FINAL STUDY REPORT

Study Title
AOAC Use-Dilution Test

Product Identity
D7 Part 1, D7 Part 2, D7 Part 3
D7 Part 1 Lot Numbers: 18-625, 18-626
D7 Part 2 Lot Numbers: 18-643, 18-644
D7 Part 3 Lot Number: 02-11-19-01

Test Microorganism
Salmonella enterica subsp. enterica serovar Reading ATCC 6967

Data Requirements
U.S. EPA OCSPP 810.2200

Author
Meredith Fenner, B.S.
Study Director

Study Completion Date
TBD

Testing Facility
Microchem Laboratory
1304 W. Industrial Blvd.
Round Rock, TX 78681

Study Sponsor
Decon7 Systems, LLC
8541 East Anderson Drive, Suite 106
Scottsdale, AZ 85255

STATEMENT OF NO DATA CONFIDENTIALITY CLAIMS

No claim of confidentiality, on any basis whatsoever, is made for any information contained in this document. I acknowledge that information not designated as within the scope of FIFRA section 10(d)(1)(A), (B), or (C) and which pertains to a registered or previously registered pesticide is not entitled to confidential treatment and may be released to the public, subject to the provisions regarding disclosure to multinational entities under FIFRA 10(g).

Company: _____

Agent/Submitter: _____

Title: _____

Date: _____

Signature: _____

GOOD LABORATORY PRACTICE COMPLIANCE STATEMENT

This study meets U.S. Environmental Protection Agency's Good Laboratory Practice Standards and requirements for 40 CFR § 160.

Records concerning test substance characteristics (i.e. composition, purity, stability, strength, solubility) are maintained by the Study Sponsor. The Study Sponsor conducted test substance characterization as to identity, strength, purity, solubility and composition, as applicable, according to 40 CFR Part 160, Subpart F [160.105] prior to its use in the study. The test substance certificate of analysis may be found attached to this report for reference.

Study Director

Company: Microchem Laboratory

Name: Meredith Fenner, B.S.

Title: Study Director

Signature: _____ Date: _____

Study Sponsor

Company: Decon7 Systems, LLC

Name: Jordan Ahern

Title: Study Sponsor

Signature: _____ Date: _____

Submitter

Company:

Name:

Title:

Signature: _____ Date: _____

QUALITY ASSURANCE STATEMENT

The following quality assurance audits were conducted in accordance with Good Laboratory Practice Standards outlined in 40 CFR §160 and reported to management and the Study Director:

Phase Inspected	Date Inspected	Date Reported to Study Director	Date Reported to Management
In Phase			
Draft Report			
Final Report			

Signature: _____Date: _____

Name: Hillary Johnson, M.S.

PERSONNEL INVOLVED IN THE STUDY

Study Director

Name: Meredith Fenner, B.S.
Title: Analyst I

Professional or Supervisory Personnel

Name: Nicole Goulding, B.S.
Title: Test Facility Management

TABLE OF CONTENTS

FINAL STUDY REPORT SUMMARY

Study Title: AOAC Use-Dilution Test

Study Identification Number: GLP2158

Test Microorganism: *Salmonella enterica subsp. enterica serovar Reading* ATCC 6967

Test Substance: Lots: D7 Lot 1 (D7 Part 1 Lot: 18-625, D7 Part 2 Lot: 18-643, D7 Part 3 Lot: 02-11-19-01)
D7 Lot 2 (D7 Part 1 Lot: 18-626, D7 Part 2 Lot: 18-644, D7 Part 3 Lot: 02-11-19-01)

Test Substance Dilution: Ready to use liquid test substances, see page 10 for preparation

Organic Soil Load: 5% v/v fetal bovine serum (FBS)

Carrier Type: Stainless steel penicylinders

Number of Carriers Per Lot: 10

Contact Time: 9 minutes 50 seconds ± 5 seconds

Exposure Temperature: 20°C ± 1°C

Neutralizer: Letheen Broth (10.0 ml) additionally supplemented to contain 0.1% Catalase

Study Results:

Test Date	Microorganism	Number Confirmed Positive Carriers/Total Number Tested		Carrier Control Avg Log_{10} CFU/Carrier
		Lot: D7 Lot 1	Lot: D7 Lot 2	
03JUL2019	*Salmonella enterica subsp. enterica serovar Reading* ATCC 6967	0/10	0/10	6.15

STUDY DATES

Study Initiation Date:	03JUL2019
Experimental Start Date/Time:	03JUL2019 / 1525
Experimental Termination Date/Time:	05JUL2019 / 1525
Study Completion Date:	TBD

TEST SUBSTANCE

Name: D7 Part 1, D7 Part 2, D7 Part 3

Lot: D7 Part 1 Lot: 18-625

Active Ingredient (concentration):	Alkyl Dimethylbenzyl Ammonium Chloride (3.03 % wt.)
Date of Manufacture:	28NOV2018
Date Received:	05JUN019
Expiration Date:	28NOV2019

Lot: D7 Part 1 Lot: 18-626

Active Ingredients (concentration):	Alkyl Dimethylbenzyl Ammonium Chloride (3.03 % wt.)
Date of Manufacture:	28NOV2018
Date Received:	05JUN019
Expiration Date:	28NOV2019

Lot: D7 Part 2 Lot: 18-643

Active Ingredients (concentration):	Hydrogen Peroxide (7.506% wt.)
Date of Manufacture:	28NOV2018
Date Received:	05JUN2019
Expiration Date:	29NOV2019

Lot: D7 Part 2 Lot: 18-644

Active Ingredients (concentration):	Hydrogen Peroxide (7.525% wt.)
Date of Manufacture:	28NOV2018
Date Received:	05JUN2019
Expiration Date:	29NOV2019

Lot: D7 Part 3 Lot: 02-11-19-01

Active Ingredients (concentration):	Diacetin (<99%, inactive ingredient activator only, for dilution)
Date of Manufacture:	28NOV2018
Date Received:	05JUN2019
Expiration Date:	28NOV2019

Form: Dilution Required Test Substance

Storage Conditions: Ambient room temperature under fluorescent lighting.

Test Substance Preparation

On the day of use, each lot of the test substance (D7 Lot 1 and D7 Lot 2) was prepared by adding an equivalent dilution of 49 parts of D7 Part 1 to 49 parts of D7 Part 2 to 2 parts of D7 Part 3. D7 Lot 1 was prepared by adding 147 ml of D7 Part 1 Lot 18-625 to 147 ml of D7 Part 2 Lot 18-643 to 6 ml of D7 Part 3 Lot 02-11-19-01. D7 Lot 2 was prepared by adding 147 ml of D7 Part 1 Lot 18-626 to 147 ml of D7 Part 2 Lot 18-644 to 6 ml of D7 Part 3 Lot 02-11-19-01. The prepared test substance appeared to be in solution as determined by visual observation on the day of use. 10 ml aliquots of the test substance were transferred into sterile 25×100 mm test tubes. The test substance was allowed to equilibrate to the exposure temperature for ≥10 minutes.

