

EVALUATION OF THE EFFICACY OF ANTIMICROBIAL HANDWASHES TO
REDUCE THE HAND-TO-HAND TRANSFER OF A MARKER ORGANISM
CRL- Ref. NO.: 03-121608-123

This study was designed to evaluate the difference in hand-to-hand transfer of bacteria when comparing an antimicrobial formula to a non-antimicrobial hand wash formulation. Two test articles identified as; Product A, Softsoap Naturals Liquid Hand Soap (non-AB) and Product B, Dial Complete™ Antimicrobial Foaming Healthcare Personnel Hand Wash (with 0.45% Triclosan) were evaluated in this study.

The study consisted of a one week pretest conditioning period and a one test day. Twelve subjects were used, 6 per product type. The test was divided into three phases; prewash baseline microbial population determination; post wash microbial population determination; bacterial transfer population. For all three phases, an area of the palm of a subjects hand was contaminated with a suspension of *Serratia marcescens* containing 10^8 - 10^9 CFU/mL, allowed to dry and then sampled using the scrub-cup technique. For baseline this was performed immediately following the drying period. For post wash determination, the palm of the hand was inoculated as above. A technician performed a wash on the subject's hand for 20 seconds. Following the 20 second wash and a 10 second rinse the hand was air dried for one minute and sampled using the scrub-cup technique. For the post transfer determination, the subject's palm was again contaminated with *S. marcescens*. A 20 second wash and 10 second rinse was performed on the subject's palm with the test product. The hand was allowed to air dry for one minute. After the drying, the subject rubbed the washed palm against the uninoculated palm for 20 seconds in a back and forth motion. Following the rub, the uninoculated palm was then sampled using the scrub-cup technique.

This study demonstrated a significant benefit from the use of antimicrobial hand soap as compared to non-medicated liquid hand soap. Following a 20 second wash of a hand inoculated with *Serratia marcescens*, Product B, Dial Complete™, significantly reduced the amount of bacteria on the hand. This reduced level of bacteria translated into significantly fewer bacteria being transferred to an uninoculated hand. After using Dial Complete™, there were only 1.07 log₁₀ average bacteria found on the uninoculated hand compared with 3.69 log₁₀ average bacteria found on the uninoculated hand after washing with non-antimicrobial hand soap.

Average Log₁₀ Bacteria Recovered

CRL Code	n	Baseline	Post Wash	Transfer
Dial Complete™ (B)	6	6.62	1.67	1.07
Soft Soap (A)	6	5.93	5.16	3.69

SUMMARY REPORT FOR

EVALUATION OF THE EFFICACY OF ANTIMICROBIAL HANDWASHES TO
REDUCE THE HAND-TO-HAND TRANSFER OF A MARKER ORGANISM

A Study to Determine the Efficiency of Hand-to-Hand Transfer
of *Serratia marcescens*

CRL Study No: 03-121608-123

April 23, 2003

FOR

The Dial Corporation
15101 North Scottsdale Road
Scottsdale, AZ 85254-2199

By

Hill Top Research, Inc
3225 North 75th Street
Scottsdale, AZ 85251

D00307

TABLE OF CONTENTS

1.0 SUMMARY 2
2.0 STUDY MONITOR 3
3.0 INVESTIGATIVE PERSONNEL 3
4.0 CLINICAL RESEARCH STANDARDS 3
5.0 PROTOCOL 3
6.0 TEST ARTICLES 3
7.0 METHOD OF STATISTICAL ANALYSIS 3
8.0 RESULTS OF STATISTICAL ANALYSIS 4
9.0 CONCLUSION 8
10.0 SIGNATURE 8
11.0 QUALITY ASSURANCE STATEMENT 8

APPENDICES

Appendix I/ Protocol

Appendix II/IRB Approval Letter, Approved Consent Forms and Subject Instructions

Appendix III/Randomization and Formula Ingredient Statement

Appendix IV/Excel Calculated Data

Appendix V/ Subject Data Collection Forms

A – Subjects Completing the Study

B – Subjects Excluded/Withdrawn

Appendix VI/Adverse Events

Appendix VII/ Media Preparation Log, Daily Autoclave Log, Balance QC Data Sheet,
Daily Temperature Log, Accumet AR20 pH Meter Standardization Log

Appendix VIII/ Hill Top Research, Inc. Final Study Report and Important Notice

1.0 SUMMARY

- The purpose of this study was to examine the benefit from handwashing treatments in reducing the transfer of transient flora from one person to another. Currently standard methods exist to evaluate the reduction of transient microorganisms following hand washing (Standard Method for Evaluation of Health Care Personnel Handwash Formulation ASTM E1174). Methods to evaluate transfer from one person to another have not been well studied. A method was developed using a Modified Cup Scrub procedure to evaluate the efficacy of an antimicrobial handwash compared to a non-medicated handsoap in reducing hand-to-hand transfer of a marker organism, *Serratia marcescens*. This study was designed to be used as a preliminary study using a smaller subject number and will be rerun using a larger subject size.
- Twelve subjects completed the study.
- Two test articles identified as: Product A, Non-medicated liquid handsoap and Product B, Antimicrobial Foaming handsoap (with 0.45% Triclosan) were evaluated in this study.
- Method Summary: In brief, the study consisted of a one week pretest conditioning period and one test day. Twelve subjects were used, six per product type. The test was divided into three phases; prewash baseline microbial population determination; post wash microbial population determination; bacterial transfer population.

For all three phases, an area of the palm of a subjects hand was contaminated with a suspension of *Serratia marcescens* containing 10^8 - 10^9 CFU/mL, allowed to dry and then sampled using the scrub-cup technique (Section 11.4 in Protocol). For baseline this was performed immediately following the drying period.

For post wash determination, the palm of the hand was inoculated as above. A technician performed a wash on the subject's hand for 20 seconds with a randomly assigned test product. Following the 20 second wash and a 10 second rinse the hand was air dried for one minute and sampled using the scrub-cup technique.

For the post transfer determination, the subject's palm of the hand was again contaminated with *S. marcescens*. A 20 second wash and 10 second rinse was performed on the subject's hand by the technician with the assigned test product. The hand was allowed to air dry for one minute. After the one minute drying, the subject rubbed the inoculated washed palm against the uninoculated palm for 20 seconds in a back and forth motion. Following the 20 second rub, the uninoculated palm was then sampled using the scrub-cup technique.

2.0 STUDY MONITOR

George Fischler
The Dial Corporation

3.0 INVESTIGATIVE PERSONNEL

Investigator: Harold Saferstein, M.D.
Sub-Investigator: Janice L. Fuls

Medical Consultant: Harold Saferstein, M.D.

4.0 CLINICAL RESEARCH STANDARDS

An Institutional Review Board in accordance with Title 21 of the Code of Federal Regulations, Parts 50 and 56 reviewed the clinical investigation, including the Informed consent. Approval by the Board was obtained prior to initiation of the investigation (see Appendix II).

5.0 PROTOCOL

The study protocol was followed with out any deviations. (See Appendix I)

6.0 TEST ARTICLES

<u>CRL Code</u>	<u>Sponsor Code</u>	<u>Description</u>	<u>No. of Units</u>
A	3539-9	Non-medicated Liquid Handsoap	2
B	3539-11	Antimicrobial Foaming Handsoap (0.45% Triclosan)	2

Randomization of the assignment of test articles for subject treatment was performed. Formula ingredient statements are attached. (See Appendix III)

7.0 METHOD OF STATISTICAL ANALYSIS

The data were statistically analyzed using analysis of variance methods.

7.0 (cont.)

The numbers of colony forming units (CFU) recovered per sample dilution were counted. The total number of CFU/mL of sampling solution was calculated. The counts obtained from the Cup Scrub Method were then expressed as CFU/cm².

Computed CFU/cm² were converted into log₁₀ per cm². The data were calculated for Pre-wash baseline microbial population on the inoculated hand, Post-wash microbial population on the inoculated hand, and the number of bacteria transferred from inoculated washed hand to uninoculated hand.

Analysis of variance techniques were used to evaluate the effectiveness of each treatment step using log₁₀ average counts.

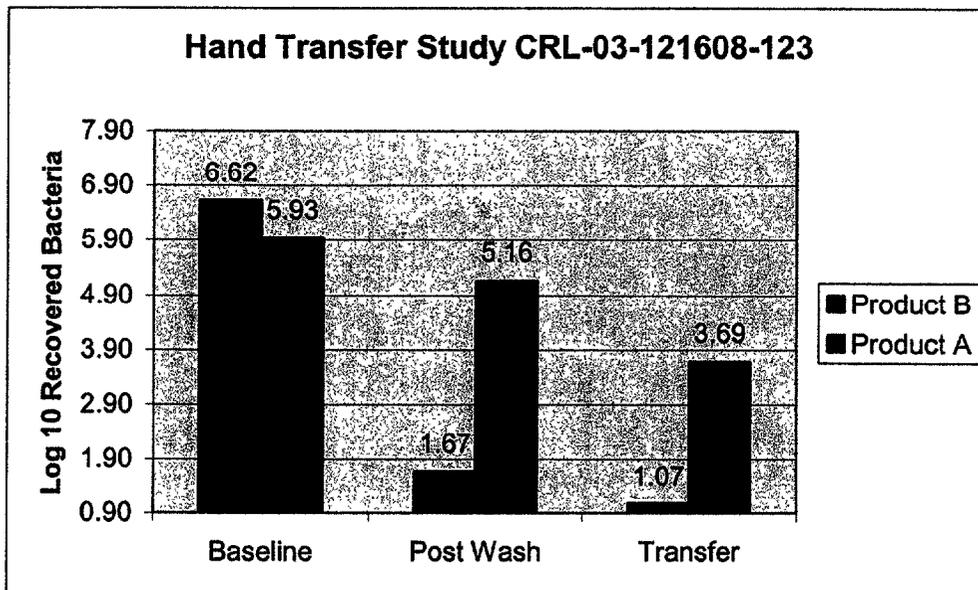
Hypothesis testing was performed at the $\alpha = 0.05$ level.

The calculated data are shown in Appendix IV.

