

Efficacy Evaluation of Health Care Personnel Handwash Products
HTR Study No. 00-105821-11

This study was performed at Hill Top Research Inc. and the procedure is a modification of ASTM E1174-94 (The Annual Book of ASTM Standards, Vol. 11.05, pp. 480-482, 1996). The protocol is aligned with the current version (E1174-00) of the ASTM method approved by ASTM in 2001. The modification to this protocol provides procedures to assure adequate rapid neutralization of the antimicrobial in the handwash formulation. A neutralizer was incorporated at both sampling points. Dial Complete™ Antibacterial Foaming Hand Wash with 1% Triclosan was used as the test product.

The study is designed to measure the reduction of transient microbial flora following routine hand washing with an antibacterial product. In this study a broth culture of *Escherichia coli* ATCC 11229 was used as an artificial contaminant bacteria on the hands. Activity was measured by comparing the microbial counts of the marker organism removed after a single use of the product to the baseline number, the number of organisms recovered from the contaminated unwashed hands. Comparisons are made again following the 11th wash of a multiple wash procedure (11). Prior to each of the eleven washes the hands were artificially contaminated with *E. coli*.

In addition to testing a 1% Triclosan containing formula, Hibiclens® with 4% CHG, which is recommended by the FDA as a control, was included in this study. Enough subjects were preenrolled to ensure the required number of subjects (45) 30 for Dial Complete™ and 15 for Hibiclens, who fulfilled the study criteria. There was a one-week wash out period where subjects refrained from using antimicrobial-containing products. On test day, subject's hands were contaminated with *E. coli* and a baseline sampling was performed. Following washing with the test product, treatments 1 & 11, subject's hands were sampled for post treatment count. The sampling fluid was enumerated for recovery of *E. coli*.

Results from the Health Care Personnel Handwash study were evaluated by comparing bacteria counts recovered from the hands following product treatment vs. the baseline counts. The bacteria counts were calculated into log counts. The log counts of each subjects left and right hand were averaged. The following log₁₀ reductions were achieved:

Product Description	WASH 1	WASH 11
Dial Complete™ EPS 3398-29A	3.78	4.04
Hibiclens® 3372-131	2.86	4.22

HILL TOP RESEARCH, INC.

REPORT FOR

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

HTR STUDY NO. 00-105821-11

October 17, 2000

FOR
THE DIAL CORPORATION
15101 North Scottsdale Road
Scottsdale, AZ 85254-2199

BY
HILL TOP RESEARCH, INC.
Main and Mill Sts.
Miamiville, OH 45147

D00215

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IMPORTANT NOTICE

1.0 SUMMARY

- The purpose of this study was to determine the ability of antimicrobial hand washing agents to give reduction of transient microbial flora (contaminants) when used in a hand washing procedure with a marker organism, *Escherichia coli* ATCC 11229.

Fifty-seven subjects completed the study.

- Two test articles identified by the sponsor as EPS 3398-29A (HTR Code A) and 3372-131 (HTR Code B) were evaluated in this study.
- The test article evaluated in this study, identified by the sponsor as EPS 3398-29A (HTR Code A), achieved a 3.79 log₁₀ reduction of the marker organism *Escherichia coli* ATCC 11229 following a single 30-second handwashing procedure. After 11 repetitive washes a 4.05 log₁₀ reduction of the marker organisms was achieved. The second test article evaluated, identified by the sponsor as 3372-131 (HTR Code B), achieved a 2.86 log₁₀ reduction of the marker organism following a single 15-second handwashing procedure and a 4.22 log₁₀ reduction of the marker organism after 11 repetitive washes.

HTR Study No.: 00-105821-11

2.0 STUDY MONITOR

Janice Fuls
The Dial Corporation

3.0 INVESTIGATIVE PERSONNEL

Investigator: Gayle K. Mulberry, M.S.
Sub-Investigators: Kathleen A. Baxter, B.S.
Ann R. Brady, A.S.

Medical Consultant: E. Linn Jones, M.D., D.A.B.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 27, 2000, 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 and Protocol Amendments #1 and #2 were followed (see Appendix II) except for the following deviations:

- The protocol states that HTR Code A was a thin colorless liquid. The product received was an orange liquid. Amendment #1 confirms that Hill Top Research, Inc received the correct lot of Product A.

5.0 PROTOCOL (CONT.)

- The daily broth culture transfers, for the marker organism used on August 7, 2000 to contaminate Subjects 11, 13 through 21, 23 and 28 were incubated at room temperature. The protocol states the broth cultures were to be incubated at $35 \pm 2^{\circ}\text{C}$. This deviation resulted in these subjects having significantly lower baseline counts than Subjects 1 through 10, 12, 22, 24 through 27, and 29 through 45. Protocol Amendment #2 added 12 additional subjects to the study to replace those affected by the deviation.
- Subject #50 touched paper towels with hands before putting them into bags on test wash #1. The protocol states that only after treatments that are not followed by a sample collection, the subjects thoroughly dry their hands and forearms with a disposable paper towel. In the opinion of the Investigator, this deviation 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

One hundred eighteen (118) subjects were enrolled in the pre-test conditioning phase. Fifty-seven (57) subjects, ten (10) males and forty-seven (47) females who met the study criteria were enrolled in the test phase and completed the study.

Sixty-one (61) 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:	July 27, 2000
Date Initiated:	August 3, 2000
Date Completed:	August 24, 2000

HTR Study No.: 00-105821-11

8.0 TEST ARTICLES

The following test articles were received by Hill Top Research.

<u>HTR Code</u>	<u>Sponsor Code</u>	<u>Description</u>	<u>No. of Units</u>	<u>Date Received</u>
A	EPS 3398-29A	White translucent plastic bottle with white plastic cap & pump nozzle with orange liquid inside	11	8/2/00
B	3372-131	Aqua plastic bottle with white plastic cap with product inside	1	7/18/00
			1	8/10/00

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

9.0 ADVERSE EVENTS

There was one adverse event 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.

A letter from the Sponsor, George Fischler, attached as Exhibit A, attest to the fact that the materials labeled EPS 3398-29A used in HTR Study No. 00-105821-11 are the same composition and formula as previously submitted test material 3372-130.

11.0 METHOD OF STATISTICAL ANALYSIS

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

11.0 METHOD OF STATISTICAL ANALYSIS (CONT.)

Bacterial counts recovered from the hands were transformed into log₁₀ counts. The data used in the statistical analysis were the averages of each subject's right and left-hand log₁₀ counts. Analysis of variance techniques were used to:

- Compare the baseline counts of subjects assigned different test articles.
- Evaluate the effectiveness of each treatment as a function of the number of treatments (within treatment analysis using log₁₀ reductions).

Percent reductions of bacterial counts from baseline were also determined.

The test articles used in this study are as follows: HTR Code A (EPS 3398-29A)
HTR Code B (Hibiclens 3372-131)

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

Data from Subjects 11, 13 through 21, 23, and 28 were not included in the analysis because of a protocol deviation (See Section 5.0 of this report.)

12.0 RESULTS OF STATISTICAL ANALYSIS

12.1 Baseline Bacterial Log Count Comparison

The source data for the baseline analysis were the average log₁₀ 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 Log₁₀ Baseline Counts

HTR Code A	HTR Code B	ANOVA p-value
8.6848	8.7030	>0.5000 ¹

¹ No significant difference between groups at baseline

12.2 Within-Treatment Analysis

The data (log₁₀ 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 log₁₀ average differences from baseline and the p-values from the ANOVA are shown below.

HTR Code	WASH I	WASH II	p-value
HTR Code A (n=30)	3.7871	4.0467	0.0840
HTR Code B (n=15)	2.8641	4.2202	<0.0001 ¹

¹ Significantly better antimicrobial activity after eleven test washes.

12.0 RESULTS OF STATISTICAL ANALYSIS (CONT.)

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 ₁₀ Reduction	95% Confidence Limits		Percent Reduction	95% Confidence Limits	
		Lower	Upper		Lower	Upper
WASH 11						
HTR Code A	3.7871	3.5273	4.0469	99.98	99.97	99.99
HTR Code B	2.8641	2.6530	3.0751	99.86	99.78	99.92
WASH 11						
HTR Code A	4.0467	3.7809	4.3125	99.99	99.98	100.00
HTR Code B	4.2202	3.9180	4.5224	99.99	99.99	100.00

The Statistical Tables of Results are shown in Appendix VII.

13.0 SUBJECT CASE REPORT FORMS

The Case Report Forms for each subject selected for the study are shown in Appendix VIII.

- Appendix VIII-A - Subjects Completing the Study
- Appendix VIII-B - Subjects Excluded/Withdrawn

14.0 CONCLUSION

Two test articles, EPS 3398-29A (HTR Code A) and 3372-131 (HTR Code B) were evaluated in this Health Care Personnel handwash study. Data from thirty subjects was used to evaluate Test article HTR Code A and data from fifteen subjects was used to evaluate Test Article HTR Code B.

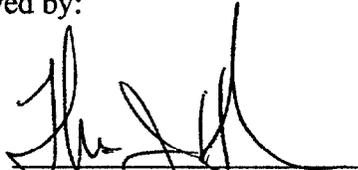
The test article evaluated in this study, identified by the sponsor as EPS 3398-29A (HTR Code A), achieved a 3.79 log₁₀ reduction of the marker organism *Escherichia coli* ATCC 11229 following a single 30-second handwashing procedure. After 11 repetitive washes a 4.05 log₁₀ reduction of the marker organisms was achieved. The second test article evaluated, identified by the sponsor as 3372-131 (HTR Code B), achieved a 2.86 log₁₀ reduction of the marker organism following a single 15-second handwashing procedure and a 4.22 log₁₀ reduction of the marker organism after 11 repetitive washes.

HTR Study No.: 00-105821-11

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 J. Hughes, B.A. 10/18/2000
Auditor, Quality Assurance Date

HTR Study No.: 00-105821-11

EXHIBIT A

Total number of pages = 1

Client Letter Verifying Sample Composition

B00225



To Ann Brady – Hilltop Research
From George Fischler
Date August 1, 2000
Subject Test Material Hilltop Study 00-105821-11

Test Material EPS 3398-29A to be used in Hilltop Study 00-105821-11 for The Dial Corporation is the same composition and formula as previously submitted Test Material 3372-130.

George Fischler
Manager – Microbiology

GEF/gef
Hilltop080100

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HTR Study No.: 00-105821-11

APPENDIX I

Total number of pages = 13

**IRB Approval Letter, Approved Consent Forms,
and Subject Instructions**

D00227

INSTITUTIONAL REVIEW BOARD

OF

PRO NO.	00-105821-11
PAGE NO.	I-1

HILL TOP RESEARCH, INC.

Nancy J. Pelc, M.D., Chairman

July 27, 2000

Gayle K. Mulberry, M.S.
Hill Top Research, Inc.
Main and Mill Streets
Miamiaville, OH 45147

Ref: 00-105821-11
Title: PROTOCOL FOR EFFICACY EVALUATION OF HEALTH CARE
PERSONNEL HANDWASH PRODUCTS
Protocol Date: July 21, 2000
Sponsor: The Dial Corporation

Dear Mr. Mulberry:

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

7-27-00

Date

NJP/sll

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 measure the ability of two liquid soap products to reduce the number of bacteria on the hands after repetitive use. Approximately ninety (90) people between and including the ages of 18 – 65 will be screened as potential subjects in this study. Forty-five (45) subjects are expected to complete the three-visit study.