PROTOCOL CHANGES

Protocol Amendment(s)

An amendment to the approved protocol was made on 12JUL2019 to correct the expiration date of test substance D7 Part 2, Lots: 18-643 and 18-644 from 28NOV2019 to 29NOV2019. The accompanying certificate of analysis indicating this expiration date, which was inadvertently incorrect on the protocol, is included in this report on page 22.

Protocol Deviation(s)

On 05JUL2019, a deviation to the approved protocol was noted, wherein the Carrier Enumeration Results were not within the range of the Study Success Criteria of less than 1.0×10^5 CFU/Carrier corresponding to a mean log density of 5.0. The demonstrated concentration of test microorganism was observed to be an average of 1.47×10^6 CFU/Carrier corresponding to a mean log density of 6.15. This deviation was not thought to have impacted the outcome of the study, as the results of the test for each lot tested against the carriers demonstrated passing results. As referenced in the Product Performance Criteria, retesting is not necessary, with a passing test of carriers above a log density of 5.0, therefore no repeat testing was performed.

TEST PROCEDURE

Test System and Media

Test System:	*Salmonella enterica subsp. enterica serovar Reading* ATCC 6967 received from the American Type Culture Collection (ATCC).
Subculture/ Neutralization Broth:	Letheen Broth (10.0 ml) additionally supplemented to contain 0.1% Catalase
Agar Medium:	Nutrient Agar

Preparation of the Test Culture

A daily culture of the test microorganism was created from the microbial library working stock. A sterile loop or pipette tip was used to inoculate a sterile 15 ml conical containing 10 ml of Nutrient Broth (NTB). This culture was gently vortex mixed and incubated for 24 hours ± 2 hours at 36°C ± 1°C.

A test culture was initiated by transferring 0.010 ml of the most recent daily transfer culture into an appropriate number of 15 ml conical tubes, each containing 10 ml of sterile NTB and incubated for 48-54 hours at 36°C±1°C.

The test cultures were vortex mixed for 3-4 seconds and allowed to dwell at room temperature for ≥ 10 minutes. The upper portion of the mixed culture(s) was removed, leaving behind any debris or clumps, and pooled in an appropriate vessel(s). For the purposes of achieving carrier counts within the range of the study, the test culture was diluted 1:5 in NTB.

Supplementation of Test Culture with Organic "Soil" Load

A 1.75 ml aliquot of FBS was added to 33.25 ml of test culture to yield a total volume of 35.0 ml of 5% fetal bovine serum organic soil load.

Preparation of Test Carriers

Stainless steel penicylinders that had been biologically screened following the Official Method of Analysis and passed with no growth were utilized as the test carriers. The carriers were soaked overnight in 1 N NaOH, and then rinsed in tap water until the alkalinity was neutral. The carriers were visually screened for defects and only those carriers without visible defects were placed into vessels with deionized water autoclave sterilized on a slow/liquid cycle for at least 20 minutes at approximately 121°C.

Carrier Inoculation with Test Culture

The deionized water was aspirated from the vessel containing the prepared carriers using a sterile serological pipette. The test culture was added to the drained vessel containing the penicylinders, such that all carriers are completely submerged in the test culture for uniform coverage of ~1 ml of test culture per carrier.

The test culture and penicylinders were allowed to dwell for 16 minutes at room temperature (24.4°C and 41% relative humidity). After the soak time had elapsed, the culture was aspirated and the penicylinders were removed from the container aseptically using a sterile wire hook, tapping the carrier against the side of the container to remove excess culture. The carriers were placed, no more than 12 carriers to a dish, in sterile Petri dishes lined with two pieces of sterile filter paper without the carriers touching. The loaded Petri dishes were covered, transferred to an incubator and dried at 36.0°C and 60% humidity for 30 minutes. The inoculated carriers were used within 2 hours of drying.

Treatment of Carriers with Test Substance

The inoculated carriers were sequentially transferred using a heat-sterilized wire hook into individual 25×100 mm test tubes containing 10 ml of test substance, at appropriate intervals to ensure careful and aseptic handling. Care was taken to avoid touching the inside of the tube with the carrier. As the first carrier was submerged into the test substance, a calibrated timer was started to measure the contact time. The carriers were placed into the test substance within ± 5 seconds of the contact time.

The tubes containing the test substance and carrier were gently swirled, 2-3 gentle rotations, then placed back at the test temperature (20°C ± 1°C) for the duration of the contact time (≤10 minutes).

After the contact time for each carrier had elapsed, each carrier was removed from the test substance using a heat-sterilized wire hook. The carriers were tapped in the lower third of the tube to remove excess test substance and transferred to a 20×150 mm tube containing 10.0 ml of the appropriate subculture/neutralization broth, such that the carrier was completely submerged. Care was taken to avoid touching the sides of the tube while transferring the carriers out of the tubes.

The procedure was repeated until all carriers had been exposed to the test substance for the specified contact time and harvested into the subculture/neutralization broth.

STUDY CONTROLS

Neutralization Confirmation

Three sterile, uninoculated carriers were transferred to individual 25×100 mm test tubes containing 10 ml of the test substance and a calibrated timer was started to measure the contact time. As the contact time elapsed, the carriers were sequentially transferred to 20×150 mm test tubes containing 10 ml of subculture/neutralization broth for neutralization, which represented the neutralization confirmation test tubes. A series of 10-fold dilutions of the test culture were performed in 9.0 ml of phosphate buffered dilution water (PBDW) such that a 0.100 ml volume of the dilution targeted 10-100 CFU. This inoculum was plated in duplicate to verify the number of CFU present. The neutralization confirmation test and control tubes were inoculated with 0.100 ml volumes of the prepared inoculum. The neutralization confirmation control was performed using multiple carrier replicates and inoculated with different dilutions of the prepared inoculum.

Enumeration of Inoculated Test Carriers

Prior to initiating the test and following the conclusion of the test, three inoculated carriers, each from a different Petri dish, were individually transferred into tubes containing 10.0 ml of subculture/neutralization broth. The six carrier density subculture/neutralization broth tubes were placed in a beaker filled with water to the level of liquid in the tubes. The beaker was held by hand in a sonicator such that the beaker bottom did not touch the bottom of the sonicator and all liquid levels were approximately equal. The beaker containing the tubes was sonicated for 1 minute ± 5 seconds, as timed by a certified digital timer. After sonication, the subculture/neutralization broth tubes from each set of three test tubes (pre test and post test) were pooled prior to enumeration. The pooled cultures were enumerated by performing a series of 10-fold dilutions in 9.0 ml of PBDW and plated in duplicate, using standard spread plating techniques. This step was performed within 2 hours of sonicating the subculture/neutralization tubes.

