | [# %] | [# %]<br>[# days] | [# %]<br>[# days] |
| Runoff or Water Body (Water and Sediment) | [# %] | [# %]<br>[# days] | [# %]<br>[# days] |
| Plant and Canopy Residue or Plant Uptake (Shoots and Roots) | [# %] | [# %]<br>[# days] | [# %]<br>[# days] |

[A] Percentages of the applied are based on the nominal application rate. For transformation products, parent-equivalent percentages of the applied are reported, considering the ratio of the molecular weights between the transformation products and the parent compound.

## E. Residue Carry-Over:

The observed $DT_{90}$ value was ___ days at Site 1. After ___ days, ___ % of the applied parent compound was detected at Site 1, and has [the/low] potential to carry over into the following season. At the end of the study, carryover of the transformation products was expected to be ____ %. [Provide details for other sites, if any.]

## III. Study Deficiencies and Reviewer's Comments

[This section is titled "Conclusions" in the original T2S template.]

[List any deficiencies with the study and any additional salient information. Specifically report any discrepancies between the nominal application rate and target application rate and related causes for the discrepancies in this section.]

[Results and conclusions contained in the Executive Summary are not repeated in this section.]

## IV. References

[List any references cited in the review.]

U.S. Environmental Protection Agency (USEPA). 2011. Guidance for Evaluating and Calculating Degradation Kinetics in Environmental Media. (Interim draft document dated Dec. 21, 2011.)

## Appendix 1: Mass Accounting Calculations

**Table X. Total on-field material balance from soil expressed as percent of the nominal application rate**
**Table Y. Dissipation due to volatilization of [analytes(s)] from soil expressed as percent of the nominal application rate**

| Sampling Intervals (days or hours) / Replicate | Percent of applied | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | # / # | # / # | # / # | # / # | # / # | # / # | # / # | # / # | # / # |
| **Site 1:** [Description (location/ soil series)] | | | | | | | | | |
| Parent Compound | [#] | [#] | [#] | [#] | [#] | n.d. | n.d. | n.d. | n.d. |
| Transformation Product 1 | [#] | [#] | [#] | [#] | [#] | [#] | [#] | n.d. | n.d. |
| Transformation Product n | n.d. | n.d. | n.d. | n.d. | n.d. | n.d. | n.d. | n.d. | n.d. |

n.d. = not detected (LOD = x mg/kg a.i. soil)

*Percent of the applied based on nominal application rate.

[Add on to table as necessary for different locations, plots, or applications.]

**Table X. Percent of the applied of [test material] in water body and sediment**

| Sampling Intervals (days) / Replicate | | Percent of applied | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | # / # | # / # | # / # | # / # | # / # | # / # | # / # | # / # |
| **Site 1:** [Description (location/ soil series)] | | | | | | | | | |
| Parent compound | water | - | - | [#] | [#] | n.d. | n.d. | n.d. | n.d. |
| | sediment | - | - | [#] | [#] | n.d. | n.d. | n.d. | n.d. |
| | total | - | - | [#] | [#] | n.d. | n.d. | n.d. | n.d. |
| Transformation product 1 | water | - | - | [#] | [#] | [#] | [#] | n.d. | n.d. |
| | sediment | - | - | [#] | [#] | [#] | [#] | n.d. | n.d. |
| | total | - | - | [#] | [#] | [#] | [#] | n.d. | n.d. |
| Transformation product n | water | n.d. | n.d. | n.d. | n.d. | n.d. | n.d. | n.d. | n.d. |
| | sediment | n.d. | n.d. | n.d. | n.d. | n.d. | n.d. | n.d. | n.d. |
| | total | n.d. | n.d. | n.d. | n.d. | n.d. | n.d. | n.d. | n.d. |

n.d. = not detected (LOD = x mg a.i./L)

*Percent of the applied based on nominal application rate.

[Add on to table as necessary for different locations, plots, or applications.]