8.0 RESULTS AND STATISTICAL ANALYSIS

Average Log₁₀ Bacteria Recovered

CRL Code	n	Baseline	Post Wash	Transfer
B	6	6.62	1.67	1.07
A	6	5.93	5.16	3.69



8.1 The comparison of the recovered log₁₀ counts from Baseline was evaluated by analysis of variance techniques to determine if any significant differences exist among the two test products. The log₁₀ average for each group was evaluated and is shown below. **No significant difference between groups in baseline counts.** (p=0.19)

Anova: Single Factor

SUMMARY

<i>Groups</i>	<i>Count</i>	<i>Sum</i>	<i>Average</i>	<i>Variance</i>
Product A	6	35.58	5.93	1.46032
Product B	6	39.74	6.623333	0.051667

ANOVA

<i>Source of Variation</i>	<i>SS</i>	<i>df</i>	<i>MS</i>	<i>F</i>	<i>P-value</i>	<i>F crit</i>
Between Groups	1.442133	1	1.442133	1.907601	0.197311	4.964591
Within Groups	7.559933	10	0.755993			
Total	9.002067	11				

8.2 The comparison of Post Wash log₁₀ recovered bacteria between test products was evaluated using analysis of variance techniques. The log₁₀ average counts were used. **Significantly fewer bacteria were recovered on the hand following a single wash treatment with Product B as compared to Product A.** (p=<0.0001)

Anova: Single Factor

SUMMARY

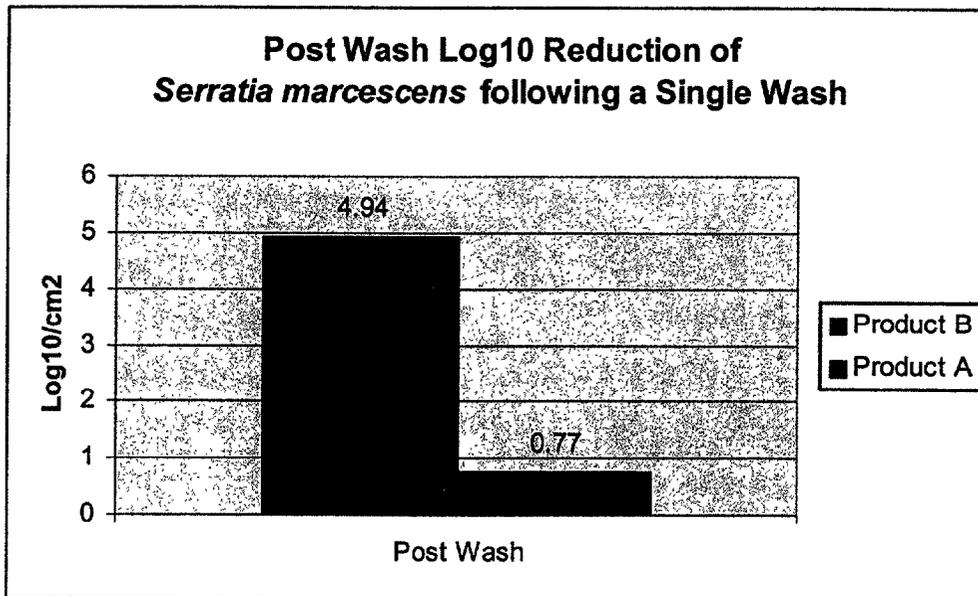
<i>Groups</i>	<i>Count</i>	<i>Sum</i>	<i>Average</i>	<i>Variance</i>
Product B	6	10.04	1.673333	1.049507
Product A	6	30.95	5.158333	0.246497

ANOVA

<i>Source of Variation</i>	<i>SS</i>	<i>df</i>	<i>MS</i>	<i>F</i>	<i>P-value</i>	<i>F crit</i>
Between Groups	36.43567	1	36.43567	56.22775	0.00002	4.964591
Within Groups	6.480017	10	0.648002			
Total	42.91569	11				

8.3 In addition to evaluating the differences in bacteria recovered, the following data show the comparison of average **log₁₀ reduction** of bacteria (the number of logs reduced from baseline) following a single wash treatment between Products B and A.

CRL Code	n	Baseline	Post Wash 1
B	6	6.62	4.94
A	6	5.93	0.77



8.4 The comparison of Post Wash log₁₀ reduction of bacteria between test products was evaluated using analysis of variance techniques. The log₁₀ average counts were used. **Significantly greater reduction of bacteria following a single wash treatment with Product B as compared to Product A. (p=<0.0001)**

8.4 (Cont.)

ANOVA: Single Factor

SUMMARY

Groups	Count	Sum	Average	Variance
Product B	6	29.68	4.946667	1.049507
Product A	6	4.63	0.771667	0.246497

ANOVA

Source of Variation	SS	df	MS	F	P-value	F crit
Between Groups	52.29188	1	52.29188	80.69713	0.000004	4.964591
Within Groups	6.480017	10	0.648002			
Total	58.77189	11				

8.5 The comparison of Transfer log₁₀ recovered bacteria between test products was evaluated using analysis of variance techniques. The log₁₀ average counts were used. **Significantly fewer bacteria were transferred to the uninoculated hand following a single wash treatment with Product B as compared to Product A. (p=<0.0001)**

ANOVA: Single Factor

SUMMARY

Groups	Count	Sum	Average	Variance
Product B	6	6.39	1.065	0.16335
Product A	6	22.16	3.693333	0.493907

ANOVA

Source of Variation	SS	df	MS	F	P-value	F crit
Between Groups	20.72441	1	20.72441	63.06336	0.00001	4.964591
Within Groups	3.286283	10	0.328628			
Total	24.01069	11				

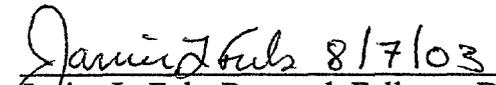
9.0 Conclusions

This study demonstrates a significant benefit from the use of antimicrobial hand soap as compared to non-medicated liquid hand soap. Following a 20 second wash of a hand inoculated with *Serratia marcescens*, Product B, antimicrobial foaming handsoap, significantly reduced the amount of bacteria on the hand. This reduced level of bacteria translated into significantly fewer bacteria being transferred to an uninoculated hand.

The data show that there are significantly higher levels of bacteria that remain on the hand washed with Product A 5.16 log₁₀ average bacteria (non-medicated) vs. Product B 1.67 log₁₀ average bacteria (Antimicrobial). This resulted in a 1.07 log₁₀ average bacteria found on the uninoculated hand after washing with Product B compared with 3.69 log₁₀ average bacteria found on the uninoculated hand after washing with Product A.

This study clearly shows a significant difference in the efficacy and potential spread of bacteria between antimicrobial soap and non-medicated soap and the data warrants additional work to evaluate the benefits of antimicrobial soap.

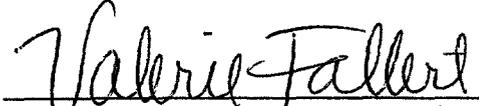
10.0 SIGNATURE


Janice L. Fuls, Research Fellow. Date
Sub-Investigator

11.0 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:

 August 7, 2003
Hill Top Quality Assurance Auditor Date

CRL Ref. No.: 03-121608-123

APPENDIX I

Total number of pages = 34

Protocol

D00316

2-1

**EVALUATION OF THE EFFICACY OF ANTIMICROBIAL
HANDWASHES TO REDUCE THE HAND-TO-HAND TRANSFER
OF A MARKER ORGANISM**

**A Study to Determine the Efficiency of Hand-to-Hand Transfer of
*Serratia marcescens***

FOR: The Dial Corporation

CRL Ref. NO.: 03-121608-123

2-1

TABLE OF CONTENTS

1.0 INTRODUCTION..... 1

2.0 OBJECTIVE..... 1

3.0 STUDY SPONSOR AND MONITOR 1

4.0 INVESTIGATIVE ORGANIZATION AND PERSONNEL 2

5.0 CLINICAL RESEARCH STANDARDS 2

6.0 EXPERIMENTAL DESIGN..... 2

7.0 STUDY MATERIAL 3

 7.1 Test Article 3

 7.2 Equipment..... 3

 7.3 Reagents and Materials..... 3

 7.4 Test Microorganism..... 4

8.0 STUDY POPULATION 4

 8.1 Subject Inclusion Criteria 4

 8.2 Subject Exclusion Criteria..... 5

 8.3 Other Study Restrictions..... 5

9.0 SUBJECT WITHDRAWAL 5

10.0 STUDY SCHEDULE 6

 10.1 Subject Qualification and Enrollment 6

 10.2 Washout Period 6

 10.3 Test Day Schedule 6

11.0 PROCEDURE 7

 11.1 Pre-Wash Baseline Microbial Population Determination..... 7

 11.2 Post-Wash Microbial Population Determination..... 8

 11.3 Bacterial Transfer Determination 8

 11.4 Hand Sampling Procedure; Cup Scrub 9

 11.5 Bacterial Counts of Sampling Solution 10

 11.6 Marker Organism and Preparation 10

12.0 DATA EVALUATION 11

13.0 ADVERSE EXPERIENCES 11

 13.1 Definitions 11

 13.2 Follow-up 12

 13.3 Notification..... 12

14.0 INTERCURRENT ILLNESS REPORTING 12

15.0 CONCOMITANT MEDICATION 12

16.0 DEVIATIONS FROM PROTOCOL 12

17.0 REPORT..... 13

18.0 NOTICE 13

19.0 PROTOCOL APPROVAL..... 14

EXHIBITS

- Exhibit A: Sample Consent Form
- Exhibit B: Subject Instructions - Handwash Study
- Exhibit C: Subject Instructions Following Study Completion

DATA COLLECTION FORMS

- 1 Demographics/Dermatological/Medical History Form
- 2 Inclusion/Exclusion Form
- 3 Intercurrent Illness/Concomitant Medication Form
- 4 Bacterial Counts
- 5 Adverse Event Report
- 6 Follow up Visit

SOURCE DOCUMENT 1

1.0 INTRODUCTION

The method used for determining the effectiveness of handwashing treatments to reduce transient microbial flora using marker organisms (Standard Method for Evaluation of Health Care Personnel Handwash Formulation ASTM E1174) is well known. The effectiveness of these treatments at reducing the transfer of organisms from one hand to another or from one person to another has not been extensively studied, nor is there a standard method for such an evaluation. A method has been proposed to evaluate the effectiveness of antimicrobial handwash treatments which compares the number of contaminants, *Serratia marcescens*, transferred hand to hand following a wash with a non-antimicrobial soap to the number transferred hand to hand following a wash with an antimicrobial soap. It is assumed that non-antimicrobial soap wash will allow transfer of a high number of bacteria, a level sufficient to measure the difference between the transfer rate from a non-antimicrobial soap washed hands to the transfer rate from an antimicrobial soap washed hand.

2.0 OBJECTIVE

The primary purpose of this study is to determine if the number of marker organisms, *S. marcescens*, transferred from a contaminated hand washed with a non-antimicrobial soap to an uncontaminated hand is sufficient to allow comparative differentiation.

