Research Report S09-27

Confidential Material

24 Hour Modified Soap Chamber Study to Assess Calcium Glycerophosphate as a Potential Agent for Reducing Skin Irritation from Dishwashing Liquids

Sponsor: AkPharma, Inc.
6840 Old Egg Harbor Road
Pleasantville, NJ 08232
Charles L. Bove
Telephone No: (609) 645-5100

Respectfully submitted by:

Gary Lee Grove, Ph.D. — 7 July 2009
Principal Investigator — Date

Charles Zerweck, Ph.D. — 7 July 2009
Director of Clinical Studies — Date

Danielle Fendrick — 7 July 2009
Director of Operations — Date

cyberDERM CLINICAL STUDIES
Lawrence Park Industrial Park
700 Parkway Drive
Broomall, PA 19008
Phone: 610-325-0112 Fax: 610-325-0881

TABLE OF CONTENTS

I. OBJECTIVE

To determine if the addition of calcium glycerophosphate to a marketed dishwashing liquid reduces irritation potential as compared to the marketed dishwashing liquid in its original formula in a modified soap chamber test.

The test sites were evaluated clinically for erythema. The skin's response was also measured instrumentally for irritation using measurements of skin surface color and transepidermal water loss.

Also taken into account were the subjects' own personal assessments, e.g., "irritation", "itching", etc.

II. EXPERIMENTAL DESIGN

A. Background

In 1979, Frosch and Kligman (J. Am. Acad. Dermatol. 1:35-41) introduced a new method for assessing the irritancy of soaps which entailed five weekday exposures to 8% solutions of test materials with subjective assessments of scaling, redness and fissuring on the following Monday. We have found that measuring transepidermal water loss rates has allowed us to greatly increase our objectivity and sensitivity of such evaluations, while at the same time decreasing the time required to run them. A full description of the modified soap chamber test has been published by Simion, et al (Contact Dermatitis 25:242-249, 1991) and it is also mentioned in some detail in Babulak, et al (J. Soc. Cosmet. Chem. 37:475-479, 1986). This method is considered standard and productive of valid results in the judgment of manufacturers of commercial dish detergents.

B. General Considerations

This study was conducted under the supervision of Gary Grove, Ph.D. and Charles Zerweck, Ph.D. at cyberDERM Clinical Studies in Broomall, Pennsylvania. Copies of Dr. Grove's and Dr. Zerweck's curriculum vitae are on file with the Sponsor.

In conducting this study, we followed current Good Clinical Practices (cGCP) and current Good Laboratory Practices (cGLP) guidelines as well as the COLIPA Efficacy Testing Guidelines.

This study was conducted from April 14-16, 2009. A calendar of events summarizing the treatments and evaluative procedures followed during this study is attached as **Appendix A**.

Pertinent details of panelist selection, treatment procedures, clinical assessments and instrumental methods are provided in the sections that follow.

C. Panelist Selection

Nineteen volunteers were recruited from a pool of healthy suburban men and women who met the inclusion/exclusion criteria detailed below. All candidates were interviewed to ascertain that they had no medical problems, had no known allergies to soaps or fragrances, and were not using concomitant medications that might interfere with the study results. Women who were either pregnant or breast-feeding were also excluded from participating in this study.

1. Inclusion Criteria

a. Male or female between the ages of 18 and 55
b. Has a Fitzpatrick Skin Type of I, II or III
c. Is in good general health
d. Is not currently taking any anti-inflammatory medication(s) and agrees to refrain from taking anti-inflammatories within 48 hours prior to the study start and for the duration of the study
e. Agrees to discontinue use of all moisturizing products to the arms for the 3 days prior to the study start and for the duration of the study
f. Agrees to refrain from showering in the evenings during the study. During the study, panelists must shower in the morning at least 1 hour or more prior to their appointment.
g. Agrees to refrain from exercising prior to each instrumental visit
h. Agrees to wear a short-sleeved shirt or a shirt with loose sleeves that can be pulled up to the elbows to each visit
i. Agrees not to apply any other products to the arms, including washing or scrubbing sites with any kind of cleanser for the duration of the study
j. Agrees to refrain from exercising while wearing the patches as this will increase the amount of damage to the sites
k. Agrees to refrain from swimming and all forms of tanning for the duration of the study.
l. Willing and able to follow all study directions and to be available for all follow-up visits for the duration of the study
m. Agrees not to wash dishes or perform any household task that will bring treated portion of skin into contact with any dish detergent containing sodium lauryl sulfate (SLS)

2. Exclusion Criteria

a. Female that is pregnant, nursing or planning a pregnancy as determined by interview
b. Is diabetic
c. Current skin condition on the inner volar forearm other than dry skin (e.g. psoriasis, eczema, atopic dermatitis, etc.).
d. Has uneven skin tone, marks, scars, scratches, etc. on their volar forearms
e. Has known sensitivity or allergy to adhesive tapes, soaps, complexion or cleansing bars, shampoos, dishwashing liquids or fragrances
f. Is currently taking anti-inflammatories or foresees the need to take anti-inflammatory medications during the study period.
g. Has the necessity to carry small children during the study
h. Female going through menopause (i.e., experiencing hot flashes)
i. Any other condition or factor the Investigator or his duly assigned representative believes may affect the skin response or the interpretation of the test results

All volunteers signed a consent form **(Appendix B)** after being informed of their obligations and risks that they might encounter as a participant in this study.

Each candidate was required to discontinue the use of all topically applied arm products 3 days prior to the start of the study until after the study completed.

At the end of the 3 days "weaning" from whatever skin care products they previously used, the suitability of each individual for acceptance into the panel was judged by Charles Zerweck, Ph.D., who served as the Expert Grader for this study. Any individuals with cuts, scratches or any clinical signs of erythema were excluded at that time. Qualified panelists were given a panelist number in order of their acceptance onto the panel. Prior to Baseline assessments and measurements, Dr. Zerweck wiped each site with an alcohol wipe.

Upon being selected into the study, the panelists were reminded of the general nature and purpose of the study and were instructed not to apply any other products nor tamper with their arms in any way during the remaining study period, particularly including washing dishes by hand under any circumstances.

D. Evaluative Procedures

1. Expert Grader Evaluations

Charles Zerweck, Ph.D. served as the Expert Grader for this study. He assessed the erythema of the 6 volar forearm test sites of each panelist using the grading scales described below:

Erythema

Grade	Description
0	None
2	Mild erythema
4	Moderate confluent erythema
6	Marked erythema with some edema
8	Marked erythema, edema, flare, possible erosion

These assessments were made by Dr. Zerweck at Baseline (prior to patch application) and approximately 24 hours after patch removal. The data for each session was manually recorded by the Expert Grader on a worksheet.

Intermediate grades were allowed so that finer distinctions could be made.

2. Personal Self-evaluations

Panelists advised study operators of their own observations and judgments on the four sites:

- Assessment of skin quality
- Assessment of irritation
- Assessment of itchiness
- Rating of all four sites relative to one another

Assessments were made at 24 hours post patch removal using the following 0-10 visual analog scale (0 = Best to 10 = Worst):

At 24 hours post patch removal, a technician, Mrs. Susan Shea, gave the panelists a questionnaire (**Appendix C**) and instructed them to rate each site relative to each other for each question. The panelists were instructed to use a pen to mark a vertical line for each site to rate it from best (0) to worst (10). The panelists were instructed to label each site's vertical line with the following site designations: RU = Right Upper, RL = Right Lower, LU = Left Upper, LL = Left

Lower. If a panelist felt that more than one site had the same exact rating, they were instructed to mark one vertical line and label it with the site designations that they felt had the same exact rating.

It should be noted that for analysis, the marks along the line were measured and converted to a 0-100 scale.

3. Cortex Technology DSM II Color Meter

Skin color was measured instrumentally using a Cortex Technology DSM II Color meter (Unit D02000.01-103). The new DSM II Color Meter offers a new and innovative approach to color measurement. Its fully handheld and lightweight design takes advantage of the latest development in color sensing technology, and the cable connected color sensing probe offers the highest degree of freedom and flexibility in operation. Further, a special lens arrangement focuses on the target area and highly reduces the influence of ambient light. The key component is an RGB Photodiode Array that corresponds to the 3 types of cones in the human retina. A specially designed white LED powered by a constant current source ensures that brightness and spectral characteristics of the illuminator do not change over time. The emitter/detector geometry is the standard 45°/0° optical train and is housed within a lightweight probe that allows the operator to directly view the target area. Alternate illuminants can be readily incorporated into the design.

The output of the device appears on an LCD display and can be sent to an interfaced PC where it can be parsed into 3 channels respectively representing the R, G, and B values of the target area in real time. Companion software routines provide several different outputs including those based on the tri-chromatic CIE L* a*and b* system as well as the Erythema and Melanin Indices derived from Farr & Diffey's 2-wavelength method.

The color meter was calibrated prior to use at each time point using a standard white tile.