TEST ARTICLES: One of the test articles is an experimental antibacterial liquid soap product. The other test material is a marketed antibacterial liquid soap product. One product will be randomly assigned to each participating subject.

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, Ban® antiperspirant/deodorant, and rubber and poly gloves to be used at least one week prior to the start of the actual study. You will be given written instructions on how to use the kit.

After at least one week, you will be required to return to the lab. You will be asked to complete another brief medical history questionnaire. 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 and wrists. You will wash your hands with a non-medicated soap. Then, your hands will be contaminated with a watery liquid containing a non-harmful bacteria (*Escherichia coli*). This liquid containing the bacteria will be spread over the surfaces of the hands, and the hands will be allowed to air dry. Following air drying, the hands will be sampled. Sampling is accomplished by having you place your hands into large plastic bags to which will be added a mild soap-like solution. A laboratory technician will massage each bagged hand for one minute. The hands will be removed from the bags and the solution from each bag will be tested to determine the number of test bacteria added to the hands. Following the baseline sampling, your hands will be rinsed with tap water and

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Hill Top Research

JUL 27 2000

Approved

washed with a non-medicated soap and dried. You will then begin the treatment part of the study. Prior to each treatment, your hands will be contaminated with bacteria as described above. Your hands and wrists will then be treated (washed) with the test material, following specific instructions. Your hands will be contaminated and treated 11 times. Your hands will be sampled (to determine the number of bacteria removed or killed by treatment) after the 1st and 11th washes. After the 1st and 11th sampling wash, the hands are washed with a non-medicated soap. Following the last sampling, your hands will be treated with alcohol, rinsed with water followed by a wash with Hibiclens®, an antibacterial soap, prior to leaving the lab.

After completing the treatment visit and until your follow-up visit, you will need to check the skin on your hands each day for any pimples, bumps or rashes. Between four and eight days after you have completed treatment, you will be required to return to the lab for a follow-up visit. 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 contamination 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 intact skin, and (2) the skin is cleansed with antibacterial products following contact with the test bacteria.

You may also develop a reaction on your hands from the test materials. A reaction could be redness, swelling, itching, cracking, peeling, or in rare cases, blistering.

No risks to you as a study participant, other than those described above, 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 application 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.

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IRB of
Hill Top Research
JUL 27 2000
Approved

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 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, workers' compensation coverage may be available. In accordance with Ohio law, Hill Top Research has secured workers' compensation coverage for participants in its studies and tests, and has paid and will pay appropriate premiums into the State Insurance Fund on behalf of such participants.

WHO TO CONTACT: If you have any questions about this study or in case of an emergency, contact Glenna, Study Coordinator, at 831-3114 ext. 2920 during business hours (M-F, 8:00 A.M. - 5:00 P.M.) or Ann Brady, Study Manager, at 831-3354 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 1-513-831-3114.

**IRB of
Hill Top Research**

JUL 27 2000

Approved

D00231

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 comply with study procedures, your participation may be terminated.

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 \$80.00 for the completion of this study. You will be compensated according to the following schedule:

If you complete	Visit 1	You will receive	\$0*
If you do not qualify	Visit 2	you will receive	\$10.00
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	\$80.00

*No payment-kit products given.

Payments 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. (Soap, shampoo, roll-on antiperspirant/deodorant and gloves)

**IRB of
Hill Top Research**
JUL 27 2000
Approved

D00232

Institution: Hill Top Research, Inc.
Investigator: Gayle K. Mulberry, M.S.
Study Title: "Efficacy Evaluation of Health Care Personnel Handwash Products"

HTR Study No. 00-105821-11

Page No. I - 7

CONSENT FORM (Revised)

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 measure the ability of two liquid soap products to reduce the number of bacteria on the hands after repetitive use. Approximately one hundred ten (110) people between and including the ages of 18 – 65 will be screened as potential subjects in this study. Fifty-seven (57) subjects are expected to complete the three-visit study.

TEST ARTICLES: One of the test articles is an experimental antibacterial liquid soap product. The other test material is a marketed antibacterial liquid soap product. One product will be randomly assigned to each participating subject.

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, Ban® antiperspirant/deodorant, and rubber and poly gloves to be used at least one week prior to the start of the actual study. You will be given written instructions on how to use the kit.

After at least one week, you will be required to return to the lab. You will be asked to complete another brief medical history questionnaire. 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 and wrists. You will wash your hands with a non-medicated soap. Then, your hands will be contaminated with a watery liquid containing a non-harmful bacteria (*Escherichia coli*). This liquid containing the bacteria will be spread over the surfaces of the hands, and the hands will be allowed to air dry. Following air drying, the hands will be sampled. Sampling is accomplished by having you place your hands into large plastic bags to which will be added a mild soap-like solution. A laboratory technician will massage each bagged hand for one minute. The hands will be removed from the bags and the solution from each bag will be tested to determine the number of test bacteria added to the hands. Following the baseline sampling, your hands will be rinsed with tap water and

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Hill Top Research**

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washed with a non-medicated soap and dried. You will then begin the treatment part of the study. Prior to each treatment, your hands will be contaminated with bacteria as described above. Your hands and wrists will then be treated (washed) with the test material, following specific instructions. Your hands will be contaminated and treated 11 times. Your hands will be sampled (to determine the number of bacteria removed or killed by treatment) after the 1st and 11th washes. After the 1st and 11th sampling wash, the hands are washed with a non-medicated soap. Following the last sampling, your hands will be treated with alcohol, rinsed with water followed by a wash with Hibiclens®, an antibacterial soap, prior to leaving the lab.

After completing the treatment visit 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 four to eight days after you have completed treatment, you will be required to return to the lab for a follow-up visit. 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 contamination 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 intact skin, and (2) the skin is cleansed with antibacterial products following contact with the test bacteria.

You may also develop a reaction on your hands from the test materials. A reaction could be redness, swelling, itching, cracking, peeling, or in rare cases, blistering.

No risks to you as a study participant, other than those described above, 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 application 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.

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Hill Top Research

AUG 10 2000

Approved 000235

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 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, workers' compensation coverage may be available. In accordance with Ohio law, Hill Top Research has secured workers' compensation coverage for participants in its studies and tests, and has paid and will pay appropriate premiums into the State Insurance Fund on behalf of such participants.

WHO TO CONTACT: If you have any questions about this study or in case of an emergency, contact Glenna, Study Coordinator, at 831-3114 ext. 2920 during business hours (M-F, 8:00 A.M. - 5:00 P.M.) or Ann Brady, Study Manager, at 831-3354 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 1-513-831-3114.

IRB of
Hill Top Research

AUG 10 2000

Approved

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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 comply with study procedures, your participation may be terminated.

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 \$80.00 for the completion of this study. You will be compensated according to the following schedule:

If you complete	Visit 1	You will receive	\$0*
If you do not qualify	Visit 2	you will receive	\$10.00
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	\$80.00

*No payment-kit products given.

Payments 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. (Soap, shampoo, roll-on antiperspirant/deodorant and gloves)

IRB of
Hill Top Research

AUG 10 2000

Approved

000237

EXHIBIT B

EVALUATION OF HEALTH CARE PERSONNEL HANDWASH
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 chlorinated 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 - 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 Emilie, Study Coordinator, at 831-3114 ext. 2324 between 8:00 a.m. - 5:00 p.m. or Ann Brady, Study Manager, after hours and on weekends at 831-3354.

IRB of
Hill Top Research
JUL 27 2000
Approved
D00239

EXHIBIT C

SUBJECT'S INSTRUCTIONS FOLLOWING STUDY COMPLETION

You have just completed participation in a clinical study, "Efficacy Evaluation of Health Care Personnel Handwash Products". During this study, your hands were in contact with a liquid containing bacteria (*Escherichia coli*). Although we do not expect you to have any adverse experience as a result of participation in this study, there is a remote possibility that an infection may develop on your hands within 4 to 8 days.

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 Emilie, Study Coordinator at (513) 831-3114 during normal business hours (8:00 am- 5 pm) or Ann Brady at (513) 831-3354 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**

JUL 27 2000

Approved

D00240

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APPENDIX II

Total number of pages = 32

Protocol and Protocol Amendments #1 and #2

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HILL TOP RESEARCH, INC.

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

FOR: THE DIAL CORPORATION

HTR STUDY NO.: 00-105821-11

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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 Health Care Personnel Handwash Bacterial Counts
- 5 Adverse Event Report
- 6 Follow up Visit

HTR Study No.:00-105821 -11

1.0 INTRODUCTION

The FDA issued a tentative final monograph (Federal Register, Vol. 59, pp. 31402 to 31452, June 17, 1994) prescribing the use of a health care personnel handwash method to demonstrate the antimicrobial efficacy of cleansing products containing antimicrobial ingredients for frequent use.

The required procedure is a modification of ASTM E-1174-87 (The Annual Book of ASTM Standards, Vol. 11.04, pp. 209-212, 1987). This protocol is aligned with a revised version of the ASTM Method currently under consideration within ASTM Technical Committee E-35.15.

The procedure is designed to simulate routine hand washing conducted for the purpose of reducing the level of hand contamination of health care personnel under conditions of frequent use. For this procedure a broth culture of *Escherichia coli* (ATCC 11229), is used as an artificial contaminant bacteria on the hands. Activity is measured by comparing the number of marker bacteria removed from artificially contaminated hands after a single use of the hand washing formulation to the baseline number, the number recovered from contaminated unwashed hands. A similar comparison is made following the 11th wash of a multiple (11) wash procedure. Prior to each of the washes, the hands are artificially contaminated with the *E. coli*.

The method described in this protocol eliminates a shortcoming common to the Proposed Monograph version of the method and the current ASTM version of the method, E1174-94. Both of these methods fail to provide procedures to assure adequate rapid neutralization of the antimicrobial in the handwash formulation. A neutralizer is only included in the hand sampling fluid used to sample the last wash and is omitted from the hand sampling fluid used to sample washes preceding the final wash. This failure to include neutralizers in the hand sampling fluid may provide data that falsely exaggerates the effectiveness of the antimicrobial handwash formulation. This issue is resolved in this protocol by requiring immediate neutralization in the hand sampling fluid at all sampling points.

2.0 OBJECTIVE

The purpose of this study is to determine the ability of antimicrobial hand-washing agents to give reduction of transient microbial flora (contaminants) when used in a hand washing procedure with a marker organism.

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3.0 STUDY SPONSOR AND MONITOR

The Dial Corporation
15101 North Scottsdale Road
Scottsdale, AZ 85254-2199
Telephone No.: (480) 754-6495
Fax No.: (480) 754-6180

REPRESENTATIVE: Janice Fuls

4.0 INVESTIGATIVE ORGANIZATION AND PERSONNEL

Hill Top Research, Inc.
Main and Mill Streets
Miamiville, Ohio 45147
Telephone No.: (513) 831-3114
Fax No.: (513) 831-1217

Investigator: Gayle K. Mulberry, M.S.
Technical Director
Microbiological Services

Sub-Investigators: Kathleen A. Baxter, B.S.
Ann R. Brady, A.S.

Medical Consultant: E. Linn Jones, M.D., D.A.B.D.

5.0 CLINICAL RESEARCH STANDARDS

The clinical investigation, including the informed consent, will be reviewed by an Institutional Review Board 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 study will be conducted in compliance with the Good Clinical Practice Regulations, the Standard Operating Procedures of Hill Top Research, Inc., the Sponsor's protocol and protocol amendment(s).

