Prospective Ground Water Monitoring of [test compound]

|  |  |
| --- | --- |
| Report: | [Provide full citation. Provide the MRID (first) if the review is unilateral.] |
| Document No.: | [MRID xxxxxxxx] |
| Guideline: | OCSPP 835.7100  [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 835.7100.’ 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**

[Registrant name] commissioned a prospective ground water monitoring study designed to evaluate the ground water contamination potential of [analytes] at a vulnerable site in [crop] production in the [region] of the United States. The study site, located in [location], was selected based on leaching vulnerability criteria. The predominant soil series at the site was [soil series]. The study was initiated on [date] and terminated [#] days later.

[#] clusters of two wells each with [#]-foot-long screens were installed on-site. Each well cluster had one shallow well with screen [#] feet below ground and one deep well with screen [#] feet below ground. [#] clusters of four lysimeters each were also installed, each with a [#]-, [#]-, [#]-, and [#]-foot-deep lysimeter. [#] lysimeter cluster(s) and [#] well(s) with a [#]-foot-long screen were also installed on a hydraulically up-gradient control subplot.

[Product name], a [formulation type] containing [#%] [active ingredient] [by weight] was applied in a series of [#] [ground broadcast] applications of [#] lbs a.i./A at [#]-day intervals starting on [date] to total [#] lbs a.i./A applied. [Tracer] was also applied once in order to provide a tracer. Soil samples ([range] feet below surface) were [regularly/irregularly] collected at [#] events up to [#] days after the initial treatment (DAIT). Water samples were collected at [#] events from lysimeters, ground water wells, and from irrigation source water up to [#] DAIT. Precipitation was supplemented with [overhead center pivot] irrigation to approximate 120% of the normal water inputs (precipitation plus irrigation based on crop water demand or historical rainfall data, whichever is greater) during the study.

Application monitoring cards indicated a cumulative total application of [#] lbs a.i./A ([#]% of the theoretical application rate). [Provide the limits of detection (LOD) for the analytes and tracer. Indicate when the analytes and tracer were first detected at each sampled soil depth, lysimeter depth, and well depth and indicate how leaching rates of the analytes compared to that of the tracer.]

[Provide the maximum concentrations of the analytes in the ground water wells and the intervals at which they occurred. Indicate whether the results were consistent with the expected mobility and (formation and) decline of the analytes. If analytes were not detected, indicate whether the LODs were reasonable.]

**I. Study Design**

[Provide a brief summary of the study design. The site selection, protocol, and other interim reports may be cited for additional detail.]

[State who commissioned the study and why. State where the study was conducted and briefly discuss why the site(s) was/were chosen.]

1. **Site Description**

[Cite by MRID any site selection or site characterization reports. Describe the study site(s), including any subplots and the control plot(s) (*e.g.*, plot dimensions, grade, crop history, and pesticide history). Characterize the soil mapping units and component soils within the study site (indicate whether the soils agree with the mapping units and their allowable variation). Characterize the soil horizons, the sources of water inputs (precipitation plus irrigation), and the target water input. State whether the control plot and irrigation pump intake (if any) were hydraulically up-gradient from the treated plots. Describe any nearby surface water features. Summarize the study author’s characterization of the site hydrogeology, including the hydraulic conductivity of the vadose and saturated zones, the water table depth and fluctuations, and the ground water flow velocity and mean hydraulic gradient.]

[Indicate the crop(s) grown on the field and provide the planting date(s) and method(s), pesticides applied and dates of application, and harvesting date(s). If available, indicate whether the yield of the crop(s) on the study site was consistent with that of the surrounding fields.]

1. **Instrumentation**

[Briefly describe and depict the locations of the lysimeters, wells, and meteorological equipment installed at the study site.]

1. **Treatment**

[Provide relevant information on the studied active ingredient and formulation applied (a brief table of environmental fate properties of the active ingredient may be helpful). Provide the application dates and rates for the active ingredient and the tracer as well as any other pertinent information regarding the application methods.]

1. **Sampling**

[Briefly describe the sampling intervals and practices for any soil, soil pore water, ground water, irrigation water, tank mix, and application monitoring samples. Also describe the sample transport, storage, and handling conditions. Indicate whether duplicate samples were collected and whether samples were composited. Indicate whether control samples were handled similarly to the other samples. Describe any fortification of field spikes.]