Ms. Jen Damia served as the instrument technician. Three sets of R, G and B readings were taken from each of the 6 volar forearm test sites at Baseline and approximately 24 hours after patch removal. The average value was calculated for each site at each time point.

4. Water Loss Measurements with the cyberDERM, inc. Evaporimeter

All water loss measurements were taken following a 25-30 minute acclimation period in a controlled environment with the relative humidity maintained at less than 50% and temperature maintained at 70 $\pm$ 2°F.

At Baseline, evaporative water loss measurements were taken by Mr. Jason Zerweck from each of the 6 volar forearm test sites as described below. Any individuals with water loss values outside the normal range (>10.0 gms/m^2hr) were excluded at this time.

Evaporative water loss measurements provide an instrumental assessment of skin barrier function. These measurements were made using a recently calibrated cyberDERM RG1 Evaporimeter System (Unit P5) (Broomall, PA) with TEWL Probes (715 and 716) that were manufactured by Cortex Technology (Hadsund, Denmark) and available in the US through cyberDERM, inc. (Broomall, PA).

This instrument is based on the vapor pressure gradient estimation method as designed by Nilsson and initially utilized by the Servo Med Evaporimeter. There are slight dimensional differences and the sensor technology is greatly improved in the DermaLab® TEWL probe but the underlying principles of the measurement remain the same. Both probes contain two sensors that measure the temperature and relative humidity at two fixed points along the axis normal to the skin surface. This arrangement is such that the device can electronically derive a value that corresponds to evaporative water loss expressed in gm/m^2hr. Evaporimetry with TEWL Probe is more fully described in two publications by Grove et al:

Grove, G.L., M.J. Grove, C. Zerweck and E. Pierce: Comparative metrology of the evaporimeter and the DermaLab® TEWL probe. Skin Res. & Tech. 5:1-8, 1999.

Grove, G.L., M.J. Grove, C. Zerweck and E. Pierce: Computerized evaporimetry using the DermaLab® TEWL probe. Skin Res. & Tech. 5:9-13, 1999.

The guidelines established for using the Servo Med Evaporimeter as described by Pinnagoda [Pinnagoda, J., R.A. Tupker, T. Anger and J. Serup. Guidelines for transepidermal water loss (TEWL) measurement. In: Contact Dermatitis 1990: 22:164-178] are quite appropriate for the DermaLab® TEWL Probe as well.

The cyberDERM RG1 Evaporimeter System is completely computerized and continuously communicates with its PC through a USB port and associated cyberDERM, inc. software for the Evaporimeters. We use the application program entitled x1WL2M that captures the water loss data from the attached evaporimeter at a sampling rate of 8 inputs/second. These inputs are graphed as a real time display

on the computer monitor. The extracted value refers to the average evaporative water loss rate collected over a twenty-second interval once steady state conditions had been achieved. These are directly transferred to an Excel file using a DDE link.

The test formulations were then applied to the test sites under occlusive chambers. Approximately 24 hours after patch removal, duplicate water loss readings were taken from each of the 6 volar forearm test sites and electronically recorded via a DDE link using a spreadsheet format based on Excel 2003 software which computes the average value for each test site. These values were also manually recorded on a worksheet that served as a back-up in case of a computer malfunction.

Such measures provide a noninvasive method for determining the barrier function of the stratum corneum. Damage leads to a disruption of the barrier and elevated water loss rates, which directly correspond to the extent of damage.

5. Test Products and Treatment Procedures

a. Test Products

The four dishwashing liquids that were tested in this study are as follows:

Rx A	Ultra Palmolive Original concentrated dish liquid + 10% CGP #033109A
Rx B	Ultra Palmolive Original concentrated dish liquid + 2% CGP #040609A
Rx C	Ultra Palmolive Original concentrated dish liquid
Rx D	Ultra Palmolive Original concentrated dish liquid + 4% CGP #032409B

cyberDERM provided the Ultra Palmolive Original concentrated dish liquid. The Sponsor provided the Ultra Palmolive Original concentrated dish liquid + 10%, + 4% and + 2% CGP. The dishwashing liquids were diluted to 10%.

b. Treatment Procedures

After the Baseline measurements were completed, the treatment technician, Charles Zerweck, Ph.D., charged each Webril padded Hilltop chamber with 0.35 ml of the appropriate test formulation and applied that chamber to its respective test site as designated by the randomization schedule (**Appendix D**). The patches remained in place for approximately 24 hours.

Approximately twenty-four hours after application, the panelists returned to the lab and Dr. Zerweck removed the chambers and rinsed the underlying test sites

thoroughly with running tap water. The sites were then patted dry with a soft paper towel.

Approximately 24 hours after removal of the occlusive chambers, panelists returned to the lab and clinical assessments and instrument measurements were repeated.

For this study, the four test products were applied under occlusion to the upper and lower sites according to the randomization schedule. The two centrally-located sites remained non-treated to serve as controls.

During the study, the following restrictions were imposed:

- Panelists may not apply any moisturizing products to the arms for the 3 days prior to study start and for the duration of the study.
- Panelists may not be currently taking any anti-inflammatory medication(s) and must refrain from taking anti-inflammatories within 48 hours prior to the study start and for the duration of the study
- Panelists may not be diabetic
- Panelist must not be going through menopause (i.e., experiencing hot flashes).
- Panelists must not have any known sensitivity or allergy to adhesive tapes, soaps, complexion or cleansing bars, shampoos, dishwashing liquids or fragrances
- Panelist must refrain from showering in the evenings during the study. During the study, panelists must shower in the morning at least 1 hour or more prior to their appointment.
- The panelists may not exercise before each instrumental visit as this will affect the measurements
- The panelists may not exercise while wearing patches as this will significantly increase the damage to the skin
- The panelists must wear a short-sleeved shirt or a shirt with loose sleeves that can be pulled up to elbows for each visit
- The panelists may not carry small children during the study as this will affect the irritation we are trying to cause and the healing process we are trying to follow
- The panelists must refrain from swimming and all forms of tanning for the duration of the study
- The panelists may not apply any other products on the arms, including intentional washing or scrubbing sites with any kind of cleanser for the duration of the study
- The panelists will agree not to wash dishes or perform any household task that will bring treated portion of skin into contact with any dish detergent containing sodium lauryl sulfate (SLS)

E. Adverse Events

If applicable, all adverse experiences, whether or not considered related to the product application, were entered on a report form. In the event of an adverse event, the Sponsor was notified within 48 hours. Copies of adverse reaction reports and follow-ups were provided to the Sponsor.

Definition
An adverse event (AE) is any undesirable event occurring to a subject during a clinical trial, whether or not considered related to the trial product. This includes events not seen at baseline.

All AE's are classified as either: Serious Adverse Events (SAE)
Non-Serious Adverse Events (AE)

Serious Adverse Event
A serious adverse event is any experience that suggests a medically significant hazard including any event that:

is fatal, is life threatening, is permanently disabling, requires in patient hospitalization (requiring overnight admission), prolongs hospitalization, causes a congenital abnormality, is diagnosed as cancer, is an over-dose or under-dose and results in inpatient hospitalization.

Pre-planned elective procedures are not to be reported as serious adverse events.

Reporting of SAE
The investigator / designate must report SAE to the Sponsor within 24 hours of knowledge of the event. The information must be provided by phone or fax to the Sponsor. In addition, the investigator must forward the completed AE form with relevant information to the IRB/Ethics Committee if applicable.

Non-Serious Adverse Event
All adverse events not classified as serious will be reported as non-serious adverse events. At each visit all adverse events observed by the investigator / designate or reported by subject spontaneously must be evaluated and recorded on the standard adverse event form. A non-serious adverse event is further classified with respect to severity and relationship to the trial product:

Severity:
Mild: Transient symptoms, easily tolerated, no interference with subjects daily activities.

Moderate: Marked symptoms, moderate interference with subjects daily activities and tolerable.
Marked: Considerable interference with subject's daily activities, not tolerable.
Note: Pre-planned elective procedures should be reported as non-serious adverse events.

Relationship to trial product:
All serious adverse events and non-serious adverse events must be evaluated by the investigator with respect to its relationship to the trial product as follows:

Probable: Good reasons and sufficient documentation to assume causal relationship
Possible: Causal relationship is likely and cannot be excluded.
Unlikely: The event is most likely related to an etiology other than the trial treatment.
Unknown: Unable to assess due to insufficient evidence, conflicting data or poor documentation.

F. Statistical Analysis

Dr. Grove was responsible for the processing and statistical analysis of the data obtained in this study. To do so, he created a sorting template based on Excel spreadsheet software and implemented on the IBM clone desktop computer. The sorted data for each parameter was then tabulated and arranged in order of panelist number for every point of evaluation. In creating these tables, column averages were computed in every case, but only to give a preliminary look at the findings.

Dr. Grove was also responsible for statistical analysis of the findings using appropriate GraphPad InStat software programs. The sorted data tables were converted into ASCII files for use in these applications. Descriptive statistics were run on each data set and compared to the column averages to insure that all imported files were correct.