**Table X. Residues of [analyte(s)] in plants and canopies expressed as % of applied**

| Sampling Intervals (days) | | Percent of applied | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Replicate | | # | # | # | # | # | # | # | # |
| | | # | # | # | # | # | # | # | # |
| **Site 1:** [Description (location/ soil series)] | | | | | | | | | |
| Parent compound | shoots | - | - | [#] | [#] | n.d. | n.d. | n.d. | n.d. |
| | roots | - | - | [#] | [#] | n.d. | n.d. | n.d. | n.d. |
| | total | - | - | [#] | [#] | n.d. | n.d. | n.d. | n.d. |
| Transformation product 1 | shoots | - | - | [#] | [#] | [#] | [#] | n.d. | n.d. |
| | roots | - | - | [#] | [#] | [#] | [#] | n.d. | n.d. |
| | total | - | - | [#] | [#] | [#] | [#] | n.d. | n.d. |
| Transformation product n | shoots | n.d. | n.d. | n.d. | n.d. | n.d. | n.d. | n.d. | n.d. |
| | roots | n.d. | n.d. | n.d. | n.d. | n.d. | n.d. | n.d. | n.d. |
| | total | n.d. | n.d. | n.d. | n.d. | n.d. | n.d. | n.d. | n.d. |

n.d. = not detected (LOD = x mg a.i./kg dry weight)

*Percent of the applied based on nominal application rate.

[Add on to table as necessary for different locations, plots, or applications.]

**Attachment 1: Chemical Names and Structures**

[A table (*i.e.*, structure table) of the chemical names, SMILES strings, CAS numbers, and structures of the test compound, identified transformation products, and reference compounds that were not identified in study samples should be either referenced as a separate, associated document or attached to the study review. Multiple versions of structures that show or do not show radiolabeling and multiple versions of chemical names and SMILES strings should not be 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 (values from individual replicates are reported, not mean values). At a minimum, repeat the table below for the test compound, identified transformation products, and reference compounds not identified in the study samples.

For multilateral reviews, chemical names, SMILES strings, structures, and CAS numbers are captured elsewhere in the Monograph. 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, the Monograph's structure table should be either referenced as a separate, associated document or attached 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.]

Degradate Table.docx

**Attachment 2: Statistics Spreadsheets and Graphs**

[Supporting electronic spreadsheet files should be inserted here (electronic attachment files should be electronically finalized as separate files as well). Electronic attachments should have 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. Electronic attachment files should be compressed into a WinZip file when three or more are prepared for a study review.]

[Hard copies of a study review and any attachment sheets from separate electronic files should be printed and finalized together as one hard copy file.]

[Example Excel files and spreadsheets follow below.]

Dissipation Study Review Tables.xls

**[Example spreadsheets for mass-balance in terms of verified analyte-equivalent percent of applied:**

**Soil Profile -**

**Example 1**
**Soil Core Sampled Incrementally**

TFD Soil Mass Balance_ex1.xls

Field Dissipation Review Attachment 2 Tables_examples.xlsx - Microsoft Excel

Security Warning Automatic update of links has been disabled Options...

