



US Environmental Protection Agency Office of Pesticide Programs

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

Standard Operating Procedure for Disinfectant Sample Login and Tracking

SOP Number: COC-01-04

Date Revised: 01-08-09

EPA/OPP MICROBIOLOGY LABORATORY
ESC, Ft. Meade, MD

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for
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SOP Number: COC-01-04

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Initiated By: _____ Date: ___/___/___

Print Name: _____

Technical Review: _____ Date: ___/___/___

Print Name: _____

Technical Staff

QA Review: _____ Date: ___/___/___

Print Name: _____

QA Officer

Approved By: _____ Date: ___/___/___

Print Name: _____

Branch Chief

Effective Date: ___/___/___

Controlled Copy No.: _____

Withdrawn By: _____ Date: ___/___/___

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1.0 SCOPE AND APPLICATION:

1.1 This protocol describes procedures used by the Microbiology Laboratory Branch for the login and tracking of disinfectant samples. Documenting the receipt, storage, handling, use, and disposal of product samples is essential. Various chain-of-custody forms are used to document the movement of all product samples from sample collection through disposal.

2.0 DEFINITIONS: None

3.0 HEALTH AND SAFETY:

3.1 Follow precautions for storage and handling as stipulated by the product manufacturer.

3.2 Flammable samples are stored in locked flammable storage cabinets.

4.0 CAUTIONS:

4.1 Condition of the primary shipping container, the product sample, and the chain-of-custody seal must be noted on the appropriate form.

4.2 Samples should be logged in and transferred to the storage facility as soon as possible by an official OPP Microbiology Laboratory sample custodian. Sample custodians are responsible for signing out samples for testing and returning the samples to the storage area following procedures outlined in this SOP.

5.0 INTERFERENCES:

5.1 Insufficient chain-of-custody documentation, illegible entries by the inspectors, or incorrect entries of sample identity by the inspectors may interfere with completion of the sample login process. Illegible, missing, or incorrect entries that may interfere with the completion of the sample login process are addressed by contacting the inspector for clarification. Deficiencies are documented. A written explanation by the inspector may be required.

5.2 Samples which arrive in poor condition will not be accepted for analysis. The contents will be discarded and the inspector and the Office of Enforcement and Compliance Assurance (OECA) will be notified to send replacement samples.

6.0 PERSONNEL QUALIFICATIONS:

- 6.1 Sample custodians for the laboratory have been identified in Section 10.3 below. Personnel may not be designated as sample custodians unless they have received training on this SOP. Training is conducted and documented as per SOP ADM-04, Training.
- 6.2 Documentation of training and familiarization with this SOP can be found in the training file for each sample custodian.

7.0 SPECIAL APPARATUS AND MATERIALS:

- 7.1 Rooms B204 and D204 at EPA's Environmental Science Center have been designated as the secured storage sites for product samples. Flammable samples are stored in the locked flammable storage cabinets in room B204. All other samples are stored in room D204. The temperature and relative humidity of sample storage rooms are monitored by the computer-based Environmental Monitoring and Alarm System (see SOP QC-05, Monitoring Environmental Parameters.)

8.0 INSTRUMENT OR METHOD CALIBRATION: Not applicable

9.0 SAMPLE HANDLING AND STORAGE:

- 9.1 Product samples will be handled and maintained for testing per the conditions outlined below in the "Procedure and Analysis" section.

10.0 PROCEDURE AND ANALYSIS:

- 10.1 Product samples are shipped to the Microbiology Laboratory to the attention of Michele Cottrill, USEPA, Environmental Science Center (ESC), 701 Mapes Road, Ft. Meade, MD 20755-5350.
- 10.2 Upon arrival at the ESC loading dock, loading dock personnel are required to contact a sample custodian who will receive the samples and initiate the Shipping and Receiving Record for Disinfectant Products (see 16.1). Loading dock personnel are required to fill in several fields of this form. In addition, the loading dock personnel or sample custodian will record a number on each primary shipping container (usually a box) to indicate the number of containers received as follows: Container #__ of __/Initials
- 10.3 Sample custodians for the laboratory are: Michele Cottrill, Jason Duncan, Jafrul

Hasan, Knoxley Japal, Rebecca Pines, Marc Rindal, Luisa Samalot-Freire, Stephen Tomasino, Kiran Verma, and Mick Yanchulis. Sample custodians are authorized to accept, place, and remove samples from the sample storage area, record chain-of-custody information, prepare product dilutions, and return samples to the storage area.