For the instrumental measurements, a Repeated Measures ANOVA test was run on the post-trauma readings obtained at each time point for each of the test products. If significant differences were noted, a post hoc test was run using Dunnett-Multiple Comparisons test.

For the Expert Grader assessments, a Friedman's ANOVA test was employed to compare the scores given at the each point in time. If significant differences were noted then these ordinal data were considered to be interval in nature so that cross-code comparisons could be run using a Dunn's Multiple Comparisons test.

For all analyses, a two tailed $p \leq 0.05$ was taken as the level of significance.

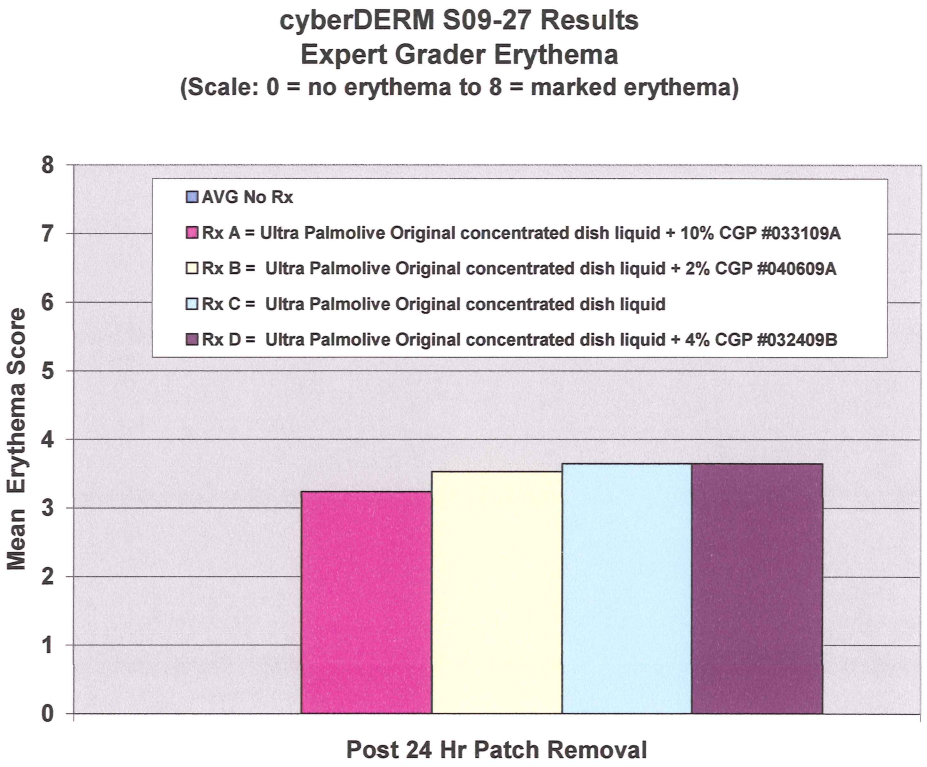
III. RESULTS

A. Panelist Accountability

Nineteen panelists were selected to begin the 3 day weaning period. All Nineteen of these panelists were scheduled and reported for the Baseline assessments. Seventeen panelists qualified for the study. Two panelists (#8 and #13) did not qualify at Baseline. **Appendix E** contains a listing of each selected panelist's age and sex. We have no reason to believe that the remaining panelists were not fully compliant with the requirements of the study.

B. Expert Grader Assessments

The decoded and sorted Expert Grader assessments from each time point are attached as **Appendix F**. This appendix contains the data and statistical analysis for scoring erythema at Baseline (prior to patch application) and approximately 24 hours after patch removal. A summary of the values observed is graphically provided in the figures shown below:



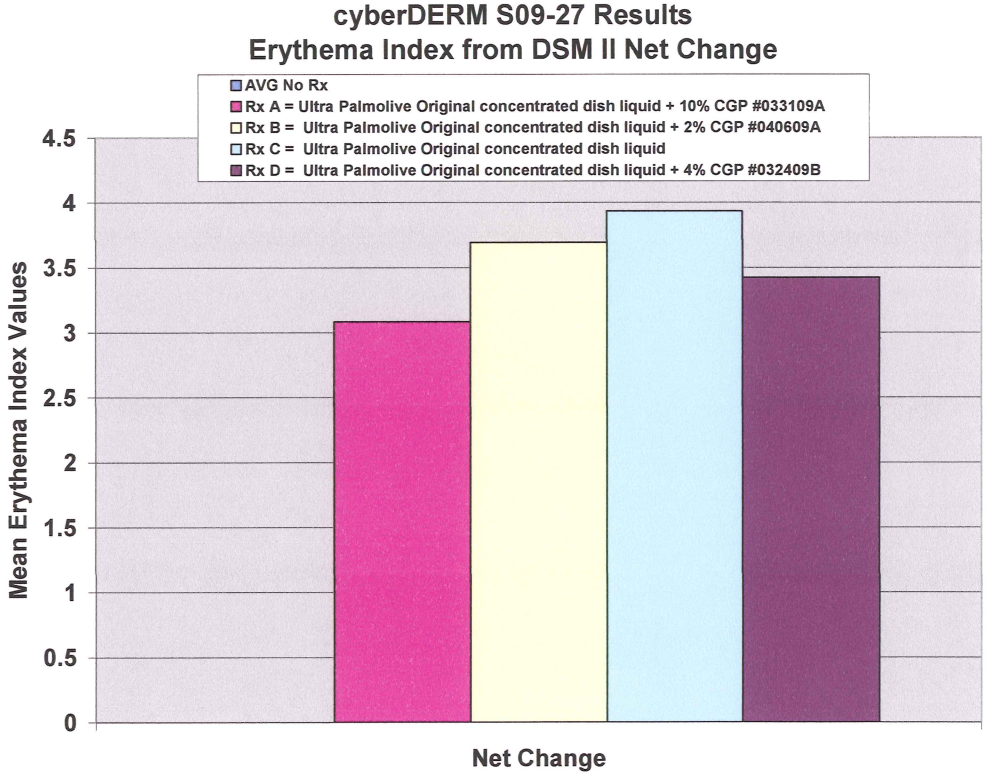
The results of Expert Grader assessments reveal that that the lowest mean erythema score 24 hours post challenge is associated with Rx A. However, there did not prove to be any statistically significant differences between the test treatments in this regard.

C. Personal Self-Evaluations

The decoded and sorted personal self-evaluations from 24 hours after patch removal are attached as **Appendix G**. This appendix contains the data for panelists' self-evaluations at approximately 24 hours after patch removal and is being provided for the Sponsor's in-house analysis.

D. DSM II Measurements

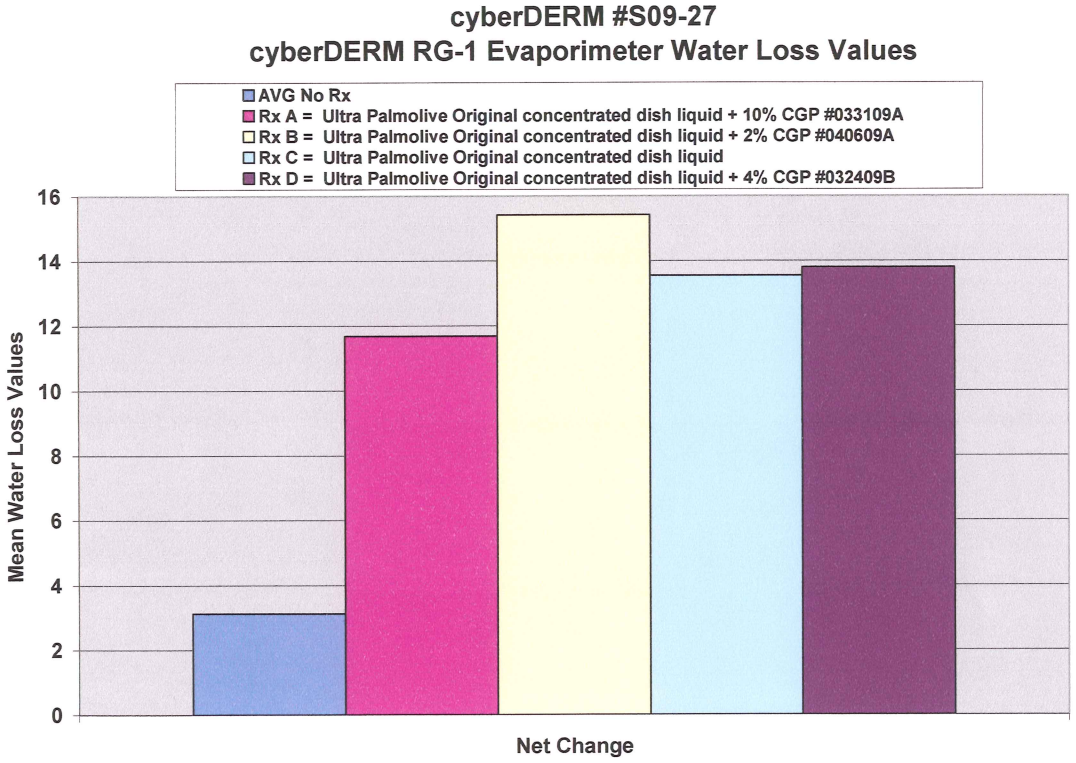
The sorted values for the DSM II Color Meter are tabulated and attached as **Appendix H**. These tables record the data obtained at Baseline (prior to patch application) and approximately 24 hours after patch removal for the treated and non-treatment sites for each of the panelists. A summary of the values observed at the follow-up session is graphically provided in the figure shown below:



The results of DSM II measurements reveal the highest increase in mean erythema index values 24 hours post challenge to be associated with Rx C (original formula without additive). However, of the remaining test formulations only Rx A (original + 10% CGP) demonstrated a significantly lower mean erythema index than Rx C ($p < 0.05$).