D12 =D11/$C$3

| | A | B | C | D | E | F | G | H | I | J | K |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | Fields for input | | | | | | | | | | |
| 2 | Test Substance | | Test | | | | | | | | |
| 3 | Nominal Application Rate (lb a.i./A) | | 0.375 | | | | | | | | |
| 4 | Total Soil Core Mass Balance | | | | | | | | | | |
| 5 | | | Bulk density | Soil Increment Concentrations (lb/A)* | | | | | | | |
| 6 | Sampling Increments (cm) | Increment Depth (cm) | (g/cm³) | Day 0 | Day 6 | Day 11 | Day 23 | Day 42 | Day [#] | Day [n] | |
| 7 | 0-7.5 | 7.5 | 1.13 | 0.32008797 | 0.28527935 | 0.22852617 | 0.16117905 | 0.09307523 | #VALUE! | #VALUE! | |
| 8 | 7.5-15 | 7.5 | 1.13 | 0.00151342 | 0.00227013 | 0.00302684 | 0.00378355 | 0.00454025 | #VALUE! | #VALUE! | |
| 9 | 15-30 | 15 | 1.13 | 0.00151342 | 0.00454025 | 0.00756709 | 0.00908051 | 0.01210735 | #VALUE! | #VALUE! | |
| 10 | 30-45 | 15 | 1.13 | 0.00151342 | 0.00454025 | 0.00756709 | 0.01059393 | 0.01513418 | #VALUE! | #VALUE! | |
| 11 | Total Soil Core Concentration (lb/A) | | | 0.325 | 0.297 | 0.247 | 0.185 | 0.125 | #VALUE! | #VALUE! | |
| 12 | % of nominal application rate | | | 86.6% | 79.1% | 65.8% | 49.2% | 33.3% | #VALUE! | #VALUE! | |
| 13 | | | | | | | | | | | |
| 14 | | | | | | | | | | | |
| 15 | *Soil Increment Concentration (lb/A) = Soil Concentration (mg/kg) x Soil Bulk Density (g/cm³) x Increment Depth (cm) x | | | | | | | | | | |
| 16 | | | kg / 1,000 g | x | lbs. / 453,592.37 mg | x | 4.05 x 10⁷ cm² / A | | | | |
| 17 | | | | | | | | | | | |
| 18 | | | | | | | | | | | |
| 19 | | | | | | | | | | | |
| 20 | | | | | | | | | | | |
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| 24 | | | | | | | | | | | |

TFD Soil Mass Balance_ex1.xls | TFD Soil Mass Balance_ex2.xls | Volatilization Mass Bal

Ready 100%

*Mass Balance calculated by the formula = Measured total soil core concentration/Nominal application rate

**Soil Profile -**

**Example 2**
**Soil Core Sampled Locally**

TFD Soil Mass Balance_ex2.xls

**Note: This is not the method specified in the guidelines. The study reviewer should use best professional judgment to determine if there is sufficient sampling conducted using this method (e.g., fine sampling at top of the core and sufficient sampling intervals within soil core).**

Field Dissipation Review Attachment 2 Tables_examples.xlsx - Microsoft Excel

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D13 =D12/$C$3

| | A | B | C | D | E | F | G | H | I | J | K |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | Fields for input | | | | | | | | | | |
| 2 | Test Substance | | Test | | | | | | | | |
| 3 | Nominal Application Rate (lb a.i./A) | | 0.375 | | | | | | | | |
| 4 | Total Soil Core Mass Balance | | | | | | | | | | |
| 5 | | | Bulk density | Soil Sample Concentrations (lb/A)* | | | | | | | |
| 6 | Sampling Depth (ft.) | Increment Depth (ft.) | (g/cm³) | Day 0 | Day 6 | Day 11 | Day 23 | Day 42 | Day [#] | Day [n] | |
| 7 | 0 | NA | NA | ND | ND | ND | ND | ND | ND | ND | |
| 8 | 1 | 1 | 1.13 | 0.12301064 | 0.09225798 | 0.09225798 | 0.00615053 | 0.00307527 | #VALUE! | #VALUE! | |
| 9 | 2 | 1.5 | 1.13 | 0.0092258 | 0.0138387 | 0.0184516 | 0.0230645 | 0.02767739 | #VALUE! | #VALUE! | |
| 10 | 4 | 2 | 1.13 | 0.00615053 | 0.0184516 | 0.03075266 | 0.03690319 | 0.04920426 | #VALUE! | #VALUE! | |
| 11 | 6 | 4 | 1.13 | 0.01230106 | 0.03690319 | 0.06150532 | 0.08610745 | 0.12301064 | #VALUE! | #VALUE! | |
| 12 | Total Soil Core Concentration (lb/A) | | | 0.151 | 0.161 | 0.203 | 0.152 | 0.203 | #VALUE! | #VALUE! | |
| 13 | % of nominal application Rate | | | 40.2% | 43.1% | 54.1% | 40.6% | 54.1% | #VALUE! | #VALUE! | |
| 14 | | | | | | | | | | | |
| 15 | | | | | | | | | | | |
| 16 | *Soil Increment Concentration (lb/A) = Soil Concentration (mg/kg) x Soil Bulk Density (g/cm³) x Increment Depth (ft.) x | | | | | | | | | | |
| 17 | | | 30.48 cm | x | kg | x | lbs. | x | 4.05 x 10⁷ cm² | | |
| 18 | | | ft. | | 1,000 g | | 453,592.37 mg | | A | | |
| 19 | | | | | | | | | | | |
| 20 | | | | | | | | | | | |
| 21 | | | | | | | | | | | |
| 22 | | | | | | | | | | | |
| 23 | | | | | | | | | | | |
| 24 | | | | | | | | | | | |