3.0 STUDY SPONSOR AND MONITOR

The Dial Corporation
15101 N. Scottsdale Rd.
Scottsdale, Arizona 85254

(480)754-6163 phone
(480)754-6180 fax

W 11-2-4
2-4

CRL Ref. No.: 03-121608-123
2-4

4.0 INVESTIGATIVE ORGANIZATION AND PERSONNEL

Investigator: Harold Saferstein, M.D.

Sub-Investigators: Janice Fuls

Medical Consultant: Harold Saferstein, M.D.

5.0 CLINICAL RESEARCH STANDARDS

The clinical investigation, including the informed consent, will be reviewed by an Institutional Review Board (IRB) in accordance with Title 21 of the Code of Federal Regulations, Parts 50 and 56. Written approval by the Board must be obtained prior to the initiation of the study. The IRB letter of approval will be kept on file at the Sponsor Site. An original signed copy for each subject participating in the study will be retained in the Sponsor's study file. Each subject will receive a signed copy.

6.0 EXPERIMENTAL DESIGN

The study will consist of a one week pretest conditioning period and one day of treatment. During the one (1) day test, twelve (12) subjects will be used, six (6) for each test product.

This will be a study utilizing a direct paired comparison test design of the population of bacteria on an inoculated washed hand to the number of organisms recovered from the opposing uninoculated hand after it has contacted the inoculated hand.

7.0 STUDY MATERIAL

7.1 Test Article

CRL Code	Sponsor Code and Description
A	Bland non-antimicrobial handwash.
B	Antimicrobial Foaming handsoap

7.2 Equipment

- 7.2.1 Colony Counter - Quebec colony counter.
- 7.2.2 Incubator - Any incubator capable of maintaining a temperature of $25 \pm 2^\circ\text{C}$ may be used.
- 7.2.3 Sterilizer - Any suitable steam sterilizer capable of producing the conditions of sterilization.
- 7.2.4 Timer (stop-clock) - One that can be read for hours, minutes and seconds.
- 7.2.5 Scrub Cups - Sterile glass cylinders with glass rod handles, height approximately 2.5 cm, inside diameter of convenient size. Useful ranges from approximately 1.5 to 4.0 cm.
- 7.2.6 Polished glass rod or hockey stick
- 7.2.7 Bacteriological Pipettes, Sterile - 10.0 mL, 5.0 mL, 2.0 mL and 1.0 mL capacity.
- 7.2.8 Water Dilution Bottles - Any container that can be sterilized, having a 150 to 200 mL capacity and a tight closure may be used.
- 7.2.9 Test Tubes and Closures - Any of suitable size.
- 7.2.10 Handwashing Sink - A sink of sufficient size to permit subjects to wash without touching hands to sink surface or other subjects.
- 7.2.11 Water faucets - located above the sink at a height, which permits the hands to be held higher than the elbow during the washing procedure.
- 7.2.12 Tap Water Temperature Regulator and Temperature Monitor - To monitor and regulate water temperature of $40 \pm 2^\circ\text{C}$.
- 7.2.13 Erlenmeyer Flask - 2 L capacity for culturing test organism.
- 7.2.14 RODaC Plate

7.3 Reagents and Materials

- 7.3.1 Kit Products for Washout Period: non-antimicrobial bar soap and shampoo, solid or roll on antiperspirant/deodorant, rubber gloves, and disposable poly gloves.
- 7.3.2 Bland soap Johnson's® baby wash *head-to-toe*.
- 7.3.3 Stripping Fluid - 0.075M phosphate buffer with 0.1% Triton X-100 (dissolve 0.41 g KH_2PO_4 , 10.3 g Na_2HPO_4 and 1.0 g Triton X-100 in 1-L purified water. Final pH 7.8 ± 0.1 . Final volume 75 ± 1.0 mL).
- 7.3.4 Dilution Fluid - Butterfield's phosphate buffered water (or other suitable diluent).
- 7.3.5 Plating Medium - Soybean casein digest agar (USP) or equivalent.
- 7.3.6 Soybean casein digest broth (USP) or equivalent.

VJ 12/11/03 2-6

CRL Ref. No.: 03-121608-123

2-6

7.0 STUDY MATERIAL (CONT.)

7.4 Test Microorganism

Serratia marcescens, ATCC 14756 is to be used as a marker organism.

8.0 STUDY POPULATION

An adequate number of potential subjects will be enrolled into the pre-test conditioning period in order to provide 12 subjects who fulfill the criteria described below and who complete the study. Subject eligibility will be based upon information provided in the Demographics/Dermatological/ Medical History Form (DCF 1) and the Inclusion/Exclusion Form (DCF 2); and completion of a written informed consent (Exhibit A).

8.1 Subject Inclusion Criteria

Subjects will be eligible for enrollment if they:

- 8.1.1 Are a male or female, 18 through 65 years old;
- 8.1.2 Have signed a written informed consent (Exhibit A);
- 8.1.3 Are in good health, as evidenced by response to the Demographics/Dermatological/ Medical History Form (DCF 1);
- 8.1.4 Have hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders;
- 8.1.5 Have fingernails that are clean and extend no longer than approximately one (1) mm past the nail bed;
- 8.1.6 Are willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and hand washing during the entire study;
- 8.1.7 Are willing to refrain from using anti-dandruff shampoo during the entire study;
- 8.1.8 Are willing to refrain from using medicated/antibacterial lotions and creams during the entire study, unless prescribed by a physician for an intercurrent illness;
- 8.1.9 Are willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness;
- 8.1.10 Are willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness; and
- 8.1.11 Are willing to comply with all study protocol requirements.

2-7

u-1410-u
2-7

8.0 STUDY POPULATION (CONT.)

8.2 Subject Exclusion Criteria

Subjects will not be enrolled in the study if they:

- 8.2.1 Are currently participating in another clinical study at this or any other facility;
- 8.2.2 Have participated in any type of arm or hand wash study within the past seven (7) days;
- 8.2.3 Have cuts, scratches, or other skin disorders on their hands or wrists;
- 8.2.4 Have known latex, soap, detergent, antibiotic and/or perfume allergies;
- 8.2.5 Have eczema or psoriasis on their hands or wrists;
- 8.2.6 Are currently pregnant;
- 8.2.7 Are currently lactating;
- 8.2.8 Have been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, any auto-immune disorder such as AIDS (or HIV positive) Lupus erythematosus, thyroiditis, rheumatoid arthritis; and/or
- 8.2.9 Have any other medical condition, which in the opinion of the Investigator(s) would preclude participation.
- 8.2.10 Have artificial nails or nail tips.
- 8.2.11 Have any responsibility for care of children under age 3 or anyone having responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
- 8.2.12 Are currently using (on the test day) or have used since the kit pick-up any topical or systemic antibiotics, topical steroids or medicated/antibacterial lotions or creams.
- 8.2.13 Had an organ transplant

8.3 Other Study Restrictions

- 8.3.1 Subjects should not use any other personal cleansing products.
- 8.3.2 Subjects should avoid chemically treated pools and hot tubs.
- 8.3.3 Subjects should avoid exposing their hands to harsh cleaning products, chlorine, or solvents.

9.0 SUBJECT WITHDRAWAL

After admission to the study, the subject may withdraw at any time for any reason. If possible, the reason for withdrawal will be recorded.

W 1214208
2-8

CRL Ref. No.: 03-121608-123

10.0 STUDY SCHEDULE

The study will be divided into three periods; subject enrollment period, a pre-test washout (conditioning) period of at least one week duration, and a one day test period.

10.1 Subject Qualification and Enrollment

Prospective subjects will visit the test facility to be screened for their eligibility to participate in the study. Eligibility will be based upon information provided in the Demographics/Dermatological/ Medical History Form (DCF 1) and the Inclusion/Exclusion Form (DCF 2); and completion of a written informed consent (Exhibit A). Qualified subjects will be given non-antibacterial containing soap, shampoo, solid-antiperspirant/deodorant, several pairs of disposable poly gloves, a pair of rubber gloves, a copy of the Subject's Study Instructions (Exhibit B). They will be instructed to use the soap, shampoo, antiperspirant/deodorant, poly gloves and rubber gloves and to follow the written instructions for the entire study period.

10.2 Washout Period

This period will last at least seven (7) days. Subjects will continue to follow the special study restrictions, use the non-antibacterial soap, shampoo, and antiperspirant/deodorant, rubber gloves and poly gloves.

10.3 Test Day Schedule

10.3.1 Screen Procedure

On the day of the test period, subjects will return to the test facility. Their hands and wrists will be re-examined to ensure that they are still free of cuts, lesions, and other skin disorders. They will also be asked if they have had any illnesses or taken any medications (proprietary or prescribed) ordered by a physician since the last visit (DCF 3). Subjects who still meet the study criteria will be eligible to continue on the study. Subjects continuing on the study will be assigned a permanent subject number.

10.3.2 Test Phases

The test is divided into three phases; pre-wash baseline microbial population determination; post-wash microbial population determination; bacterial transfer determination.

10.3.2.1 Pre-Wash Baseline Determination

An area of the palm of a subjects hand is contaminated with a suspension of *S. marcescens* containing 10^8 - 10^9 CFU/mL, allowed to dry, and then sampled using the scrub-cup technique to determine the baseline contamination level that will be used to calculate handwash efficacy. The hand is then decontaminated using 70% alcohol.

April 11, 2003
Page 6 of 14

D00324

U-121100 102-0

24

10.0 STUDY SCHEDULE (CONT.)

10.3.2.2 Post-Wash Population Determination

An area of the palm of the same hand of the subject is again contaminated with a suspension of *S. marcescens* containing 10^8 - 10^9 CFU/mL and allowed to dry. A laboratory technician then washes the single hand for a specified period of time, rinsed, and sampled as for the pre-wash determination. The hand is then decontaminated using alcohol. The comparison of the bacterial population from this hand to the population of the unwashed contaminated hand (see Pre Wash Baseline Determination 10.3.2.1) determines the effectiveness of the wash treatment in reducing the number of bacteria on the hand.

10.3.2.3 Bacterial Transfer Determination

An area of the palm of subject's same hand is contaminated with a suspension of *S. marcescens* containing 10^8 - 10^9 CFU/mL and allowed to dry. The single hand is then washed by a laboratory technician for a specified period of time, rinsed and allowed to dry. The subject then rubs the contaminated washed hand against their other clean uncontaminated un-washed hand for a specified period of time. The transfer hand is then sampled to determine the number of organisms that have been transferred from the contaminated, washed hand. The comparison of the bacterial population from this "transfer hand" to the population of the contaminated washed hand (see Post Wash Determination 10.3.2.2) determines the effectiveness of the treatment in reducing the transfer of bacteria one hand to the other.

