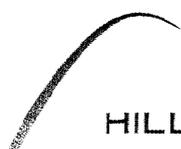


**APPENDIX B (ii)**

**Efficacy Evaluation of Triclosan Handwashing Products  
for Use in the Health Care Environment**

**Conducted at Hill Top Biolabs  
Miamiville, Ohio**

**October 2001**



HILL TOP RESEARCH, INC.

**REPORT FOR**

**EFFICACY EVALUATION OF  
HEALTH CARE PERSONNEL HANDWASH PRODUCTS**

**HTR STUDY NO. 01-109127-11**

October 19, 2001

FOR  
CIBA SPECIALTY CHEMICALS CORPORATION  
4090 Premier Drive  
High Point, NC 27265

BY  
HILL TOP RESEARCH, INC.  
Main and Mill Streets  
Miami, OH 45147

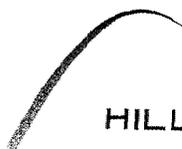
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**APPENDICES**

- Appendix I/IRB Approval Letter, Approved Consent Forms and Subject Instructions
- Appendix II/Protocol
- Appendix III/ Miscellaneous Procedural Information
- Appendix IV/Subjects Excluded/Withdrawn from Study
- Appendix V/Adverse Events
- Appendix VI/Test for Adequacy of Neutralizer
- Appendix VII/ Statistical Tables
- Appendix VIII/ Subject Data Collection Forms
  - A – Subjects Completing the Study
  - B – Subjects Excluded/Withdrawn

**IMPORTANT NOTICE**



HILL TOP RESEARCH, INC.

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## 1.0 SUMMARY

- The purpose of this study was to determine the ability of hand-washing agents to give reduction of transient microbial flora (contaminants) when used in a hand washing procedure with a marker organism, *Serratia marcescens* ATCC 14756.

Forty-five subjects completed the study.

- Two test articles identified by the sponsor as 3456-38, [REDACTED] (HTR Code A) and [REDACTED] (HTR Code B) were evaluated in this study.
- The test article evaluated in this study, identified by the sponsor as 3456-38, [REDACTED] (HTR Code A), achieved a 3.2202 log<sub>10</sub> reduction of the marker organism *Serratia marcescens* ATCC 14756 following a single 30-second handwashing procedure. After 11 repetitive washes a 2.8070 log<sub>10</sub> reduction of the marker organisms was achieved. The second test article evaluated, identified by the sponsor as [REDACTED] (HTR Code B), achieved a 2.6017 log<sub>10</sub> reduction of the marker organism following a single 30-second handwashing procedure and a 3.4781 log<sub>10</sub> reduction of the marker organism after 11 repetitive washes.

Thirty subjects participated in the evaluation of test article HTR Code A and fifteen in the evaluation of test article HTR Code B.

HTR Study No.: 01-109127-11

## 2.0 STUDY MONITOR

  
Ciba Specialty Chemicals Corporation

## 3.0 INVESTIGATIVE PERSONNEL

**Investigator:** Gayle K. Mulberry, M.S.

**Sub-Investigators:** Kathleen A. Baxter, B.S.

Ann R. Brady, B.A.G.S.

**Medical Consultant:** Joseph G. Daddabbo, M.D.

**Biostatistician:** James P. Bowman, M.S.

**Manager Biostatistics:** Barbara M. Fath

## 4.0 CLINICAL RESEARCH STANDARDS

The clinical investigation, including the informed consent, was reviewed by an Institutional Review Board in accordance with Title 21 of the Code of Federal Regulations, Parts 50 and 56. Approval by the Board was obtained on July 31, 2001, prior to initiation of the investigation (see Appendix I).

This study was conducted according to applicable Good Clinical Practices and the Standard Operating Procedures of Hill Top Research, Inc.

## 5.0 PROTOCOL

The Study Protocol was followed (see Appendix II). Three deviations occurred during the course of the study.