Carrier Sterility Control

An uninoculated carrier was harvested into a 25×150 mm tube containing 10.0 ml of subculture/neutralization broth and incubated alongside the test materials.

Viability Control

An inoculated, untreated test carrier was harvested into a 25×150 mm tube containing 10.0 ml of subculture/neutralization broth and incubated alongside the test materials.

Subculture/Neutralization Sterility Control

A 25×150 mm tube containing 10.0 ml of subculture/neutralization broth was incubated alongside test materials.

Media Sterility Controls

A volume of 0.1 ml of PBDW was added to sterile growth agar and incubated alongside test materials to confirm sterility of the serial dilution media at the time of test.

A volume of 0.1 ml of NTB was added to sterile growth agar and incubated alongside test materials to confirm sterility of culture diluent at the time of test.

A volume of 0.1 ml of FBS was added to sterile agar and incubated alongside test materials to confirm organic soil sterility at the time of test.

A plate containing only sterile growth agar used in this study was incubated alongside test materials to confirm sterility of media at the time of test.

Test Microorganism Purity Control

The test culture used in this study was subcultured onto growth agar medium and incubated alongside the test materials to morphologically confirm the presence of target microorganism and absence of contaminant microorganism.

Incubation of Tubes and Control Plates

Test tube racks were shaken thoroughly prior to transfer to the incubator. All tubes and plates were incubated at 36°C ± 1°C for 48 hours ± 2 hours.

CALCULATIONS AND STATISTICAL ANALYSIS

The following were calculations used in the study. Calculation variables may have been adjusted based on volumes and dilutions used.

$$\frac{(\text{Average CFU for } 10^{-x}) + (\text{Average CFU for } 10^{-y}) + (\text{Average CFU for } 10^{-z})}{10^{-x} + 10^{-y} + 10^{-z}} = \text{CFU/ml of Control Carriers}$$

where 10^{-X}, 10^{-Y}, and 10^{-Z} are examples of dilutions that may be used

CFU/Carrier of Control Carriers = [(CFU/ml) × 10 ml]

$$\text{Control Carrier Mean} = \frac{(\text{Log}_{10}\text{ CFU/Carrier Pooled Pre Carriers} + \text{Log}_{10}\text{ CFU/Carrier Pooled Post Carriers})}{\text{Log}_{10}\text{ Density}} \quad \text{2}$$

Average Neutralization Confirmation Inoculum = (CFU on plate 1 + CFU on plate 2) / 2

Statistical Analysis

No statistical analysis was performed.

SUCCESS CRITERIA

The experimental success (controls) criteria follow:

- The test microorganism must demonstrate a concentration of at least 1.0×10^4 CFU/Carrier corresponding to a mean log density of 4.0 and not above 1.0×10^5 CFU/Carrier corresponding to a mean log density of 5.0.
- The subculture/neutralization broth sterility control tube demonstrates no growth.
- The carrier sterility control subculture/neutralization broth tube demonstrates no growth.
- The viability control subculture/neutralization broth tube demonstrates growth.
- At least one neutralization confirmation inoculum dilution demonstrates an average concentration of ≤100 CFU.
- The neutralization confirmation subculture/neutralization broth tube corresponding to the inoculum average concentration of ≤100 CFU demonstrates growth.
- The media sterility controls demonstrate no growth.
- The test microorganism purity control plate demonstrates the presence of the target microorganism and absence of contaminant microorganisms.

The Environmental Protection Agency performance criteria for disinfection follow:

- 10 of the 10 carriers tested must be negative for growth per lot at the proposed contact time.

Retesting guidance for disinfection follows:

- When a test passes and the $\log_{10}$ density of the test carriers is above 5.0, no retesting is necessary.
- When a test passes and the $\log_{10}$ density of the test carriers is below 4.0, retesting is necessary.
- When a test fails and the $\log_{10}$ density of the test carriers is below 5.0, no retesting is necessary.
- When a test fails and the $\log_{10}$ density of the test carriers is above 4.0, retesting may be conducted.

STUDY RECORD AND TEST SUBSTANCE RETENTION

Study Record Retention

The original (or certified copy) of the study report, protocol, and corresponding raw data will be held in the archives of Microchem Laboratory for a minimum of five years following the study completion date. Afterward, Microchem reserves the right to transfer the documents to the Study Sponsor (or Sponsor Representative, if applicable) at the Sponsor's expense. For studies not meeting the performance criteria for submission or for studies that have been canceled prior to the generation of valid data, the original (or certified copy) of the final study report, protocol, and corresponding raw data will be held in the archives of Microchem Laboratory for a minimum of two years following the study completion date at which time they may be removed from the archive or transferred to the Sponsor's archive at their expense.

If requested by the Study Sponsor (or Sponsor Representative), the study file may be transferred to the Study Sponsor's archive at the Study Sponsor's expense prior to the time frames listed.

All test facility records including, but not limited to, standard operating procedures, quality assurance inspection records, temperature and equipment records including maintenance, inspection and calibration, and employee training records will be maintained at Microchem Laboratory indefinitely.

Test Substance Retention

The test substance (or test control, test article, test device, as applicable) may be returned to the Study Sponsor at the Study Sponsor's request and expense following study completion unless otherwise requested to be returned earlier. If the Study Sponsor does not request return of the sample, it will be disposed >90 days following the study completion. Arrangements may be made for extended storage as necessary, at the Sponsor's request and expense.

RESULTS

Table 1: Carrier Enumeration Control Results

Test Microorganism	Test Date	Carrier	CFU/Carrier	Log_{10} Density	Mean Log_{10} Density
Salmonella enterica subsp. enterica serovar Reading ATCC 6967	03JUL2019	Pre Treatment	1.83×10^6	6.26	6.15
		Post Treatment	1.10×10^6	6.04	

Table 2: Test Results

Test Microorganism	Test Substance	Test Date	Number of Carriers Tested	Number of Test Tubes Showing Growth	Number of Test Tubes Confirmed as Test Organism
Salmonella enterica subsp. enterica serovar Reading ATCC 6967	D7 Lot 1	03JUL2019	10	0	N/A
	D7 Lot 2		10	0	N/A

Table 4: Neutralization Confirmation Results

Test Microorganism	Test Substance	Test Date	Target Inoculum	Plate Counts (CFU)	Average Inoculum Concentration (CFU)	Neutralization Test and Control Results Positive for Growth
Salmonella enterica subsp. enterica serovar Reading ATCC 6967	D7 Lot 1	03JUL2019	10-100 CFU	TNTC / TNTC	TNTC	Yes
	D7 Lot 2			57 / 54	55.5	Yes
				8 / 7	7.5	Yes

Counts of over 100 CFU recorded as too numerous to count (TNTC).

