ACCURATUS
—LAB SERVICES—
THE ANTIMICROBIAL AUTHORITY

FINAL STUDY REPORT

STUDY TITLE

Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces

Virus: Human Coronavirus

PRODUCT IDENTITY

Barbicide
Lot LH081518-1 and Lot LH081518-2

TEST GUIDELINE

OCSPP 810.2200

PROTOCOL NUMBER

KIN01091718.COR

AUTHOR

Mary J. Miller, M.T.
Study Director

STUDY COMPLETION DATE

July 22, 2019

PERFORMING LABORATORY

Accuratus Lab Services
1285 Corporate Center Drive, Suite 110
Eagan, MN 55121

SPONSOR

King Research, Inc.
7025 W. Marcia Rd
Milwaukee, WI 53223

SPONSOR REPRESENTATIVE

Lewis & Harrison, LLC
122 C Street NW, Suite 505
Washington, DC 20001

PROJECT NUMBER

A26790

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 sec. 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: King Research, Inc.

Company Agent: Daniel Bellehumeur

Director of Quality, Compliance, Tech Serv.
Title

Signature

Date: 07/29/2019

GOOD LABORATORY PRACTICE STATEMENT

The study referenced in this report was conducted in compliance with U.S. Environmental Protection Agency Good Laboratory Practice (GLP) regulations set forth in 40 CFR Part 160 with the following exceptions:

Stability testing of the compounds was not performed by the Sponsor prior to use in the study or concurrent with the study per 40 CFR Part 160.

Submitter: _____ Date: 07/22/2019

Sponsor: _____ Date: 07/22/2019

Study Director: Mary J. Miller Date: 7-22-19
Mary J. Miller, M.T.

QUALITY ASSURANCE UNIT SUMMARY

Study: Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces

The objective of the Quality Assurance Unit is to monitor the conduct and reporting of non-clinical laboratory studies. This study has been performed in accordance to standard operating procedures and the study protocol. In accordance with Good Laboratory Practice regulation 40 CFR Part 160, the Quality Assurance Unit maintains a copy of the study protocol and standard operating procedures and has inspected this study on the date(s) listed below. Studies are inspected at time intervals to assure the integrity of the study. The findings of these inspections have been reported to Management and the Study Director.

Phase Inspected	Date of Phase Inspection	Date Reported to Study Director	Date Reported to Management
Critical Phase Audit: Preparation of Test Substance	January 9, 2019	January 9, 2019	January 10, 2019
Critical Phase Audit: Treatment of Virus Films with the Test Substance	February 4, 2019	February 4, 2019	February 4, 2019
Critical Phase Audit: Preparation of Virus Films	March 1, 2019	March 1, 2019	March 4, 2019
Draft Report	March 18, 2019	March 18, 2019	July 22, 2019
Final Report	July 19, 2019	July 19, 2019	

Quality Assurance Specialist: _____ Date: 7-22-19

STUDY PERSONNEL

STUDY DIRECTOR: Mary J. Miller, M.T.

Professional Personnel Involved:

Shanen Conway, B.S.	- Manager, Study Director Operations
Erica Flinn, B.A.	- Manager, Virology Laboratory Operations
Katherine A. Paulson, M.L.T.	- Lead Virologist
Miranda Peskar, B.S.	- Virologist
Kasey Thompson, B.S.	- Associate Virologist

STUDY REPORT

GENERAL STUDY INFORMATION

Study Title: Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces

Project Number: A26790

Protocol Number: KIN01091718.COR

Sponsor:
King Research, Inc.
7025 W. Marcia Rd
Milwaukee, WI 53223

Sponsor Representative:
Lewis & Harrison, LLC
122 C Street NW, Suite 505
Washington, DC 20001

Testing Facility:
Accuratus Lab Services
1285 Corporate Center Drive, Suite 110
Eagan, MN 55121

TEST SUBSTANCE IDENTITY

Test Substance Name: Barbicide

Lot/Batch(s): Lot LH081518-1 and Lot LH081518-2

Manufacture Date: August 15, 2018

Test Substance Characterization
Test substance characterization as to identity, strength, purity, and uniformity, as applicable, according to 40 CFR, Part 160, Subpart F [160.105], was documented prior to its use in the study. The stability of the test substance was not documented prior to or concurrent with the study. The Test Substance Certificate of Analysis Reports may be found in Attachments III-IV.

STUDY DATES

Date Sample Received: December 7, 2018
Study Initiation Date: January 2, 2019
Experimental Start Date: January 9, 2019 (Start time: 1:15 p.m.)
Experimental End Date: March 11, 2019 (End time: 5:55 a.m.)
Study Completion Date: July 22, 2019

OBJECTIVE

The objective of this study was to evaluate the virucidal efficacy of a test substance for registration of a product as a virucide. The test procedure was to simulate the way in which the product is intended to be used. This method is in compliance with the requirements of and may be submitted to the U.S. Environmental Protection Agency (EPA).

SUMMARY OF RESULTS

Test Substance:	Barbicide, Lot LH081518-1 and Lot LH081518-2
Dilution:	2:32 defined as 2 oz test substance + 32 oz of 200 ppm sterile, un-softened tap water
Virus:	Human Coronavirus, ATCC VR-740, Strain 229E
Exposure Time:	10 minutes
Exposure Temperature:	Room temperature (20.0°C)
Organic Soil Load:	1% fetal bovine serum
Efficacy Result:	Two lots of Barbicide (Lot LH081518-1 and Lot LH081518-2) met the performance requirements specified in the study protocol. The test substance **demonstrated a ≥3 $\log_{10}$ reduction** in titer of Human Coronavirus under these test conditions as required by the U.S. EPA.

TEST HISTORY

The initial assay performed on January 9, 2019, was repeated on February 4, 2019, to demonstrate at least a 3-log reduction in viral titer beyond the cytotoxic level of the test substance as required for a valid test.

See Attachment I for the invalid data from the January 9, 2019 assay.

The repeat assay performed on February 4, 2019, was repeated on March 1, 2019, due to random bacterial contamination in the WI-38 cell cultures for the test and neutralization control for Lot LH081518-2, which prevented the evaluation of the cells for the presence of test virus infectivity and/or cytotoxicity for the test and neutralization control for Lot LH081518-2.

See Attachment II for the invalid data from the February 4, 2019 assay.

Valid results were obtained from the assay performed on March 1, 2019, and may be found in the body of this report.