Subject Nos. 1, 3, 5 and 6 wet their hands after receiving the test product for wash #1. The protocol states that the subject will wet their hands before receiving the test product.

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## 5.0 PROTOCOL (CONT.)

Subject No. 27 lathered for only 10 seconds and rinsed for 35 seconds on wash 8. The protocol states that subjects will wash hands for 15 seconds and rinse for 30 seconds.

Subject No. 42 lathered for only 10 seconds and rinsed for 35 seconds on wash 6. The protocol states that subjects will wash hands for 15 seconds and rinse for 30 seconds.

In the protocol, HTR Code A is described as a thin colorless liquid. Upon receipt of HTR Code A, the liquid is described as pink. The Sponsor lot code is identical in the protocol and on HTR Code A.

In the opinion of the Investigator, these deviations did not compromise the integrity of the study.

The media, dilution fluid and other items used in the study but not defined in the protocol are shown in Appendix III, "Miscellaneous Procedural Information."

## 6.0 SUBJECTS

Eighty (80) subjects were enrolled in the pre-test conditioning phase. Forty-five (45) subjects, eleven (11) males and thirty-four (34) females who met the study criteria were enrolled in the test phase and completed the study.

Thirty-five (35) subjects were excluded or withdrew from the study. The subject's screening number and reason each subject was excluded or withdrew are shown in Appendix IV.

## 7.0 STUDY SCHEDULE

Screening/Conditioning Dates:	August 6, 2001
Date Initiated:	August 14, 2001
Date Completed:	October 18, 2001

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### 8.0 TEST ARTICLES

The following test article assigned Hill Top Research Code HTR A and identified as follows was received from [REDACTED] Ciba Specialty Chemicals Corporation on August 2, 2001 for evaluation in this study. The test article assigned HTR B was purchased by Hill Top Research on July 2, 2001 for use in the study:

<u>HTR Code</u>	<u>Sponsor Code</u>	<u>Description</u>	<u>No. of Units</u>
A	3456-38, [REDACTED]	[REDACTED] plastic bottle [REDACTED] unit containing [REDACTED] liquid	10
B	[REDACTED] Lot: 4563C, Exp: 12/02	[REDACTED] plastic quart bottle [REDACTED] containing liquid	1

Test articles will be returned to sponsor within one week of issuance of final report.

### 9.0 ADVERSE EVENTS

There were nine adverse events reported during the course of the study. (See Appendix V).

### 10.0 TEST FOR ADEQUACY OF NEUTRALIZER

A report on testing performed to demonstrate the effectiveness of the antimicrobial neutralizer used in this study is shown in Appendix VI.

## 11.0 METHOD OF STATISTICAL ANALYSIS

The data were statistically analyzed using analysis of variance methods. The statistical methods are described below.

Bacterial counts recovered from the hands were transformed into  $\log_{10}$  counts. The data used in the statistical analysis were the averages of each subject's right and left-hand  $\log_{10}$  counts. Analysis of variance techniques were used to evaluate the effectiveness of each treatment as a function of the number of treatments (within treatment analysis using  $\log_{10}$  reductions) and to compare the baseline counts of subjects assigned to the two test articles.

Percent reductions of bacterial counts from baseline were also determined.

The test articles used in this study were HTR Code A (Lot Code 3456-38 Foaming handwash) and HTR Code B (Lot Code 4563C [REDACTED]).

Hypothesis testing was performed at the  $\alpha=0.05$  level.

## 12.0 RESULTS OF STATISTICAL ANALYSIS

### 12.1 Baseline Bacterial Log Count Comparison

The source data for the baseline analysis were the average  $\log_{10}$  values for the right and left hands of each subject. Potential differences among the treatment groups at baseline were examined using a one-factor analysis of variance procedure.