Neutralization confirmation requirement met for both lots as demonstrated by positive result in at least one neutralization control tube when inoculated with an average CFU of ≤100.

CFU = colony forming unit

RESULTS (cont.)

Table 6: Control Results

Control Parameter	Test Date 03JUL2019
Viability Control	Growth Observed
Subculture/Neutralization Sterility Control	No Growth Observed
PBDW Sterility Control	No Growth Observed
Growth Agar Sterility Control	No Growth Observed
Carrier Sterility Control	No Growth Observed
Organic Soil Load Sterility Control	No Growth Observed
Test Microorganism Purity Control	Pure Target Microorganism
Culture Diluent Sterility Control	No Growth Observed

Table 7: Organism Propagation Conditions

Test Culture	Transfer Date and Time	Incubation Temperature Range	Culture Incubation Time
Initial Daily Culture	30JUN2019 / 1204	36°C ± 1°C	23 hours 11 minutes
Final Test Culture (Transfer #2)	01JUL2019 / 1153		49 hours 35 minutes

STUDY CONCLUSION

Test substance D7 (D7 Part 1 Lot: 18-625, D7 Part 2 Lot: 18-643 and D7 Part 1 Lot: 18-626, D7 Part 2 Lot: 18-644) was tested against *Salmonella enterica subsp. enterica serovar Reading* ATCC 6967 in the presence of 5% (v/v) FBS organic soil load. A total of 10 contaminated carriers were exposed to each lot of the test substance for a contact time of 9 minutes 50 seconds ± 5 seconds at a test temperature of 20°C ± 1°C and then chemically neutralized.

Following a 9 minute 50 second ± 5 second contact time, D7 (D7 Part 1 Lot: 18-625, D7 Part 2 Lot: 18-643) disinfected 10 out of 10 carriers and D7 (D7 Part 1 Lot: 18-626, D7 Part 2 Lot: 18-644) disinfected 10 out of 10 carriers.

Under the conditions of this assay, D7 (D7 Part 1 Lot: 18-625, D7 Part 2 Lot: 18-643 and D7 Part 1 Lot: 18-626, D7 Part 2 Lot: 18-644) met the requirements stated in the U.S. EPA Product Performance Test Guidelines - Disinfectants for Use on Environmental Surfaces as outlined in OCSPP 810.2200 and the success criteria detailed in the approved protocol.

The study was carried out in compliance with the approved protocol and all experimental controls met the established acceptance criteria, except where otherwise noted on page 10 of this report.

There were no circumstances that may have affected the quality or the integrity of the data.

REFERENCES

- "Association of Official Analytical Chemists, International." *AOAC Official Method 964.02*. Testing Disinfectants Against *Pseudomonas aeruginosa*. Revised 2013.
- "Clinical and Laboratory Standard Institue." Informational supplement M100 ED29:2019. Performance Standards for Antimicrobial Susceptibility Testing, 28th Edition.
- U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention, Product Performance Test Guidelines OCSPP 810.2000: General Considerations for Testing Public Health Pesticides – Guidance for Efficacy Testing (February 2018).
- U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention, Product Performance Test Guidelines OCSPP 810.2200: Disinfectants for Use on Environmental Surfaces Guidance for Efficacy Testing. February 2018.
- Guidance Document – Disinfectant Drugs. Health Canada. January 2014.
- Guidance Document – Safety and Efficacy Requirement for Hard Surface Disinfectant Drugs. Health Canada. January 2014.
- Additional references included in the specific protocol

PROTOCOL AMENDMENT

Protocol Amendment – GLP2158 – P2404
Page 1 of 1

Amendment 1:

The signed protocol P2404 was amended on 12JUL2019, with regards to the Test Substance Expiration Date for each lot of D7 Part 2, found on page 10 of the protocol. Upon initiation of the study, the expiration date was inadvertently incorrectly recorded.

The following found on page 10 for Test Substance Batch Numbers: D7 Part 2 (18-643, 18-644):

- Expiration Date(s) 28NOV2019

Were amended to:

- Expiration Date(s) 29NOV2019

A certificate of analysis for all active ingredients of the test substances will be included in the final study report for reference.

12JUL2019

Date Signed (dd/mmm/yyyy)

Role: Study Director
Name: Meredith Fenner
Company: Microchem Laboratory
Address: 1304 W. Industrial Blvd.
Round Rock, TX 78681

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PROTOCOL

MICROCHEM LABORATORY

Protocol Number: P2404 GLP Study ID: GLP2158 03JUL2019 MF

AOAC Use-Dilution Test

Test Microorganism
Salmonella enterica subsp. enterica serovar Reading ATCC 6967

Data Requirement
U.S. EPA OCSPP 810.2200

Study Sponsor
Jordan Ahern
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Testing Facility
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Round Rock, Texas 78681

Author
Meredith Fenner, B.S.

Date
01JUL2019

PROTOCOL (cont.)

AOAC Use Dilution Test

Protocol Number: P2404

I. Introduction

This document details the materials and procedure for evaluating the efficacy of a liquid disinfectant using the AOAC Use-Dilution Method in accordance with Good Laboratory Practice Standards (GLPS) stipulated by 40 CFR 160. This document also explains the terms and conditions of testing.

II. Purpose

The purpose of this study is to document the efficacy of the test substance against the test system (microorganism) under the parameters specified in this protocol.

III. Justification for the Selection of Test System (Microorganism)

The United States Environmental Protection Agency (USEPA) requires specific antimicrobial claims made for disinfectants sold in the United States to be supported by relevant test systems (microorganisms) as outlined in the United States Environmental Protection Agency Product Performance Test Guidelines, OCSPP 810.2200: Disinfectants for Use on Environmental Surfaces – Guidance for Efficacy Testing.

IV. Terms and Conditions

Studies by Microchem Laboratory are conducted in accordance with general terms and conditions posted on www.MicrochemLab.com/terms

Prior to study initiation, Microchem Laboratory should receive the approved and signed protocol, test substance and payment. Changes to the signed, approved protocol will require amendment and may incur additional fees. Cancellation of the study any time after study initiation may result in a cancellation fee of up to 100% of the total study cost, to be determined by laboratory management at its sole discretion.