TFD Soil Mass Balance_ex1.xls | TFD Soil Mass Balance_ex2.xls | Volatilization Mass Ba

Ready 100%

* Increment depth based on centered finite difference of local sampling depths.
* Mass Balance calculated by the formula = Measured total soil core concentration/Nominal Application Rate

**Volatilization**

Volatilization Mass Balance.xls

Field Dissipation Review Attachment 2 Tables_examples.xlsx - Microsoft Excel

Security Warning Automatic update of links has been disabled Options...

B8 =B7/$B$3

| | A | B | C | D | E | F | G |
|---|---|---|---|---|---|---|---|
| 1 | Fields for input | | | | | | |
| 2 | Test Substance | Test | | | | | |
| 3 | Nominal Application Rate (lb a.i./A) | 320 | | | | | |
| 4 | Volatilization Mass Balance | | | | | | |
| 5 | | Hour 0 to Hour 4 | Hour 4 to Hour 8 | Hour 8 to Hour 12 | Hour 12 to Hour 16 | Hour 16 to Hour 20 | Hour 20 to Hour 24 |
| 6 | Sampling Period (hours) | 4 | 4 | 4 | 4 | 4 | 4 |
| 7 | Mass Loss From Soil (lb/A)* | 128.4745784 | 64.23728918 | 1.284745784 | 0.642372892 | 0.513898313 | 0.385423735 |
| 8 | % of nominal application rate | 40.1% | 20.1% | 0.4% | 0.2% | 0.2% | 0.1% |
| 9 | | | | | | | |
| 10 | | | | | | | |
| 11 | *Mass Loss From Soil (lb/A) = Soil Flux ($\mu g/m^2 s$) x Sampling Period (hours) x | | | 3,600 s | x | $10^{-6}$ g | x |
| 12 | | | | hour | | µg | |
| 13 | | | | | | | |
| 14 | | | | lb. | x | 4,046.9 $m^2$ | |
| 15 | | | | 453.59 g | | A | |
| 16 | | | | | | | |
| 17 | | | | | | | |
| 18 | | | | | | | |
| 19 | | | | | | | |
| 20 | | | | | | | |
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| 24 | | | | | | | |

TFD Soil Mass Balance_ex2.xls | Volatilization Mass Balance.xls | Water Body Mass Bal

Ready 100%

***Mass Balance for sampling period calculated using the following formula = Total Measured Volatile Flux/Nominal Application Rate**

**Water Body (Water and Sediment)**

Water Body Mass Balance.xls

Field Dissipation Review Attachment 2 Tables_examples.xlsx - Microsoft Excel

Security Warning Automatic update of links has been disabled Options...