11.0 PROCEDURE

11.1 Pre-Wash Baseline Microbial Population Determination

11.1.1 Subjects wash their hands for 20 seconds with bland soap (7.3.2) and rinse for 10 seconds with warm water ($40^{\circ}\text{C} \pm 2^{\circ}\text{C}$). The hands are dried with paper towels.

11.1.2 The subjects sanitize their hands with 70% isopropanol for 30 seconds and then allow them to air-dry for at least one minute.

11.1.3 Using a template, a 1½ inch square area on the palm of the designated "test hand" is delineated with a marking pen.

11.1.4 A 0.1mL aliquot of the *S. marcescens* suspension is dispensed onto the delineated area and evenly spread with a sterile glass rod or hockey stick.

11.1.5 The inoculated area is allowed to air dry for five minutes.

11.1.6 After drying the "test hand" is sampled.

05-12-1000 ~ 2-10

11.0 PROCEDURE (CONT.)

- 11.1.7 Each subject's "test hand" is sampled according to the procedures in Section 11.4 Hand Sampling Procedure.
- 11.1.8 After sampling is completed, decontaminate the palm of the hand area with 70% isopropanol for 30 seconds and air-dry for at least one minute.
- 11.1.9 Proceed with dilution and plating of the sample using dilution fluid (Section 7.3.4).

11.2 Post-Wash Microbial Population Determination

- 11.2.1 Using a template, delineate a 1½-inch square area on the palm of the "test hand" with a marking pen.
- 11.2.2 Dispense a 0.1 mL aliquot of the *S. marcescens* suspension onto the delineated area and evenly spread the inoculum with a sterile polished glass rod or hockey stick.
- 11.2.3 Allow the inoculated area to air dry for five minutes.
- 11.2.4 With a moistened gloved hand a laboratory technician washes the inoculated "test hand" for 20 ± 2 seconds with a predetermined amount of designated test material. Rinse the hand for 10 seconds and gently allow to air dry for one minute.
- 11.2.5 Sample the "test hand" after drying.
- 11.2.6 Sample each subject's "test hand" according to the hand sampling procedure listed in Section 11.4.
- 11.2.7 Disinfect the palm of the hand with 70% isopropanol for 30 seconds and air-dry.
- 11.2.8 Proceed with dilution plating of the sample using dilution fluid (Section 7.3.4).

11.3 Bacterial Transfer Determination

- 11.3.1 Using a template, delineate a 1½-inch square area on the palm of the "test hand" with a marking pen.
- 11.3.2 Dispense a 0.1 mL aliquot of the *S. marcescens* suspension onto the delineated area and evenly spread the inoculum with a sterile glass rod or hockey stick.
- 11.3.3 Allow the inoculated area to air dry for five minutes.
- 11.3.4 With a moistened gloved hand a laboratory technician will wash the inoculated "test hand" for 20 ± 2 seconds with a predetermined amount of the test material. Rinse the hand for 10 seconds and allow it to air dry.
- 11.3.5 Place the palm of the inoculated, washed "test hand" against the palm of the uninoculated hand "transfer hand". Rub the palms back and forth in a typical hand wash motion for 20 ± 2 seconds.

11.0 PROCEDURE (CONT.)

- 11.3.6 Sample each subject's "transfer hand" according to the procedures in Hand Sampling Procedures (Section 11.4).
- 11.3.7 Sample each subject's "test hand" with a RODaC plate
- 11.3.8 After all sampling is completed, wash the hands with soap and then decontaminate the hands with 70% isopropanol for 30 seconds and allow to air-dry.
- 11.3.8 Proceed with dilution plating of the samples using dilution fluid (Section 7.3.4).
- 11.3.9 Conduct a final control count on the test suspension of *S. marcescens*.

11.4 Hand Sampling Procedure; Cup Scrub Procedure

- 11.4.1 Place a sterile glass scrub cup on the designated sampling area of the "test hand". The technician will press the cup firmly against the skin surface during the sampling procedure to prevent leakage of the sampling fluid.
- 11.4.2 Pipette 2.0 mL of the stripping fluid (Section 7.3.3) into the cup.
- 11.4.3 Scrub the area in the cup with moderate pressure for 60 ± 6 seconds using a sterile polished glass rod.
- 11.4.4 Remove the sampling fluid with a sterile pipette and transfer the fluid to a sterile sample tube.
- 11.4.5 Repeat steps 11.4.1.2 through 11.4.1.4 and pool the samples. NOTE: The same pipettes, cup and glass rod can be used for both washes of a single site.

Label all collected samples with an Investigator derived code to assure that the individuals who prepare the plates and count the colonies are unaware of the sources of the sampling solution.

11.0 PROCEDURE (CONT.)

11.5 Bacterial Counts of Sampling Solution

- 11.5.1 Pour plate in duplicate aliquots of the sampling fluid or dilutions of the fluid on soybean casein digest agar plates (Section 7.3.5)
- 11.5.2 Plate dilutions of the samples representing dilutions of 10^{-1} through 10^{-6} of milliliter aliquots of the sample fluid.
- 11.5.3 Incubate the prepared plates for 48 ± 4 hours at $25 \pm 2^{\circ}\text{C}$. Use standard plate counting procedures to count only red pigmented colonies. Record all plate counts on DCF 4.

11.6 Marker Organism and Preparation

Use *S. marcescens*, ATCC 14756 to challenge the efficacy of the test materials.

- 11.6.1 Prepare a stock culture of *S. marcescens*, ATCC 14756 by aseptically transferring at least three isolated colonies from an agar plate to 10 mL of sterile soybean casein digest broth (SCDB) (Section 7.3.6) and incubate at $25 \pm 2^{\circ}\text{C}$ for 24 ± 4 hours. Make a series of at least three but no more than ten 24-hour broth transfers in 10 mL volumes from this broth culture. If testing occurs on multiple days, it is desirable to use a test culture with the same number of transfers from the source.
- 11.6.2 Inoculate a 250mL flask containing 100-mL of SCDB with 0.1 mL of a 24-hour broth transfer. Incubate the flask for 24 ± 4 hours at $25 \pm 2^{\circ}\text{C}$. Stir or shake the suspension prior to any withdrawal of culture, whether for hand contamination or for numbers assay. Do not use a suspension for more than eight hours.
- 11.6.3 Assay the suspension for the number of organisms at the beginning and end of the use period.

2-13

CRL Ref. No.: 03-121608-123

2-13

12.0 DATA EVALUATION

The number of colony forming units (CFU) recovered per sample dilution will be tabulated. The total number of CFU per mL of sampling solution will be calculated.

- a) Counts obtained from samples collected using the Cup Scrub Method will be expressed as CFU per cm².

The data will be tabulated and descriptive statistics shown. Additionally the following will be calculated.

- a) Pre-wash baseline microbial population on the inoculated hand.
- b) Post-wash microbial population on the inoculated hand.
- c) Number of bacteria transferred from inoculated washed hand to uninoculated hand.

13.0 ADVERSE EXPERIENCES

13.1 Definitions

An **Adverse Event/Experience** is any unexpected or undesirable experience occurring to a subject during a study, which may or may not be related to the test article. All adverse event/experiences will be recorded (Data Collection Form 5) and reported according to the Standard Operating Procedures of Hill Top Research, Inc.

A **Serious Adverse Drug Event/Experience** is any adverse drug experience occurring at any dose that results in any of the following outcomes:

- death;
- a life-threatening adverse drug experience;
- inpatient hospitalization or prolongation of existing hospitalization;
- a persistent or significant disability/incapacity;
- a congenital anomaly/birth defect

Important medical event/experiences that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse drug experience when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

An **Unexpected Adverse Drug Event/Experience** is any adverse drug event/experience not listed in the current labeling for the test article or the current investigator's brochure

CRL Ref. No.: 03-121608-123
2-14

13.0 ADVERSE EXPERIENCES (CONT.)

13.2 Follow-up

If an **Adverse Event/Experience** occurs, the subject under the direction of the Investigator (or designee), may be referred to Hill Top's consultant physician for treatment.

Serious or Unexpected Drug Event/Experience will be followed to resolution to the extent possible (e.g., medical attention by subject's primary care physician).

13.3 Notification

The sponsor will be notified of all adverse event/experiences. Any **Serious or Unexpected Adverse Drug Event/Experience** which occurs during the study must be reported promptly by the investigator to the sponsor and the reviewing IRB, where applicable, within 24-hours of the information being reported to Hill Top Research, Inc.

14.0 INTERCURRENT ILLNESS REPORTING

If a subject reports that he/she has had an intercurrent illness during the wash-out period or during the one (1) day test period, the illness and any new medication taken will be documented on DCF 3. The subject may be discontinued from the study at the discretion of the Investigator(s).

15.0 CONCOMITANT MEDICATION

If the subject has taken any medication (proprietary or prescribed) ordered by a physician, information pertaining to that medication intake will be recorded appropriately on either DCF 3 or DCF 5.

16.0 DEVIATIONS FROM PROTOCOL

Any deviation from the protocol, not previously agreed to by the Sponsor and Investigator(s), that occur during the conduct of the study will be documented.

CRL Ref. No.: 03-121608-123
2-15

17.0 REPORT

The final report will summarize the method, data and conclusions relative to the test articles and the subjects. Source data will be retained by the testing facility. The original source data will be maintained according to the investigator's standard operating procedure. Copies of transcribed data will be incorporated in the report.

18.0 NOTICE

No amendments to the protocol will be permitted without approval from the Study Sponsor, Investigator and where applicable, the Institutional Review Board. Such changes will be documented in writing. Approval by the Board must be obtained prior to initiation of the amendment.

03-121608-123
2-16

CRL Ref. No.: 03-121608-123
2-16

19.0 PROTOCOL APPROVAL

HILL TOP RESEARCH, INC.

By: Harold L. Saferstein 4/18/03
Harold Saferstein, M.D. (Date)
Investigator

By: Janice Fuls 4/18/03
Janice Fuls (Date)
Sub-Investigator

The Dial Corporation

By: George Fischler 18 April 2003
George Fischler (Date)

EXHIBIT A

SAMPLE CONSENT FORM

CONDITIONING PERIOD FOR ANTIMICROBIAL HAND WASHING STUDIES

You will be issued Dove Bar Soap, Ban unscented anti-perspirant/deodorant, and Johnson's baby shampoo today, to be used in place of the products you regularly use in these categories. You will also be issued latex gloves and poly gloves to use if your hands will come into contact with detergents, harsh soaps or chemicals.

This conditioning period is required for you to be eligible for a Hand Wash study. It does not guarantee you will qualify for a study. If you do not qualify for a Hand Wash study, there will not be any payment.

