Standard Efficacy Report + Summary Template

3/23/05

The following template may be used as a guide by testing laboratories in formatting and summarizing efficacy study reports.

Study Title

Product Identity

Data Requirement

Author
(name)
(corporate title)

Study Completion Date

(Date final report is signed by study director.)

Testing Facility

(include address)

Laboratory Project Number (Study File)

STATEMENT OF NO DATA CONFIDENTIALITY CLAIMS

No claim of confidentiality is made for any information contained in this study on the basis of its falling within the scope of FIFRA section 10(d)(1)(A), (B), or (C).

Company: _____

Company Agent: _____ Date: _____
(typed name)

_____ _____
Title Signature

Alternate No.1:

STATEMENT OF DATA CONFIDENTIALITY CLAIMS

Information claimed confidential on the basis of its falling within the scope of FIFRA section 10(d)(1)(A), (B), or (C) has been removed to a confidential appendix, and is cited by cross-reference number in the body of the study.

Company: _____

Company Agent: _____ Date: _____
(typed name)

_____ _____
Title Signature

GOOD LABORATORY PRACTICE COMPLIANCE STATEMENT

This study meets the requirements of 40 CFR § 160.

(Alternative No.1: This study meets the requirements of 40 CFR § 160 with the following exceptions: *if any exceptions during study*)

(Alternative No.2: This study does not meet the requirements of 40 CFR § 160. A detailed list of exceptions must be included.)

SUBMITTER: [Insert Corporate Name]

_____ (Signature) _____ DATE: _____
Typed Name
Title

SPONSOR: [Insert Corporate Name]

_____ (Signature) _____ DATE: _____
Typed Name
Title

STUDY DIRECTOR:

_____ (Signature) _____ DATE: _____
Typed Name
Title

TABLE OF CONTENTS

EFFICACY STUDY SUMMARY

STUDY TITLE: (Title of study performed including test method name)

LABORATORY PROJECT #: (Lab identification number assigned to study.)

GUIDELINE: (EPA Guideline # and label claim being supported by testing)

TESTING FACILITY: (Name of testing laboratory)

STUDY DATES:
STUDY INITIATION DATE: (Date the protocol is signed by study director)
STUDY COMPLETION DATE: (Date final report is signed by study director)

GLP COMPLIANCE: (Description of compliance with 40CFR§160)

TEST SUBSTANCE:
DESCRIPTION: (Product use-pattern, as per label, and form)
% ACTIVE INGREDIENT: (Ingredient(s) name and percent claimed on label)

DILUTION: (Product dilution used in testing, include dilution instructions)

TEST CONDITIONS:
SOIL LOAD: (Organic load used in testing)
WATER: (Water type and hardness used in testing)
CONTACT TIME: (Contact time of disinfectant used in testing)
TEMPERATURE: (Temperature used in testing)
OTHER: (Describe other modifications to test, e.g. surface, additional organisms, re-use.)

TEST RESULTS: (form - Positive carriers/total carriers, log reduction, etc.)

Test Organism	Identification #	Test Results (form)		
		Lot #####	Lot #####	Lot #####*

***60 day old Sample**

CONTROL RESULTS: (Statement verifying that all controls met specifications of method and/or protocol, reference the appropriate pages in the study report)

CONCLUSION: (Did study meet EPA Guideline? Under what conditions?)

QUALITY ASSURANCE STATEMENT

Study Title:

Study #:

In accordance with the Good Laboratory Practice Standards (EPA 40 CFR § 160), quality assurance audits of this study were conducted and reported to management and the study director as listed below:

Audit Date	Phase Audited	Date Reported to Study Director	Date Reported to Management

(Signature) _____ _____

Typed Name Date

QA Title

STUDY PERSONNEL

STUDY DIRECTOR: _____ (Signature)

Typed Name
Corporate Title

[Other scientists or professionals involved in the study must sign the report. The names of the supervisory personnel involved in the study should be included in the final report. Names of laboratory personnel may be included in the final report.]

STUDY REPORT

STUDY TITLE: (Brief title of the study.)

SPONSOR: (Name, Corporation Name, and address.)

TEST FACILITY: (Corporation Name and test facility address.)

TEST SUBSTANCE IDENTIFICATION

TEST SUBSTANCE NAME: (Include code number or CAS number, active ingredient, EPA Reg. # as applicable)

LOT/BATCH NUMBER(S): (Test substance lot/batch numbers, manufacture date, expiration date. Clearly identify the 60-day-old sample.)

DESCRIPTION OF TEST SUBSTANCE: (Describe test substance as received [i.e. color, clarity, viscosity, concentration], container [market or otherwise as applicable], storage conditions, and expiration date.)

CHEMICAL CHARACTERIZATION: (The identity, solubility, stability, strength, purity, and chemical composition "*was/was not*" provided. Reference where the information may be found in the submission. May be attached as an appendix if provided to the testing facility).