D22 =(D20+D12)/$C$3

| | A | B | C | D | E | F | G | H | I | J | K | L | M | N | O | P |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | Fields for Input | | | | | | | | | | | | | | | |
| 2 | Test Substance | | Test | | | | | | | | | | | | | |
| 3 | Nominal Application Rate (lb a.i./A) | | 0.375 | | | | | | | | | | | | | |
| 4 | Total Water Column Mass Balance | | | | | | | | | | | | | | | |
| 5 | | | | Water increment concentrations (lb/A)* | | | | | | | | | | | | |
| 6 | Sampling Depth (ft.) | Increment Depth (ft.) | | Day [#] | Day [#] | Day [#] | Day [#] | Day [#] | Day [#] | Day [n] | | | | | | |
| 7 | 0 | NA | | ND | ND | ND | ND | ND | ND | ND | | | | | | |
| 8 | 1 | 1 | | 0.013594 | 0.000544 | 0 | 5.44E-06 | 2.72E-06 | #VALUE! | #VALUE! | | | | | | |
| 9 | 2 | 1.5 | | 0.008156 | 0.002039 | 1.63E-05 | 2.04E-05 | 2.45E-05 | #VALUE! | #VALUE! | | | | | | |
| 10 | 4 | 2 | | 0.002719 | 0.002719 | 0.002719 | 3.26E-05 | 4.35E-05 | #VALUE! | #VALUE! | | | | | | |
| 11 | 6 | 4 | | 0.001087 | 0.032625 | 0.025012 | 0.016312 | 0.005437 | #VALUE! | #VALUE! | | | | | | |
| 12 | Total Water Column Concentration (lb/A) | | | 0.026 | 0.038 | 0.028 | 0.016 | 0.006 | #VALUE! | #VALUE! | | | | | | |
| 13 | % of nominal application - water borne material | | | 6.8% | 10.1% | 7.4% | 4.4% | 1.5% | #VALUE! | #VALUE! | | | | | | |
| 14 | | | Bulk density | Sediment increment concentration (lb/A)* | | | | | | | | | | | | |
| 15 | Sampling Increment (ft.) | Increment Depth (ft.) | ($g/cm^3$) | Day [#] | Day [#] | Day [#] | Day [#] | Day [#] | Day [#] | Day [n] | | | | | | |
| 16 | 0-0.25 | 0.25 | 1.13 | 0.325209 | 0.289844 | 0.232183 | 0.163758 | 0.094564 | #VALUE! | #VALUE! | | | | | | |
| 17 | 0.25-0.50 | 0.25 | 1.13 | 0.001538 | 0.002306 | 0.003075 | 0.003844 | 0.004613 | #VALUE! | #VALUE! | | | | | | |
| 18 | 0.5-1.0 | 0.5 | 1.13 | 0.001538 | 0.004613 | 0.007688 | 0.009226 | 0.012301 | #VALUE! | #VALUE! | | | | | | |
| 19 | 1.0-1.5 | 0.5 | 1.13 | 0.001538 | 0.004613 | 0.007688 | 0.010763 | 0.015376 | #VALUE! | #VALUE! | | | | | | |
| 20 | Total Sediment Core Concentration (lb/A) | | | 0.329822 | 0.301376 | 0.250634 | 0.187591 | 0.126855 | #VALUE! | #VALUE! | | | | | | |
| 21 | % of nominal application rate - sediment borne material | | | 88.0% | 80.4% | 66.8% | 50.0% | 33.8% | #VALUE! | #VALUE! | | | | | | |
| 22 | % of nominal application rate - total material | | | 94.77% | 90.48% | 74.24% | 54.39% | 35.30% | #VALUE! | #VALUE! | | | | | | |
| 23 | | | | | | | | | | | | | | | | |
| 24 | | | | | | | | | | | | | | | | |
| 25 | *Water Increment Concentration (lb/A) = Water Concentration (µg/L) x Increment Depth (ft.) x | | | | | | | | | | | | | | | |
| 26 | | | 28.31 L | x | $ft.^2$ | x | $10^{-6}$ g | x | lb. | | | | | | | |
| 27 | | | $ft.^3$ | | 43,560 A | | µg | | 453.59 g | | | | | | | |
| 28 | | | | | | | | | | | | | | | | |
| 29 | *Sediment Increment Concentration (lb/A) = Sediment Concentration (mg/kg) x Bulk Density ($g/cm^3$) x Increment Depth (ft.) x | | | | | | | | | | | | | | | |
| 30 | | | 30.48 cm | x | kg | x | lbs. | x | $4.05 \times 10^7$ $cm^2$ | | | | | | | |
| 31 | | | ft. | | 1,000 g | | 453,592.37 mg | | A | | | | | | | |
| 32 | | | | | | | | | | | | | | | | |