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6.0 EXPERIMENTAL DESIGN

This will be a two sample (test article) study utilizing a direct paired comparison test design of baseline bacterial populations vs. post treatment bacterial populations. The study will consist of a one-week pretest conditioning period and one day of treatment. Forty-five (45) subjects are expected to start and complete the study, thirty (30) using HTR Code A and fifteen (15) using HTR Code B.

7.0 STUDY MATERIAL

7.1 Test Article

<u>HTR Code</u>	<u>Code and Description</u>	
A	<u>Test Formulation:</u>	Foaming handwash
	<u>Lot Code:</u>	3372-130
	<u>Description:</u>	thin colorless liquid
B	<u>Test Formulation:</u>	Hibiclens
	<u>Lot Code:</u>	3372-131
	<u>Description:</u>	clear red liquid

7.2 Equipment

- 7.2.1 Colony Counter - Quebec colony counter.
- 7.2.2 Incubator - Any incubator capable of maintaining a temperature of $35 \pm 2^\circ\text{C}$ 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 Plastic Bags to Sample Hands - Low bioburden - Glad Food Storage Bags, 29.2 cm x 31.8 cm. (Note: Bioburden is determined according to Hill Top Microbiology Department SOP No. 11-TOPC-20-0016A.)
- 7.2.6 Bacteriological Pipettes, Sterile - 10.0 mL, 5.0 mL, 2.0 mL and 1.0 mL capacity.
- 7.2.7 Water Dilution Bottles - Any container that can be sterilized, having a 150 to 200 mL capacity and a tight closure may be used.
- 7.2.8 Test Tubes and Closures - Any of suitable size.
- 7.2.9 Handwashing Sink - A sink of sufficient size to permit subjects to wash without touching hands to sink surface or other subjects.

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7.0 STUDY MATERIAL (CONT.)

7.2 Equipment (Cont.)

- 7.2.10 Water faucets - located above the sink at a height, which permits the hands to be held higher than the elbow during the washing procedure.
- 7.2.11 Tap Water Temperature Regulator and Temperature Monitor - To monitor and regulate water temperature of $40 \pm 2^\circ\text{C}$.
- 7.2.12 Erlenmeyer Flask - 2 L capacity for culturing test organism.

7.3 Reagents and Materials

- 7.3.1 Kit Products for Washout Period: non-antimicrobial bar soap and shampoo, roll on antiperspirant/deodorant, rubber gloves, and disposable poly gloves.
- 7.3.2 Baby San® liquid castile soap. Ecolab Inc.
- 7.3.3 Stripping Fluid with Neutralizer - 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 distilled water containing an inactivator which rapidly quenches the antimicrobial activity of the test article(s). 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) containing an antimicrobial inactivator specific for the test formulation.
- 7.3.5 Plating Medium - Nutrient Agar with MUG
- 7.3.6 Tryptic Soy Broth (BBL or Difco)

7.4 Test Microorganism

Escherichia coli (ATCC 11229) 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 45 subjects who fulfill the criteria described below and who complete the study. The subjects will be randomly assigned to two treatment groups, one for each test article. 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).

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8.0 STUDY POPULATION (CONT.)

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.

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 soap, detergent, 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, or AIDS (or HIV positive); 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.

8.0 STUDY POPULATION (CONT.)

8.3 Other Study Restrictions

- 8.3.1 Subjects should not use any other personal cleansing products.
- 8.3.2 Subjects should avoid hot tubs and swimming.
- 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.

10.0 PROCEDURE

The study will be divided into three phases; 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, roll-on-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.

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10.0 PROCEDURE (CONT.)

10.3 Test Day Schedule

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.

The following outlines the schedule of procedures for the test day:

- a. Subjects will wash with a mild soap for 15 seconds. (Section 10.3.1)
- b. Subjects' hands will be contaminated and baseline sampling performed. (Section 10.3.2)
- c. Subjects' hands treated with the test articles, each treatment preceded by hand contamination. (Section 10.3.3)
- d. Following treatments 1 and 11, subjects hands are sampled for post-treatment count and the *E. coli* in the sampling fluid enumerated. (Sections 10.3.5 and 10.3.6).
- e. Following each sampling of subject's hands the hands are washed with castile soap (7.3.2) and rinsed.
- f. After the hand sampling following treatment 11, the Subjects' hands will be rinsed with 70% Isopropyl Alcohol, rinsed with water and washed with Hibiclens (Section 10.3.7) upon completing the castile soap wash.

10.3.1 Conditioning Wash

All subjects, prior to the baseline sampling perform a 15-second wash using a non-antimicrobial liquid soap, Baby San® (Section 7.3.2). This procedure, described below, removes oil and dirt and familiarizes the subjects with the treatment procedure.

- 10.3.1.1 Five mL of Baby San® Soap is dispensed into cupped hands and distributed over all surfaces of the hands taking care not to lose the substance.
- 10.3.1.2 After the material is spread, a small amount of tap water $40 \pm 2^\circ\text{C}$ is added, and the hands and lower third of the forearms are completely lathered for 15 seconds in a vigorous manner.
- 10.3.1.3 The hands and forearms are then rinsed under running tap water $40 \pm 2^\circ\text{C}$ for 30 seconds.
- 10.3.1.4 The hands are thoroughly dried with a disposable paper towel.

10.0 PROCEDURE (CONT.)

10.3.2 Baseline Bacteria Count

After completing the conditioning wash, a total volume of 4.5 mL of *E. coli* (ATCC 11229) suspension (Section 10.4), (minimum of 10^8 organisms per mL) is added into the subjects' cupped hands in 1.5 mL increments. After each 1.5 mL aliquot is added, the suspension is rubbed thoroughly over the surface of both hands, not going above the wrist. Each application and spreading should last approximately twenty (20) seconds. Between each aliquot the hands will be held away from the body and allowed to air dry for approximately thirty (30) seconds. Following the third 1.5mL aliquot the hands are held motionless away from the body and allowed to air dry for 90 ± 5 seconds.

(NOTE: The hands may not be completely dry at this time.)

Plastic bags having documented low bioburden, (Section 7.2.5) are placed on the subject's right and left hands. A 75 mL aliquot of stripping solution (Section 7.3.3) is aseptically added into each bag and the bacterial sampling procedure is carried out as described under Section 10.3.5 (Bacterial Sampling Procedure). The hands and forearms are then washed thoroughly with castile soap (Section 7.3.2) and dried.

10.3.3 Multiple Treatment Procedure

Prior to each treatment, the subject's hands will be contaminated with 4.5 mL of the *E. coli* suspension as described in Section 10.3.2

After completing the contamination step, the subjects perform a treatment with the assigned test article, under close supervision. The treatment procedure follows that described in the Section 10.3.4 (Method for Treating Hands). The lower third of the forearm is to be included in the wash procedure.

This procedure is repeated a total of 11 times with at least five minutes between each treatment. Within five (5) minutes of completing the 1st and 11th treatments, the hands are sampled as described in Section 10.3.5 (Bacterial Sampling Procedure).

10.3.4 Method for Treating Hands

10.3.4.1 Test Article HTR Code A - Dispense two (2) pumps (3.2 mL) from the test article container into cupped palm of one hand and distribute over all surfaces of both hands. The material is worked vigorously over all surfaces of the hands and lower third of the forearm for thirty (30) seconds. (A small amount of water may be added to moisten the hands if necessary after approximately 15 seconds.) Particular attention is to be paid to the area between the fingers, beneath the nails and around the thumb. Rinse hands under running tap water for 30 seconds.

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10.0 PROCEDURE (CONT.)

10.3.4.2 Test Article HTR Code B - Immediately prior to treating the hands are to be wetted with small amount of water by passing hands rapidly under the tap. Dispense 5.0 ml from a syringe into cupped palm of one hand and distribute over all surfaces of both hands. The material is worked vigorously over all surfaces of the hands and lower third of the forearm for fifteen (15) seconds. Particular attention is to be paid to the area between the fingers, beneath the nails and around the thumb. Rinse hands under running tap water for 30 seconds.

NOTE: After treatments that are not followed by a sample collection, the subjects will thoroughly dry their hand and forearms with a disposable paper towel.

10.3.5 Bacterial Sampling Procedure

Plastic bags having low bioburden (Section 7.2.5) will be placed on the subject's right and left hands. A 75 mL aliquot of stripping fluid with neutralizer (Section 7.3.3) is aseptically added into each bag. The bag on each hand is secured and massaged for one minute in a uniform manner by a lab technician. An aliquot of the fluid is aseptically obtained directly from the bagged hands within one minute of completing the massaging and immediately placed into tubes containing sterile Dilution Fluid (Section 7.3.4).

Fluid samples for bacteria counts are to be labeled by an Investigator derived code so that the individuals who prepare the plates and count the colonies are unaware of the sources of the sampling solution.

After each bacterial sampling, subjects will wash their hands under running warm tap water $40 \pm 2^{\circ}\text{C}$ with 5 mL of castile soap (7.3.2) to help remove residual stripping fluid.

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10.0 PROCEDURE (CONT.)

10.3.6 Bacterial Counts of Sampling Solution

Aliquots of the stripping fluid or dilutions of the fluid are spread plated in duplicate on Nutrient Agar with MUG plates (Section 7.3.5).

The dilutions of the baseline sample plated represent dilutions of 10^{-3} through 10^{-5} milliliter aliquots of the stripping fluid. The aliquots or dilutions of the treatment sample fluid plated represent dilutions of 10^{-1} through 10^{-4} milliliter aliquots of the stripping fluid.

The prepared plates are to be incubated for 18 - 24 hours at $35 \pm 2^{\circ}\text{C}$. Standard plate counting procedures are used to count only florescent (mug) colonies. The actual plate counts are recorded on the form entitled Handwash Bacterial Count Form (Data Collection Form 4).

10.3.7 Disinfection of Hands

After the final sampling is completed, subjects' hands and wrists will be treated for at least thirty (30) seconds with 70% Isopropyl Alcohol, rinsed with water, then washed for at least 60 seconds with 5 mL of Hibiclens.

To ensure that any delayed adverse events, such as primary skin infections, are reported to the Study Investigator, all test subjects will be given a copy of Subjects' Instructions Following Study Completion (Exhibit C) before leaving the clinical site after they have completed the study. This sheet will instruct the subjects to examine their hands daily until the final scheduled visit for the presence of pimples, blisters, or raised, red itching bumps surrounded by erythema and/or edema that may be indicative of a skin infection. Subjects, who notice such lesions, will be instructed to call the clinical test site. The subjects will return to the clinical test site within eight (8) days after the study procedures have been completed to have their hands examined by the Medical Consultant. The Medical Consultant will complete Data Collection Form 6 for each subject on their follow-up visit.

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10.0 PROCEDURE (CONT.)

10.4 Marker Organism and Preparation

E. coli (ATCC 11229) will be used to challenge the efficacy of the test materials.

A stock culture of *E. coli* (ATCC 11229) is prepared by aseptically transferring one colony from an agar plate or slant to 10 mL of sterile Tryptic Soy Broth (TSB) (Section 7.3.6) which is then incubated at $35 \pm 2^\circ\text{C}$ for 24 ± 4 hours. A series of at least three but no more than 10 additional 24 hour broth transfers are made in 10 mL of TSB from this broth culture.

