Sample storage stability of [test compound(s)] in [frozen soil, water, *etc.*]

|  |  |
| --- | --- |
| Report: | [Provide full citation. Provide the MRID (first) if the review is unilateral.] |
| Document No.: | [MRID xxxxxxxx] |
| Guideline: | Non-guideline[Currently, storage stability studies that support environmental fate studies do not fall under a specific OCSPP guideline. If this review is multilateral, also provide the guideline numbers under which participating agencies are reviewing the study.] |
| Statements: | [Indicate whether the study was conducted in compliance with FIFRA GLP standards and whether signed and dated Data Confidentiality, GLP Compliance, Quality Assurance, and Authenticity Certification statements were provided. If the study was not conducted in compliance with FIFRA GLP standards, indicate why or how it deviated.] |
| Classification: | This study is [provide classification and 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 Signature:and title.] Date: [Type date of signature.] |

**Executive Summary**

The storage stability of [test compound(s)] in frozen [environmental medium or media] was investigated. Untreated samples were collected from the study site(s) at [location(s), state(s)/province(s), country], which was/were studied in [MRID(s)], and spiked with [concentration(s)] of [test compound(s)]. The field spikes were shipped and stored frozen ([temperature] °C) under the same conditions as field samples for [#] intervals of up to [#] days. [Indicate whether substantial degradation of test compound(s) occurred, the duration for which degradation was insubstantial, and any degradation half-life(s) if calculable.] [If this study was not conducted with field spikes in support of a field study, modify the executive summary to reflect the study design and state the purpose of the study, if known.]

**I. Material and Methods**

Provide (a) small image(s) of the active ingredient(s) in the right margin.

**A. Materials**

**1. Test Materials** [Test compound]
 Chemical purity: [percentage (HPLC)]

 Batch number: [value]

 [Repeat or tabulate the information in this section for multiple analytes.]

**B. Study Design**

1. **Experimental conditions**

Untreated samples were collected from the study site(s) at [location(s), state(s)/province(s), country], which was/were studied in [MRID(s)], and spiked with [concentration(s)] of [test compound(s)]. The field spikes were prepared by weighing [mean±s.d. units] of [medium] into individual [type of] bottles. These spikes were shipped and stored frozen ([temperature] °C) under the same conditions as field samples for [#] intervals of up to [#] days after fortification. [Indicate whether the spikes were fortified in the field or in the laboratory and, if in the laboratory, the duration(s) of storage prior to fortification in the previous statement.] The fortification solution(s) contained [concentration(s)] of [test compound(s)] in [concentration(s) of solvent]. Spikes were fortified with [volume] of fortification solution, resulting in a fortification concentration(s) of [concentration] of [test compound(s)].

1. **Sampling**

[Single or duplicate] spikes were taken for analysis at [list intervals after treatment]. [Alternatively, indicate if spikes were treated at each interval, with a single analysis of all spikes occurring on the final day of fortification.]

1. **Analytical procedures**

[Briefly describe the analytical procedure for the analyses of spiked samples, including a summary of the extraction and clean up steps, the chromatograph column, mobile phase, and detector, and the detection limits (LOD, LOQ) of each analyte. Provide references for the environmental chemistry method(s) used and its associated independent laboratory validation(s).]

**II. Results and Discussion**

[Indicate whether substantial degradation of test compound(s) occurred, the duration for which degradation was insubstantial, and any degradation half-life(s) if calculable. Calculate degradation half-lives using single first-order kinetics with non-linear regression of the percentages of the applied against time. Provide associated model parameters (C0 and k) and statistics (r2 and p).]

Table 1. Storage stability of [test compound(s)] in [frozen soil, water, *etc.*] expressed as percentage of the applied [Duplicate table as needed for additional test compounds and media.]

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **[Frozen medium]** |  |  |  |  |  |  |  |  |  |  |  |  |
| **Storage 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] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] | [#] |

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

**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**

**[**Attach a table (*i.e.*, structure table) of the chemical names, SMILES strings, CAS numbers, and structures of the analytes or refer to this table if it exists in a separate, associated document. Do not include in the table multiple versions of chemical names and SMILES strings. 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 (with columns for %AR left blank). At a minimum, repeat the table below for the analytes.

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

[Sample structure table with the minimum information needed.]

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

[Sample EFED ROCKS memorandum format for structure tables.]



Attachment 2: Statistics Spreadsheets and Graphs



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

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

[The attached Excel file has two example spreadsheets for results 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 March, 2012. If these equations are not current, replace them with the applicable equations from current guidance.]

Single First-Order (SFO) Model

$C\_{t}=C\_{0}e^{-kt}$ (eq. 1)

where,

 Ct = concentration at time t (%)

 C0 = 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 *C0* and *k* to minimize the objective function (SSFO) shown in equation 4.

DT50 = natural log (2)/k (eq. 2)

DT90 = ln (10)/k (eq. 3)

$S\_{SFO}=\sum\_{}^{}(C\_{model},t-C\_{d,t})^{2}$ (eq. 4)

where,

SSFO = objective function of SFO model fit (%2)

n = number of data points (-)

Cmodel,t = modelled value at time corresponding to Cd,t (%)

Cd,t = experimental concentration at time t (%)