1. **Documentation**

[Catalog by MRID and date of submission all submitted site selection and site characterization, monitoring plan design, other study protocol, quarterly progress, termination, and final reports and any amendments. Briefly summarize any Agency reviews of these reports, indicating any approvals or waivers. Full details of submitted reports are provided in the References section.]

**II. Analysis**

1. **Moisture Conditions**

[Characterize the precipitation, irrigation, and evapotranspiration during the study. Indicate how much water was available for recharge and storage after evapotranspiration. Indicate whether cumulative water inputs (precipitation plus irrigation, *e.g.*, on a monthly scale) were 120% of normal water inputs, based on crop water demand or historical rainfall data (*e.g.*, the 30-year normal mean precipitation), whichever is greater). Indicate whether any substantial runoff events occurred.]

[Summarize the soil moisture during the study, highlighting any sharp increases at lower depths and their causes.]

1. **Analytical Methods**

[Summarize the analytical methods used in the study, briefly describing the extraction, clean-up, and analysis procedures for each matrix and analyte, and the resulting limits of detection (LOD) and quantitation (LOQ). Indicate whether the environmental chemistry methods (ECM) were successfully validated by an independent laboratory. Indicate whether the methods were validated using the type of medium most difficult to extract for each environmental medium. Provide the MRIDs of the ECM and ILV reports.]

**1. Method Recoveries (Laboratory Spikes)**

[Describe the blanks, method blanks, and fresh laboratory fortifications prepared and analyzed concurrently with test samples. More specifically, for the laboratory spikes, tabulate the percent recovery per concentration, matrix, and analyte, reporting the mean ± relative standard deviation (RSD), the range, and the sample size. Discuss any poor recoveries and any interference from the blanks.]

**2. Storage Stability (Field Spikes)**

[Describe the fortifications prepared on-site that were shipped, stored, and analyzed under similar conditions to the test samples. More specifically, tabulate the percent recovery per concentration, matrix, and analyte, reporting the mean ± relative standard deviation (RSD), the range, and the sample size. Discuss any poor recoveries. Indicate the maximum storage length and whether it is comparable to the maximum storage length of test samples. Also summarize any available storage stability data for a relevant matrix that was submitted in a separate study report and provide the MRID.]

**III. Results**

1. **Application Rate Monitoring**

[Provide and briefly discuss the results of any tank mix samples and application monitoring samples. Indicate whether the individual and cumulative application rates were verified.]

1. **Tracer**

[Provide the background concentrations of the tracer (*e.g.*, bromide) in soil prior to treatment. Characterize the leaching of the tracer, indicating the sampling intervals when the tracer was first observed at elevated concentrations and when the tracer was at a maximum concentration at each sampled soil depth, lysimeter depth, and ground water well depth. Provide graphs of the tracer concentrations per time at shallow ground water wells and at deep wells.]

1. **Analyte(s)**

[Characterize the leaching of the analytes, indicating the sampling intervals when they were first observed at or above the LOD, when they were at a maximum concentration, and when they were last observed at each sampled soil depth, lysimeter depth, and ground water well depth. Indicate how their leaching compared to that of the tracer and to abnormal meteorological events. Indicate whether the results were consistent with the expected mobility and (formation and) decline of the compounds. Provide graphs for each analyte of their concentrations per time at shallow ground water wells and at deep wells (tabulated results are placed in the attached Excel spreadsheet).]

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

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

**V. References** [List any references cited in the review, including submitted site selection and site characterization, monitoring plan design, protocol, progress, termination, and final reports and any amendments, providing their MRIDs. Also list any Agency reviews of or responses to these reports, providing their DP barcodes.]

**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. This formatting includes table columns for MRIDs and associated study data such as maximum and final concentrations of transformation products and their intervals. At a minimum, repeat the table below for the analytes.

For multilateral reviews, chemical names, SMILES strings, structures, and CAS numbers are captured elsewhere in the Monograph[[1]](#footnote-1). 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 four example spreadsheets, one for each of two analytes, one for the tracer, and one for water inputs.]

Attachment 3: Study Base Map

[Insert the base map from the study report.]

1. A Monograph is a collection of multiple study reviews and data summaries prepared by government agencies into a single document that follows an OECD format. Typically, Tier II Summaries prepared by industry are updated by government agencies based on agency-review and then placed within the Monograph. [↑](#footnote-ref-1)