A 2-liter flask containing 1000 mL of TSB is inoculated with 1.0 mL of a 24-hour broth transfer. The flask is incubated for 24 ± 4 hours at $35 \pm 2^\circ\text{C}$. Prior to any withdrawal of culture, whether for hand contamination or for numbers assay, the suspension is stirred or shaken. A suspension is not used for more than eight hours.

The suspension is assayed for the number of organisms at the beginning and end of the use period.

11.0 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 as well as the number per hand.

The data will be evaluated using parametric statistical analyses as follows:

Bacterial counts recovered from the hands will be transformed into log counts. The log count of each subjects left and right hand will be averaged. The changes from baseline counts at each sampling interval will be obtained for each test article.

An analysis of variance will be performed on the data to:

Compare baseline counts of subjects assigned different test articles.

Evaluate the effectiveness of each treatments as a function of the number of treatments (within treatment analysis).

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12.0 ADVERSE EXPERIENCES

12.1 Definitions

An Adverse Event/Experience/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

12.2 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).

12.3 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.

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13.0 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).

14.0 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.

15.0 DEVIATIONS FROM PROTOCOL

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

16.0 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 on microfilm. The original source data will be maintained according to the investigator's standard operating procedure. A copy of the source documents may be obtained upon request of the Study Sponsor. Copies of transcribed data will be incorporated in the report.

17.0 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.

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18.0 PROTOCOL APPROVAL

HILL TOP RESEARCH, INC.

By: *Gayle K. Mulberry* 7-24-00
Gayle K. Mulberry (Date)
Investigator

THE DIAL CORPORATION

By: *Jamie Stule* 7-25-00
(Date)

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EXHIBIT A

SAMPLE CONSENT FORM

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 measure the ability of two liquid soap products to reduce the number of bacteria on the hands after repetitive use. Approximately ninety (90) people between and including the ages of 18 – 65 will be screened as potential subjects in this study. Forty-five (45) subjects are expected to complete the three-visit study.

TEST ARTICLES: One of the test articles is an experimental antibacterial liquid soap product. The other test material is a marketed antibacterial liquid soap product. One product will be randomly assigned to each participating subject.

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, Ban® antiperspirant/deodorant, and rubber and poly gloves to be used at least one week prior to the start of the actual study. You will be given written instructions on how to use the kit.

After at least one week, you will be required to return to the lab. You will be asked to complete another brief medical history questionnaire. 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 and wrists. You will wash your hands with a non-medicated soap. Then, your hands will be contaminated with a watery liquid containing a non-harmful bacteria (*Escherichia coli*). This liquid containing the bacteria will be spread over the surfaces of the hands, and the hands will be allowed to air dry. Following air drying, the hands will be sampled. Sampling is accomplished by having you place your hands into large plastic bags to which will be added a mild soap-like solution. A laboratory technician will massage each bagged hand for one minute. The hands will be removed from the bags and the solution from each bag will be tested to determine the number of test bacteria added to the hands. Following the baseline sampling, your hands will be rinsed with tap water and

- washed with a non-medicated soap and dried. You will then begin the treatment part of the study. Prior to each treatment, your hands will be contaminated with bacteria as described above. Your hands and wrists will then be treated (washed) with the test material, following specific instructions. Your hands will be contaminated and treated 11 times. Your hands will be sampled (to determine the number of bacteria removed or killed by treatment) after the 1st and 11th washes. After the 1st and 11th sampling wash, the hands are washed with a non-medicated soap. Following the last sampling, your hands will be treated with alcohol, rinsed with water followed by a wash with Hibiclens®, an antimicrobial soap, prior to leaving the lab.

After completing the treatment visit 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 eight days after you have completed treatment, you will be required to return to the lab for a follow-up visit. 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 contamination 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 intact skin, and (2) the skin is cleansed with antibacterial products following contact with the test bacteria.

You may also develop a reaction on your hands from the test materials. A reaction could be redness, swelling, itching, cracking, peeling, or in rare cases, blistering.

No risks to you as a study participant, other than those described above, 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 application 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 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, workers' compensation coverage may be available. In accordance with Ohio law, Hill Top Research has secured workers' compensation coverage for participants in its studies and tests, and has paid and will pay appropriate premiums into the State Insurance Fund on behalf of such participants.

WHO TO CONTACT: If you have any questions about this study or in case of an emergency, contact Glenna, Study Coordinator, at 831-3114 ext. 2920 during business hours (M-F, 8:00 A.M. - 5:00 P.M.) or Ann Brady, Study Manager, at 831-3354 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 1-513-831-3114.

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 comply with study procedures, your participation may be terminated.

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 \$80.00 for the completion of this study. You will be compensated according to the following schedule:

If you complete	Visit 1	You will receive	\$0*
If you do not qualify	Visit 2	you will receive	\$10.00
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	\$80.00

*No payment-kit products given.

Payments 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. (Soap, shampoo, roll-on antiperspirant/deodorant and gloves)

EXHIBIT B**EVALUATION OF HEALTH CARE PERSONNEL HANDWASH**
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 chlorinated 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 - 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 Emilie, Study Coordinator, at 831-3114 ext. 2324 between 8:00 a.m. - 5:00 p.m. or Ann Brady, Study Manager, after hours and on weekends at 831-3354.

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 #:	00-105821-11

Gender: <input type="checkbox"/> Male(1) <input type="checkbox"/> Female(2)	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:

Comments:

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

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

D00265

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

HTR Study No.: 00-105821-11

Page No.: II - 25

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Subject Qualification	____/____/____ mm dd yy	____/____/____ F M L	Permanent #:	00-105821-11

INCLUSION CRITERIA

Check one		Subject:
YES	NO	
		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			Subject:
YES	NO	N/A	
			1. Is currently participating in another clinical study at this or any other facility ?
			2. Has participated in any type of hand or arm wash study within the past 7 days ?
			3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
			4. Has artificial nails or nail tips?
			5. Has soap, detergent, and/or perfume allergies ?
			6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	7. 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
			8. Is currently lactating ? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA
			9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, or AIDS (or HIV positive) ?
			10. Has another medical condition which in the opinion of the Investigator would preclude participation ?

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 00266

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Test Period	<u> </u> / <u> </u> / <u> </u> mm dd yy	<u> </u> / <u> </u> / <u> </u> F M L	Permanent #:	00-105821-11

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

IV. 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

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS
CFU/mL of Sampling Solution

Date	Subject Initials	Subject Screen #	Study #
<u> </u> / <u> </u> / <u> </u>	<u> </u> / <u> </u> / <u> </u>	Permanent #:	00-105821-11
mm dd yy	F M L		

BASELINE					
LEFT HAND DILUTIONS			RIGHT HAND DILUTIONS		
10 ⁻³	10 ⁻⁴	10 ⁻⁵	10 ⁻³	10 ⁻⁴	10 ⁻⁵
CFU/mL _____ Counted by: _____ / _____			CFU/mL _____ Counted by: _____ / _____		

LEFT HAND				WASH 1		RIGHT HAND		
10 ^{-1*}	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ^{-1*}	10 ⁻²	10 ⁻³	10 ⁻⁴	
CFU/mL _____ Counted by: _____ / _____				CFU/mL _____ Counted by: _____ / _____				

LEFT HAND				WASH 11		RIGHT HAND		
10 ^{-1*}	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ^{-1*}	10 ⁻²	10 ⁻³	10 ⁻⁴	
CFU/mL _____ Counted by: _____ / _____				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 in duplicate.
 TNTC – Too Numerous To Count

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

Data Collection Form 5A

Subject Initials _____ Subject # _____

Study No. 00-105821-11

Page No. II-28

ADVERSE EVENTS

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

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

Symptom / Event	Onset Date	End Date	SAE ¹ Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Initials/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	____/____/____ mm dd yy	____/____/____ F M L	Permanent #:	00-105821-11

Date Subject Entered the Study: ____/____/____ mm dd yy	Follow-Up Visit Date: ____/____/____ mm dd yy
--	--

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?

YES NO If yes, complete below:

Clinical Observations: (Include date of onset and descriptions/severity/locations, etc.)

Comments: _____

Has the subject had any health related issues since the treatment procedure?

YES NO If yes, complete below

Comments: _____

Medical Consultant's Signature:	Recorded by:	Date ____/____/____ mm dd yy
--	---------------------	---

August 2, 2000

HTR Ref.: 00-105821-11

Page: II-32

PROTOCOL AMENDMENT #1

Efficacy Evaluation of Health Care Personnel Handwash Products

Reason for change:

This amendment is needed to change the lot code for HTR Code A.

Page 3, STUDY MATERIAL, 7.1, Test Article, HTR Code A,

Which reads:

Lot Code: 3372-130

Changed to read:

Lot Code: EPS 3398-29A

Attached is a memo from the sponsor concerning the formula composition of the test article, EPS 3398-29A which is replacing 3372-130.

Approved for: HILL TOP RESEARCH, INC.

By: Gayle K. Mulberry 8-2-00
Gayle K. Mulberry, M.S. Date
Investigator

By: Naunfel 8-2-00
IRB Date

Accepted by: DIAL CORPORATION

By: George Fisher 2 Aug 2000
George Fisher Date
Sponsor Representative
GEORGE FISHER

IRB of
Hill Top Research

AUG 2, 2000

Approved

000272

08/10/2000 11:25 5136311217

HILL TOP RESEARCHING

PAGE 02

Post-it* Fax Note	7671	Date	8-10-00	# of pages	1
To	Ann Brady	From	Janice Fuls		
Co./Dept.	Hill Top	Co.	Dial		
Phone #		Phone #			
Fax #	513-831-1217	Fax #	480-754-6180		

HTR Ref: 00-105821-11

Page: II-35

AMENDMENT #2

Amendment of Human Care Personnel Handwash Products

Reason for change:

This amendment is needed to add 12 additional people to the test phase. The additional subjects are required because data from 12 subjects tested on Aug 7, 2000 is not considered valid due to a protocol deviation. The test culture was grown at ~25° C instead of 35 ± 2° C as specified in the protocol. The inoculum count obtained from this culture was about 1 log lower than expected resulting in baseline hands counts about 1 log lower than expected.

Page 3, EXPERIMENTAL DESIGN, 6.0, third sentence,

Which reads:

Forty-five (45) subjects are expected to start and complete the study, thirty (30) using HTR Code A and fifteen (15) using HTR Code B.

Changed to read:

Fifty-seven (57) subjects are expected to start and complete the study, thirty (30) subjects with usable data for HTR Code A and fifteen (15) subjects with usable data for HTR Code B.

Attached is the revised consent form with the changes mentioned above.

Approved for: HILL TOP RESEARCH, INC.

By: Gayle K. Mulberry 8-10-00
Date
Investigator

By: L. Lea Johnston 8-10-00
Date
IRB

Accepted by: DIAL CORPORATION

By: Janice Fuls 8-10-00
Date
Sponsor Representative

**IRB of
Hill Top Research
AUG 10 2000
Approved**

D00273

HTR-Study No. 00-105821-11

Formula Ingredient Statement

EPS 3398-29A Code A, Foaming Antimicrobial Handsoap

Active Ingredient: 1.0% Triclosan

Other Ingredients: Water (aqua), Sodium Xylenesulfonate, Dipropylene Glycol, Ammonium Lauryl Sulfate, Cocamidopropyl Betaine, Fragrance (Parfum), Sodium Phosphate, Citric Acid, Red 4, Yellow 5.

3372-131 Code B, Hibiclens

Active Ingredient: 4% Chlorhexidine gluconate

Ingredients: Fragrance, isopropyl alcohol 4%, purified water, Red 40 and other ingredients in a nonalkaline base.