The Dove Bar Soap, Ban anti-perspirant/deodorant, and Johnson's baby shampoo are marketed products and should not produce irritation. If any irritation or discomfort does occur, ask any staff member to arrange a meeting for you with the appropriate personnel to determine if it is product related. During business hours (M-F, 8 am - 4:30 pm), call Chris at 480-754-6438. Evenings and weekends, call Laura at 602-677-2610.

You will be scheduled for an appointment to return to the test facility. We require you to avoid moisturizers during the conditioning period. Also do not take antibiotics. If antibiotics are necessary, please notify Hill Top Research at the phone number above.

I have read all the above information and was given an opportunity to ask questions about any part of my participation in the conditioning period. Answers to such questions (if any) were satisfactory. I am eighteen years of age or older and freely and without reservation agree to use the Dove Bar Soap, Ban unscented anti-perspirant/deodorant, and Johnson's baby shampoo provided. I have received a copy of this form and a bar of Dove bar soap, Ban unscented anti-perspirant/deodorant, and Johnson's baby shampoo, 1 pair of latex gloves and several pair of light weight poly gloves.

Subject Signature

Date

Witnessed By _____

Date _____

CONDITIONING PERIOD FOR ANTIMICROBIAL HAND WASHING STUDIES

You will be issued Dove Bar Soap, Ban unscented anti-perspirant/deodorant, and Johnson's baby shampoo today, to be used in place of the products you regularly use in these categories. You will also be issued latex gloves and poly gloves to use if your hands will come into contact with detergents, harsh soaps or chemicals.

This conditioning period is required for you to be eligible for a Hand Wash study. It does not guarantee you will qualify for a study. If you do not qualify for a Hand Wash study, there will not be any payment.

The Dove Bar Soap, Ban anti-perspirant/deodorant, and Johnson's baby shampoo are marketed products and should not produce irritation. If any irritation or discomfort does occur, ask any staff member to arrange a meeting for you with the appropriate personnel to determine if it is product related. During business hours (M-F, 8 am - 4:30 pm), call Chris at 480-754-6438. Evenings and weekends, call Laura at 602-677-2610.

You will be scheduled for an appointment to return to the test facility. We require you to avoid moisturizers during the conditioning period. Also do not take antibiotics. If antibiotics are necessary, please notify Hill Top Research at the phone number above.

I have read all the above information and was given an opportunity to ask questions about any part of my participation in the conditioning period. Answers to such questions (if any) were satisfactory. I am eighteen years of age or older and freely and without reservation agree to use the Dove Bar Soap, Ban unscented anti-perspirant/deodorant, and Johnson's baby shampoo provided. I have received a copy of this form and a bar of Dove bar soap, Ban unscented anti-perspirant/deodorant, and Johnson's baby shampoo, 1 pair of latex gloves and several pair of light weight poly gloves.

Appointment date and time: _____

**IRB of
Hill Top Research
APR 15 2003
Approved**

D00335

Institution: Clinical Research Lab
Investigator: Harold Saferstein, M.D.

CRL Ref. No.: 03-121608-123

Page No. 2-21

Study Title: "Evaluation of the Efficacy of Antimicrobial Handwashes to Reduce the Hand-to-Hand Transfer of a Marker Organism"

CONSENT FORM

INTRODUCTION: You are being asked to take part in a research study. Before you give your consent to be a subject, it is important that you take enough time to read and understand what your participation would involve. In preparing this consent form, it has been necessary to use some technical language. Please ask questions if there is anything you do not understand.

You will be given a signed copy of this consent form and any other necessary written information prior to the start of the study.

PURPOSE: The purpose of this research study is to determine the number of marker bacteria transferred from a contaminated hand washed with a non-antibacterial soap to an uncontaminated hand. Approximately twelve (12) people between and including the ages of 18 - 65 will be screened as potential subjects in this study. At least twelve (12) subjects are expected to complete the three-visit study.

TEST ARTICLES: You will be assigned a marketed soap product.

STUDY PROCEDURES: Prior to enrollment in the test, you will be asked to complete a brief medical history questionnaire. It is possible that you may not be able to participate based on your answers to these questions. If you qualify, you will be given a kit containing non-antibacterial bar soap, shampoo, antiperspirant/deodorant and gloves to be used at least one week prior to the start of the actual study. You will be given written instructions on which antibacterial/antimicrobial products to avoid using during this study.

After about one week, you will be required to return to the lab. You will be asked to complete another brief medical history questionnaire. The skin on your hands will also be checked for visible cuts, scratches or rashes on them. It is possible that you may not be able to participate based on your answers to these questions or the condition of the skin on your hands.

If you are selected to participate in this study, your hands will be washed with a soap, rinsed with tap water and dried with paper towels. Then, your hands will be rinsed with alcohol and air dried about 1 minute. A 1½ inch square is marked on the palm of one of your hands with a permanent marker.

**IRB of
Hill Top Research
APR 21 2003
A p p r o v e d**

D00336

A small droplet of watery liquid containing bacteria (*Serratia marcescens*) will be spread on the marked site. The liquid on your hand will air dry for at least 5 minutes. This hand will be sampled by a laboratory technician who will wash the hand with a mild soap like solution. The sampling method involves placing a glass cup on the palm of your hand, adding a defined volume of liquid and briefly massaging with a polished glass stick. The solution from the glass cup will be tested to determine the number of test bacteria added to the hand.

After sampling is completed, the palm of your hand will be treated with alcohol and air dried for about 1 minute. One of your hands will be marked as described above and a liquid containing bacteria is added and air dried. A technician will wash your hand with the test soap and allow it to air dry. Your hand will be sampled by the method above.

After sampling, the palm of your hand will be treated again with alcohol and air dried. Your hand will be marked and the bacteria is added and air dried. A technician will wash your hand with the test soap and allow it to air dry. The palms of both of your hands are rubbed together and the hand that was not washed will be sampled by the sampling method mentioned above. After the final sample is taken, your hands will be washed for approximately 60 seconds with an antibacterial soap and water, rinsed with alcohol and air dried.

After completing the test portion of the study and until your follow-up visit, you will need to check the skin on your hands each day for any pimples, bumps or rashes. Within 4-8 days after you have completed treatment, you will be required to return to the lab for a follow-up visit. The skin on your hands will be checked for infection by a Dermatologist trained in observing infection.

FEMALES OF CHILDBEARING POTENTIAL: You may not participate in this study if you are pregnant or nursing. As part of giving your consent you must agree to have a urine pregnancy test at the start of the study.

RISKS: The risks associated with this test are primarily related to infection with the test bacteria. For healthy persons, the possibility of a skin infection exists; however, this possibility is remote because, (1) test bacteria are applied only to healthy or uninjured skin, and (2) the skin is cleansed with antibacterial products following contact with the test bacteria. Your forearms may also show a "reaction." A "reaction" could be pimples, blisters or raised bumps surrounded by redness and/or swelling. It is unlikely, but possible, that a rash could develop.

IRB of
Hill Top Research
APR 21 2003
Approved
D00337

No risks to you as a study participant, other than those described above as "reactions," are anticipated during the study. Reactions are usually due to irritation, although an allergic reaction might occur. If you become allergic, it is possible that future exposures to the same ingredient may cause a skin reaction. If this occurs, you will be provided with information to minimize the chance for future exposures.

You may experience risks or side effects that are not known at this time. You will be informed in a timely manner if new information becomes available that may influence your willingness to continue in this study.

BENEFITS: You will not benefit from the applications of test product but the study results may allow a new or improved product to be marketed.

ALTERNATIVE PROCEDURES/TREATMENTS: Because you are not being treated for a medical condition, alternative treatments do not apply to this study.

CONFIDENTIALITY: Information concerning you that is obtained in connection with this study will be kept confidential by Hill Top Research, except that the sponsoring company whose product is being tested will receive a copy of the study records. The records will be coded to protect your identity. In addition, the sponsoring company, the Institutional Review Board (IRB) and government regulatory agencies, including the U.S. Food and Drug Administration (FDA), may inspect the records of the study. Information obtained in the study may be used for medical or scientific publication, but your identity will remain confidential.

MEDICAL TREATMENT: If in the course of this study you experience illness, discomfort or injury that appears to be a result of the study, Hill Top Research will provide you with medical care at no cost to you. Providing such medical care is not an admission of legal responsibility. If such illness, discomfort or injury does occur, ask any staff member to arrange a meeting for you with the appropriate personnel.

In certain cases of illness or injury resulting from this study, insurance benefits may be available.

WHO TO CONTACT: If you have any questions about this study or in case of an emergency, contact Chris, Study Coordinator at 480-754-6438 during business hours (M-F, 8:00 A.M. - 5:00 P.M.) or Laura, Study Manager at 602-677-2610 after hours. In addition, if you have any questions as to your rights as a research subject, contact the Institutional Review Board of Hill Top Research, Nancy J. Pelc, M.D., Chairman, at 1-800-669-1947.

IRB of
Hill Top Research
APR 21 2003
Approved
D00338

VOLUNTARY PARTICIPATION/WITHDRAWAL: Your participation in this research study is strictly voluntary. You may refuse to participate or may discontinue participation at any time during the study without penalty or loss of benefits to which you are otherwise entitled.

If you agree to participate in this study, you are also agreeing to provide Hill Top Research with accurate information and to follow study instructions as given to you. If you fail to follow the study instructions, your participation may be ended.

Your participation in the study may be discontinued at any time without your consent by the Investigator, the IRB, the FDA, or the sponsoring company.

COMPENSATION: You will be paid \$75.00 for the completion of this study. You will be compensated according to the following schedule:

If you do not qualify	Visit 1	You will receive	\$10.00 if eliminated
If you complete	Visit 1	You will receive	0*
If you do not qualify	Visit 2	You will receive	\$15.00
If you qualify but are eliminated as an extra subject	Visit 2	You will receive	\$20.00
If you complete	Visit 2	You will receive	\$50.00
If you complete	Visit 3	You will receive	\$75.00

* No payment-kit products given.

Payment will be made at the end of the study.

There are no anticipated expenses to you for participating in this study. All test related materials will be provided at no cost to you. (non-antibacterial bar soap, shampoo and antiperspirant/deodorant)

**IRB of
Hill Top Research**
APR 21 2003
Approved

000339

EXHIBIT B

SUBJECT INSTRUCTIONS

Today you will be given a kit of products (bar soap, shampoo, and deodorant/antiperspirant) to use exclusively during this study. Please set aside all products you normally use in these categories and use only the products in the kit. In addition, please refrain from using perfumes, deodorants or antiperspirants (other than the ones furnished), powders and anti-dandruff hair shampoos, and do not swim in a chemically treated pool or hot tub during the study.