- 10.4 Each shipping container is inspected by a sample custodian for external structural damage, tampering, and evidence of leaks or spills. Any sign of damage, tampering, or leaks or spills is documented on the Shipping and Receiving Record for Disinfectant Products (see 16.1) and any chain-of-custody forms provided by the inspector. A photograph is taken of the shipping container.
- 10.5 The shipping container is opened and the contents are inspected. The plastic bag and the chain-of-custody seals are closely inspected for damage or signs of tampering. Individual samples are inspected for leakage or damage by a sample custodian. The sample custodian will review the chain-of-custody documentation sent by the inspector, and if necessary apply signature and date of receipt. The sample custodian will review all paperwork sent by the inspector to identify any pertinent information such as lot number, sample expiration date, storage conditions, etc. Then, the sample custodian will initiate a History of Official Sample Form (EPA Form 3540-17) (see 16.2). A photograph is taken of the product sample.
- 10.6 For product samples which arrive from sources other than official inspector collection (for example, products purchased from the internet, direct shipment from the registrant, etc.), initiate chain of custody documentation beginning with the Shipping and Receiving Record for Disinfectant Products (section 10.2) through the History of Official Sample Form (section 10.7). Fill out the appropriate sections of the form. Take a photograph of the shipping container prior to opening. Take a photograph of the product sample after inspection. Place the sample container in a plastic bag, and seal. Fill out the official seal.
- 10.7 Correct and complete entry of information on the History of Official Sample Form is an essential component to the chain-of-custody documentation. One form is used per unique product sample number. The sample custodian who received the shipment may request another sample custodian to complete the History of Official Sample Form, as long as the sample custodian completing the Form performs the actual inspection of the shipping container and sample. For clarification purposes, follow the guidance for data entry for the specified fields listed below; fields #1-#4 are self-explanatory:

10.7.1 #5. DATE RECEIVED: Enter the date the shipment was received by the

laboratory. This date will be the same as the date entered on the Shipping and Receiving Record for Disinfectant Products.

- 10.7.2 #6. RECEIVED BY: The signature of the sample custodian responsible for receiving the shipment from the loading dock personnel is required; date of signature is also required. The sample custodian signing as the sample receiver may not necessarily be the individual who completes the History of Official Sample Form.
- 10.7.3 #7. RECEIVED FROM: Record the name of the ESC loading dock personnel and the person who actually shipped the package to the ESC (inspector, administrative assistant).
- 10.7.4 #8. SENT VIA: Enter the name of the shipping company and type of delivery.
- 10.7.5 #9. SAMPLE CONDITION: Record as Good or Poor; if Poor, describe the condition in detail in #15 REMARKS.
- 10.7.6 #10. CONDITION OF SEALS: Record as Good or Poor; if Poor, describe the condition in detail in #15 REMARKS.
- 10.7.7 #11. SEALED BY: Enter the name which appears on the seals (the name should also appear on inspector's chain-of-custody paperwork).
- 10.7.8 #12. DATE SEALED: Enter the date taken from the seals. The seal date must be the date of collection specified on the inspector's chain-of-custody paperwork. If a sample was sealed on a date other than the date of collection, contact OECA for guidance on whether or not the sample has been compromised.
- 10.7.9 #13. PIECES RECEIVED: Enter the number of seals and the number and type of product containers per seal.
- 10.7.10 #14. PLACE STORED: Enter the official sample storage room (B204 or D204).
- 10.7.11 #15. REMARKS: Record notable items such as damaged samples, labeling clarification, name of the sample custodian completing the History of Official Sample Form (if different from the individual in #6), and lot number. (Note: Record lot number on the History of Official Sample Form only if the inspector has recorded a lot number on his

paperwork. Do not assume that codes imprinted on containers are lot numbers. If the inspector failed to record a lot number on his paperwork, the sample lot number will be considered to be unknown.).