HTR Study No.: 00-105821-11

APPENDIX III

Total number of pages = 1

Miscellaneous Procedural Information

MISCELLANEOUS PROCEDURAL INFORMATION

1. Stripping Solution with Neutralizer

The stripping solution with neutralizer used for sampling contained 0.41 g KH_2PO_4 , 10.3 g Na_2HPO_4 , 10.0 g Tween 80, 3.0 g Lecithin and 1.0 g Triton X-100, in one liter purified water. The pH was adjusted to 7.8 ± 0.1 prior to dispensing into water dilution bottles, or other suitable containers, to yield a final volume of 75 ± 1.0 mL after autoclaving at 121°C .

2. Dilution Fluid: Butterfield's Phosphate Buffer with Neutralizer

The dilution fluid contained 1.25 mL AOAC Phosphate Buffer Stock* with 3.0 g Lecithin, and 10.0 g Tween 80 in one liter purified water. The pH was adjusted to 7.2 ± 0.2 prior to dispensing into tubes, to yield a final volume of 9.0 ± 0.1 mL after autoclaving at 121°C .

*The AOAC Phosphate Buffer Stock contained 34.0 g KH_2PO_4 in one liter of purified water. The pH was adjusted to 7.2 prior to dispensing into water dilution bottles, to yield a final volume of approximately 100 mL after autoclaving at 121°C .

Note: Recipes which are given as liter volumes may be prepared in greater or lesser volumes.

HTR Study No.: 00-105821-11

APPENDIX IV

Total number of pages = 1

Subjects Excluded/Withdrawn from the Study

D00277

Subjects Excluded/Withdrawn from the Study

Subject Screening No.	Reason
101, 102, 107, 108, 123, 113, 123, 125, 126, 128, 131, 135, 139, 142, 145, 145, 152, 157, 158, 162, 166, 168, 169, 172, 175, 176, 177, 179, 180, 182, 189, 190, 197, 198, 202, 205, 208, 209, 211, 213, 216, 222, 223	Subjects withdrew prior to test day – personal reasons
106, 138, 151, 156, 185, 186, 203, 206, 217, 220	Subjects excluded – cut/scabs on hand/wrist
181	Subject excluded – hepatitis
150	Subject excluded – diabetic
212	Subject excluded by investigator due to medical condition
159	Subject excluded – could not remove ring
178, 214, 215	Subjects excluded – extra subject
204	Subjects excluded – currently enrolled on another study

HTR Study No.: 00-105821-11

APPENDIX V

Total number of pages = 1

Adverse Event

D00279

Data Collection Form 5A

Subject Initials JAM Subject # 42

Study No. 00-105821-11

Page No. II-303

ADVERSE EVENTS

8/27/00

Symptom / Event	Onset Date	End Date	SAE ¹ Y/N	Severity	Action Taken	Outcome	Relationship	Investigator Initials/Date
Erythema	08/18/00	08/20/00	N	mod.	1	1	3**	C. J. 8-20-00
Entry Date	Comment/Note: ** Maybe related to application of test organism. <i>① 8/21/00</i>							Initials
08/18/00	Subject noticed redness @ Right dorsal hand p 2nd or 3rd wash on 08/18/00 - moderate erythema c few papules @ hand - also mild edema.							
	Mild erythema few papules @ dorsal hand.							08/18/00

Symptom / Event	Onset Date	End Date	SAE ¹ Y/N	Severity	Action Taken	Outcome	Relationship	Investigator Initials/Date
Erythema (continued from above)					NA EC	8-28-00		
Entry Date	Comment/Note:							Initials
8-20-00	Hands were clear on this date							C. J.
8-22-00								8/20/00
8-27								8/22/00
								C. R. J.

Symptom / Event	Onset Date	End Date	SAE ¹ Y/N	Severity	Action Taken	Outcome	Relationship	Investigator Initials/Date
NA EC 8-28-00								
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

HTR Study No.: 00-105821-11

APPENDIX VI

Total number of pages = 4

Test for Adequacy of Neutralizer

D00281

TEST FOR ADEQUACY OF THE NEUTRALIZER

1.0 OBJECTIVE

To assess the effectiveness of a neutralizer system in quenching the activity of two test articles in recovery media used in the Health Care Personnel Handwash study, Ref. No. 00-105821-11.

2.0 TEST ARTICLES

The following test articles were received by Hill Top Research on July 18, 2000.

<u>Sponsor Code</u>	<u>Description</u>
3372-130*	White translucent plastic bottle (approx. 8 oz.) with white pump nozzle unit with colorless liquid inside
3372-131	Aqua plastic bottle with white plastic cap with product inside

*This material is the same composition and formulation as EPS 3398-29A (see sponsor's letter in Exhibit A).

3.0 PROCEDURE

Two subjects, each using one of the following test articles, Sponsor codes 3372-130 or 3372-131, washed their hands eleven times according to the protocol directions. One hand was stripped after eleven washes using stripping solution with neutralizer¹. A 1.0 mL aliquot of the stripping solution was added to a 9.0 mL tube of dilution fluid with neutralizer². A 10.0 mL aliquot of stripping solution with neutralizer was also collected and placed in a sterile tube.

A 0.1 mL aliquot of diluted *Escherichia coli* ATCC 11229 was added to the test and control tubes to achieve a final concentration of 10 – 100 CFU/mL. The diluted culture was a 24 ± 4 hour Tryptic Soy Broth³ culture of *E. coli* ATCC 11229 and was serially diluted to 10⁻⁵ in 0.9% saline⁴.

After mixing, aliquots from the inoculated tubes were plated immediately and again at 30 minutes by spreading 1.0 mL across three Nutrient Agar with MUG⁵ plates in duplicate. The plates were incubated at 35 ± 2°C for 18 - 24 hours.

HTR Study No.: 00-105821-11

3.0 PROCEDURE (CONT.)

After incubation, the numbers of *E. coli* colony forming units were enumerated.

Numbers and toxicity control tubes were also prepared. The numbers control consisted of 10.0 mL 0.9% saline. The toxicity controls consisted of 1.0 mL of stripping solution with neutralizer in 9.0 mL dilution fluid with neutralizer and 10.0 mL of stripping solution with neutralizer. These controls were inoculated and plated in the same manner as the collected samples.

4.0 RESULTS

Results are shown in the Tables of Results.

5.0 CONCLUSIONS

The neutralizer system is considered effective if recovery is $\geq 50\%$ of the corresponding numbers control. In this study, the neutralizer effectively neutralized the antimicrobials.

TABLE OF RESULTS
RECOVERY OF *E. COLI* ATCC 11229

ARTICLE	TIME	PLATE COUNTS*						CFU/mL	% RECOVERY
		46	38	49	50	32	47		
Numbers Control	0 min.	46	38	49	50	32	47	1.3×10^2	NA**
	30 min.	46	57	55	56	61	52	1.6×10^2	NA
Toxicity Control – 10.0 mL Stripping Solution with Neutralizer	0 min.	41	35	45	54	36	31	1.2×10^2	92
	30 min.	57	56	47	47	47	52	1.5×10^2	94
Toxicity Control - 1.0 mL Stripping Solution with Neutralizer into 9.0 mL Diluent with Neutralizer	0 min.	42	44	32	36	38	48	1.2×10^2	92
	30 min.	56	48	67	49	43	44	1.5×10^2	94
Sponsor Code 3372-130 – 10 mL Stripping Solution with Neutralizer	0 min.	0	0	0	0	0	0	$<1.0 \times 10^0$	0
	30 min.	0	0	0	0	0	0	$<1.0 \times 10^0$	0
Sponsor Code 3372-130 – 1 mL Stripping Solution with Neutralizer into 9.0 mL Diluent with Neutralizer	0 min.	55	49	39	51	48	56	1.5×10^2	115
	30 min.	53	39	42	49	55	36	1.4×10^2	88
Sponsor Code 3372-131 – 10 mL Stripping Solution with Neutralizer	0 min.	45	44	45	41	46	55	1.4×10^2	108
	30 min.	46	37	39	43	44	42	1.2×10^2	75
Sponsor Code 3372-131 – 1 mL Stripping Solution with Neutralizer into 9.0 mL Diluent with Neutralizer	0 min.	42	44	38	58	69	55	1.5×10^2	115
	30 min.	34	51	50	48	47	38	1.3×10^2	81

*1.0 mL spread across three plates.

**NA = Not Applicable

$$0 \text{ Minute \% Recovery} = \frac{\text{Count at 0 min.}}{\text{Numbers Control Count at 0 min.}} \times 100$$

$$30 \text{ Minute \% Recovery} = \frac{\text{Count at 30 min.}}{\text{Numbers Control Count at 30 min.}} \times 100$$

REFERENCES

1. **Stripping Solution with Neutralizer**

The stripping solution with neutralizer used for sampling contained 0.41 g KH_2PO_4 , 10.3 g Na_2HPO_4 , 10.0 g Tween 80, 3.0 g Lecithin and 1.0 g Triton X-100, in one liter purified water. The pH was adjusted to 7.8 ± 0.1 prior to dispensing into water dilution bottles, or other suitable containers, to yield a final volume of 75 ± 1.0 mL after autoclaving at 121°C .

2. **Dilution Fluid: Butterfield's Phosphate Buffer with Neutralizer**

The dilution fluid contained 1.25 mL AOAC Phosphate Buffer Stock* with 3.0 g Lecithin, and 10.0 g Tween 80 in one liter purified water. The pH was adjusted to 7.2 ± 0.2 prior to dispensing into tubes, to yield a final volume of 9.0 ± 0.1 mL after autoclaving at 121°C .

4. **Tryptic Soy Broth**

The broth contained 30.0 g Tryptic Soy Broth powder in one liter purified water. The pH was 7.3 ± 0.2 . The media was dispensed into tubes and sterilized by autoclaving at 121°C .

4. **0.9% Saline**

The saline contained 9.0 g NaCl in one liter purified water. The material was dispensed into tubes to yield a final volume of 9.0 ± 0.1 mL after autoclaving at 121°C . For the numbers control, the volume of saline was aseptically adjusted to 10.0 mL.

5. **Nutrient Agar with MUG**

The plating medium contained 23.0 g Nutrient Agar powder and 0.1 g MUG powder in one liter purified water. The pH was 6.8 ± 0.2 . The media was autoclaved at 121°C . After autoclaving and tempering, the media was aseptically dispensed into sterile Petri dishes, approximately 18 - 20 mL per plate.

*The AOAC Phosphate Buffer Stock contained 34.0 g KH_2PO_4 in one liter of purified water. The pH was adjusted to 7.2 prior to dispensing into water dilution bottles, to yield a final volume of approximately 100 mL after autoclaving at 121°C .

Note: Recipes which are given as liter volumes may be prepared in greater or lesser volumes.

APPENDIX VII

Total number of pages = 20

Statistical Tables

Table 1	Summary of CFU counts and log conversions
Table 2a	Mean summary of \log_{10} averages
Table 2b	Mean summary of \log_{10} average reductions
Table 3	Means summary of \log_{10} reductions from baseline, percent microbial reductions, and confidence limits
Table 4	Analysis of variance for comparison of test article \log_{10} baseline counts
Table 5	Analysis of variance to evaluate the effectiveness of each treatment as a function of the number of treatments

HTR Study Number 00-105821-11
 Table 1. Summary of CFU counts and log conversions.