Beginning today, no body lotions, medicated creams or ointments should be applied to any area of your skin. Also, do not take any antibiotics. These medications may affect the bacteria of the skin. If antibiotics are necessary due to illness, please report this to Hill Top Research at the phone number below.

Please use the rubber gloves provided with the product kit for all household chores involving detergents, acid, alkalis, and solvents until the completion of the study.

SUBJECT SCHEDULE

TEST DAY

Time of Visit: _____

1. Plan to arrive at the laboratory about 10 minutes before your scheduled time. You are expected to be prompt.
2. Please wear clothing that will allow easy access to your hands.
3. You will be required to remove all jewelry, watches, and bracelets before washing.
4. You will undergo a supervised wash regimen at the laboratory.
5. Approximate time at the laboratory - 4 hours.
6. Additional instructions will be provided for the Follow Up Visit.

FOLLOW UP VISIT

Time of Visit: _____

1. A Dermatologist will check your hands for infection
2. Approximate time at the lab - 1/2 hour.

If you have any questions regarding this study, please contact Chris, Study Coordinator, at 480-754-6438 between 8:00 a.m. - 5:00 p.m. or Laura, Study Manager, after hours and on weekends at 602-677-2610.

**IRB of
Hill Top Research
APR 21 2003
Approved
D00341**

EXHIBIT C

SUBJECT'S INSTRUCTIONS FOLLOWING STUDY COMPLETION

You have just completed participation in a clinical study, "A Pilot Study to Determine the Efficiency of Hand to Hand Transfer of *Serratia marcescens*". During this study, your hands were in contact with a liquid containing bacteria (*Serratia marcescens*). Although we do not expect you to have any adverse experience as a result of participation in this study, there is a possibility that an infection may develop on your hands.

To determine whether you have developed an infection from the test bacteria, we would like you to examine your hands and wrists daily. If you notice the appearance of any pimples, blisters or raised bumps surrounded by redness and/or swelling, please contact Chris, Study Coordinator at (480) 754-6438 during normal business hours (8:00 am- 5 pm) or Laura at (602) 677-2610 after hours.

You are required to return to the test site for a follow-up visit. Your follow-up is scheduled for:

Date

Time

Thank you for your cooperation.

**IRB of
Hill Top Research**

APR 21 2003

Approved

000710

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Subject Qualification	____/____/____ mm dd yy	____/____/____ F M L	Permanent #:	03-121608-123

Gender: <input type="checkbox"/> Male <input type="checkbox"/> Female	Age: _____ Years
---	------------------

Does the subject have any of the following at the treatment sites?

I. DERMATOLOGIC DISORDER	No	Yes	Don't Know
1. Psoriasis ?			
2. Eczema ?			
3. Skin Cancer ?			
4. Skin Allergies ? Please specify:			
5. Hives ?			

Does the Subject have any of the following (present and past)?

II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies.? Please specify.			
2. Hepatitis ?			
3. Heart and Vascular Disease?			
4. Liver Disease ?			
5. Kidney Disease ?			
6. Tuberculosis ?			
7. Diabetes ? Controlled? Diet [] Oral [] Insulin []			
8. Cancer ?			
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.) ?			
10. Organ transplant ?			
11. Any other condition not listed ? Please specify:			

Is the subject taking any medication? If yes, please specify below:

III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic ?			
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs ?			
3. Heart Medication ?			
4. Insulin ?			
5. Other ?			

Comments:

Based on the above medical history, the subject is: Qualified or Not qualified for the study.

Interviewer's Signature:	Date: ____/____/____ mm dd yy
--------------------------	----------------------------------

**Data Collection Form 2
INCLUSION / EXCLUSION FORM**

CRL Ref. No.: 03-121608-123
Page No.: 2-29

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Subject Qualification	___/___/___ mm dd yy	___/___/___ F M L	Permanent #:	03-121608-123

INCLUSION CRITERIA

Check one

YES NO Subject:

		1. Is 18 through 65 years ?
		2. Has signed informed consent ?
		3. Is healthy as evidenced by responses on DCF 1 ?
		4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders ?
		5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed ?
		6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study ?
		7. Is willing to refrain from using anti-dandruff shampoo during the entire study ?
		8. Is willing to refrain from using medicated/antibacterial lotions and creams during the entire study, unless prescribed by a physician for an intercurrent illness ?
		9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness ?
		10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness ?
		11. Is willing to comply with all study protocol requirements ?

EXCLUSION CRITERIA

Check one

YES NO N/A Subject:

			1. Is currently participating in another clinical study at this or any other facility ?
			2. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
			3. Has participated in any type of hand or arm wash study within the past 7 days ?
			4. Has cuts, lesions, or other skin disorders on their hands or wrists ?
			5. Has artificial nails or nail tips?
			6. Has soap, detergent, antibiotic and/or perfume allergies ?
			7. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	8. Is currently pregnant ? <input type="checkbox"/> Yes <input type="checkbox"/> No Of child-bearing potential: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Surgically Sterile, year _____ <input type="checkbox"/> Post-menopausal If of child bearing potential - β -HCG Test Results: <input type="checkbox"/> negative <input type="checkbox"/> positive
			9. Is currently lactating ?
			10. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, or auto-immune disease such as rheumatoid arthritis, Lupus erythematosus, thyroiditis, AIDS (or HIV positive) ?
			11. Has another medical condition which in the opinion of the Investigator would preclude participation ?
			12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?.

Based upon dermatologic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is:

Qualified **Not Qualified** for participation in this study.

Reasons for disqualification: _____ Interviewer's Initials/Date: _____ / _____

Investigator's Signature: _____	Date: ___/___/___ mm dd yy
---------------------------------	-------------------------------

D00344

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Test Period	____/____/____ mm dd yy	____/____/____ F M L	Permanent #:	03-121608-123

I. Is skin on subject's hands and wrists still free of dermatoses, cuts, lesions, and other skin disorders? Yes No
 If no, please indicate condition: _____

II. Has subject used non-antibacterial soap and followed the instructions in Appendix B? Yes No
 If no, please explain: _____

III. Is subject currently using or has used since the kit pick-up any topical or systemic antibiotics, topical steroids or medicated/antibacterial lotions or creams or taken any medication ordered by a physician.
 Yes No If yes, please explain: _____

IV. Has subject been ill since the last visit? Yes (Complete below) No

V. Has subject used any oral or topical medication? Yes (Complete below) No

Based upon the above responses, the subject is: Qualified Not Qualified to continue on the study.
 Reasons for disqualification: _____

TO BE COMPLETED IF SUBJECT HAS AN INTERCURRENT ILLNESS

Date of Onset: _____ Date Reported: _____ Date Resolved: _____

Describe condition: _____

Was reaction related to treatment? Not related Possibly related Definitely related Other (explain)

Action Taken: None Continued on study Withdrawn from the study Consulted physician
 Medication taken (Complete below) Hospitalized Other (explain)

Additional Comments: _____

CONCOMITANT MEDICATION

Medication (Oral or Systemic)	Total Daily Dose	Start Date Mm / dd / yy	Stop Date mm / dd / yy	Indication (Reason for Taking)
		/ /	/ /	
		/ /	/ /	
		/ /	/ /	

Comments:

Interviewer's Signature: _____ Date: ____/____/____
 mm dd yy

BACTERIAL COUNTS
CFU/mL of Sampling Solution

Date	Subject Initials	Subject Screen #	Study #
<u> </u> / <u> </u> / <u> </u> mm dd yy	<u> </u> / <u> </u> / <u> </u> F M L	Permanent #:	03-121608-123

BASELINE					
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻⁵	10 ⁻⁶
CFU/mL _____			Counted by : _____ / _____		

POST WASH					
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻⁵	10 ⁻⁶
CFU/mL _____			Counted by : _____ / _____		

TRANSFER					
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻⁵	10 ⁻⁶
CFU/mL _____			Counted by : _____ / _____		

Calculations by: _____ / _____ Raw data reviewed by _____ / _____
 Calculations Verified by: _____ / _____

*10⁻¹ dilution is the sum of 1.0 mL spread across 3 plates.
 TNTC – Too Numerous To Count
 Underlined values are used for calculation of CFU/mL

Investigator's Signature: _____	Date: _____ / _____ / _____ mm dd yy
---------------------------------	---

Data Collection Form 5A

Subject Initials _____ Subject # _____

Study No. 03-121608-123

Page No. 2-32

ADVERSE EVENTS

Symptom / Event	Onset Date	End Date	SAE ¹ Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
Entry Date	Comment/Note:							Initials

Symptom / Event	Onset Date	End Date	SAE ¹ Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
Entry Date	Comment/Note:							Initials

Symptom / Event	Onset Date	End Date	SAE ¹ Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
Entry Date	Comment/Note:							Initials

Note: Severity, Relationship and Outcome MUST be determined by principal investigator.

- Severity:** 1=Mild 2=Moderate 3=Severe
- Relationship:** 1=Definite 2=Probable 3=Possible 4=Unrelated
- Action Taken:** 1=None 2=Rx Therapy 3=Discontinued Study 4=Other (specify)
- Outcome:** 1=Resolved w/o sequelae 2=Resolved w/ sequelae (describe) 3=Ongoing 4=Death

¹Serious Adverse Event/Experience

FOLLOW-UP VISIT

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Follow-up Visit	<u> </u> / <u> </u> / <u> </u> mm dd yy	<u> </u> / <u> </u> / <u> </u> F M L	Permanent #:	03-121608-123

Date Subject Entered the Study: <u> </u> / <u> </u> / <u> </u> mm dd yy	Follow-Up Visit Date: <u> </u> / <u> </u> / <u> </u> mm dd yy
<p>Does the subject's hands have the presence of pimples, blisters, or raised itching bumps surrounded by erythema and/or edema that may be indicative of a skin infection?</p> <p><input type="checkbox"/> YES <input type="checkbox"/> NO If yes, complete below:</p> <p>Clinical Observations: (Include date of onset and descriptions/severity/locations, etc.)</p> <hr/> <hr/> <hr/> <p>Comments:</p> <hr/> <hr/> <hr/>	
<p>Has the subject had any health related issues since the treatment procedure?</p> <p><input type="checkbox"/> YES <input type="checkbox"/> NO If yes, complete below</p> <p>Comments:</p> <hr/> <hr/> <hr/>	

Medical Consultant's Signature:		Date <u> </u> / <u> </u> / <u> </u> mm dd yy
--	--	--

AUTHORIZATION FOR USE AND DISCLOSURE OF PERSONAL HEALTH INFORMATION

We are asking you to take part in a research study that was described in the informed consent. To do this research, the study staff will need to collect health information that identifies you.