Microchem Laboratory may repeat studies at its cost in the event of an unintended protocol non-conformance that affects the study outcome, or for studies which yield invalid control results. If the Sponsor requests a specific neutralizer to be utilized in testing and test controls indicate incomplete or inadequate neutralization, repeat testing will be at the Study Sponsor's expense for applicable testing. Repeat testing may be conducted under the current initiated protocol and Microchem Laboratory GLP study identification number. In addition, the Study Sponsor is responsible for the cost of all studies performed to confirm the outcome of a previous study and for ensuring that the study will meet their regulatory objectives.

The Study Sponsor must obtain written consent from Microchem Laboratory to use or publish its protocols, study reports (or parts thereof), logo or employee names for marketing purposes.

V. Test Substance Characterization and Handling

As stated in 40 CFR Part 160 Subpart F [160.105], each batch (lot) of test substance shall be characterized as to identity, strength, purity, composition, and solubility (as applicable), and shall be documented prior to use in this assay. Stability of the test formula shall be determined prior to or concomitantly with this study. If the requirements set forth in 40 CFR Part 160 Subpart F [160.105] have not been met, this will be noted in the Good Laboratory Practice compliance statement in the study report. Certificates of Analysis (C of A) will be appended to the study report, if provided by the Study Sponsor.

Test substances are handled as follows:

- The test substance is stored at ambient (room) temperature under fluorescent lighting or in a cabinet.
- The test substance is shaken or otherwise mixed well immediately prior to use (if applicable).
- The test substance is handled safely in accordance with the chemical risks it may pose, stated in the SDS or by the Study Sponsor during the course of pre-study communication.

PROTOCOL (cont.)

VI. Study Dates

The listed proposed experimental start and completion dates are estimates based on the current laboratory schedule and may change based on when the test substance, sponsor signed protocol, and payment (if applicable) are received at the testing laboratory. To avoid scheduling delays, assure that all paperwork is completed fully and accurately.

Proposed Experimental Start Date: **03JUL2019**
Proposed Experimental Termination Date: **10JUL2019**

VII. Procedure for the Identification of the Test System

Microchem Laboratory maintains Standard Operating Procedures which outline the procedures for receipt, storage, and tracking of microorganisms. The vessels, racks, and trays containing the test system are labeled with microorganism identifiers to maintain microorganism traceability. Information regarding the microorganism identity, strain, propagation procedure, media utilized, etc. is documented in the study raw data. Following testing, the microorganism identity of positive test replicates is confirmed following the appropriate macroscopic, microscopic, and biochemical assays. All studies are assigned a unique identification number which is labeled on the test and control vessels, racks, trays, etc. Additionally, Standard Operating Procedures are also in place for the receipt, storage, and usage tracking of all test and control substances utilized in testing. These procedures are followed to identify and document the test system.

VIII. Test System (Microorganism)

Microorganism	Growth Media	Incubation Conditions
Salmonella enterica subsp. enterica serovar Reading ATCC 6967	Nutrient broth	Aerobic at 36 ± 1°C

The microorganism to be utilized in testing was received from the American Type Culture Collection (ATCC).

IX. Procedure

Preparation of the Test Substance

- The test substance will be used per Sponsor request.
- If a dilution of the test substance is requested by the Sponsor, the diluted test substance will be used within three hours of preparation.
- Unless otherwise requested by the Sponsor, if a dilution of the test substance is required, a ≥1.0 ml or ≥1.0 g of the test substance will be used to prepare the test substance using volumetric glassware. For liquid products, a v/v dilution will be made and for solids, a w/v dilution will be made.
- If synthetic hard water is requested as the diluent, it will be prepared following Microchem Laboratory Standard Operating Procedures for the specific water type. The hardness range will be -10% to +5% of the specified hardness.
- If unsoftened tap water is requested as the diluent, the water will be autoclave sterilized. The water hardness will be determined on the day of testing and adjusted to the hardness range if necessary. The hardness range will be -10% to +5% of the specified hardness.
- A 10 ml aliquot of the test substance is transferred by sterile disposable serological pipette, or other means as appropriate, into sterile 25 × 100 mm test tubes.
- The tubes containing the test substance are equilibrated to the test temperature for ≥10 minutes prior to initiating testing or recording test substance temperature.

PROTOCOL (cont.)

AOAC Use Dilution Test

Protocol Number: P2404

Preparation of Test Carriers

- Stainless steel penicylinders that have been biologically screened following the AOAC Official Method of Analysis are utilized as the test carrier.
- The carriers are soaked overnight in 1 N NaOH, and then rinsed in tap water until the alkalinity is neutral.
- The carriers are visually screened for defects and only those carriers without visible defects are placed into containers containing deionized water and autoclave sterilized.

Preparation of Test Culture

- A daily culture of the test microorganism is created from the microbial library working stock. A sterile loop or pipette tip is used to inoculate a sterile 15 ml conical containing 10 ml of the growth medium listed in section VIII of this protocol. This culture is gently vortex mixed and incubated for 24 hours ± 2 hours in the conditions listed in section VIII of this protocol.
- Subsequent daily transfers (≤5) are made by transferring 0.010 ml of the most recent daily transfer culture into 15 ml conical tubes containing 10 ml sterile of the growth medium listed in section VIII of this protocol and incubated for 24 hours ± 2 hours in the conditions listed in section VIII of this protocol. Only one daily transfer is required prior to initiation of the test culture. The culture tube is vortex mixed prior to transfer.
- A test culture is initiated by transferring 0.010 ml of the most recent daily transfer culture into an appropriate number of 15 ml conical tubes, each containing 10 ml sterile of the growth medium listed in section VIII of this protocol and incubated for 48-54 hours in the conditions listed in section VIII of this protocol.
- Test cultures are vortex mixed for 3-4 seconds and allowed to dwell at room temperature for ≥ 10 minutes.
- The upper portion of the mixed culture(s) is removed, leaving behind any debris or clumps, and pooled in an appropriate vessel(s).
- For the purpose of achieving carrier counts within the range of the study, dilution or concentration of the final test culture may be performed using the culture medium used to generate the test culture. Manipulation of the final test culture should be made prior to the addition of the organic soil load.

Supplementation of Test Culture with Organic "Soil" Load

- If requested by the Study Sponsor, an organic soil load will be added to the pooled test culture.
- The test culture is swirled gently to thoroughly mix.