09:47 Wednesday, August 23, 2000

HTR Code=A: EPS 3398-29A

Subject	Wash	Left			Right			Log10 Average	Log10 Reduction
		CFU/mL	CFU/Hand	Log10 CFU/Hand	CFU/mL	CFU/Hand	Log10 CFU/Hand		
1	Baseline	2.4E6	1.8E+08	8.2553	1.5E6	1.1E+08	8.0512	8.1532	.
	Wash 1	3.5E1	2.6E+03	3.4191	1.5E1	1.1E+03	3.0512	3.2351	4.9181
	Wash 11	3.0E1	2.3E+03	3.3522	5.0E1	3.8E+03	3.5740	3.4631	4.6901
2	Baseline	8.6E6	6.5E+08	8.8096	8.7E6	6.5E+08	8.8146	8.8121	.
	Wash 1	1.7E3	1.3E+05	5.1055	3.1E3	2.3E+05	5.3664	5.2360	3.5761
	Wash 11	8.4E2	6.3E+04	4.7993	9.4E2	7.1E+04	4.8482	4.8238	3.9883
3	Baseline	1.1E7	8.3E+08	8.9165	1.2E7	9.0E+08	8.9542	8.9353	.
	Wash 1	1.9E3	1.4E+05	5.1538	2.0E4	1.5E+06	6.1761	5.6650	3.2704
	Wash 11	2.2E2	1.7E+04	4.2175	1.8E2	1.4E+04	4.1303	4.1739	4.7614
5	Baseline	4.6E6	3.5E+08	8.5378	4.1E6	3.1E+08	8.4878	8.5128	.
	Wash 1	3.1E2	2.3E+04	4.3664	1.5E1	1.1E+03	3.0512	3.7088	4.8040
	Wash 11	3.4E2	2.6E+04	4.4065	4.8E2	3.6E+04	4.5563	4.4814	4.0314
6	Baseline	9.4E6	7.1E+08	8.8482	9.8E6	7.4E+08	8.8663	8.8572	.
	Wash 1	2.1E3	1.6E+05	5.1973	2.5E3	1.9E+05	5.2730	5.2351	3.6221
	Wash 11	6.8E2	5.1E+04	4.7076	4.1E2	3.1E+04	4.4878	4.5977	4.2595
7	Baseline	7.6E6	5.7E+08	8.7559	9.2E6	6.9E+08	8.8388	8.7974	.
	Wash 1	3.1E3	2.3E+05	5.3664	2.2E3	1.7E+05	5.2175	5.2920	3.5054
	Wash 11	4.8E2	3.6E+04	4.5563	1.4E2	1.1E+04	4.0212	4.2887	4.5086
8	Baseline	1.3E7	9.8E+08	8.9890	1.1E7	8.3E+08	8.9165	8.9527	.
	Wash 1	6.5E1	4.9E+03	3.6880	1.6E3	1.2E+05	5.0792	4.3836	4.5692
	Wash 11	5.2E2	3.9E+04	4.5911	9.0E2	6.8E+04	4.8293	4.7102	4.2425
9	Baseline	1.3E7	9.8E+08	8.9890	1.4E7	1.1E+09	9.0212	9.0051	.
	Wash 1	2.4E3	1.8E+05	5.2553	3.4E7	2.6E+09	9.4065	7.3309	1.6742
	Wash 11	2.4E2	1.8E+04	4.2553	8.6E2	6.5E+04	4.8096	4.5324	4.4727
10	Baseline	1.1E7	8.3E+08	8.9165	1.0E7	7.5E+08	8.8751	8.8958	.
	Wash 1	8.8E2	6.6E+04	4.8195	1.3E3	9.8E+04	4.9890	4.9043	3.9915
	Wash 11	5.5E1	4.1E+03	3.6154	2.0E1	1.5E+03	3.1761	3.3958	5.5000
11	Baseline	6.2E5	4.7E+07	7.6675	6.0E5	4.5E+07	7.6532	7.6603	.
	Wash 1	<1.0E1	7.5E+02	2.8751	<1.0E1	7.5E+02	2.8751	2.8751	4.7853
	Wash 11	1.0E2	7.5E+03	3.8751	1.2E2	9.0E+03	3.9542	3.9147	3.7457
13	Baseline	1.6E5	1.2E+07	7.0792	2.7E5	2.0E+07	7.3064	7.1928	.
	Wash 1	1.0E1	7.5E+02	2.8751	<1.0E1	7.5E+02	2.8751	2.8751	4.3177
	Wash 11	1.0E1	7.5E+02	2.8751	<1.0E1	7.5E+02	2.8751	2.8751	4.3177
14	Baseline	1.6E5	1.2E+07	7.0792	1.4E5	1.1E+07	7.0212	7.0502	.
	Wash 1	<1.0E1	7.5E+02	2.8751	2.0E1	1.5E+03	3.1761	3.0256	4.0246
	Wash 11	<1.0E1	7.5E+02	2.8751	<1.0E1	7.5E+02	2.8751	2.8751	4.1751
15	Baseline	2.5E5	1.9E+07	7.2730	2.5E5	1.9E+07	7.2730	7.2730	.
	Wash 1	<1.0E1	7.5E+02	2.8751	<1.0E1	7.5E+02	2.8751	2.8751	4.3979
	Wash 11	<1.0E1	7.5E+02	2.8751	<1.0E1	7.5E+02	2.8751	2.8751	4.3979
19	Baseline	2.5E5	1.9E+07	7.2730	3.0E5	2.3E+07	7.3522	7.3126	.

Where score has been recorded as <1.0E1, a score of 1.0E1 will be used in the analysis.
 Subjects 11, 13 - 21, 23, and 28 will not be included in any analyses due to deviations with the test culture.

D00287

HTR Study Number 00-105821-11
 Table 1. Summary of CFU counts and log conversions.

09:47 Wednesday, August 23, 2000

HTR Code=A: EPS 3398-29A

Subject	Wash	Left			Right			Log10 Average	Log10 Reduction
		CFU/mL	CFU/Hand	Log10 CFU/Hand	CFU/mL	CFU/Hand	Log10 CFU/Hand		
19	Wash 1	<1.0E1	7.5E+02	2.8751	2.5E1	1.9E+03	3.2730	3.0740	4.2386
	Wash 11	<1.0E1	7.5E+02	2.8751	<1.0E1	7.5E+02	2.8751	2.8751	4.4375
21	Baseline	8.2E5	6.2E+07	7.7889	1.1E6	8.3E+07	7.9165	7.8527	.
	Wash 1	5.1E2	3.8E+04	4.5826	4.4E2	3.3E+04	4.5185	4.5506	3.3021
	Wash 11	2.9E3	2.2E+05	5.3375	3.6E3	2.7E+05	5.4314	5.3844	2.4683
22	Baseline	7.1E6	5.3E+08	8.7263	6.0E6	4.5E+08	8.6532	8.6898	.
	Wash 1	2.6E2	2.0E+04	4.2900	4.2E2	3.2E+04	4.4983	4.3942	4.2956
	Wash 11	1.2E2	9.0E+03	3.9542	1.4E2	1.1E+04	4.0212	3.9877	4.7021
24	Baseline	6.4E6	4.8E+08	8.6812	8.8E6	6.6E+08	8.8195	8.7504	.
	Wash 1	9.6E3	7.2E+05	5.8573	5.3E3	4.0E+05	5.5993	5.7283	3.0221
	Wash 11	3.8E3	2.9E+05	5.4548	2.6E3	2.0E+05	5.2900	5.3724	3.3780
25	Baseline	4.6E6	3.5E+08	8.5378	6.3E6	4.7E+08	8.6744	8.6061	.
	Wash 1	4.3E3	3.2E+05	5.5085	2.8E3	2.1E+05	5.3222	5.4154	3.1907
	Wash 11	4.2E2	3.2E+04	4.4983	4.2E2	3.2E+04	4.4983	4.4983	4.1078
26	Baseline	9.0E6	6.8E+08	8.8293	6.8E6	5.1E+08	8.7076	8.7684	.
	Wash 1	8.7E3	6.5E+05	5.8146	1.3E3	9.8E+04	4.9890	5.4018	3.3666
	Wash 11	2.6E3	2.0E+05	5.2900	2.2E3	1.7E+05	5.2175	5.2538	3.5147
27	Baseline	5.0E6	3.8E+08	8.5740	5.8E6	4.4E+08	8.6385	8.6063	.
	Wash 1	8.3E2	6.2E+04	4.7941	4.0E2	3.0E+04	4.4771	4.6356	3.9706
	Wash 11	5.2E2	3.9E+04	4.5911	5.4E2	4.1E+04	4.6075	4.5993	4.0070
29	Baseline	8.1E6	6.1E+08	8.7835	9.3E6	7.0E+08	8.8435	8.8135	.
	Wash 1	4.1E3	3.1E+05	5.4878	5.2E2	3.9E+04	4.5911	5.0395	3.7741
	Wash 11	1.0E3	7.5E+04	4.8751	2.0E3	1.5E+05	5.1761	5.0256	3.7880
30	Baseline	9.0E6	6.8E+08	8.8293	1.0E7	7.5E+08	8.8751	8.8522	.
	Wash 1	3.2E2	2.4E+04	4.3802	4.0E1	3.0E+03	3.4771	3.9287	4.9235
	Wash 11	2.2E3	1.7E+05	5.2175	1.3E3	9.8E+04	4.9890	5.1032	3.7489
32	Baseline	4.8E4	3.6E+06	6.5563	9.0E3	6.8E+05	5.8293	6.1928	.
	Wash 1	<1.0E1	7.5E+02	2.8751	<1.0E1	7.5E+02	2.8751	2.8751	3.3177
	Wash 11	5.5E1	4.1E+03	3.6154	6.0E1	4.5E+03	3.6532	3.6343	2.5585
33	Baseline	7.6E6	5.7E+08	8.7559	1.0E7	7.5E+08	8.8751	8.8155	.
	Wash 1	2.8E2	2.1E+04	4.3222	8.6E2	6.5E+04	4.8096	4.5659	4.2496
	Wash 11	2.2E2	1.7E+04	4.2175	2.6E2	2.0E+04	4.2900	4.2538	4.5617
35	Baseline	8.6E6	6.5E+08	8.8096	1.1E7	8.3E+08	8.9165	8.8630	.
	Wash 1	6.6E3	5.0E+05	5.6946	2.8E3	2.1E+05	5.3222	5.5084	3.3546
	Wash 11	9.2E3	6.9E+05	5.8388	1.5E3	1.1E+05	5.0512	5.4450	3.4180
36	Baseline	8.4E6	6.3E+08	8.7993	7.7E6	5.8E+08	8.7616	8.7804	.
	Wash 1	1.3E2	9.8E+03	3.9890	8.5E1	6.4E+03	3.8045	3.8967	4.8837
	Wash 11	1.5E1	1.1E+03	3.0512	1.5E1	1.1E+03	3.0512	3.0512	5.7293
39	Baseline	1.1E7	8.3E+08	8.9165	1.0E7	7.5E+08	8.8751	8.8958	.
	Wash 1	9.7E3	7.3E+05	5.8618	1.0E4	7.5E+05	5.8751	5.8684	3.0273

Where score has been recorded as <1.0E1, a score of 1.0E1 will be used in the analysis.
 Subjects 11, 13 - 21, 23, and 28 will not be included in any analyses due to deviations with the test culture.

000288

HTR Study Number 00-105821-11
 Table 1. Summary of CFU counts and log conversions.