E. cyberDERM RG-1 Water Loss Measurements

The decoded and sorted water loss data from each time point are attached as **Appendix I.** These tables record the data obtained at Baseline (prior to patch application) and approximately 24 hours after patch removal for the treated and non-treatment sites for each of the panelists. A summary of the values observed at the follow-up sessions is graphically provided in the figure shown below:



The results of evaporative water loss measurements reveal a marked increase in mean water loss values 24 hours post test patch removal associated with all of the test formulations. Of these Rx A appeared to be the mildest by demonstrating the least increase over Baseline. Subsequent statistical analysis did not however reveal significant differences between any of the formulations.

IV. CONCLUSIONS

Based on the results of this study there are indications that addition of Calcium Glycerophosphate to a commercial dishwashing formulation may reduce potential skin irritation due to test exposure. The test formulation with the highest concentration of Calcium Glycerophosphate (10%) was found associated with reduced redness development and a reduction in detergent induced damage to the integrity of the skins natural barrier.

V. PROPRIETARY REPORT AND NON-ENDORSEMENT POLICY

This research report is considered to be proprietary and confidential by cyberDERM, inc. It is not to be shared with any third party except appropriate government regulatory agencies, media broadcast standards advertising divisions, or the National Advertising Division (NAD) of the Better Business Bureau (BBB) without written consent of an officer of cyberDERM Clinical Studies or cyberDERM, inc. The name of cyberDERM, inc., cyberDERM Clinical Studies, any officer, employee or collaborating scientist are not to be used for any advertising, promotional or sales purposes without the written consent of cyberDERM, inc. or cyberDERM Clinical Studies. If there are any questions regarding this policy, please contact Dr. Gary Grove.

VI. RECORD RETENTION

Please be advised that the records for this study will remain on file at cyberDERM, inc. (or a remote storage site) for a period of 1 year from the issue date of the final report and then destroyed unless we are notified otherwise by the Sponsor using the form accompanying this final report. It is the duty of the Sponsor to ensure that the completed form is promptly returned to cyberDERM.

Appendix A: Calendar of Events

cyberDERM
CLINICAL STUDIES

cyberDERM# S09-27: 24 HOUR SOAP CHAMBER STUDY

PROCEDURES	Baseline	+24 hours after patch application	+ 24 hours after patch removal
	Visit 1	Visit 2	Visit 3
Expert Grader Erythema assessments	X		X
Cortex Technology DSM II Color Meter measurements	X		X
cyberDERM Evaporimeter measurements	X		X
Patches applied to 6 sites (randomized)	X		
Patches removed at lab and sites rinsed		X	

PRE-TRIAL CONDITIONING:
Panelists will stop the use of all moisturizing products on the arms for the 3 days prior to the study start.

PANEL:
Twenty panelists will be recruited in order to finish with 16 panelists. The panel will consist of male and female panelists between the ages of 18 and 55 with a Fitzpatrick Skin Type of I, II or III.

TEST SITES:
Six test sites will be located on the volar forearms with three sites being on each arm.

TEST PRODUCTS:
The four test products will be supplied by the Sponsor.

TREATMENT PROCEDURES:
Four of the six sites will be patched with the test products according to the randomization schedule. One centrally located site on each arm will remain non-treated/non-patched to serve as controls.

cyberDERM
CLINICAL STUDIES

cyberDERM# S09-27: 24 HOUR SOAP CHAMBER STUDY (continued)

SOAP CHAMBER PROCEDURE:
The four test products will be applied under occlusion to the 4 designated volar forearm test sites according to the randomization schedule. The soap chamber patches will be worn for 24 hours and removed at the lab and the sites will be rinsed and gently patted dry.

CLINICAL ASSESSMENTS:
Expert Grader assessments of erythema on the 6 volar forearm test sites at Baseline and approximately 24 hours post patch removal.

INSTRUMENTAL ASSESSMENTS:
The following non-invasive measurements will be taken from each of the 6 test sites on the panelist's volar forearms at Baseline and approximately 24 hours post patch removal:

- Triplicate Cortex Technology DSM II Color Meter measurements
- Duplicate cyberDERM RG-1 Evaporimeter measurements

PANELIST ASSESSMENTS:
Panelists will advise study operators of their own observations and judgments on the four sites:

- Assessment of skin quality
- Assessment of irritation, itchiness, etc., if any
- Rating of all four sites relative to one another

DATA ANALYSIS & REPORT GENERATION (continued on next page):
For the instrumental measurements, a Repeated Measures ANOVA test will be run on the post-trauma readings obtained at each time point for each of the test products. If significant differences are noted, a post hoc test will be run using Fisher's Least Significant Differences test.

For the Expert Grader assessments, a Friedman's ANOVA test will be employed to compare the scores given at the each point in time. If significant differences are noted then these ordinal data will be considered to be interval in nature so that cross-code comparisons could be run as described above.

For all analyses, a two tailed $p \leq 0.05$ will be taken as the level of significance.

CLINICAL STUDIES

cyberDERM# S09-27: 24 HOUR SOAP CHAMBER STUDY (continued)

DATA ANALYSIS & REPORT GENERATION (continued from previous page):
A draft report will be completed by cyberDERM Clinical Studies and will be forwarded to the Sponsor for review and approval. A final report will be issued after approval of the draft report.

Appendix B: Sample Consent Form

CONSENT FORM

cyberDERM #S09-27

STUDY TITLE: 24 Hour Modified Soap Chamber Study to Assess Calcium Glycerophosphate as a Potential Agent for Reducing Skin Irritation from Dishwashing Liquids

PURPOSE OF STUDY:
The purpose of the study is to evaluate the irritation potential of four dishwashing liquids approximately 24 hours after they have been applied to the skin under occlusion for 24 hours.

DURATION OF STUDY:
3 days pre-trial conditioning and 3 days of testing
(Duration of study may be subject to change by Sponsor/Investigator-see below*)

DESCRIPTION OF PROCEDURE:
During the 3 day wean, approximately 20 panelists will stop the use of all moisturizing products on their arms.

VISIT 1
Please shower this morning, at least 1 hour or more prior to your appointment. Do not exercise prior to your appointment. Please wear a short-sleeved shirt or a shirt with loose sleeves that can be pulled or rolled up to the elbows.

At your first appointment, you will report to the lab to accommodate for Baseline measurements. A technician will use a non-toxic skin marking pen to outline 6 sites on your left and right volar forearms (3 sites on each arm). Measurements will be taken of skin surface water loss and skin surface color to determine the normal values for your skin surface. If measurements are in the anticipated range, you will be accepted onto the final panel. After measurements are completed, a technician will wipe each site with an alcohol wipe and will let the sites dry. The technician will then apply patches to 4 of the 6 sites on your left and right volar forearms. One site on each arm will intentionally not be patched. Each patch will contain a different test product. These patches will be worn for 24 hours. Please take care to not get the patches wet. Please do not carry small children while wearing the patches. Please do not exercise while wearing the patches.

VISIT 2:
Please shower this morning, at least 1 hour or more prior to your appointment. Do not exercise prior to your appointment. Please wear a short-sleeved shirt or a shirt with loose sleeves that can be pulled or rolled up to the elbows.

You will return to the lab approximately 24 hours later to have the patches removed and the sites rinsed and patted dry. After the patches are removed, please do not

carry small children and please do not exercise until after your final study assessments are completed.

VISIT 3:
Please shower this morning, at least 1 hour or more prior to your appointment. Do not exercise prior to your appointment. Please wear a short-sleeved shirt or a shirt with loose sleeves that can be pulled or rolled up to the elbows.

You will report back to the test facility approximately 24 hours after the patches were removed to accommodate to the room conditions. Visual and instrumental assessments will be taken again on the 6 volar forearm test sites. You will complete a self-assessment questionnaire where you will rate each site relative to each other.