Your personal health information includes, but is not limited to, information that was collected for your entry into the study and information collected during the study. The purpose of collecting this information is to allow *Hill Top Research, Inc.* study staff to conduct the study.

Study records that identify you will be kept confidential as required by law. Federal Privacy Regulations provide safeguards for privacy, security, and authorized access. Except when required by law, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier in study records disclosed outside *Hill Top Research, Inc.* For records disclosed outside of *Hill Top Research, Inc.*, we will use your initials and assign a unique code number to the information that is sent to the sponsor.

You may decide not to give permission for the release of your personal health information for the study. In that case, you will not be able to participate in the study.

Your permission to share your personal health information for this study does not have an expiration date. If you no longer want to share your personal health information, you may cancel your permission at any time by writing *Hill Top Research, Inc.* at the address below:

Hill Top Research @ Clinical Research Lab
% Laura Wilkes, Site Manager
15101 North Scottsdale Rd.
Scottsdale, AZ 85254

If you cancel your permission after you have started the study, *Hill Top Research, Inc.* will stop collecting your personal health information. Although they will stop collecting new information about you, they will need to use the information already collected to evaluate the study results. If you start the study, then cancel your permission, you will not be able to continue to participate in the study.

The sponsor and *Hill Top Research, Inc.* will make every reasonable effort to keep your personal health information private. Once the study staff shares your personal health information from the study, federal privacy laws may not keep the information private. There may be state laws or other federal laws that would protect the privacy of this information.

By signing this form, you authorize the use and disclosure of your personal health information for this research study. You will receive a copy of this form after you have signed it.

Name of Subject or Subject's Representative

Signature of Subject or Subject's Representative

Date

If signed by Representative, explain authority to act for Subject

CRL Ref. No.: 03-121608-123

APPENDIX II

Total number of pages = 11

IRB Approval Letter, Approved Consent Form and Subject Instructions

000351

INSTITUTIONAL REVIEW BOARD

OF

HILL TOP RESEARCH, INC.

Nancy J. Pelc, M.D., Chairman

April 21, 2003

Laura Wilkes
Dial Corporation
15101 N. Scottsdale Rd.
Scottsdale, AZ 85254

Ref: CRL No. 03-121608-123
Title: EVALUATION OF THE EFFICACY OF ANTIMICROBIAL
HANDWASHES TO REDUCE THE HAND-TO-HAND TRANSFER
OF A MARKER ORGANISM
Protocol Date: April 11, 2003
Sponsor: The Dial Corporation

Dear Ms. Wilkes:

The Institutional Review Board of Hill Top Research, Inc. has reviewed and approved the above referenced study by the expedited review procedure. Documents included in this review were: protocol, consent form, subject instructions and safety information. Approval of this study has been granted for one year from the date of this letter.

Please remember that the FDA requires you to receive approval from the IRB for any amendments or changes in the protocol or consent form and for any new advertisements. Serious and unexpected adverse experiences and unanticipated problems involving risk to subjects must be reported promptly to the IRB. If the study is expected to last beyond the one-year approval, you must request re-approval for continuation at least 30 days in advance of the expiration date.

The Institutional Review Board of Hill Top Research, Inc. is a duly constituted institutional review board under CFR, Title 21, Parts 50 and 56.

Sincerely,



Nancy J. Pelc, M.D.
Chairman

4-21-03

Date

NJP/sll

CONDITIONING PERIOD FOR ANTIMICROBIAL HAND WASHING STUDIES

You will be issued Dove Bar Soap, Ban unscented anti-perspirant/deodorant, and Johnson's baby shampoo today, to be used in place of the products you regularly use in these categories. You will also be issued latex gloves and poly gloves to use if your hands will come into contact with detergents, harsh soaps or chemicals.

This conditioning period is required for you to be eligible for a Hand Wash study. It does not guarantee you will qualify for a study. If you do not qualify for a Hand Wash study, there will not be any payment.

The Dove Bar Soap, Ban anti-perspirant/deodorant, and Johnson's baby shampoo are marketed products and should not produce irritation. If any irritation or discomfort does occur, ask any staff member to arrange a meeting for you with the appropriate personnel to determine if it is product related. During business hours (M-F, 8 am - 4:30 pm), call Chris at 480-754-6438. Evenings and weekends, call Laura at 602-677-2610.

You will be scheduled for an appointment to return to the test facility. We require you to avoid moisturizers during the conditioning period. Also do not take antibiotics. If antibiotics are necessary, please notify Hill Top Research at the phone number above.

I have read all the above information and was given an opportunity to ask questions about any part of my participation in the conditioning period. Answers to such questions (if any) were satisfactory. I am eighteen years of age or older and freely and without reservation agree to use the Dove Bar Soap, Ban unscented anti-perspirant/deodorant, and Johnson's baby shampoo provided. I have received a copy of this form and a bar of Dove bar soap, Ban unscented anti-perspirant/deodorant, and Johnson's baby shampoo, 1 pair of latex gloves and several pair of light weight poly gloves.

Subject Signature

Date

Witnessed By _____

Date _____

CONDITIONING PERIOD FOR ANTIMICROBIAL HAND WASHING STUDIES

You will be issued Dove Bar Soap, Ban unscented anti-perspirant/deodorant, and Johnson's baby shampoo today, to be used in place of the products you regularly use in these categories. You will also be issued latex gloves and poly gloves to use if your hands will come into contact with detergents, harsh soaps or chemicals.

This conditioning period is required for you to be eligible for a Hand Wash study. It does not guarantee you will qualify for a study. If you do not qualify for a Hand Wash study, there will not be any payment.

The Dove Bar Soap, Ban anti-perspirant/deodorant, and Johnson's baby shampoo are marketed products and should not produce irritation. If any irritation or discomfort does occur, ask any staff member to arrange a meeting for you with the appropriate personnel to determine if it is product related. During business hours (M-F, 8 am - 4:30 pm), call Chris at 480-754-6438. Evenings and weekends, call Laura at 602-677-2610.

You will be scheduled for an appointment to return to the test facility. We require you to avoid moisturizers during the conditioning period. Also do not take antibiotics. If antibiotics are necessary, please notify Hill Top Research at the phone number above.

I have read all the above information and was given an opportunity to ask questions about any part of my participation in the conditioning period. Answers to such questions (if any) were satisfactory. I am eighteen years of age or older and freely and without reservation agree to use the Dove Bar Soap, Ban unscented anti-perspirant/deodorant, and Johnson's baby shampoo provided. I have received a copy of this form and a bar of Dove bar soap, Ban unscented anti-perspirant/deodorant, and Johnson's baby shampoo, 1 pair of latex gloves and several pair of light weight poly gloves.

Appointment date and time: _____

IRB of
Hill Top Research
APR 15 2003
Approved

D00354

Institution: Clinical Research Lab
Investigator: Harold Saferstein, M.D.

CRL Ref. No.: 03-121608-123

Page No. 2-21

Study Title: "Evaluation of the Efficacy of Antimicrobial Handwashes to Reduce the Hand-to-Hand Transfer of a Marker Organism"

CONSENT FORM

INTRODUCTION: You are being asked to take part in a research study. Before you give your consent to be a subject, it is important that you take enough time to read and understand what your participation would involve. In preparing this consent form, it has been necessary to use some technical language. Please ask questions if there is anything you do not understand.

You will be given a signed copy of this consent form and any other necessary written information prior to the start of the study.

PURPOSE: The purpose of this research study is to determine the number of marker bacteria transferred from a contaminated hand washed with a non-antibacterial soap to an uncontaminated hand. Approximately twelve (12) people between and including the ages of 18 - 65 will be screened as potential subjects in this study. At least twelve (12) subjects are expected to complete the three-visit study.

TEST ARTICLES: You will be assigned a marketed soap product.

STUDY PROCEDURES: Prior to enrollment in the test, you will be asked to complete a brief medical history questionnaire. It is possible that you may not be able to participate based on your answers to these questions. If you qualify, you will be given a kit containing non-antibacterial bar soap, shampoo, antiperspirant/deodorant and gloves to be used at least one week prior to the start of the actual study. You will be given written instructions on which antibacterial/antimicrobial products to avoid using during this study.

After about one week, you will be required to return to the lab. You will be asked to complete another brief medical history questionnaire. The skin on your hands will also be checked for visible cuts, scratches or rashes on them. It is possible that you may not be able to participate based on your answers to these questions or the condition of the skin on your hands.

If you are selected to participate in this study, your hands will be washed with a soap, rinsed with tap water and dried with paper towels. Then, your hands will be rinsed with alcohol and air dried about 1 minute. A 1½ inch square is marked on the palm of one of your hands with a permanent marker.

IRB of
Hill Top Research

APR 21 2003

Approved

D00355

A small droplet of watery liquid containing bacteria (*Serratia marcescens*) will be spread on the marked site. The liquid on your hand will air dry for at least 5 minutes. This hand will be sampled by a laboratory technician who will wash the hand with a mild soap like solution. The sampling method involves placing a glass cup on the palm of your hand, adding a defined volume of liquid and briefly massaging with a polished glass stick. The solution from the glass cup will be tested to determine the number of test bacteria added to the hand.

After sampling is completed, the palm of your hand will be treated with alcohol and air dried for about 1 minute. One of your hands will be marked as described above and a liquid containing bacteria is added and air dried. A technician will wash your hand with the test soap and allow it to air dry. Your hand will be sampled by the method above.

After sampling, the palm of your hand will be treated again with alcohol and air dried. Your hand will be marked and the bacteria is added and air dried. A technician will wash your hand with the test soap and allow it to air dry. The palms of both of your hands are rubbed together and the hand that was not washed will be sampled by the sampling method mentioned above. After the final sample is taken, your hands will be washed for approximately 60 seconds with an antibacterial soap and water, rinsed with alcohol and air dried.

After completing the test portion of the study and until your follow-up visit, you will need to check the skin on your hands each day for any pimples, bumps or rashes. Within 4-8 days after you have completed treatment, you will be required to return to the lab for a follow-up visit. The skin on your hands will be checked for infection by a Dermatologist trained in observing infection.

FEMALES OF CHILDBEARING POTENTIAL: You may not participate in this study if you are pregnant or nursing. As part of giving your consent you must agree to have a urine pregnancy test at the start of the study.

RISKS: The risks associated with this test are primarily related to infection with the test bacteria. For healthy persons, the possibility of a skin infection exists; however, this possibility is remote because, (1) test bacteria are applied only to healthy or uninjured skin, and (2) the skin is cleansed with antibacterial products following contact with the test bacteria. Your forearms may also show a "reaction." A "reaction" could be pimples, blisters or raised bumps surrounded by redness and/or swelling. It is unlikely, but possible, that a rash could develop.

