US Environmental Protection Agency
Office of Pesticide Programs

Office of Pesticide Programs
Microbiology Laboratory
Environmental Science Center, Ft. Meade, MD

Standard Operating Procedure for
Preparation and Review of Product Performance Reports

SOP Number: ADM-01-08

Date Revised: 09-15-23

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Title	Preparation and Review of Product Performance Reports
Revisions Made	• Minor editorial changes made. • Section 1, Definitions: 2. Quality Assurance Statement: at the end added: … to affirm the study was conducted in accordance with EPA Good Laboratory Practices • Section 14: Attachment removed, instead Appendix A used.

SOP Number	ADM-01-08
Title	Preparation and Review of Product Performance Reports
Scope	This protocol describes the preparation and review of performance reports related to regulatory or enforcement activities for disinfectant products tested for efficacy against one or more microorganisms.
Application	This SOP is applicable for preparation of all performance reports generated by the Microbiology Laboratory Branch (MLB).

	Approval	Date
SOP Developer	Kiran Verma Digitally signed by Kiran Verma Date: 2023.09.15 09:13:09 -04'00'	09/15/23
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Date SOP issued:	09/15/23
Controlled copy number:	0
Date SOP withdrawn:	

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1. Definitions	Additional abbreviations/definitions are provided in the text. 1. Performance Report = A report documenting the outcome of a product efficacy evaluation as tested with a specific method. The performance report contains information referred to in Section 12.1. 2. Quality Assurance (QA) Statement = A statement issued by the Quality Assurance Officer (QAO) or designee of the Microbiology Laboratory Branch that identifies the quality assurance audit trail and review of the report to affirm the study was conducted in accordance with EPA's Good Laboratory Practices (GLP).
2. Health and Safety	Not applicable
3. Personnel Qualifications and Training	Refer to SOP ADM-04, OPP Microbiology Laboratory Training.
4. Instrument Calibration	Not applicable
5. Sample Handling and Storage	Not applicable
6. Quality Control	1. The OPP Microbiology Laboratory conforms to 40 CFR Part 160, Good Laboratory Practice (GLP) Standards. Appropriate quality control measures are integrated into each SOP. 2. Studies are tracked in the Master Schedule which is maintained electronically and archived as per SOP QA-04, Master Schedule Preparation.
7. Interferences	1. Incomplete paperwork and documentation can impede the report process and may further impact regulatory and enforcement actions.
8. Non-conforming Data	1. Document any non-conformances and follow up with appropriate corrective action(s). Procedures are consistent with SOP ADM-07, Non-Conformance Reports.
9. Data Management	1. Archive data consistent with SOP ADM-03, Records and Archives. 2. Archive completed reports in electronic format on the designated network drive. File original test data sheets, study protocols, and attachments in room D217. Only authorized personnel have access to D217.
10. Cautions	None
11. Special	None

Apparatus and Materials	
12. Procedure and Analysis	1. A performance report consists of information associated with testing of a product and may include documents such as the study protocol, data sheets, labels, chain of custody (COC) forms, as well as documents required under Good Laboratory Practice Standards such as the GLP Statement and Quality Assurance audit information. The performance report and Biological Report of Analysis forms are sent along with a transmittal memo, which summarizes the testing history and is signed by the Branch Chief. 2. Compile and finalize the performance report within 14 business days after all data collection is completed.
12.1 Contents and Format of a Typical Performance Report	Refer to Appendix A for general report format. The performance report is assembled sequentially and consists of, but is not limited to, the following: a. Quality Assurance Unit Statement b. Title Page c. GLP Statement (includes signatures) d. Study Protocol and Attachments e. Test Coordinator and Analyst Signature Page (includes signatures) f. Data Summary Sheets g. Photocopies of Test Data Sheets (e.g., Test Information Sheet, Results Sheet, Confirmation Sheet, Carrier Count Data sheet and Spreadsheet, Vitek™ automated identification system for bacteria printouts, and Test Sheets related to Neutralization Confirmation Assays [when applicable]). h. Photocopies of the Chain of Custody documentation i. Photocopies or photographs of product label on sample container. j. Accompanying the Performance Report is (are) the completed Biological Report(s) of Analysis (BRA) (see section 14) (EPA Form 8510-14).
12.2 Preparation of the Report	a. Assemble the draft report and associated BRA, check it for completeness, and submit to another analyst for peer review. b. Complete a Report Preparation and Quality Control Checklist (see section 14). c. Prepare a draft transmittal memo.