STUDY INITIATION DATE: (Date the protocol signed by study director.)
EXPERIMENTAL START DATE: (First date the test substance applied to the test system.)
EXPERIMENTAL END DATE: (Last date data was collected from the system.)
STUDY COMPLETION DATE: (Date the study director signs the final report.)

STUDY OBJECTIVE: (To determine the *"name of test"* or "*name of test substance*" against the test strains at "*insert test conditions, i.e. soil, hard water, temperature,*" as stated in the approved protocol)

TEST METHOD: (Official name of the test method used, i.e. AOAC Use Dilution, with the complete citation for its publication, as stated in the approved protocol)

TEST SYSTEM/STRAINS: (Describe the test organisms, whether viral, bacterial, or fungal strains, as stated in the approved protocol. Include source of strains.)

STUDY MATERIALS

MEDIA
(Identify each type of culture media used in the study, including neutralizing media. If using non-standard media or modified media, describe in detail).

REAGENTS
(Identify each reagent [soil load, diluents, hard water, stains] and concentrations used in the study. If using non-standard or modified reagents, describe in detail)

EQUIPMENT
(Identify all critical equipment used in the study.)

TEST METHOD

PREPARATION OF TEST SUBSTANCE
(Describe the preparation of the test substance. Describe in detail the dilution or special handling required, i.e. mix "x" parts test substance with "y" parts diluent, specify by weight or by volume).

PREPARATION OF TEST SYSTEM/STRAINS
(Describe the preparation of the test strains prior to the mixture with the test system: e.g. dilution, spectrophotometry, pellicle removal, thawing, preparation of cell lines, addition of soil load, drying on carriers/slides/Petri dishes)

EXPOSURE CONDITIONS
(Describe the procedure used to expose the test system to the test substance: contact time, time variance, temperature, mixing procedure, specific quantities of all materials, and methods of transferring liquids/carriers.)

TEST SYSTEM RECOVERY
(Describe the procedure used to neutralize and recover the test system/strain. Include time periods, temperatures, incubation conditions, enumeration method)

PROTOCOL CHANGES

PROTOCOL AMENDMENTS
(List all Protocol Amendments [planned changes that occurred after the protocol was signed by sponsor and Study Director] that occurred during the study. All protocol amendments must be properly documented and may be attached along with the protocol to the final report for further clarification.)

PROTOCOL DEVIATIONS
(List all Protocol Deviations [unforeseen circumstances/unplanned changes] that occurred during the study. Unplanned changes are those that were not anticipated by the Sponsor or the Study Director and thus did not go through the amendment process.)

CONTROLS

PREPARATION OF CONTROL(S)
(Describe all controls conducted in the study. Include but not limited to neutralization, sterility, time zero, and viability. Describe the procedure, dilutions, contact times, recovery methods, enumeration, carrier counts, neutralization, incubation parameters, and temperatures.)

STUDY ACCEPTANCE CRITERIA

STUDY REQUIREMENTS

1) List requirements for control, neutralization, strain quantification.
2) Performance criteria (To be determined by referenced published sources, i.e. EPA documents, standard methods, or prior agreement with the agency.)

DATA ANALYSIS

CALCULATIONS
(Describe the mathematical transformation, calculations or operations performed on the raw data.)

STATISTICAL ANALYSIS
(Describe the statistical methods used to analyze the data.)

STUDY RETENTION

Data Retention
(Describe the data retention process for your facility [final report, protocol, raw data], included the location of the storage unit.)

Specimen Retention
(Describe the retention of the specimens for your facility, including location).

STUDY RESULTS

Control and Neutralization Results (Tables 1-2)
(Present and discuss the performance of the neutralization and carrier count controls based upon the Study Acceptance Criteria, Method reference [AOAC, ASTM], and the EPA Guidelines.)

Study Results (Table 3 - #)
(Present and discuss the performance of the test substances based upon the Study Acceptance Criteria and the Method Reference [AOAC, ASTM.])

STUDY CONCLUSION

(Discuss the performance of each test substance lot based upon the EPA Guidelines.)

REPORT SUBMITTED BY:

_____	_____
Study Director	Study Completion Date

TABLE 1: Carrier Control Results

(Control Results will vary according to the Protocol. An example of Carrier Control Counts is provided.)

TEST ORGANISM	DATE PERFORMED	RESULT (cfu/carrier)

TABLE 2: Neutralization Results

(Neutralization Results will vary according to the Protocol.)

		NEUTRALIZATION CONFIRMATION			
SAMPLE ID	ORGANISM	DATE PERFORMED	INOCULUM (cfu/mL)	No. SUBCULTURE TUBES TESTED	RESULTS

TABLE 3: Test Results

(Tables of Test Results will vary with each study. Format to be based on data required and expectations of sponsor.)

TEST ORGANISM	IDENTIFICATON #	TEST RESULTS (form)		
		Lot #####	Lot #####	Lot #####*

* 60 day old sample