09:47 Wednesday, August 23, 2000

HTR Code=A: EPS 3398-29A

Subject	Wash	Left			Right			Log10 Average	Log10 Reduction
		CFU/mL	CFU/Hand	Log10 CFU/Hand	CFU/mL	CFU/Hand	Log10 CFU/Hand		
39	Wash 11	1.0E4	7.5E+05	5.8751	7.2E3	5.4E+05	5.7324	5.8037	3.0920
43	Baseline	6.5E6	4.9E+08	8.6880	6.6E6	5.0E+08	8.6946	8.6913	.
	Wash 1	7.1E2	5.3E+04	4.7263	1.6E3	1.2E+05	5.0792	4.9028	3.7885
	Wash 11	4.0E3	3.0E+05	5.4771	2.4E3	1.8E+05	5.2553	5.3662	3.3251
44	Baseline	3.0E6	2.3E+08	8.3522	3.6E6	2.7E+08	8.4314	8.3918	.
	Wash 1	1.4E2	1.1E+04	4.0212	2.0E2	1.5E+04	4.1761	4.0986	4.2931
	Wash 11	3.3E2	2.5E+04	4.3936	2.4E3	1.8E+05	5.2553	4.8244	3.5673
45	Baseline	1.2E7	9.0E+08	8.9542	1.2E7	9.0E+08	8.9542	8.9542	.
	Wash 1	8.8E2	6.6E+04	4.8195	2.2E3	1.7E+05	5.2175	5.0185	3.9357
	Wash 11	1.2E3	9.0E+04	4.9542	6.2E2	4.7E+04	4.6675	4.8108	4.1434
46	Baseline	6.2E6	4.7E+08	8.6675	7.7E6	5.8E+08	8.7616	8.7145	.
	Wash 1	2.1E3	1.6E+05	5.1973	2.9E3	2.2E+05	5.3375	5.2674	3.4471
	Wash 11	7.0E2	5.3E+04	4.7202	8.2E2	6.2E+04	4.7889	4.7545	3.9600
47	Baseline	8.7E6	6.5E+08	8.8146	1.1E7	8.3E+08	8.9165	8.8655	.
	Wash 1	1.2E2	9.0E+03	3.9542	1.4E3	1.1E+05	5.0212	4.4877	4.3778
	Wash 11	1.5E1	1.1E+03	3.0512	5.4E2	4.1E+04	4.6075	3.8293	5.0362
48	Baseline	9.4E6	7.1E+08	8.8482	1.1E7	8.3E+08	8.9165	8.8823	.
	Wash 1	7.3E3	5.5E+05	5.7384	2.0E3	1.5E+05	5.1761	5.4572	3.4251
	Wash 11	5.1E3	3.8E+05	5.5826	1.2E4	9.0E+05	5.9542	5.7684	3.1139
49	Baseline	8.2E6	6.2E+08	8.7889	8.0E6	6.0E+08	8.7782	8.7835	.
	Wash 1	1.3E3	9.8E+04	4.9890	5.2E2	3.9E+04	4.5911	4.7900	3.9935
	Wash 11	1.3E3	9.8E+04	4.9890	7.4E2	5.6E+04	4.7443	4.8666	3.9169
53	Baseline	1.2E7	9.0E+08	8.9542	1.2E7	9.0E+08	8.9542	8.9542	.
	Wash 1	2.3E3	1.7E+05	5.2368	3.2E3	2.4E+05	5.3802	5.3085	3.6457
	Wash 11	2.7E3	2.0E+05	5.3064	5.2E2	3.9E+04	4.5911	4.9487	4.0055
55	Baseline	6.6E6	5.0E+08	8.6946	8.6E6	6.5E+08	8.8096	8.7521	.
	Wash 1	2.9E3	2.2E+05	5.3375	3.1E3	2.3E+05	5.3664	5.3519	3.4001
	Wash 11	6.0E3	4.5E+05	5.6532	2.7E3	2.0E+05	5.3064	5.4798	3.2723

Where score has been recorded as <1.0E1, a score of 1.0E1 will be used in the analysis.
 Subjects 11, 13 - 21, 23, and 28 will not be included in any analyses due to deviations with the test culture.

000289

HTR Study Number 00-105821-11
 Table 1. Summary of CFU counts and log conversions.

09:47 Wednesday, August 23, 2000

HTR Code=B: 3372-131 Hibiclens

Subject	Wash	Left			Right			Log10 Average	Log10 Reduction
		CFU/mL	CFU/Hand	Log10 CFU/Hand	CFU/mL	CFU/Hand	Log10 CFU/Hand		
4	Baseline	8.0E6	6.0E+08	8.7782	8.8E6	6.6E+08	8.8195	8.7988	.
	Wash 1	1.8E4	1.4E+06	6.1303	2.4E4	1.8E+06	6.2553	6.1928	2.6060
	Wash 11	2.0E3	1.5E+05	5.1761	2.0E3	1.5E+05	5.1761	5.1761	3.6228
12	Baseline	1.5E6	1.1E+08	8.0512	2.0E6	1.5E+08	8.1761	8.1136	.
	Wash 1	4.3E3	3.2E+05	5.5085	1.4E4	1.1E+06	6.0212	5.7649	2.3488
	Wash 11	3.2E2	2.4E+04	4.3802	4.6E2	3.5E+04	4.5378	4.4590	3.6546
16	Baseline	6.6E5	5.0E+07	7.6946	7.6E5	5.7E+07	7.7559	7.7252	.
	Wash 1	5.2E2	3.9E+04	4.5911	3.8E2	2.9E+04	4.4548	4.5230	3.2023
	Wash 11	6.0E1	4.5E+03	3.6532	2.0E1	1.5E+03	3.1761	3.4147	4.3106
17	Baseline	5.4E5	4.1E+07	7.6075	6.6E5	5.0E+07	7.6946	7.6510	.
	Wash 1	2.3E2	1.7E+04	4.2368	3.2E2	2.4E+04	4.3802	4.3085	3.3425
	Wash 11	5.5E1	4.1E+03	3.6154	1.2E2	9.0E+03	3.9542	3.7848	3.8662
18	Baseline	6.5E5	4.9E+07	7.6880	9.2E5	6.9E+07	7.8388	7.7634	.
	Wash 1	6.0E2	4.5E+04	4.6532	8.6E2	6.5E+04	4.8096	4.7314	3.0320
	Wash 11	6.0E1	4.5E+03	3.6532	7.5E1	5.6E+03	3.7501	3.7017	4.0617
20	Baseline	4.6E5	3.5E+07	7.5378	4.0E5	3.0E+07	7.4771	7.5075	.
	Wash 1	6.5E1	4.9E+03	3.6880	3.5E1	2.6E+03	3.4191	3.5536	3.9539
	Wash 11	<1.0E1	7.5E+02	2.8751	<1.0E1	7.5E+02	2.8751	2.8751	4.6324
23	Baseline	2.4E5	1.8E+07	7.2553	5.0E5	3.8E+07	7.5740	7.4147	.
	Wash 1	3.4E2	2.6E+04	4.4065	2.2E2	1.7E+04	4.2175	4.3120	3.1026
	Wash 11	1.2E2	9.0E+03	3.9542	2.5E1	1.9E+03	3.2730	3.6136	3.8010
28	Baseline	6.5E5	4.9E+07	7.6880	7.7E5	5.8E+07	7.7616	7.7248	.
	Wash 1	4.0E2	3.0E+04	4.4771	7.9E2	5.9E+04	4.7727	4.6249	3.0999
	Wash 11	4.0E4	3.0E+06	6.4771	1.2E2	9.0E+03	3.9542	5.2157	2.5091
31	Baseline	1.1E7	8.3E+08	8.9165	9.6E6	7.2E+08	8.8573	8.8869	.
	Wash 1	1.3E4	9.8E+05	5.9890	9.6E3	7.2E+05	5.8573	5.9232	2.9637
	Wash 11	9.8E2	7.4E+04	4.8663	2.9E3	2.2E+05	5.3375	5.1019	3.7850
34	Baseline	7.4E6	5.6E+08	8.7443	8.3E6	6.2E+08	8.7941	8.7692	.
	Wash 1	7.8E3	5.9E+05	5.7672	1.1E4	8.3E+05	5.9165	5.8418	2.9274
	Wash 11	2.2E2	1.7E+04	4.2175	8.2E2	6.2E+04	4.7889	4.5032	4.2660
37	Baseline	7.1E6	5.3E+08	8.7263	7.2E6	5.4E+08	8.7324	8.7294	.
	Wash 1	9.2E3	6.9E+05	5.8388	5.3E3	4.0E+05	5.5993	5.7191	3.0103
	Wash 11	7.4E2	5.6E+04	4.7443	5.6E2	4.2E+04	4.6232	4.6838	4.0456
38	Baseline	6.6E6	5.0E+08	8.6946	6.0E6	4.5E+08	8.6532	8.6739	.
	Wash 1	3.7E3	2.8E+05	5.4433	4.5E3	3.4E+05	5.5283	5.4858	3.1881
	Wash 11	9.0E1	6.8E+03	3.8293	5.3E2	4.0E+04	4.5993	4.2143	4.4596
40	Baseline	6.8E6	5.1E+08	8.7076	9.1E6	6.8E+08	8.8341	8.7708	.
	Wash 1	2.4E3	1.8E+05	5.2553	7.1E3	5.3E+05	5.7263	5.4908	3.2800
	Wash 11	1.6E2	1.2E+04	4.0792	9.0E2	6.8E+04	4.8293	4.4542	4.3166
41	Baseline	7.8E6	5.9E+08	8.7672	8.2E6	6.2E+08	8.7889	8.7780	.

Where score has been recorded as <1.0E1, a score of 1.0E1 will be used in the analysis.
 Subjects 11, 13 - 21, 23, and 28 will not be included in any analyses due to deviations with the test culture.

D00290

HTR Study Number 00-105821-11
 Table 1. Summary of CFU counts and log conversions.