REQUIREMENTS:

- Panelists may not apply any moisturizing products to the arms for the 3 days prior to study start and for the duration of the study.
- Panelists may not be currently taking any anti-inflammatory medication(s) and must refrain from taking anti-inflammatories within 48 hours prior to the study start and for the duration of the study
- Panelists may not be diabetic
- Panelists must not be going through menopause (i.e., experiencing hot flashes).
- Panelists must not have any known sensitivity or allergy to adhesive tapes, soaps, complexion or cleansing bars, shampoos, dishwashing liquids or fragrances
- Panelist must refrain from showering in the evenings during the study. During the study, panelists must shower in the morning at least 1 hour or more prior to their appointment.
- The panelists may not exercise before each instrumental visit as this will affect the measurements
- The panelists may not exercise while wearing patches as this will significantly increase the damage to the skin
- The panelists must wear a short-sleeved shirt or a shirt with loose sleeves that can be pulled up to elbows for each visit
- The panelists may not carry small children during the study as this will affect the irritation we are trying to cause and the healing process we are trying to follow
- The panelists must refrain from swimming and all forms of tanning for the duration of the study
- The panelists may not apply any other products on the arms, including intentional washing or scrubbing sites with any kind of cleanser for the duration of the study
- The panelists will agree not to wash dishes or perform any household task that will bring treated portion of skin into contact with any dish detergent containing sodium lauryl sulfate (SLS)

LIST OF MATERIALS:
4 coded dishwashing liquids diluted to 10%, Sharpie marker, cyberDERM RG1 Evaporimeter, Cortex Technology DSM II Color Meter, Hilltop Chambers, Adhesive Tape

ANTICIPATED RISKS AND POSSIBLE SIDE EFFECTS:
There are no risks associated with the instrumental measurements.

The adhesive tape on the patches that will be applied to the volar forearm will pull on the skin before it comes off and this may feel like removal of a Band-Aid.

It is anticipated that the dishwashing solution patches which will be diluted to 10% will cause irritation at the site and possible lightening or darkening of the skin, possible allergic reaction and/or skin irritation including, but not limited to, redness, dryness, itching, burning/stinging, blistering. This is usually temporary but could persist for a long time (even permanent). The amount of irritation will vary between individuals depending on their sensitivity.

As in the case of any unforeseen irritation, some individuals may have reactions resulting in possible lightening or darkening of the skin, possible allergic reaction and/or skin irritation including, but not limited to, redness, dryness, itching, burning/stinging, blistering. This is usually temporary but could persist for a long time (even permanent).

If it is determined that an allergic reaction has occurred, you can expect an allergic reaction to the material if you encounter it at a later date. Whenever possible, you will be told the name of the product/ingredient that caused the allergic reaction in order that you may avoid contact with it in the future.

Your risk may be increased in some situations. You should not participate in this study if you have an active skin infection, psoriasis, active dermatitis. You should also not participate in this study if you are sensitive to cosmetics, toiletries or any other skin care products.

Your participation in this study may involve risks that are currently unforeseeable or unknown.

Significant new findings identifying additional risks that become known during the course of this study will be provided to you.

You should report any unusual symptoms or signs you may notice during the study, even if you consider such symptoms or signs to be minor or unrelated to the study.

BENEFITS:
There are no known direct benefits to you as a participant in this investigational study. The findings or results, however, will permit the sponsor to determine the effects of these products.

ALTERNATIVE TREATMENT:
As this study is for research purposes only, an alternative would be to not participate in this study.

CONFIDENTIALITY:
Records of your participation in this study will be held confidential so far as permitted by law. However, the investigator, the sponsor, and under certain circumstances, the Food and Drug Administration (FDA) will be able to inspect and have access to confidential data which identifies you by name. Any publication of the data will not identify you. By signing this consent form, you authorize the investigator to release your medical records to the sponsor and the FDA.

PAYMENT SCHEDULE: $_____ if complete the entire study
<<<<IF YOU ARE NON-COMPLIANT WITH THE REQUIREMENTS OF THE STUDY YOU WILL BE DISMISSED.>>>>

If you decide to withdraw from the research study, you should notify the technician and/or investigator of your intention to do so and you will be compensated up to the time of withdrawal at the rate of $_____ per visit.

*In the event that the study is changed by the Sponsor (for example, cancellation of study or number and/or duration of the visits), the payment schedule may be changed to reflect this alteration in study design. The subject fee will be pro-rated based on the amount of visits completed but will not be less than the rate of $_____ per visit.

VOLUNTARY PARTICIPATION/WITHDRAWAL:
The investigator can end your participation in this study at any time without your consent for the following reasons: the occurrence of serious side effects, any change in your medical condition that may interfere with the study, pregnancy, failure to attend study visits, failure to follow the treatment regimen or study instructions, or cancellation of the study, or for administrative reasons.

Your participation in this study is entirely voluntary. If you withdraw from the research study, you should notify the technician and/or investigator of your intention to do so and you will be compensated up to the time of withdrawal. You can refuse to participate in the study or quit at any time without loss of any rights or benefits to which you would be entitled. If you quit or are withdrawn from the study, you may be asked to have study ending tests and procedures for your safety.

COMPENSATION FOR STUDY-RELATED INJURY:
Any questions of injuries resulting from this study should be referred to Dr. Gary Grove at cyberDERM Clinical Studies at 610-325-0112. In the case of after hour emergencies, please call Dr. Charles Zerweck at 610-627-9236 or Dr. Gary Grove at 610-358-2381 or 610-348-4152. In the event that you develop an adverse reaction, side effect, or complication as a result of your participation in this study, emergency medical treatment will be provided at no cost to you. If the study personnel feel it is appropriate, you will be referred to a Consulting Physician for evaluation and treatment. Medical consultation will be arranged for any subject who would like his/her responses to be evaluated by a Physician. cyberDERM has a Consulting Dermatologist available for this purpose. Study personnel will arrange to have him contact you to answer questions concerning this study and/or make an appointment for you upon request. No additional compensation is available. You will not lose any of your legal rights as a research subject by signing this consent form.

Please feel free to ask any questions regarding the study. We will not be able however; to disclose the name of the sponsoring company due to confidentiality.

CONSENT:
I hereby consent to take part in the experimental study described above under the supervision of Dr. Gary Grove and his staff. I understand that minor revisions could be made during this study, and that this will be fully explained to me, and at that time I will have the option to continue this study or withdraw. I understand that the study may involve some risks. This and my part in the study have been clearly explained and demonstrated to me and I have had complete freedom to ask any questions about the study. I understand that I am free to withdraw my consent and to discontinue my participation in this project at any time. I also certify that I have brought to the attention of the investigator any changes in health status and drug use that have occurred since my initial exam. I understand and consent to what I am to do in these studies to be performed by Dr. Grove and his assistants in properly carrying out this study. FURTHERMORE, I UNDERSTAND THAT CERTAIN PRODUCTS IN THIS STUDY ARE HIGHLY PROPRIETARY TO THE SPONSOR. THEREFORE I AGREE TO KEEP SECRET THE PRODUCTS AND ALL INFORMATION PERTAINING THERETO.

I CERTIFY I AM NOT PREGNANT OR NURSING AND DO NOT PLAN A PREGNANCY DURING THIS STUDY. _____ (initials)

I HAVE NO CHANGES TO MY MEDICAL HISTORY CARD: _____ (initials)

I CERTIFY THAT I AM NOT CURRENTLY PARTICIPATING IN AND WILL NOT PARTICIPATE IN ANOTHER STUDY ON MY VOLAR FOREARMS FOR THE DURATION OF THIS STUDY: _____ (initials)

Please sign both copies of this informed consent and return both to the study investigator. You will receive a signed and dated copy for your records.

Signature of Volunteer	Printed Name of Volunteer	Date

Person conducting consent discussion

cyberDERM CLINICAL STUDIES

Appendix C: Self-Assessment

SELF-ASSESSMENT
24 Hours Post Patch Removal

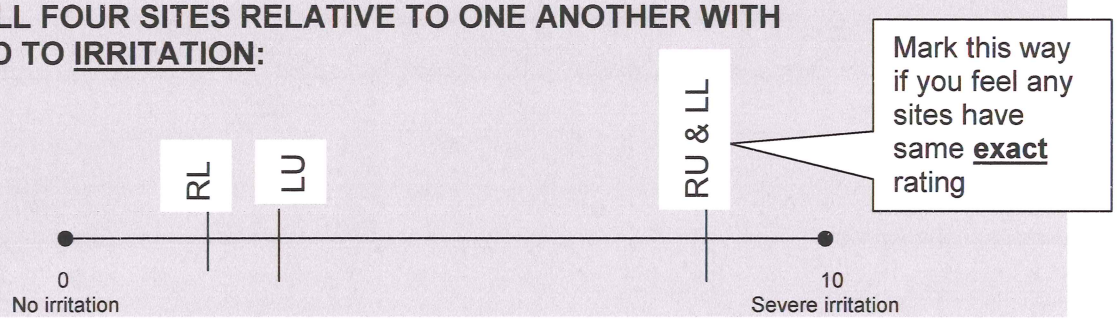
cyberDERM #S09-27

#_____ ID_____

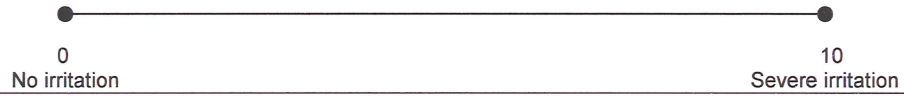
Rate each site relative to each other for each question. Use a pen to mark a vertical line for each site to rate it from best (0) to worst (10). Label each site's vertical line with the following site designations: RU = Right Upper, RL = Right Lower, LU = Left Upper, LL = Left Lower. If you feel that more than one site has the same exact rating, mark one vertical line and label it with the site designations that you feel have the same exact rating.