Mean  $\log_{10}$  Baseline Counts

HTR Code A	HTR Code B	ANOVA p-value
9.2442	9.2374	>0.5000 <sup>1</sup>

<sup>1</sup> No significant difference between groups at baseline

**12.0 RESULTS OF STATISTICAL ANALYSIS (CONT.)**

**12.2 Within-Treatment Analysis**

The data (log<sub>10</sub> reductions) were evaluated by analysis of variance techniques to determine the existence, if any, of significant differences between test washes for each test article. The log<sub>10</sub> average differences from baseline and the p-values from the ANOVA are shown below.

HTR Code		Mean Log <sub>10</sub> Reductions		p-value
		WASH I	WASH 11	
HTR Code A	(n=30)	3.2202	2.8070	<0.0001 <sup>1</sup>
HTR Code B	(n=30)	2.6017	3.4781	<0.0001 <sup>2</sup>

<sup>1</sup> Significantly better antimicrobial activity after one test wash.

<sup>2</sup> Significantly better antimicrobial activity after eleven test washes.

**12.3 Percent Reduction of Bacterial Counts**

The log reduction and percent reductions of bacterial counts and associated confidence limits are presented below.

HTR Code	Log <sub>10</sub> Reduction	95% Confidence Limits		Percent Reduction	95% Confidence Limits	
		Lower	Upper		Lower	Upper
<b>WASH I</b>						
HTR Code A	3.2202	3.0982	3.3422	99.94%	99.92%	99.95%
HTR Code B	2.6017	2.4848	2.7185	99.75%	99.67%	99.81%
<b>WASH 11</b>						
HTR Code A	2.8070	2.6336	2.9804	99.84%	99.77%	99.90%
HTR Code B	3.4781	3.3587	3.5975	99.97%	99.96%	99.97%

The Statistical Table of Results is shown in Appendix VII.

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### 13.0 SUBJECT DATA COLLECTION FORMS

The Data Collection Forms for each subject selected for the study is shown in Appendix VIII.

Appendix VIII-A - Subjects Completing the Study

Appendix VIII-B - Subjects Excluded/Withdrawn

### 14.0 CONCLUSION

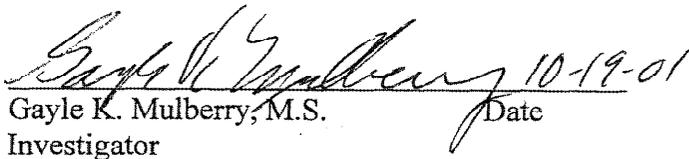
Two test articles were evaluated in this Health Care Personnel Handwash Study, (HTR Code A) identified by the sponsor as 3456-38, Foaming Handwash and (HTR Code B) identified as [REDACTED]

Thirty subjects participated in the evaluation of test article HTR Code A and fifteen in the evaluation of test article HTR Code B.

The test article identified as 3456-38, [REDACTED] (HTR Code A), achieved a 3.2202  $\log_{10}$  reduction of the marker organism *Serratia marcescens* ATCC 14756 following a single 30-second handwashing procedure. After 11 repetitive washes a 2.8070  $\log_{10}$  reduction of the marker organisms was achieved. The second test article evaluated, [REDACTED] (HTR Code B), achieved a 2.6017  $\log_{10}$  reduction of the marker organism following a single 30-second handwashing procedure and a 3.4781  $\log_{10}$  reduction of the marker organism after 11 repetitive washes.

### 15.0 SIGNATURE

HILL TOP RESEARCH, INC.

  
Gayle K. Mulberry, M.S. Date  
Investigator

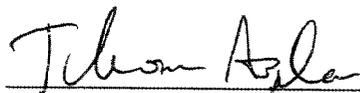
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**16.0 QUALITY ASSURANCE STATEMENT**

This study was inspected in accordance with the Standard Operating Procedures of Hill Top Research, Inc. To assure compliance with the study protocol, the Quality Assurance Unit performed an inspection during the conduct of this study and completed an audit of the study records, and final report.

Report reviewed by:



Thomas Asplan, A.A.S., B.S.  
Auditor, Quality Assurance

10/19/01

Date