09:47 Wednesday, August 23, 2000

----- HTR Code=B: 3372-131 Hibiclens -----

Subject	Wash	Left			Right			Log10 Average	Log10 Reduction
		CFU/mL	CFU/Hand	Log10 CFU/Hand	CFU/mL	CFU/Hand	Log10 CFU/Hand		
41	Wash 1	6.9E3	5.2E+05	5.7139	1.3E4	9.8E+05	5.9890	5.8515	2.9266
	Wash 11	1.6E2	1.2E+04	4.0792	8.0E1	6.0E+03	3.7782	3.9287	4.8493
42	Baseline	5.4E6	4.1E+08	8.6075	6.0E6	4.5E+08	8.6532	8.6303	.
	Wash 1	4.0E4	3.0E+06	6.4771	2.2E4	1.7E+06	6.2175	6.3473	2.2830
50	Wash 11	3.3E3	2.5E+05	5.3936	2.9E3	2.2E+05	5.3375	5.3655	3.2648
	Baseline	7.5E6	5.6E+08	8.7501	8.2E6	6.2E+08	8.7889	8.7695	.
51	Wash 1	1.3E4	9.8E+05	5.9890	8.2E3	6.2E+05	5.7889	5.8889	2.8806
	Wash 11	5.5E1	4.1E+03	3.6154	5.0E1	3.8E+03	3.5740	3.5947	5.1748
52	Baseline	1.0E7	7.5E+08	8.8751	1.3E7	9.8E+08	8.9890	8.9320	.
	Wash 1	1.1E4	8.3E+05	5.9165	8.9E3	6.7E+05	5.8245	5.8705	3.0616
54	Wash 11	1.9E2	1.4E+04	4.1538	5.0E2	3.8E+04	4.5740	4.3639	4.5681
	Baseline	1.6E7	1.2E+09	9.0792	1.3E7	9.8E+08	8.9890	9.0341	.
56	Wash 1	3.6E3	2.7E+05	5.4314	3.4E3	2.6E+05	5.4065	5.4190	3.6151
	Wash 11	5.5E1	4.1E+03	3.6154	4.8E2	3.6E+04	4.5563	4.0859	4.9482
57	Baseline	4.3E6	3.2E+08	8.5085	6.1E6	4.6E+08	8.6604	8.5845	.
	Wash 1	7.0E3	5.3E+05	5.7202	8.9E3	6.7E+05	5.8245	5.7723	2.8122
57	Wash 11	1.2E2	9.0E+03	3.9542	1.9E2	1.4E+04	4.1538	4.0540	4.5304
	Baseline	5.2E6	3.9E+08	8.5911	4.4E6	3.3E+08	8.5185	8.5548	.
57	Wash 1	3.4E3	2.6E+05	5.4065	1.3E4	9.8E+05	5.9890	5.6978	2.8570
	Wash 11	1.2E2	9.0E+03	3.9542	1.5E3	1.1E+05	5.0512	4.5027	4.0521
57	Baseline	4.4E6	3.3E+08	8.5185	4.4E6	3.3E+08	8.5185	8.5185	.
	Wash 1	3.2E4	2.4E+06	6.3802	2.4E4	1.8E+06	6.2553	6.3177	2.2008
57	Wash 11	2.2E3	1.7E+05	5.2175	2.6E2	2.0E+04	4.2900	4.7538	3.7648

Where score has been recorded as <1.0E1, a score of 1.0E1 will be used in the analysis.
 Subjects 11, 13 - 21, 23, and 28 will not be included in any analyses due to deviations with the test culture.

000291

HTR Study Number 00-105821-11
 Table 2a. Mean summary of log10 averages.

09:47 Wednesday, August 23, 2000

		Log10 Average	Std. Dev.	N
HTR Code				
A: EPS 3398-29A	Baseline	8.6848	0.5035	30
	Wash 1	4.8977	0.8711	30
	Wash 11	4.6381	0.6985	30
B: 3372-131 Hibiclens	Baseline	8.7030	0.2152	15
	Wash 1	5.8389	0.2791	15
	Wash 11	4.4828	0.4842	15

Subjects 11, 13 - 21, 23, and 28 are not included in analysis due to deviations with the test culture.

000292

HTR Study Number 00-105821-11
 Table 2b. Mean summary of log10 average reductions.

09:47 Wednesday, August 23, 2000

		Log10 Average Reductions from Baseline	Std. Dev.	N
HTR Code				
A: EPS 3398-29A	Wash 1	3.7871	0.6957	30
	Wash 11	4.0467	0.7118	30
B: 3372-131 Hibiclens	Wash 1	2.8641	0.3811	15
	Wash 11	4.2202	0.5456	15

Subjects 11, 13 - 21, 23, and 28 are not included in analysis due to deviations with the test culture.

000293

Table 3. Means summary of the log10 reductions from baseline, percent microbial reductions, and confidence limits.

		Confidence Interval			Confidence Interval		
		Average Log10 Difference	Log10 Lower Limit	Log10 Upper Limit	Percent Reduction	Percent Lower Limit	Percent Upper Limit
HTR Code							
A: EPS 3398-29A	Wash 1	3.7871	3.5273	4.0469	99.98	99.97	99.99
	Wash 11	4.0467	3.7809	4.3125	99.99	99.98	100.00
B: 3372-131 Hibiclens	Wash 1	2.8641	2.6530	3.0751	99.86	99.78	99.92
	Wash 11	4.2202	3.9180	4.5224	99.99	99.99	100.00

Subjects 11, 13 - 21, 23, and 28 are not included in analysis due to deviations with the test culture.

D00294

Table 4. Analysis of variance comparison of test article log10 baseline counts (using the average of left and right hands).

The GLM Procedure

Class Level Information

Class	Levels	Values
HTRCode	2	HTR Code A HTR Code B

Number of observations 45

Subjects 11, 13 - 21, 23, and 28 are not included in analysis due to deviations with the test culture.

000295

Table 4. Analysis of variance comparison of test article log₁₀ baseline counts (using the average of left and right hands).

The GLM Procedure

Dependent Variable: lgavg

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	0.00328248	0.00328248	0.02	0.8949
Error	43	7.99951246	0.18603517		
Corrected Total	44	8.00279495			

R-Square	Coeff Var	Root MSE	lgavg Mean
0.000410	4.962878	0.431318	8.690883

Source	DF	Type I SS	Mean Square	F Value	Pr > F
HTRCode	1	0.00328248	0.00328248	0.02	0.8949

Source	DF	Type III SS	Mean Square	F Value	Pr > F
HTRCode	1	0.00328248	0.00328248	0.02	0.8949

Subjects 11, 13 - 21, 23, and 28 are not included in analysis due to deviations with the test culture.

D00296

Table 4. Analysis of variance comparison of test article log10 baseline counts (using the average of left and right hands).

The GLM Procedure

Tukey's Studentized Range (HSD) Test for lgavg

NOTE: This test controls the Type I experimentwise error rate, but it generally has a higher Type II error rate than REGWQ.

Alpha	0.05
Error Degrees of Freedom	43
Error Mean Square	0.186035
Critical Value of Studentized Range	2.85208
Minimum Significant Difference	0.2751
Harmonic Mean of Cell Sizes	20

NOTE: Cell sizes are not equal.

Means with the same letter are not significantly different.

Tukey Grouping	Mean	N	HTRCode
A	8.7030	15	HTR Code B
A	8.6848	30	HTR Code A

Subjects 11, 13 - 21, 23, and 28 are not included in analysis due to deviations with the test culture.

Table 5. Analysis of variance to evaluate the effectiveness of each treatment as a function of the number of treatments (using the log10 count differences from baseline for each test article).

----- HTRCode=HTR Code A -----

The GLM Procedure

Class Level Information

Class	Levels	Values
Subject	30	1 2 3 5 6 7 8 9 10 22 24 25 26 27 29 30 32 33 35 36 39 43 44 45 46 47 48 49 53 55
eval	2	Wash 1 Wash 11

Number of observations 60

Subjects 11, 13 - 21, 23, and 28 are not included in analysis due to deviations with the test culture.

Table 5. Analysis of variance to evaluate the effectiveness of each treatment as a function of the number of treatments (using the log10 count differences from baseline for each test article).

----- HTRCode=HTR Code A -----

The GLM Procedure

Dependent Variable: lgdiff

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	30	20.58586738	0.68619558	2.17	0.0198
Error	29	9.15503065	0.31569071		
Corrected Total	59	29.74089804			

R-Square Coeff Var Root MSE lgdiff Mean
 0.692174 14.34454 0.561864 3.916917

Source	DF	Type I SS	Mean Square	F Value	Pr > F
Subject	29	19.57520114	0.67500694	2.14	0.0225
eval	1	1.01066625	1.01066625	3.20	0.0840

Source	DF	Type III SS	Mean Square	F Value	Pr > F
Subject	29	19.57520114	0.67500694	2.14	0.0225
eval	1	1.01066625	1.01066625	3.20	0.0840

Subjects 11, 13 - 21, 23, and 28 are not included in analysis due to deviations with the test culture.

D00299

Table 5. Analysis of variance to evaluate the effectiveness of each treatment as a function of the number of treatments (using the log10 count differences from baseline for each test article).

----- HTRCode=HTR Code A -----

The GLM Procedure

Level of eval	N	-----lgdiff-----	
		Mean	Std Dev
Wash 1	30	3.78713081	0.69574561
Wash 11	30	4.04670305	0.71178346

Subjects 11, 13 - 21, 23, and 28 are not included in analysis due to deviations with the test culture.

D00300

Table 5. Analysis of variance to evaluate the effectiveness of each treatment as a function of the number of treatments (using the log10 count differences from baseline for each test article).

----- HTRCode=HTR Code A -----

The GLM Procedure

Tukey's Studentized Range (HSD) Test for lgdiff

NOTE: This test controls the Type I experimentwise error rate, but it generally has a higher Type II error rate than REGWQ.

Alpha	0.05
Error Degrees of Freedom	29
Error Mean Square	0.315691
Critical Value of Studentized Range	2.89240
Minimum Significant Difference	0.2967

Means with the same letter are not significantly different.

Tukey Grouping	Mean	N	eval
A	4.0467	30	Wash 11
A	3.7871	30	Wash 1

Subjects 11, 13 - 21, 23, and 28 are not included in analysis due to deviations with the test culture.

Table 5. Analysis of variance to evaluate the effectiveness of each treatment as a function of the number of treatments (using the log10 count differences from baseline for each test article).

----- HTRCode=HTR Code B -----

The GLM Procedure

Class Level Information

Class	Levels	Values
Subject	15	4 12 31 34 37 38 40 41 42 50 51 52 54 56 57
eval	2	Wash 1 Wash 11

Number of observations 30

Subjects 11, 13 - 21, 23, and 28 are not included in analysis due to deviations with the test culture.

D00302

Table 5. Analysis of variance to evaluate the effectiveness of each treatment as a function of the number of treatments (using the log10 count differences from baseline for each test article).

----- HTRCode=HTR Code B -----

The GLM Procedure

Dependent Variable: lgdiff

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	15	18.90341699	1.26022780	16.18	<.0001
Error	14	1.09049279	0.07789234		
Corrected Total	29	19.99390978			

R-Square Coeff Var Root MSE lgdiff Mean
 0.945459 7.879211 0.279092 3.542131

Source	DF	Type I SS	Mean Square	F Value	Pr > F
Subject	14	5.11080660	0.36505761	4.69	0.0033
eval	1	13.79261040	13.79261040	177.07	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
Subject	14	5.11080660	0.36505761	4.69	0.0033
eval	1	13.79261040	13.79261040	177.07	<.0001

Subjects 11, 13 - 21, 23, and 28 are not included in analysis due to deviations with the test culture.

000303

Table 5. Analysis of variance to evaluate the effectiveness of each treatment as a function of the number of treatments
(using the log10 count differences from baseline for each test article).

----- HTRCode=HTR Code B -----

The GLM Procedure

Level of eval	N	-----lgdiff-----	
		Mean	Std Dev
Wash 1	15	2.86408004	0.38107907
Wash 11	15	4.22018281	0.54564521

Subjects 11, 13 - 21, 23, and 28 are not included in analysis due to deviations with the test culture.

Table 5. Analysis of variance to evaluate the effectiveness of each treatment as a function of the number of treatments
(using the log10 count differences from baseline for each test article).

----- HTRCode=HTR Code B -----

The GLM Procedure

Tukey's Studentized Range (HSD) Test for lgdiff

NOTE: This test controls the Type I experimentwise error rate, but it generally has a higher Type II error rate than REGWQ.

Alpha	0.05
Error Degrees of Freedom	14
Error Mean Square	0.077892
Critical Value of Studentized Range	3.03319
Minimum Significant Difference	0.2186

Means with the same letter are not significantly different.

Tukey Grouping	Mean	N	eval
A	4.2202	15	Wash 11
B	2.8641	15	Wash 1

Subjects 11, 13 - 21, 23, and 28 are not included in analysis due to deviations with the test culture.