SAMPLE:

RATE ALL FOUR SITES RELATIVE TO ONE ANOTHER WITH REGARD TO IRRITATION:



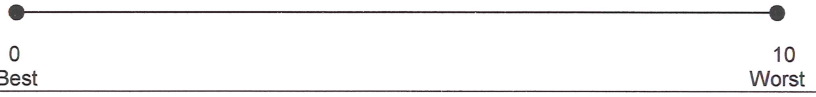
RATE ALL FOUR SITES RELATIVE TO ONE ANOTHER WITH REGARD TO IRRITATION:



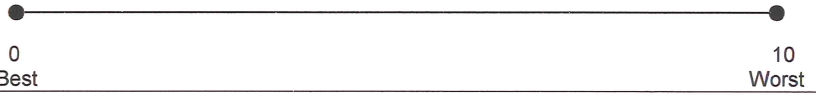
RATE ALL FOUR SITES RELATIVE TO ONE ANOTHER WITH REGARD TO ITCHING:

CONTINUED ON NEXT PAGE

RATE ALL FOUR SITES RELATIVE TO ONE ANOTHER WITH REGARD TO THE OVERALL QUALITY IT LEAVES YOUR SKIN IN:



RATE ALL FOUR SITES RELATIVE TO ONE ANOTHER FROM BEST TO WORST:



Appendix D: Randomization Schedule

cyberDERM CLINICAL STUDIES

cyberDERM #S09-27

RANDOMIZATION SCHEDULE

A = Ultra Palmolive Original concentrated dish liquid + 10% CGP #033109A

B = Ultra Palmolive Original concentrated dish liquid + 2% CGP #040609A

C = Ultra Palmolive Original concentrated dish liquid

D = Ultra Palmolive Original concentrated dish liquid + 4% CGP #032409B

#	ID	RU	RC	RL	LU	LC	LL
1	X007	A	No Rx	C	D	No Rx	B
2	S133	D	No Rx	B	C	No Rx	A
3	M284	C	No Rx	A	B	No Rx	D
4	R069	A	No Rx	D	C	No Rx	B
5	S088	C	No Rx	B	A	No Rx	D
6	P040	B	No Rx	A	D	No Rx	C
7	S170	A	No Rx	C	D	No Rx	B
8	M228	C	No Rx	D	A	No Rx	B
9	M293	B	No Rx	D	C	No Rx	A
10	H006	A	No Rx	B	C	No Rx	D
11	S007	C	No Rx	A	D	No Rx	B
12	M044	D	No Rx	B	A	No Rx	C
13	G024	B	No Rx	C	D	No Rx	A
14	K074	D	No Rx	A	B	No Rx	C
15	T022	B	No Rx	D	A	No Rx	C
16	H085	D	No Rx	C	B	No Rx	A
17	M202	A	No Rx	C	B	No Rx	D
18	K004	B	No Rx	D	A	No Rx	C
19	K083	C	No Rx	A	B	No Rx	D

DNQ at Baseline

Appendix E: Demographic Data

cyberDERM CLINICAL STUDIES

cyberDERM #S09-27

Demographic Data

#	ID	AGE	SEX
1	X007	54	F
2	S133	45	F
3	M284	24	F
4	R069	41	F
5	S088	52	F
6	P040	46	F
7	S170	44	F
8	M228	36	F
9	M293	44	M
10	H006	39	F
11	S007	55	F
12	M044	44	F
13	G024	51	F
14	K074	52	F
15	T022	53	F
16	H085	46	F
17	M202	40	M
18	K004	55	F
19	K083	54	F

DNQ at Baseline

Appendix F: Expert Grader Assessments

Decoded & Sorted Data **cyberDERM #S09-27**

Expert Grader Assessment of Erythema over Time

(Scale 0 = no erythema to 8 =marked erythema)

A = Ultra Palmolive Original concentrated dish liquid + 10%
B = Ultra Palmolive Original concentrated dish liquid + 2%
C = Ultra Palmolive Original concentrated dish liquid
D = Ultra Palmolive Original concentrated dish liquid + 4%

		Baseline					Post 24 Hr Patch Removal				
#	ID	AVG No Rx	Rx A	Rx B	Rx C	Rx D	AVG No Rx	Rx A	Rx B	Rx C	Rx D
1	X007	0	0	0	0	0	0	5	2	3	4
2	S133	0	0	0	0	0	0	4	5	2	3
3	M284	0	0	0	0	0	0	1	3	4	3
4	R069	0	0	0	0	0	0	1	4	2	3
5	S088	0	0	0	0	0	0	4	3	3	3
6	P040	0	0	0	0	0	0	1	0	3	2
7	S170	0	0	0	0	0	0	2	3	5	4
8	M228										
9	M293	0	0	0	0	0	0	4	3	5	3
10	H006	0	0	0	0	0	0	4	5	5	4
11	S007	0	0	0	0	0	0	1	3	1	2
12	M044	0	0	0	0	0	0	4	6	5	5
13	G024										
14	K074	0	0	0	0	0	0	3	3	2	4
15	T022	0	0	0	0	0	0	4	4	5	4
16	H085	0	0	0	0	0	0	5	5	6	5
17	M202	0	0	0	0	0	0	4	4	5	4
18	K004	0	0	0	0	0	0	5	4	4	5
19	K083	0	0	0	0	0	0	3	3	2	4
	Mean	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**	**3.24**	**3.53**	**3.65**	**3.65**
	SD	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**	**1.48**	**1.37**	**1.50**	**0.93**

Statistical Summary for cyberDERM Study S09-27 Expert Grader's Ratings of Erythema at Post 24 Hr Patch Removal

Summary of Data

Group	Number of Points	Mean	Standard Deviation	Standard Error of Mean	Median
Rx A 10%	17	3.235	1.480	0.3590	4.000
Rx B 2%	17	3.529	1.375	0.3334	3.000
Rx C 0%	17	3.647	1.498	0.3632	4.000
Rx D 4%	17	3.647	0.9315	0.2259	4.000

Friedman Test (Nonparametric Repeated Measures ANOVA)

The P value is 0.6305, considered not significant.

The P value is approximate (from chi-square distribution) because at least one row has two or more identical values.

Calculation detail

Group	Sum of Ranks
Rx A 10%	37.500
Rx B 2%	42.000
Rx C 0%	46.000
Rx D 4%	44.500

Number of Rows = 17 Number of Columns = 4

Friedman Statistic Fr = 1.729 (corrected for ties)

Statistical Summary for cyberDERM Study S09-27
Expert Grader's Ratings of Erythema at
Post 24 Hr Patch Removal
(Continued)

Dunn's Multiple Comparisons Test

If the difference between rank sum means is greater than 19.868 then the P value is less than 0.05.

Comparison	Rank Sum Difference		P value
Rx A 10% vs. Rx B 2%	-4.500	ns	P>0.05
Rx A 10% vs. Rx C 0%	-8.500	ns	P>0.05
Rx A 10% vs. Rx D 4%	-7.000	ns	P>0.05
Rx B 2% vs. Rx C 0%	-4.000	ns	P>0.05
Rx B 2% vs. Rx D 4%	-2.500	ns	P>0.05
Rx C 0% vs. Rx D 4%	1.500	ns	P>0.05

The data contain ties, however, this post test does not correct for ties.

* * *

Comments: Although the expert grader has rated the sites treated with Rx A which contains 10% CGP as being the less irritated, these differences are not significant.