	d. Once the peer review is complete, submit the draft report to the Study Director or designee who reviews the draft report for errors and completeness. e. Incorporate any suggested corrections/changes made by the study director. f. Alternatively, if there are only minor comments, the study director may submit the draft report directly to the Quality Assurance Unit (QAU).
12.3 Quality Assurance Unit Review of a Draft Report	a. The lead analyst submits the draft report and all subsequent corrections/changes for review by the QAU. b. The QAU reviews the draft report for completeness and determines whether additional revisions/corrections are necessary. c. If errors are noted by the QAU, the QAU either communicates or makes notations in the draft report and returns it to the lead analyst. d. The lead analyst ensures all required revisions/corrections are completed by the appropriate analyst(s) and submits the final report and signed Biological Report of Analysis (see section 14) to the QAU for final review. Once reviewed by QAU, the lead analyst page stamps the final report (e.g., stamped on paper report, addition of footer to electronic report). e. The QAU verifies that all corrections or required revisions have been made and issues the QA statement affirming that the study has been conducted in accordance with GLP guidelines. f. The lead analyst submits the page stamped report, now known as the final performance report along with the signed BRA and a draft transmittal memo to the branch chief for signatures. g. The branch chief reviews the final performance report and adds signatures and date to the BRA(s). h. The signed final performance report and signed BRA along with a transmittal memo are sent by the branch chief or designee to the study sponsor. i. The QAU sends a “Record of Customer Feedback” form (see SOP ADM-08) to solicit feedback on the quality of the laboratory services. j. The lead analyst ensures that the transmittal memo, BRA, and full report are stored electronically. k. Archive the original test data sheets, study protocols, and attachments

	in appropriate folders. If a paper copy of the final performance report is generated, archive it appropriately.
13. Data Analysis/ Calculations	1. None
14. Forms and Data Sheets	1. Appendix A: General Antimicrobial Report Format 2. Test sheets are stored separately from the SOP under the following file names: Report Preparation and Quality Control Checklist ADM-01-08_F1.docx Biological Report of Analysis (EPA HQ Form 8510-14), Pages 1 and 2 ADM-01-08_F2.docx
15. References	1. None

Appendix A

General Antimicrobial Report Format

Develop a report as described below for ALL product tests (passing and failing). Put the documents in the order noted on this list, whether in a paper or electronic report. The BRA and draft transmittal are independent of the body of the report but should be submitted with the report. Tabs are only required for paper versions of the report. A report may have additional components depending on the method and the outcome of the test.

Front section: **(no tab required)**
Title Page (Not numbered)
QA Statement (Not numbered)
GLP Statement
Study Protocol
Test Parameters (signed by AD)
Analyst Signature Page (for the study)

For each organism) – tab separately (label the tab by organism)
Data Summary Sheet
Test Information Sheet
Test Results Sheet
Confirmation Sheet
Vitek™ Printouts
Carrier Count Data Sheet
Carrier Count Spreadsheet
Neutralization Results Sheet (if conducted)

Chain of Custody Documentation (label tab as "Chain of Custody")
Shipping and receiving record (optional: package receiving log)
History of Official Sample
Laboratory COC form
Seal Log
Correspondence from the company
'Label' copies

In addition, the following documentation should be submitted for QA review in a separate folder. Once the report has been reviewed the documentation noted below can be placed under a separate tab in the lab copy only of the report as "Supporting Documentation".

Test Organism tracking log
Time Recording Sheets (carrier transfer, carrier inoculation)
Media sterility and performance summary sheet
Gram Stain Worksheet (if used)
Serial dilution/plating form
Equipment form
Any unique information specific to the product (prep forms for unusual neutralizers, emails about soil ingredients etc.)