Carrier Inoculation with Test Culture

- Deionized water is aspirated from the container containing the prepared carriers using a sterile serological pipette.
- The test culture is added to the drained vessel containing the penicylinders, such that all carriers are completely submerged in the test culture for uniform coverage (~1 ml of culture per carrier is maintained).
- The test culture and penicylinders are allowed to dwell for 15 minutes ± 2 minutes at room temperature.
- After 15 minutes ± 2 minutes have elapsed, the culture is aspirated and penicylinders are removed from the container aseptically using a sterile wire hook (carriers may be tapped or shaken prior to removal to remove excess culture) and are placed, no more than 12 carriers to a dish, on sterile double filter paper-lined sterile Petri dishes. Carriers are placed on end, evenly spaced in the dish, such that they do not touch one another. If any carriers fall over, they are discarded from use in the test.
- Loaded Petri dishes are covered, transferred to an incubator or humidity controlled chamber at 36 °C ± 1 °C and allowed to dry for 40 minutes ± 2 minutes, or until visibly dry. As this microorganism is not specified in the official AOAC Use Dilution method, alternate drying conditions (temperature, time, and humidity levels) may be necessary to achieve maximum survival of the microorganism following drying. The drying conditions will be documented in the raw data and reported.
- Inoculated carriers are used within 2 hours of drying.

PROTOCOL (cont.)

Treatment of Carriers with Test Substance

- Inoculated carriers are sequentially transferred using a heat-sterilized wire hook into individual 25 × 100 mm test tubes containing 10 ml of test substance, at appropriate intervals to ensure careful and aseptic handling. As the first carrier is submerged in the test substance, a calibrated timer is started to measure the contact time.
  - Every attempt is made to ensure that carriers, wire hook tip, and wire hook handle are not allowed to touch the sides of the test tube during this step. If a contaminated penicylinder touches the sides of the test tube going into the test substance, then that test tube and the corresponding subculture/neutralization tube is noted.
- Tubes containing test substance and carrier are gently swirled, 2-3 gentle rotations, then placed back at test temperature for the duration of the contact time.
- Exposure temperature, at the start and end of the contact time, as well as the ambient room relative humidity will be documented in the datasheet and subsequently reported in the final study report.
- After the contact time for each carrier has elapsed, each carrier is removed from the test substance using a heat-sterilized wire hook. Carriers are tapped in the lower third of the tube to remove excess test substance. Carriers are then transferred to a 20 × 150 mm tube containing 10 ml of the appropriate subculture/neutralization broth, such that it is completely submerged.
- The procedure is repeated until all protocol specified efficacy carriers have been exposed to the test substance for the specified contact time and harvested into subculture/neutralization broth.
- If neutralization of the test substance is a concern, a secondary neutralization transfer from the primary neutralizer may be performed. Within 25-60 minutes of the initial transfer, transfer the carriers using a sterile wire hook to a second subculture tube containing a 10 ml aliquot of the subculture medium that may contain appropriate neutralizer. Carriers are transferred in the same order as in the test however the transfers do not need to be timed.

Neutralization Confirmation

- A sterile uninoculated carrier is transferred to a 25 × 100 mm test tube containing 10 ml of the test substance and a calibrated timer is started to measure the contact time.
- After the contact time has elapsed, the carrier is transferred using a heat-sterilized wire hook to 20 × 150 mm test tube containing 10 ml of subculture/neutralization broth for primary neutralization.
  - This tube represent the primary neutralization confirmation test tube.
  - If necessary, the carrier is transferred into a secondary 25 × 150 mm tube containing 10 ml of subculture/neutralization broth within 25 to 60 minutes of the initial primary transfer.
- A series of 10-fold dilutions of the test culture are performed in 9 ml of phosphate buffered dilution water (PBDW) such that a 0.1 ml volume of the dilution targets 10-100 CFU. This inoculum is plated in duplicate to verify the number of CFU present.
- The neutralization confirmation test tubes (primary and secondary, if applicable) are inoculated with 0.1 ml volumes of the prepared inoculum.
- The neutralization confirmation control may be performed using multiple carrier replicates and inoculated with different dilutions of the prepared inoculum.
- If more than one concentration of test substance is assayed, only the most concentrated dilution of the test substance will be evaluated in this control.
- If more than one contact time is requested, this control will be performed using the shortest requested contact time only.

Enumeration of Control Carriers

- After the inoculated carriers have dried, 3 carriers are randomly selected from different dishes and are individually transferred into 20 × 150 mm tubes containing 10 ml of subculture/neutralization broth. These carriers represent the carrier density at the beginning of the test.
- Similarly, following the conclusion of the test, 3 more carriers are randomly selected from different dishes and are individually transferred into 20 × 150 mm tubes containing 10 ml of subculture/neutralization broth. These carriers represent the carrier density at the end of the test.

PROTOCOL (cont.)

- The six (3 pre test and 3 post test) carrier density subculture/neutralization broth tubes are placed in a beaker filled with water to the level of liquid in the tubes. The beaker is held in a sonicator so that the beaker bottom does not touch the bottom of the sonicator and all liquid levels are approximately equal.
- The beaker containing the tubes is sonicated for 1 minute ± 5 seconds, as timed by a certified digital timer.
- After sonication, the subculture/neutralization broth tubes from each set of three test tubes (pre test and post test) are pooled prior to enumeration.
- The pooled cultures are enumerated by performing serial 10-fold dilutions in 9 ml PBDW and a 0.1 ml aliquot of the appropriate dilutions are plated in duplicate using standard pour and/or spread plating techniques.
  - For example, the pooled cultures are diluted out to the 10^{-3} dilution. 0.1 ml of the 10^{-1}, 10^{-2} and the 10^{-3} dilution are plated representing the 10^{-2}, 10^{-3}, and 10^{-4} dilution per ml of the carrier set.
- This step is performed within 2 hours of sonication of the subculture/neutralization tubes.

Carrier Sterility Control

- An uninoculated carrier is harvested into a 20 × 150 mm tube containing 10 ml of subculture/neutralization broth and incubated alongside the test materials.

Viability Control

- An inoculated, untreated test carrier is harvested into a 20 × 150 mm tube containing 10 ml of subculture/neutralization broth and incubated alongside the test materials.

Subculture/Neutralization Sterility Control

- A 20 × 150 mm tube containing 10 ml of subculture/neutralization broth is incubated alongside test materials.

Media Sterility Controls

- A volume of PBDW is added to sterile growth agar and incubated alongside test materials to confirm sterility of the serial dilution media at the time of test.
- A volume of culture diluent is added to sterile growth agar and incubated alongside test materials to confirm sterility of culture diluent at the time of test, if applicable.
- A volume of fetal bovine serum is added to sterile agar and incubated alongside test materials to confirm soil sterility at the time of test, if applicable.
- A plate containing only sterile growth agar used in this study is incubated alongside test materials to confirm sterility of media at the time of test.

Test Microorganisms Purity Control

- The test culture used in this study is subcultured onto growth agar medium and incubated alongside the test materials to morphologically confirm the presence of target microorganism and absence of contaminant microorganism.