Appendix G: Personal Self-Evaluation Data

Decoded & Sorted Data **cyberDERM #S09-27**

RATING FOR ALL FOUR SITES RELATIVE TO ONE ANOTHER WITH REGARD TO IRRITATION

A = Ultra Palmolive Original concentrated dish liquid + 10% CGP #033109A

B = Ultra Palmolive Original concentrated dish liquid + 2% CGP #040609A

C = Ultra Palmolive Original concentrated dish liquid

D = Ultra Palmolive Original concentrated dish liquid + 4% CGP #032409B

scale: 0 = no irritation to 100 = severe irritation					
#	ID	Rx A	Rx B	Rx C	Rx D
1	X007	48.7	24.0	24.0	37.7
2	S133	43.2	77.9	6.2	17.7
3	M284	54.9	18.6	51.7	22.8
4	R069	19.1	70.4	12.3	61.0
5	S088	29.2	27.4	27.4	27.4
6	P040	0.0	0.0	53.8	0.0
7	S170	15.3	15.3	15.3	15.3
8	M228				
9	M293	92.5	6.5	79.5	18.7
10	H006	5.2	7.8	10.8	15.2
11	S007	2.3	2.3	2.3	2.3
12	M044	17.2	70.2	70.2	17.2
13	G024				
14	K074	2.7	2.7	2.7	2.7
15	T022	30.5	22.2	15.5	5.0
16	H085	25.5	25.5	11.9	11.9
17	M202	7.5	60.9	12.3	69.3
18	K004	49.8	35.1	85.0	85.0
19	K083	0.6	52.0	0.6	81.0
	Mean	**26.1**	**30.5**	**28.3**	**28.8**
	SD	**25.1**	**26.1**	**28.3**	**27.9**

Decoded & Sorted Data **cyberDERM #S09-27**

RATING OF ALL FOUR SITES RELATIVE TO ONE ANOTHER WITH REGARD TO ITCHING

A = Ultra Palmolive Original concentrated dish liquid + 10% CGP #033109A

B = Ultra Palmolive Original concentrated dish liquid + 2% CGP #040609A

C = Ultra Palmolive Original concentrated dish liquid

D = Ultra Palmolive Original concentrated dish liquid + 4% CGP #032409B

scale: 0 = no itching to 100 = severe itching					
#	ID	Rx A	Rx B	Rx C	Rx D
1	X007	0.7	0.7	0.7	0.7
2	S133	76.2	83.1	51.3	57.2
3	M284	16.7	5.4	12.6	8.9
4	R069	4.2	57.3	8.8	46.8
5	S088	0.0	0.0	0.0	0.0
6	P040	0.0	0.0	54.6	0.0
7	S170	14.2	14.2	14.2	14.2
8	M228				
9	M293	4.9	4.9	4.9	4.9
10	H006	3.4	7.2	10.1	13.7
11	S007	2.3	2.3	2.3	2.3
12	M044	7.1	76.6	76.6	7.1
13	G024				
14	K074	4.5	4.5	4.5	4.5
15	T022	6.7	4.0	2.3	5.3
16	H085	11.4	11.4	4.5	4.5
17	M202	83.7	10.8	10.8	83.7
18	K004	56.1	65.6	74.5	84.9
19	K083	1.6	1.6	1.6	82.9
	Mean	**17.3**	**20.6**	**19.7**	**24.8**
	SD	**27.0**	**29.3**	**26.4**	**32.3**

Decoded & Sorted Data **cyberDERM #S09-27**

RATING OF ALL FOUR SITES RELATIVE TO ONE ANOTHER WITH REGARD TO THE OVERALL QUALITY IT LEAVES YOUR SKIN IN

A = Ultra Palmolive Original concentrated dish liquid + 10% CGP #033109A

B = Ultra Palmolive Original concentrated dish liquid + 2% CGP #040609A

C = Ultra Palmolive Original concentrated dish liquid

D = Ultra Palmolive Original concentrated dish liquid + 4% CGP #032409B

scale: 0 = best to 100 = worst					
#	ID	Rx A	Rx B	Rx C	Rx D
1	X007	46.4	17.7	17.7	34.7
2	S133	16.7	53.2	12.3	6.7
3	M284	62.0	40.9	68.8	33.3
4	R069	10.0	69.9	14.8	58.1
5	S088	24.2	22.8	22.8	22.8
6	P040	0.0	0.0	53.1	0.0
7	S170	14.4	74.9	74.9	36.8
8	M228				
9	M293	94.7	6.5	82.0	17.8
10	H006	1.9	8.9	13.2	5.6
11	S007	20.3	37.6	11.9	33.8
12	M044	16.1	89.5	76.2	31.8
13	G024				
14	K074	74.3	15.0	6.4	59.7
15	T022	17.6	7.5	13.3	3.1
16	H085	67.1	51.5	78.2	51.5
17	M202	76.9	52.1	69.2	44.5
18	K004	72.5	45.2	61.2	84.2
19	K083	12.3	12.3	12.3	83.5
	Mean	**36.9**	**35.6**	**40.5**	**35.8**
	SD	**30.9**	**27.0**	**30.0**	**25.8**

Decoded & Sorted Data **cyberDERM #S09-27**

RATING OF ALL FOUR SITES RELATIVE TO ONE ANOTHERFROM BEST TO WORST

A = Ultra Palmolive Original concentrated dish liquid + 10% CGP #033109A

B = Ultra Palmolive Original concentrated dish liquid + 2% CGP #040609A

C = Ultra Palmolive Original concentrated dish liquid

D = Ultra Palmolive Original concentrated dish liquid + 4% CGP #032409B

scale: 0 = best to 100 = worst					
#	ID	Rx A	Rx B	Rx C	Rx D
1	X007	49.2	18.8	18.8	38.9
2	S133	16.0	55.5	9.5	4.6
3	M284	74.6	28.1	80.8	35.3
4	R069	11.0	74.8	19.0	64.2
5	S088	25.5	23.5	23.5	23.5
6	P040	0.0	0.0	100.0	0.0
7	S170	18.7	82.9	82.9	37.6
8	M228				
9	M293	82.7	10.0	64.9	24.5
10	H006	4.3	13.5	17.1	7.9
11	S007	13.8	27.9	4.7	21.6
12	M044	19.6	87.8	75.8	38.8
13	G024				
14	K074	75.8	28.3	10.8	57.6
15	T022	16.0	7.6	12.4	3.5
16	H085	67.9	56.7	75.9	56.7
17	M202	89.4	89.4	80.5	80.5
18	K004	34.9	50.9	72.7	86.7
19	K083	2.9	2.9	2.9	84.2
	Mean	**35.4**	**38.7**	**44.2**	**39.2**
	SD	**30.9**	**30.8**	**35.0**	**28.5**

Appendix H: DSM II Data

Decoded & Sorted Data **cyberDERM #S09-27**

Erythema Index from DSM II over Time

A = Ultra Palmolive Original concentrated dish liquid + 10% CGP #033109A

B = Ultra Palmolive Original concentrated dish liquid + 2% CGP #040609A

C = Ultra Palmolive Original concentrated dish liquid

D = Ultra Palmolive Original concentrated dish liquid + 4% CGP #032409B

		Baseline							Post 24 Hr Patch Removal							Net Change						
#	ID	Right No Rx	Left No Rx	AVG No Rx	Rx A	Rx B	Rx C	Rx D	Right No Rx	Left No Rx	AVG No Rx	Rx A	Rx B	Rx C	Rx D	Right No Rx	Left No Rx	AVG No Rx	Rx A	Rx B	Rx C	Rx D
1	X007	11.3	9.0	10.1	10.1	10.1	11.8	10.2	10.8	8.5	9.6	12.8	12.0	15.7	12.9	-0.5	-0.5	-0.5	2.7	1.9	3.9	2.7
2	S133	9.2	9.9	9.5	10.0	12.4	10.8	11.6	9.9	10.6	10.2	11.3	14.7	11.9	11.0	0.7	0.7	0.7	1.3	2.2	1.1	-0.5
3	M284	14.1	12.4	13.3	14.1	12.9	14.2	12.6	13.6	12.5	13.1	14.0	15.4	16.9	15.0	-0.6	0.1	-0.2	-0.2	2.5	2.7	2.4
4	R069	10.8	10.4	10.6	10.9	10.5	10.8	11.6	10.5	10.1	10.3	12.0	14.6	10.7	14.1	-0.3	-0.3	-0.3	1.1	4.2	-0.1	2.5
5	S088	7.9	9.1	8.5	10.4	9.4	8.1	10.1	9.3	9.5	9.4	12.9	12.9	11.6	12.8	1.3	0.4	0.9	2.5	3.5	3.5	2.7
6	P040	9.5	11.4	10.4	10.8	9.8	9.7	9.7	9.0	10.3	9.7	10.4	10.2	10.6	9.3	-0.4	-1.0	-0.7	-0.4	0.4	1.0	-0.4
7	S170	10.8	11.6	11.2	9.7	10.4	10.1	11.6	11.3	12.5	11.9	12.6	13.0	15.3	14.8	0.5	0.9	0.7	2.9	2.6	5.2	3.2
8	M228																					
9	M293	10.1	10.7	10.4	11.5	8.1	8.6	10.6	9.2	9.8	9.5	17.0	11.9	13.5	15.9	-0.9	-0.9	-0.9	5.5	3.8	4.9	5.2
10	H006	8.1	10.1	9.1	8.3	8.5	9.5	10.1	7.8	9.2	8.5	12.9	12.7	14.9	13.5	-0.3	-0.9	-0.6	4.6	4.3	5.4	3.4
11	S007	11.0	11.4	11.2	11.1	12.3	10.2	12.1	11.8	11.4	11.6	12.1	12.9	11.7	12.3	0.8	0.0	0.4	0.9	0.6	1.5	0.3
12	M044	8.5	9.0	8.8	9.5	8.7	8.3	9.4	9.1	9.0	9.1	13.5	15.8	14.9	13.8	0.6	0.1	0.3	4.0	7.1	6.6	4.4
13	G024																					
14	K074	11.5	10.5	11.0	10.2	10.9	11.2	12.5	11.6	10.1	10.8	13.6	14.9	14.5	15.2	0.1	-0.4	-0.2	3.4	4.1	3.3	2.7
15	T022	9.4	10.4	9.9	11.4	11.0	11.0	10.6	10.4	9.8	10.1	15.7	16.5	16.0	16.0	1.0	-0.6	0.2	4.3	5.5	5.0	5.4
16	H085	10.6	11.3	11.0	12.8	12.0	11.4	10.5	9.9	10.9	10.4	20.0	19.0	21.0	17.9	-0.7	-0.5	-0.6	7.2	7.0	9.6	7.5
17	M202	11.3	12.3	11.8	11.3	11.3	13.1	12.2	11.8	12.1	11.9	14.7	17.1	17.3	19.1	0.5	-0.2	0.1	3.4	5.7	4.2	6.9
18	K004	13.1	12.7	12.9	13.4	14.1	12.8	12.7	12.1	13.1	12.6	19.9	19.7	19.7	19.2	-1.0	0.4	-0.3	6.5	5.5	6.9	6.4
19	K083	10.2	10.8	10.5	10.3	10.1	10.0	10.9	10.0	10.0	10.0	13.2	11.9	12.2	14.4	-0.2	-0.8	-0.5	2.8	1.8	2.2	3.5
	Mean			**10.60**	**10.93**	**10.73**	**10.68**	**11.12**			**10.52**	**14.01**	**14.42**	**14.62**	**14.54**			**-0.09**	**3.08**	**3.69**	**3.93**	**3.42**
	SD			**1.30**	**1.45**	**1.65**	**1.69**	**1.06**			**1.29**	**2.71**	**2.60**	**3.02**	**2.61**			**0.55**	**2.15**	**2.03**	**2.46**	**2.35**

