BIODOX™

CONCENTRATED LIQUID STERILIZER

Study Title

Protocol for the AOAC International Use-Dilution Methods (955.14, 955.15, & 964.02)

Product Identity

BIODOX CONCENTRATED LIQUID STERILIZER

Data Requirement

40 CFR PART 158—DATA REQUIREMENTS
FOR PESTICIDES Subpart W—Antimicrobial Pesticides Guideline No. 810.2200

Author

Taylor Dreves
Microbiologist II

Study Completion Date

10-26-2021

Testing Facility

Q Laboratories 1930 Radcliff Drive
Cincinnati, OH 45204
(513) 471-1300

Laboratory Project Number (Study File)

QL 370181

1.0 EFFICACY STUDY SUMMARY

STUDY TITLE:	**Protocol for the AOAC International Use-Dilution Methods (955.14, 955.15, & 964.02)**
LABORATORY PROJECT #:	QL 370181
GUIDELINE:	Guideline No. 810.2200 using Official Methods of Analysis of the AOAC International, Chapter 6, Disinfectants, Use-Dilution Methods (955.14, 955.15, & 964.02). Current edition. AOAC International, 2275 Research Blvd., Suite 300, Rockville, MD 20850 [Section 14.1, 14.2, and 14.3 of Appendix 1].
TESTING FACILITY:	Q Laboratories 1930 Radcliff Drive Cincinnati, OH 45204
STUDY DATES:	
STUDY INITIATION DATE:	06-09-2021
STUDY COMPLETION DATE:	10-26-2021
GLP COMPLIANCE:	Q Laboratories has developed and implemented a quality management system that enhances our ability to provide testing services that consistently meet client expectations and regulatory requirements. All testing was performed in accordance with EPA Good Laboratory Practice Standards (GLPS), as specified in 40 CFR Part 160. Periodic phase audits of the study were conducted by the Quality Assurance Unit to ensure testing compliance and a review of the final report by the QAU was conducted in accordance with 40 CFR,Part 160.35, subpart B.
TEST SUBSTANCE:	
DESCRIPTION:	BioDox CONCENTRATED LIQUID STERILIZER
% ACTIVE INGREDIENT:	Chlorine Dioxide (ClO2), 0.4 %
DILUTION:	½ oz or 15 mL or 1 tbsp of substance to 32 oz (946 mL) water
TEST CONDITIONS:	5% fetal bovine serum
SOIL LOAD:	Test substance is diluted in AOAC hard water solution
WATER:	prepared according to EPA SOP MB-30-02 [Section14.4 of Appendix 1] to use-dilution.
CONTACT TIME:	3 minutes ± 5 seconds
TEMPERATURE:	Ambient Temperature (20 - 25 °C)
OTHER:	The inoculum applied includes 5% fetal bovine serum.

TEST RESULTS:

Positive carriers/total carriers

Test Organism	*Identification #*	*Test Results (form)*		
		Lot 000136	*Lot 00015*	*Lot 00016*
Salmonella enterica	*ATCC* 10708*	*0*	*0*	*0*
Staphylococcus aureus	*ATCC 6538*	*0*	*0*	*0*
Pseudomonas aeruginosa	*ATCC 15442*	*0*	*0*	*0*

American Type Culture Collection

CONTROL RESULTS:

The control carriers for S. aureus and P. aeruginosa were between 1.0 x 106 to 1.0 x 107 CFU/carrier. The control carriers for S. enterica were between 1.0 x 105 to 1.0 x 106 CFU/carrier. Growth occurred in all viability control tubes. Growth did not occur in any of the sterility tubes. Neutralization was considered adequate and meet the specification in Section 13.0 of Appendix 1. For media quality controls, comparable growth acceptance was within 50 - 200 %. No growth occurred in the media sterility control. No disrupted pellicles of P. aeruginosa test culture were used. No contamination occurred in the subculture tubes.

CONCLUSION:

Based on the results presented in this study report, the test article met the performance standard: (0) positive carriers out of sixty (60) for each lot, when tested against Staphylococcus aureus, Pseudomonas aeruginosa, and Salmonella enterica. The performance standard listed in 810.2200 for S. aureus and P. aeruginosa is no more than three positive carriers out of 60 per test. The performance standard for S. enterica is no more than one positive carrier out of 60 per test. All testing was performed in accordance with EPA Good Laboratory Practice Standards (GLPS), as specified in 40 CFR Part 160. Periodic phase audits of the study were conducted by the Quality Assurance Unit to ensure testing compliance and a review of the final report by the QAU was conducted in accordance with 40 CFR, Part 160.35, subpart B.

For more information regarding this Efficacy Study with Q Labs, please contact us and we would love to share more of our amazing results.

BioCentric Solutions

Manufactured in the USA by BioCentric Solutions
12400 Loma Rica Dr. Grass Valley, CA 95945
www.biocentric.solutions

The BioCentric Solutions Ethos

BioDox™ was developed by BioCentric Solutions, a company that believes in creating the most effective solutions to dangerous pathogens without harming people or our planet. Our mission is to create safe and effective solutions that improve the health of the world around us.