Volatilization Mass Balance.xls | Water Body Mass Balance.xls | Plant and Canopy.xls

Ready 77%

***Mass Balance for sampling period calculated using the following formula= Measured total water column or sediment core concentration /Nominal application rate**

**Plant and Canopy Residues**

Plant and Canopy.xls

Field Dissipation Review Attachment 2 Tables_examples.xlsx - Microsoft Excel

Security Warning Automatic update of links has been disabled Options...

B15 =B14/$C$3

| | A | B | C | D | E | F | G | H |
|---|---|---|---|---|---|---|---|---|
| 1 | **Fields for input** | | | | | | | |
| 2 | **Test Substance** | | **Test** | | | | | |
| 3 | **Nominal Application Rate (lb a.i./A)** | | **0.315** | | | | | |
| 4 | **Total Plant and Canopy Mass Balance** | | | | | | | |
| 5 | | | | | | | | |
| 6 | | **Day [#]** | **Day [#]** | **Day [#]** | **Day [#]** | **Day [#]** | **Day [#]** | **Day n** |
| 7 | | | | **Root residue concentration** | | | | |
| 8 | **Concentration (lb/A)** | **0.3** | **0.25** | **0.2** | **0.1** | **0.1** | **0.05** | **0.01** |
| 9 | **% of nominal application** | **95.24%** | **79.37%** | **63.49%** | **31.75%** | **31.75%** | **15.87%** | **3.17%** |
| 10 | | | | **Shoot residue concentration** | | | | |
| 11 | **Concentration (lb/A)** | **0.01** | **0.01** | **0.01** | **0.05** | **0.01** | **0.01** | **0.01** |
| 12 | **% of nominal application** | **3.17%** | **3.17%** | **3.17%** | **15.87%** | **3.17%** | **3.17%** | **3.17%** |
| 13 | | | | **Total plant and canopy residue concentrations** | | | | |
| 14 | **Concentration (lb/A)** | **0.31** | **0.26** | **0.21** | **0.15** | **0.11** | **0.06** | **0.02** |
| 15 | **% of nominal application** | **98.41%** | **82.54%** | **66.67%** | **47.62%** | **34.92%** | **19.05%** | **6.35%** |
| 16 | | | | | | | | |
| 17 | | | | | | | | |
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| 23 | | | | | | | | |
| 24 | | | | | | | | |
| 25 | | | | | | | | |

Water Body Mass Balance.xls | Plant and Canopy.xls | Ready | 100%

***Mass Balance for sampling period calculated using the following formula= Measured total shoot or root residue concentration /Nominal applicatio rate**

## Attachment 3: Calculations

Calculations were performed by the reviewer using [indicate program(s) used for calculations] and the following equations. [The following equations are anticipated to reflect the NAFTA kinetics guidance as of January, 2012. If these equations are not current, they should be replaced by the applicable equations from current guidance.]

### Single First-Order (SFO) Model

$$C_t = C_0 e^{-kt} \quad \text{(eq. 1)}$$

where,

$C_t$ = concentration at time t (%)
$C_0$ = initial concentration (%)
e = Euler's number (-)
k = SFO rate constant of decline ($d^{-1}$)
t = time (d)

The SFO equation is solved [with the Excel Solver] by adjusting $C_0$ and $k$ to minimize the objective function ($S_{SFO}$) shown in equation 9.