- 10.8 Sample collection and chain-of-custody information will be maintained in the Disinfectant Product Field Chain-of-Custody Documentation from Inspector notebook. Deficiencies in paperwork accompanying the shipment (i.e. lack of field chain-of-custody papers) are documented.
 - 10.9 Complete the Comprehensive Sample Log form (see 16.5). This log will be stored in a notebook in room D217.
 - 10.10 Prior to testing, a sample custodian initiates a Laboratory Chain-of-Custody Form (see 16.3) and a Chain-of Custody Seal Log (see 16.4) for each product sample received.
 - 10.11 The Laboratory Chain-of-Custody Form is filled out whenever a product sample is removed from storage.
 - 10.12 Prior to completion of the draft performance report, the product label will be photocopied or photographed directly from a product container; a copy will be filed in the Disinfectant Product Field Chain-of-Custody Documentation from Inspector notebook. In addition, sample numbers found on the product containers will be photocopied; copies will be filed in the Disinfectant Product Field Chain-of-Custody Documentation from Inspector notebook.
 - 10.13 Broken chain-of-custody seals are retained on a Chain-of-Custody Seal Log (see 16.4). A new chain-of-custody seal will be established on the sample as per the directions in the Pesticides Inspection Manual (see ref. 15.1).
- 11.0 DATA ANALYSIS/CALCULATIONS: None
- 12.0 DATA MANAGEMENT/RECORDS MANAGEMENT:
- 12.1 Data will be recorded promptly, legibly, and in indelible ink on the Shipping and Receiving Record for Disinfectant Products, History of Official Sample Form (EPA Form 3540-17), Comprehensive Sample Log, Laboratory Chain-of-Custody Form and Chain-of Custody Seal Log forms. Completed forms are archived in notebooks kept in secured file cabinets in room D217. Only authorized personnel have access to the secured files. Archived data is subject to OPP's official retention schedule contained in SOP ADM-03, Records and Archives.

13.0 QUALITY CONTROL:

13.1 Timely, accurate, and legible sample information recorded in ink is required on all chain-of-custody documentation.

13.2 For quality control purposes, the required information is documented on the appropriate forms (see 16.0).

14.0 NONCONFORMANCE AND CORRECTIVE ACTION:

14.1 Any deviation from the protocol will be documented.

14.2 Entry errors or entry omissions will be corrected immediately upon discovery.

15.0 REFERENCES:

15.1 Pesticides Inspection Manual (Chapter 9) 2002. See <http://www.epa.gov/compliance/resources/publications/monitoring/fifra/manuals/fifra/index.html>.

16.0 FORMS AND DATA SHEETS:

16.1 Shipping and Receiving Record for Disinfectant Product Sample Form

16.2 History of Official Sample Form (EPA Form 3540-17; 2001 version)

16.3 Laboratory Chain-of-Custody Form

16.4 Chain-of-Custody Seal Log


16.5 Comprehensive Sample Log

16.1 Shipping and Receiving Record for Disinfectant Product Samples Form
OPP Microbiology Laboratory

Shipping and Receiving Record for Disinfectant Product Samples	
<p><u>Loading Dock Personnel</u> (Date/Initials): _____</p> <p>Shipping Container # ____ of ____ Date and Time Received: _____ Received By: _____ Received From: _____ Type of Delivery: _____ Tracking Number (if available): _____</p> <p>_____</p> <p><u>Sample Custodian</u> (Date/Initials): _____</p> <p>Condition of Primary Shipping Container: _____ Product Name(s): _____ _____</p> <p>EPA Reg. No.(s): _____ _____</p> <p>Sample Numbers: _____ _____ _____ _____</p>	<p><u>Loading Dock Personnel</u> (Date/Initials): _____</p> <p>Shipping Container # ____ of ____ Date and Time Received: _____ Received By: _____ Received From: _____ Type of Delivery: _____ Tracking Number (if available): _____</p> <p>_____</p> <p><u>Sample Custodian</u> (Date/Initials): _____</p> <p>Condition of Primary Shipping Container: _____ Product Name(s): _____ _____</p> <p>EPA Reg. No.(s): _____ _____</p> <p>Sample Numbers: _____ _____ _____ _____</p>

16.2 History of Official Sample Form (EPA Form 3540-17)

PAGE 1 OF _____

 UNITED STATES ENVIRONMENTAL PROTECTION AGENCY HISTORY OF OFFICIAL SAMPLE - LABORATORY	1. SAMPLE NO.	2. REGISTRATION NO.
	3. PRODUCT	
4. LABORATORY		
5. DATE RECEIVED		
6. RECEIVED BY		
7. RECEIVED FROM		
8. SENT VIA		
9. SAMPLE CONDITION		
10. CONDITION OF SEALS		
11. SEALED BY		
12. DATE SEALED		
13. PIECES RECEIVED		
14. PLACE STORED		
15. REMARKS		

16.4 Chain-of-Custody Seal Log
OPP Microbiology Laboratory

Chain-of-Custody Seal Log	
<u>Product Information:</u> Product EPA Reg. #: _____ Product Name: _____ Sample #: _____ Date Product Received: ____/____/____	
Date/Initials	Apply Seals Below (1 seal per row)

