

**HILL TOP RESEARCH, INC.**

**VOLUME 3**

**REPORT FOR**

**ASSESSMENT OF RAPID GERMICIDAL  
(TIME KILL) ACTIVITY FOR HAND PRODUCT**

**For:**

**3554-194**

**3554-196**

**HTR Study No. 03-122096-106**

**August 14, 2003**

**FOR**

**BAYER CHEMICALS CORPORATION**

**100 Bayer Rd.**

**Building 14**

**Pittsburgh, PA 15205-9741**

**BY**

**HILL TOP RESEARCH, INC.**

**Main & Mill Streets**

**Miamiville, OH 45147**

HTR Study No. 03-122096-106  
Bayer Chemicals Corporation

**TITLE:** ASSESSMENT OF RAPID GERMICIDAL (TIME KILL)  
ACTIVITY FOR HAND PRODUCT

**TEST  
ARTICLES:** 1) 3554-194  
2) 3554-196

**AUTHOR:** Kathleen A. Baxter, B.S.

**STUDY  
COMPLETED ON:** August 14, 2003

**PERFORMING  
LABORATORY:** Hill Top Research, Inc.  
Main and Mill Streets  
Miamiville, Ohio 45147

**LABORATORY  
PROJECT NO.:** 03-122096-106

**SPONSORED BY:** Bayer Chemicals Corporation  
100 Bayer Rd.  
Building 14  
Pittsburgh, PA 15205-9741

**SUBMITTED BY:** Bayer Chemicals Corporation  
100 Bayer Rd, Bld. 14  
Pittsburgh, PA 15205-9741

**DATE  
SUBMITTED:** August 26, 2003

**HILL TOP RESEARCH, INC.**

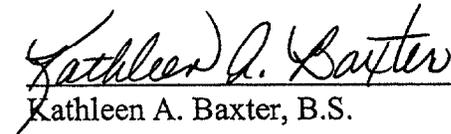
**ASSESSMENT OF RAPID GERMICIDAL  
(TIME KILL) ACTIVITY FOR HAND PRODUCT**

**COMPLIANCE STATEMENT**

This study was conducted in accordance with Good Laboratory Practice Standards (21 CFR Part 58).

The sponsor was responsible for and maintains the information pertaining to the physical and chemical characterization studies of the test and control articles under the conditions of the testing program (21 CFR Part 58.105).

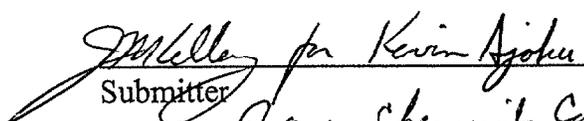
HILL TOP RESEARCH, INC.

  
\_\_\_\_\_  
Kathleen A. Baxter, B.S.  
Study Director  
Microbiology Business Unit

8/15/03  
Date

  
\_\_\_\_\_  
Bayer Chemicals Corporation  
Sponsor

8/23/03  
Date

  
\_\_\_\_\_  
Submitter  
Bayer Chemicals Corporation

8/23/03  
Date

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## 1.0 SUMMARY

- Two test articles, identified by the sponsor as 3554-194 and 3554-196, were tested for cidal effectiveness at a 75% concentration (vol/vol) in sterile purified water, with exposure times of 30 seconds and 60 seconds at 20-25°C, against the microorganisms, *Corynebacterium minutissimum*, ATCC 23347, *Enterococcus faecalis*, ATCC 29212, *Enterococcus faecium* (VRE), ATCC 51559, *Staphylococcus aureus*, ATCC 6538, *Staphylococcus aureus*, ATCC 29213, *Staphylococcus epidermidis*, ATCC 12228, *Staphylococcus aureus* (MRSA), ATCC 33591, *Staphylococcus aureus* (clinical isolate/MRSA), ATCC 2857, *Streptococcus pneumoniae* ATCC 6303 and *Streptococcus pyogenes*, ATCC 19615.
- Results of testing are summarized in Appendix I of the report including percent and log<sub>10</sub> reductions in numbers of organisms for both exposure periods.

## **2.0 PURPOSE**

The purpose of the study was to measure the ability of an antibacterial agent to rapidly reduce a known population of bacteria.

## **3.0 STUDY SPONSOR AND REPRESENTATIVE**

Bayer Chemicals Corporation  
100 Bayer Rd.  
Building 14  
Pittsburgh, PA 15205-9741

REPRESENTATIVE: Kevin Ajoku

## **4.0 INVESTIGATIVE PERSONNEL**

Study Director:	Kathleen A. Baxter, B.S.
Study Manager:	Jane M. Young, B.S.
Study Coordinator:	Patricia M. Schario, B.S.

## **5.0 STUDY SCHEDULE**

Study Initiation Date:	July 22, 2003
Study Completion Date:	August 14, 2003

## **6.0 TEST ARTICLES**

Two test articles, identified as 3554-194 and 3554-196 were received from the Dial Corporation for Bayer Chemicals Corporation on July 9, 2003 for use in this study.

The test articles will be destroyed thirty days after the completion of the study.

**7.0 PROTOCOL**

The study protocol as described in Appendix IV was followed.

**8.0 RESULTS**

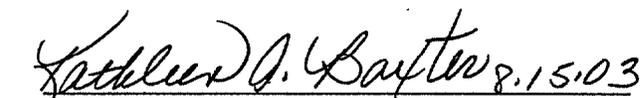
The Summary Tables of Results are presented in Appendix I and the Tables of Results are presented in Appendix II.

**9.0 CONCLUSION**

Results of testing are summarized in Appendix I of the report including percent and  $\log_{10}$  reductions in numbers of organisms for both exposure periods.

**10.0 SIGNATURE**

**HILL TOP RESEARCH, INC.**

  
Kathleen A. Baxter, B.S.                      Date

Study Director  
Microbiology Business Unit

**HILL TOP RESEARCH, INC.**

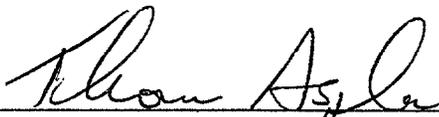
**QUALITY ASSURANCE STATEMENT**

This study was inspected in accordance with the SOP's of the Hill Top Research, Inc. QA findings derived from the inspection(s) during the conduct of the study and from the inspections of the final report are documented and have been reported to the appropriate personnel.

<u>Date of Inspection</u>	<u>Date Findings Reported to Study Director</u>	<u>Date Findings Reported to Management</u>
<u>7-24-03</u>	<u>7-25-03</u>	<u>8-01-03</u>
<u>                    </u>	<u>                    </u>	<u>                    </u>
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<u>                    </u>	<u>                    </u>	<u>                    </u>

Report	Date Reviewed	Date Reported to Study Director
Final	8-14-03	8-15-03

Reviewed by:

  
\_\_\_\_\_  
Thomas Asplan, A.A.S., B.S.                      8/15/03  
Auditor, Quality Assurance                      Date