$DT_{50}$ = natural log (2)/k (eq. 2)

$DT_{90}$ = ln (10)/k (eq. 3)

### Indeterminate Order Rate Equation (IORE) Model

$$C_t = \left[C_0^{(1-N)} - (1 - N)k_{IORE}t\right]^{\left(\frac{1}{1-N}\right)} \quad \text{(eq. 4)}$$

where,

N = order of decline rate (-)
$k_{IORE}$ = IORE rate constant of decline ($d^{-1}$)

This equation is solved [with the Excel Solver] by adjusting $C_0$, $k_{IORE}$, and $N$ to minimize the objective function for IORE ($S_{IORE}$), see equation 9. Half-lives for the IORE model are calculated using equation 5, which represents a first-order half-life that passes through the $DT_{90}$ of the IORE model. (Traditional $DT_{50}$ and $DT_{90}$ values for the IORE model can be calculated using equations 6 and 7.)

$$t_{IORE} = \frac{\log(2)}{\log(10)} \frac{{C_0}^{1-N}\left(1-0.1^{(1-N)}\right)}{(1-N)k_{IORE}} \quad \text{(eq. 5)}$$

$$DT_{50} = \frac{(C_0/2)^{(1-N)} - C_0^{(1-N)}}{k(N-1)} \quad \text{(eq. 6)}$$

$$DT_{90} = \frac{(C_0/10)^{(1-N)} - C_0^{(1-N)}}{k(N-1)} \quad \text{(eq. 7)}$$

**Double First-Order in Parallel (DFOP) Model**

$$C_t = C_0 g^{-k_1 t} + C_0(1-g)^{-k_2 t} \quad \text{(eq. 8)}$$

where,

g = the fraction of $C_0$ applied to compartment 1 (-)
$k_1$ = rate constant for compartment 1 ($d^{-1}$)
$k_2$ = rate constant for compartment 2 ($d^{-1}$)

If $C_0 \times g$ is set equal to $a$ and $C_0(1-g)$ is set equal to $c$, then the equation can be solved [with the Excel Solver] for $a$, $c$, $k_1$, and $k_2$ by minimizing the objective function ($S_{DFOP}$) as described in equation 9.

$DT_{50}$ and $DT_{90}$ values can be calculated using equations 2 and 3, with $k_1$ or $k_2$ in place of k.

**Objective Function:** SFO, IORE, and DFOP are solved by minimizing the objective function ($S_{SFO}$, $S_{IORE}$, or $S_{DFOP}$).

$$S_{SFO}, S_{IORE}, \text{ or } S_{DFOP} = \sum(C_{model,t} - C_{d,t})^2 \quad \text{(eq. 9)}$$

where,

$S_{SFO}$ , $S_{IORE}$, or $S_{DFOP}$ = objective function of kinetics model fit ($\%^2$)
n = number of data points (-)
$C_{model,t}$ = modelled value at time corresponding to $C_{d,t}$ (%)
$C_{d,t}$ = experimental concentration at time t (%)

**Critical Value to Determine Whether SFO is an Adequate Kinetics Model**

If $S_{SFO}$ is less than $S_C$, the SFO model is adequate to describe kinetics. If not, the faster of $t_{IORE}$ or the DFOP $DT_{50}$ for compartment 2 should be used.

$$S_c = S_{IORE}\left(1 + \frac{p}{n-p} F(\alpha, p, n-p)\right) \quad \text{(eq. 10)}$$

where,

$S_c$ = the critical value that defines the confidence contours ($\%^2$)
p = number of parameters (3 in this case)
α = the confidence level (0.50 in this case)
F(α, p, n-p) = F distribution with α level of confidence and degrees of freedom p and n-p

## Section III. Field Dissipation Study Review Considerations

This list of considerations is provided to help reviewers assess the acceptability of field dissipation studies. This list is not a screen or a checklist and should not be attached to the study reviews. Listed considerations carry unequal weight and should be evaluated using best professional judgment. All information from the study and from similar studies should be considered to determine whether any deficiencies affect the study classification.

» Raw measured data and representative chromatographs were provided.

» The test sites were located in the United States or in ecoregions representative of domestic (USA) sites.

» The sites used for this study were clearly shown to have no previous use history involving this or closely related compounds or was clearly shown to contain no background residues or analytical interferences.