Incubation of Tubes and Enumeration and Control Plates

- Test tube racks are shaken thoroughly prior to transfer to the incubator.
- All tubes and plates are incubated in the conditions listed in section VIII of this protocol for 48 hours ± 2 hours.

PROTOCOL (cont.)

Confirmation of Positive Tubes Following Incubation

- Tubes are assessed for the presence of growth by visual observation of turbidity and/or a colorimetric result of the subculture/neutralization broth.
- The number of tubes showing visible turbidity or a colorimetric change will be documented as positive (+) pending confirmation. If turbidity is not present, the total number of tubes demonstrating no growth will be documented as negative (-).
  - If a colorimetric subculture/neutralization broth is used, but the test system does not produce a colorimetric change and no positive tubes are observed, ≥ 20% of the negative tubes are confirmed to be a negative result by plating on growth media.
- All presumptive positive tubes will be struck onto the appropriate growth agar to confirm along with the viability control in order to confirm the observed growth is due to the target microorganism.
- All confirmatory plates are incubated for 18-24 hours in the conditions listed in section VIII of this protocol.
- A Gram stain will be performed from the presumptive positive streak plate on each colony type. The colony morphology of each isolated colony type will be documented in the raw data.
- Other appropriate biochemical analysis may be performed for confirmation of the test microorganism.
- The number of confirmed positive tubes will be documented in the raw data and reported along with any confirmed contaminants.

X. Calculations

The following are calculations to be used in the study. Calculation variables may be adjusted based on volumes and dilutions used.

$$\frac{(\text{Average CFU for } 10^{-x}) + (\text{Average CFU for } 10^{-y}) + (\text{Average CFU for } 10^{-z})}{10^{-x} + 10^{-y} + 10^{-z}} = \text{CFU/ml of Control Carriers Set}$$

Where 10^{-X}, 10^{-Y}, and 10^{-Z} are examples of dilutions that may be used.

$$[(\text{CFU/ml of Control Carriers Set}) \times 10 \text{ ml (volume of neutralization broth per tube)}] = \text{CFU/Carrier of Control Carriers Set}$$

$$\text{Control Carrier Mean Log Density} = \frac{(\text{Log}_{10} \text{ CFU/Carrier Pooled Pre Carriers} + \text{Log}_{10} \text{ CFU/Carrier Pooled Post Carriers})}{2}$$

$$\text{Neutralization Confirmation Inoculum} = (\text{CFU on Plate 1} + \text{CFU on plate 2}) / 2$$

PROTOCOL (cont.)

XI. Proposed Statistical Analysis

Not applicable.

XII. Methods for the Control of Bias

Not applicable.

XIII. Study Success Criteria

The experimental success (controls) criteria follow:

- The test microorganism must demonstrate a concentration of at least 1.0×10^4 CFU/Carrier corresponding to a mean log density of 4.0 and not above 1.0×10^5 CFU/Carrier corresponding to a mean log density of 5.0.
- The subculture/neutralization broth sterility control tube demonstrates no growth.
- The carrier sterility control subculture/neutralization broth tube demonstrates no growth.
- The viability control subculture/neutralization broth tube demonstrates growth.
- At least one neutralization confirmation inoculum dilution demonstrates an average concentration of ≤100 CFU.
- The neutralization confirmation test subculture/neutralization broth tube corresponding to the inoculum average concentration of ≤100 CFU demonstrates growth.
- The media sterility controls demonstrate no growth.
- The test microorganism purity control plate demonstrates the presence of the target microorganism and absence of contaminant microorganisms.

XIV. Product Performance Criteria

The Environmental Protection Agency performance standard for additional bacteria require the test substance to kill all of the test microorganisms on all 10 carriers (i.e. no positive carriers).

Retesting guidance for disinfection follows:

- When a test passes and the $\log_{10}$ density of the test carriers is above 5.0, no retesting is necessary.
- When a test passes and the $\log_{10}$ density of the test carriers is below 4.0, retesting is necessary.
- When a test fails and the $\log_{10}$ density of the test carriers is below 4.0, no retesting is necessary.
- When a test fails and the $\log_{10}$ density of the test carriers is above 5.0, retesting may be conducted.

XV. Reporting

- Results are reported accurately and fully, in accordance with Environmental Protection Agency GLP (40 CFR Part 160). A draft report will be provided for review by the Study Sponsor prior to study completion.

PROTOCOL (cont.)

XVI. Study Record and Test Substance Retention

- The original (or certified copy) of the study report, protocol, and corresponding raw data will be held in the archives of Microchem Laboratory for a minimum of five years following the study completion date. Afterward, Microchem reserves the right to transfer the documents to the Study Sponsor (or Sponsor Representative, if applicable) at the Sponsor's expense. For studies not meeting the performance criteria for submission or for studies that have been canceled prior to the generation of valid data, the original (or certified copy) of the final study report, protocol, and corresponding raw data will be held in the archives of Microchem Laboratory for a minimum of two years following the study completion date at which time they may be removed from the archive or transferred to the Sponsors archive at their expense.
- If requested by the Study Sponsor (or Sponsor Representative), the study file may be transferred to the Study Sponsor's archive at the Study Sponsor's expense prior to the time frames listed.
- All test facility records including, but not limited to, standard operating procedures, quality assurance inspection records, temperature and equipment records including maintenance, inspection and calibration, and employee training records will be maintained at Microchem Laboratory indefinitely.
- The test substance (or test control, test article, test device, as applicable) may be returned to the Study Sponsor at the Study Sponsor's request and expense following study completion unless otherwise requested to be returned earlier. If the Study Sponsor does not request return of the sample, it will be disposed >90 days following the study completion. Arrangements may be made for extended storage as necessary, at the Sponsor's request and expense.

XVII. Quality Assurance

The study is conducted in accordance with Microchem Laboratory's Quality Management System and 40 CFR Part 160 and will undergo a full quality assurance review. All protocol amendments will be fully recorded and reported, as well as any deviations from the protocol.

XVIII. References

- "Association of Official Analytical Chemists, International." AOAC Official Method 964.02. Testing Disinfectants Against Pseudomonas aeruginosa. Revised 2013.
- U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention, Product Performance Test Guidelines OCSPP 810.2000: General Considerations for Testing Public Health Pesticides – Guidance for Efficacy Testing (February 2018).
- U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention, Product Performance Test Guidelines OCSPP 810.2200: Disinfectants for Use on Environmental Surfaces Guidance for Efficacy Testing. February 2018.
- Guidance Document – Disinfectant Drugs. Health Canada. January 2014.
- Guidance Document – Safety and Efficacy Requirement for Hard Surface Disinfectant Drugs. Health Canada. January 2014.