IRB of
Hill Top Research
APR 21 2003
A p p r o v e d

000356

No risks to you as a study participant, other than those described above as "reactions," are anticipated during the study. Reactions are usually due to irritation, although an allergic reaction might occur. If you become allergic, it is possible that future exposures to the same ingredient may cause a skin reaction. If this occurs, you will be provided with information to minimize the chance for future exposures.

You may experience risks or side effects that are not known at this time. You will be informed in a timely manner if new information becomes available that may influence your willingness to continue in this study.

BENEFITS: You will not benefit from the applications of test product but the study results may allow a new or improved product to be marketed.

ALTERNATIVE PROCEDURES/TREATMENTS: Because you are not being treated for a medical condition, alternative treatments do not apply to this study.

CONFIDENTIALITY: Information concerning you that is obtained in connection with this study will be kept confidential by Hill Top Research, except that the sponsoring company whose product is being tested will receive a copy of the study records. The records will be coded to protect your identity. In addition, the sponsoring company, the Institutional Review Board (IRB) and government regulatory agencies, including the U.S. Food and Drug Administration (FDA), may inspect the records of the study. Information obtained in the study may be used for medical or scientific publication, but your identity will remain confidential.

MEDICAL TREATMENT: If in the course of this study you experience illness, discomfort or injury that appears to be a result of the study, Hill Top Research will provide you with medical care at no cost to you. Providing such medical care is not an admission of legal responsibility. If such illness, discomfort or injury does occur, ask any staff member to arrange a meeting for you with the appropriate personnel.

In certain cases of illness or injury resulting from this study, insurance benefits may be available.

WHO TO CONTACT: If you have any questions about this study or in case of an emergency, contact Chris, Study Coordinator at 480-754-6438 during business hours (M-F, 8:00 A.M. - 5:00 P.M.) or Laura, Study Manager at 602-677-2610 after hours. In addition, if you have any questions as to your rights as a research subject, contact the Institutional Review Board of Hill Top Research, Nancy J. Pelc, M.D., Chairman, at 1-800-669-1947.

IRB of
Hill Top Research
APR 21 2003
Approved

000000

VOLUNTARY PARTICIPATION/WITHDRAWAL: Your participation in this research study is strictly voluntary. You may refuse to participate or may discontinue participation at any time during the study without penalty or loss of benefits to which you are otherwise entitled.

If you agree to participate in this study, you are also agreeing to provide Hill Top Research with accurate information and to follow study instructions as given to you. If you fail to follow the study instructions, your participation may be ended.

Your participation in the study may be discontinued at any time without your consent by the Investigator, the IRB, the FDA, or the sponsoring company.

COMPENSATION: You will be paid \$75.00 for the completion of this study. You will be compensated according to the following schedule:

If you do not qualify	Visit 1	You will receive	\$10.00 if eliminated
If you complete	Visit 1	You will receive	0*
If you do not qualify	Visit 2	You will receive	\$15.00
If you qualify but are eliminated as an extra subject	Visit 2	You will receive	\$20.00
If you complete	Visit 2	You will receive	\$50.00
If you complete	Visit 3	You will receive	\$75.00

* No payment-kit products given.

Payment will be made at the end of the study.

There are no anticipated expenses to you for participating in this study. All test related materials will be provided at no cost to you. (non-antibacterial bar soap, shampoo and antiperspirant/deodorant)

**IRB of
Hill Top Research**
APR 21 2003
Approved

000358

EXHIBIT B**SUBJECT INSTRUCTIONS**

Today you will be given a kit of products (bar soap, shampoo, and deodorant/antiperspirant) to use exclusively during this study. Please set aside all products you normally use in these categories and use only the products in the kit. In addition, please refrain from using perfumes, deodorants or antiperspirants (other than the ones furnished), powders and anti-dandruff hair shampoos, and do not swim in a chemically treated pool or hot tub during the study.

Beginning today, no body lotions, medicated creams or ointments should be applied to any area of your skin. Also, do not take any antibiotics. These medications may affect the bacteria of the skin. If antibiotics are necessary due to illness, please report this to Hill Top Research at the phone number below.

Please use the rubber gloves provided with the product kit for all household chores involving detergents, acid, alkalis, and solvents until the completion of the study.

SUBJECT SCHEDULE**TEST DAY**

Time of Visit: _____

1. Plan to arrive at the laboratory about 10 minutes before your scheduled time. You are expected to be prompt.
2. Please wear clothing that will allow easy access to your hands.
3. You will be required to remove all jewelry, watches, and bracelets before washing.
4. You will undergo a supervised wash regimen at the laboratory.
5. Approximate time at the laboratory - 4 hours.
6. Additional instructions will be provided for the Follow Up Visit.

FOLLOW UP VISIT

Time of Visit: _____

1. A Dermatologist will check your hands for infection
2. Approximate time at the lab - 1/2 hour.

If you have any questions regarding this study, please contact Chris, Study Coordinator, at 480-754-6438 between 8:00 a.m. - 5:00 p.m. or Laura, Study Manager, after hours and on weekends at 602-677-2610.

**IRB of
Hill Top Research**

APR 21 2003

Approved

000360

EXHIBIT C

SUBJECT'S INSTRUCTIONS FOLLOWING STUDY COMPLETION

You have just completed participation in a clinical study, "A Pilot Study to Determine the Efficiency of Hand to Hand Transfer of *Serratia marcescens*". During this study, your hands were in contact with a liquid containing bacteria (*Serratia marcescens*). Although we do not expect you to have any adverse experience as a result of participation in this study, there is a possibility that an infection may develop on your hands.

To determine whether you have developed an infection from the test bacteria, we would like you to examine your hands and wrists daily. If you notice the appearance of any pimples, blisters or raised bumps surrounded by redness and/or swelling, please contact Chris, Study Coordinator at (480) 754-6438 during normal business hours (8:00 am- 5 pm) or Laura at (602) 677-2610 after hours.

You are required to return to the test site for a follow-up visit. Your follow-up is scheduled for:

Date Time

Thank you for your cooperation.

**IRB of
Hill Top Research
APR 21 2003
Approved
D00361**

CRL Ref. No.: 03-121608-123

APPENDIX III

Total number of pages = 2

Copy of Randomization and Formal Ingredient Statement

D00362

9	B	L
1	A	R
12	A	L
11	B	L
10	B	L
4	B	R
8	A	L
5	B	R
7	B	R
3	A	L
2	A	R
6	A	R

Per sponsor's request they wanted the subject numbers randomized, as well as the product presentation and the right and left hands.

KW (11)
4-22-03

CRL-03-121608-123

Formula Ingredient Statement

3539-9 Foaming Antimicrobial Handsoap: Product B

Active Ingredient: 0.45% Triclosan

Other Ingredients: Water (aqua), Sodium Xylenesulfonate, Dipropylene Glycol, Glycerin, Ammonium Lauryl Sulfate, Cocamidopropyl Betaine, Fragrance (Parfum), Disodium Phosphate, Citric Acid, Sodium PCA, Polyquaternium-10, Cetyl Alcohol, Aloe Barbadensis Leaf Juice, Methyl-Paraben, Propyl-Paraben, Red 4, Yellow 5.

3539-11 Non-medicated Liquid Handsoap: Product A

Ingredients: Water, Sodium C14-16 Olefin Sulfonate, Lauramide DEA, Glycol Stearate, Sodium Chloride, Cocamidopropyl Betaine, Citric Acid, Fragrance, DMDM Hydantoin, Polyquaternium-7, Aloe Barbadensis Gel, Tetrasodium EDTA, Glycerin, Silk Peptide, Hydrolyzed Silk Protein.

D00364

CRL Ref. No.: 03-121608-123

APPENDIX IV

Total number of pages = 1

Excel Calculated Data

D00365

CRL-03-121608-123

Product A

Subject		CFU/mL	CFU/4 mL	CFU/cm ²	Log ₁₀ / cm ²
1	Baseline	5.70E+06	2.30E+07	4.70E+06	6.67
	Post Wash	2.20E+05	8.80E+05	1.80E+05	5.25
	Transfer	1.00E+04	4.00E+04	8.10E+03	3.90
3	Baseline	7.40E+05	3.00E+06	6.10E+05	5.78
	Post Wash	1.40E+05	5.60E+05	1.10E+05	5.04
	Transfer	6.50E+03	2.60E+04	5.30E+03	3.72
8	Baseline	6.50E+06	2.60E+07	5.30E+06	6.72
	Post Wash	1.10E+05	4.40E+05	9.00E+05	5.95
	Transfer	3.60E+04	1.40E+05	2.80E+04	4.44
2	Baseline	3.30E+06	1.30E+07	2.60E+06	6.41
	Post Wash	6.00E+04	2.40E+05	4.90E+04	4.69
	Transfer	5.40E+03	2.20E+04	4.50E+03	3.65
6	Baseline	4.40E+03	1.80E+04	3.70E+03	3.56
	Post Wash	5.00E+04	2.00E+05	4.10E+04	4.61
	Transfer	1.50E+04	6.00E+04	1.20E+04	4.07
12	Baseline	3.60E+06	1.40E+07	2.80E+06	6.44
	Post Wash	3.20E+05	1.30E+06	2.60E+05	5.41
	Transfer	3.00E+02	1.20E+03	2.40E+02	2.38

Product B

4	Baseline	7.00E+06	2.80E+07	5.70E+06	6.75
	Post Wash	<10	<40	8.00E+00	0.90
	Transfer	<10	<40	8.00E+00	0.90
5	Baseline	5.80E+06	2.30E+07	4.70E+06	6.67
	Post Wash	3.80E+03	1.50E+04	3.10E+03	3.49
	Transfer	9.50E+01	3.80E+02	7.80E+01	1.89
7	Baseline	4.00E+06	1.60E+07	3.30E+06	6.51
	Post Wash	8.00E+01	3.20E+02	6.50E+01	1.81
	Transfer	<10	<40	8.00E+00	0.90
9	Baseline	1.20E+07	4.80E+07	9.80E+06	6.99
	Post Wash	1.00E+01	4.00E+01	8.00E+00	0.90
	Transfer	1.00E+01	4.00E+01	8.00E+00	0.90
10	Baseline	2.90E+06	1.20E+07	2.40E+06	6.38
	Post Wash	1.30E+02	5.20E+02	1.10E+02	2.04
	Transfer	<10	<40	8.00E+00	0.90
11	Baseline	3.60E+06	1.40E+07	2.80E+06	6.44
	Post Wash	<10	<40	8.00E+00	0.90
	Transfer	<10	<40	8.00E+00	0.90