» A bare-ground subplot was studied for all terrestrial field dissipation studies. The test site (including soil type) was typical of the proposed use pattern. If intended application was to a cropped surface, then subplots included these cropped surfaces as well.

» The study design included an untreated replicate treatment subplots.

» The study was conducted under required labeled or typical use conditions (*e.g.*, time of year, time of day, typical agricultural practices).

» Irrigation: The study design included sufficient water to meet the crop need in quantity and timing. If the use pattern includes irrigation to supplement the water requirements of the plant, then the study was conducted under irrigated conditions. In this case, the study design should ensure appropriate timing and sufficient water to meet 110% to 120% of the crop need. Also, in the case of bare plots, the site should receive sufficient water at the appropriate time to meet the crop water need for the intended crop in that use pattern. In other words, a bare plot site conducted for a corn use should receive 110% to 120% of the water need for corn in that use area. Alternatively, if the use pattern does not involve irrigation, then the field studies do not necessarily have to be conducted with supplemental irrigation. However, it may be necessary to prepare the site for irrigation in case of drier than normal conditions. For nonirrigated sites, the study design should ensure that 110% to 120% of normal monthly rainfall is delivered to the site.

» An adequate number of sites were used (generally 4-6) in different areas representative of the intended usage. Fewer sites are required for limited use patterns.

» A Typical End Use Product (TEP) was used, or an adequate justification was provided for the alternative chosen.

» Test substance was added to the soil at the highest recommended label rate for a single application or the highest recommended rate for each of multiple applications as well as at the minimum retreatment interval, if applicable.

» Specifics were provided regarding time of year, meteorological conditions during exposure, *etc.*

» Soil texture was adequately characterized using the USDA classification system.

» Soil taxonomy was adequately characterized using the USDA or, for foreign soils, the WRB classification system (Citation: USEPA, 2011).

- » Samples were selected randomly.
- » Sampling and testing was done to a sufficient depth to define leaching (that is to the depth of no detection of either parent or degradate) at all sampling intervals, or a rationale was given for not doing so.
- » Monitoring adequately detected all major degradates or degradates of toxicological concern identified in all abiotic degradation and biodegradation studies.
- » The study was conducted until patterns of decline of parent and patterns of formation/decline of degradates were established (*i.e.*, until at least 75% of residues have dissipated from the soil profile or 2 years, whichever occurs first).
- » The depth to the water table was reported.
- » Sampling intervals were adequate to define the half-life under field conditions and to track any vertical movement associated with rainfall.
- » Half-lives of parent and major degradates under field conditions were determined.
- » A storage stability study was conducted using either spiked field and spiked laboratory samples to determine the stability of samples under typical lab storage conditions. This study was conducted for at least as long as the longest duration of field sample storage.
- » An independently validated environmental chemistry method(s) was/were submitted to evaluate the precision and accuracy of the analytical method(s) used in the field study.
- » Detection and quantitation limits were reported.
- » A reasonable attempt was made to identify the parent and all major degradates identified from laboratory studies.
- » The soil-water balance was measured and reported.
- » The soil cores were of sufficient number with minimal compositing for each sampling time to define the heterogeneity of the soil and pesticide degradation. A sufficient number of soil cores were sampled (a minimum of 15 cores per 1 m x 2 m area).
- » Residue monitoring in different field media (soil, water bodies, plants, or air) started at the beginning application period.
- » Field, travel, and laboratory spiked samples were deployed and related data provided. An adequate number of spiked samples at multiple fortification levels were sampled consistent with the sampling periods of the appropriate field dissipation study module.

**References**

U.S. Environmental Protection Agency (USEPA). 2011. Guidance for Determining the Acceptability of Environmental Fate Studies Conducted with Foreign Soils. May 20, 2012. On-line at: http://www.epa.gov/pesticides/science/efed/policy_guidance/team_authors/environmental_fate_tech_team/soils_foreign.htm (accessed Apr. 2, 2012).