PROTOCOL (cont.)

AOAC Use Dilution Test

Protocol Number: P2404

Specific Testing Parameters to be completed by the Study Sponsor/Representative - all fields need to be completed before testing may commence

Test Substance Name	D7 Part 1, D7 Part 2, D7 Part 3 (activator only)
Test Substance Batch Numbers	D7 Part 1 (18-625, 18-626), D7 Part 2 (18-643, 18-644), D7 Part 3 (02-11-19-01)
Manufacture Date(s)	28NOV2018
Expiration Date(s)	28NOV2019
Test Substance Shipment Status	☑ Use test substance already present at Microchem. □ Test substance will be shipped. Estimated arrival date, if known:
Test Substance Storage	☑ Room temperature (default for all packages unless otherwise advised) □ 2-8°C □ Other:
Test Substance Hazards	□ None known ☑ SDS attached □ Other:
Test Substance Active Ingredient	□ Alcohol □ Iodophor □ Peracetic Acid ☑ Peroxide ☑ Quaternary Ammonia □ Sodium Hypochlorite □ Phenol □ Other:
Active Ingredient Level	☑ At or below Lower Certified Limit (LCL) □ At or below nominal
Active Ingredient Concentration as submitted (for neutralization information only, not for chemical characterization)	D7 Part 1: Lot 18-625 – 3.03% Peroxide, Lot 18-626 – 3.03% Peroxide D7 Part 2: Lot 18-643 – 7.506% Quaternary Ammonia, Lot 18-644 – 7.525% Quaternary Ammonia D7 Part 3: Lot 02-11-19-01 <99% Diacetin (inactive ingredient activator only)
Test Substance Dilution	□ Ready to Use ☑ Dilution ratio: (e.g. 1 oz per gallon) 49 parts D7 Part 1, 49 parts D7 Part 2, 2 parts D7 Part 3
Dilution to be made	□ N/A ☑ Dilute by adding see above test substance to diluent (please specify volumes to be used for dilution, eg. 1 ml to 127 ml diluent) Note, an equivalent dilution may be made unless otherwise noted
Test Substance Diluent	□ 200 ppm autoclave sterilized Tap Water (hardness range is 180-210 ppm) □ 400 ppm AOAC Synthetic Hard Water (hardness range is 360-420 ppm) □ 375 ppm OECD Hard Water (hardness range is 338 – 394 ppm) ☑ Other: see above
Organic Soil Load	□ None ☑ 5% fetal bovine serum □ Other:
Contact Time(s)	9 minutes 50 seconds ± 5 seconds

PROTOCOL (cont.)

AOAC Use Dilution Test

Protocol Number: P2404

Continuation of Specific Testing Parameters to be completed by the Study Sponsor/Representative - all fields need to be completed before testing may commence

Exposure Temperature	☑ 20 ± 1°C ☐ Other:
Number of Test Carriers Per Batch	☑ 10 ☐ Other:
Neutralization/Subculture Broth	☑ Microchem to determine. Sponsor authorizes pre-test neutralization confirmation assay to be conducted to determine appropriate neutralizer, if needed. Additional fees may apply per price quotation. ☐ Use:
EPA 40 CFR Part 160.31(d) requires testing facility management to assure that the test, control, and reference substances have been appropriately tested for identity, strength, purity, stability and uniformity, as applicable.	Applicable identity, strength, purity, stability, and uniformity testing has been or will be completed prior to efficacy testing: ☑ Yes ☐ No - Performed under 40 CFR Part 160 regulations? ☑ Yes ☐ No Stability testing has been or will be completed prior to efficacy testing or concomitantly with efficacy testing: ☑ Yes ☐ No - Performed under 40 CFR Part 160 regulations? ☑ Yes ☐ No If no is marked for either question, compliance status will be noted in the GLP compliance statement in the final report.
Certificate of Analysis (CoA)	☑ CoA for each batch provided. CoA will be appended in the final report. ☐ CoA will not be provided.
Procedure Modifications	☑ Testing to be performed as outlined in the protocol. ☐ The following protocol modifications are to be performed:
Regulatory Agency(s) that report may be submitted to	☑ EPA ☐ Health Canada

PROTOCOL (cont.)

AOAC Use Dilution Test

Protocol Number: P2404

XIX. Authorized Personnel

- Due to Microchem Laboratory confidentiality policy, study information will only be released to the Study Sponsor/Sponsor Representative who has signed the protocol unless otherwise noted in writing. Please list any additional personnel authorized to receive information regarding this study.

1. Matt Bluhm
2. Joe Drake
3. Brian Narducci
4. _____

XX. Protocol Approval

"I, the Study Sponsor, have read and understand the study protocol. By signing this protocol I am certifying that the information and parameters accurately describe the test(s) to be completed in accordance with Good Laboratory Practice Standards (GLPS) stipulated by 40 CFR 160. I have also read, understand and agree to the terms and conditions listed in the protocol."

Study Sponsor/Representative Signature Approving Protocol

JORDAN AHERN
Study Sponsor Printed Name

Study Sponsor/Sponsor Representative Signature

7/3/19
Date

jahern@decon7.com
Email address

480-339-2858 ext 414
Phone

Microchem Laboratory Study Director

Meredith Fenner
Study Director Printed Name

Study Director Signature

03JUL2019
Date

Page 12 of 12
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CERTIFICATE OF ANALYSIS

Baum's Castorine Co., Inc.
Manufacturing Chemists Since 1879

11/30/2018

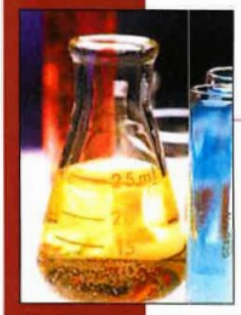
Certificate of Analysis D7 Part 1

The active [Alkyl DimethylbenzeyQuat.] concentration is assayed using method BCQCSP-2.11.
Expiration date to all product is 11/28//2019.

batch number	%wt. Alkyl Dimethylbenzyl Ammonium Chloride	LCL	UCL
18-625	3.03	3.04	3.36
18-626	3.03	3.04	3.36

www.baumscastorine.com

CERTIFICATE OF ANALYSIS (cont.)



Baum's Castorine Co., Inc.
Manufacturing Chemists Since 1879

11/30/2018

Certificate of Analysis D7 Part 2

D7 Part 2 is assayed for %wt.H_2O_2 using method BCQCSP – 6.44. Expiration date to all product is 11/29/2019.

batch number	%wt. H_2O_2	LCL	UCL
18-643	7.506	7.51	8.3
18-644	7.525	7.51	8.3

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