Statistical Summary for cyberDERM Study S09-27
Erythema Index from DSMII Treated Sites Only

Summary of Data

Group	Number of Points	Mean	Standard Deviation	Standard Error of Mean	Median
Rx A 10%	17	3.088	2.160	0.5240	2.900
Rx B 2%	17	3.688	2.031	0.4926	3.800
Rx C 0%	17	3.935	2.473	0.5998	3.900
Rx D 4%	17	3.429	2.357	0.5716	3.200

Repeated Measures Analysis of Variance

The P value is 0.1031, considered not significant.

Intermediate calculations. ANOVA Table:

Source of variation	Degrees of freedom	Sum of squares	Mean square
Treatment (between columns)	3	6.706	2.235
Individual (between rows)	16	278.08	17.380
Random (residual)	48	49.329	1.028
Total	67	334.12	

F = 2.175 =MStreatment/MSresidual

Assumption test: Was the matching effective?
This test uses a second value of F and a different P value.
F = 16.912 =(MSindividual/MSresidual)

The P value is < 0.0001, considered extremely significant.
Effective matching (or blocking) results in significant variation among means.
With these data, the matching appears to be effective.

Dunnett Multiple Comparisons Test

Control column: Rx C 0%

If the value of q is greater than 2.428 then the P value is less than 0.05.

Comparison	Mean Difference	q		P value
Rx C 0% vs Rx A 10%	0.8471	2.436	*	P<0.05
Rx C 0% vs Rx B 2%	0.2471	0.7105	ns	P>0.05
Rx C 0% vs Rx D 4 %	0.5059	1.455	ns	P>0.05

* * *

Comments: Highly directional trends are seen in the data which corresponds to the level of CGP. In fact, sites treated with Rx A which contains CGP at 10% is significantly less Red than the vehicle control with no CGP.

Appendix I: cyberDERM RG-1 Water Loss Data

Decoded & Sorted Data **cyberDERM #S09-27**

Mean TEWL Rates as measured with RG-1 Computerized Evaporimeter over Time

A = Ultra Palmolive Original concentrated dish liquid + 10% CGP #033109A

B = Ultra Palmolive Original concentrated dish liquid + 2% CGP #040609A

C = Ultra Palmolive Original concentrated dish liquid

D = Ultra Palmolive Original concentrated dish liquid + 4% CGP #032409B

		Baseline							Post 24 Hr Patch Removal							Net Change						
#	ID	Right No Rx	Left No Rx	AVG No Rx	Rx A	Rx B	Rx C	Rx D	Right No Rx	Left No Rx	AVG No Rx	Rx A	Rx B	Rx C	Rx D	Right No Rx	Left No Rx	AVG No Rx	Rx A	Rx B	Rx C	Rx D
1	X007	6.3	4.6	5.4	6.4	5.1	6.9	4.2	7.2	6.8	7.0	15.1	16.5	15.0	14.8	1.0	2.2	1.6	8.7	11.4	8.1	10.6
2	S133	6.4	5.8	6.1	5.9	7.1	5.7	6.4	8.3	7.5	7.9	14.1	22.4	15.3	14.6	1.9	1.7	1.8	8.2	15.4	9.6	8.3
3	M284	4.1	3.9	4.0	3.7	4.3	4.9	4.5	10.6	9.9	10.3	7.2	9.4	8.7	9.8	6.5	6.0	6.2	3.4	5.1	3.8	5.3
4	R069	6.1	4.8	5.5	3.0	4.6	3.8	5.0	6.0	5.8	5.9	9.4	18.5	11.1	15.1	-0.1	1.0	0.4	6.4	13.9	7.3	10.1
5	S088	7.8	7.3	7.5	7.3	7.3	7.7	8.3	10.6	8.9	9.8	18.1	18.0	20.8	18.7	2.8	1.6	2.2	10.8	10.7	13.1	10.4
6	P040	2.7	3.5	3.1	3.3	3.8	3.1	3.0	4.0	3.4	3.7	7.3	9.4	15.5	8.5	1.2	-0.1	0.6	3.9	5.6	12.4	5.5
7	S170	5.6	6.5	6.0	4.5	6.5	5.5	6.1	6.6	6.5	6.6	13.7	19.4	20.1	18.6	1.0	0.0	0.5	9.2	12.8	14.6	12.5
8	M228																					
9	M293	7.2	8.7	7.9	7.9	5.5	6.7	7.5	15.6	15.1	15.4	15.1	12.0	19.5	16.8	8.4	6.5	7.4	7.2	6.4	12.7	9.3
10	H006	5.6	5.1	5.4	5.6	5.1	4.8	5.5	7.6	8.7	8.1	16.9	24.3	28.7	20.1	1.9	3.6	2.8	11.3	19.2	23.9	14.6
11	S007	4.2	3.5	3.8	4.2	3.3	4.4	3.1	5.4	4.5	5.0	10.9	9.6	9.6	9.9	1.2	1.1	1.1	6.7	6.3	5.2	6.8
12	M044	5.9	5.5	5.7	5.6	6.9	6.0	6.6	14.8	11.9	13.3	21.5	21.0	12.9	11.5	8.8	6.4	7.6	15.8	14.1	6.9	4.8
13	G024																					
14	K074	5.2	4.2	4.7	4.7	3.9	5.8	6.2	8.1	7.0	7.5	16.3	21.1	12.6	22.0	2.9	2.7	2.8	11.6	17.2	6.8	15.8
15	T022	7.6	6.9	7.2	6.7	7.4	7.1	7.5	12.2	9.7	11.0	21.5	33.2	22.0	27.0	4.6	2.8	3.7	14.8	25.7	14.9	19.5
16	H085	7.9	8.4	8.2	8.7	8.1	8.2	8.6	13.1	13.1	13.1	42.9	41.0	41.0	36.8	5.2	4.7	4.9	34.2	32.9	32.8	28.2
17	M202	5.1	6.1	5.6	5.0	5.5	5.0	6.2	6.6	10.9	8.8	15.6	34.4	32.0	40.1	1.5	4.8	3.1	10.6	28.9	27.0	33.9
18	K004	5.7	7.6	6.6	7.7	5.5	7.7	7.3	11.1	11.8	11.4	35.4	33.4	33.2	37.3	5.4	4.2	4.8	27.7	27.9	25.5	29.9
19	K083	4.2	3.8	4.0	4.4	3.6	4.6	4.6	5.2	5.6	5.4	12.4	12.3	10.3	13.7	1.0	1.8	1.4	8.0	8.6	5.7	9.2
	Mean			**5.70**	**5.57**	**5.50**	**5.76**	**5.92**			**8.83**	**17.25**	**20.92**	**19.31**	**19.72**			**3.13**	**11.68**	**15.42**	**13.55**	**13.80**
	SD			**1.47**	**1.68**	**1.49**	**1.45**	**1.67**			**3.24**	**9.31**	**9.64**	**9.39**	**9.95**			**2.34**	**8.05**	**8.76**	**8.69**	**8.98**

Statistical Summary for cyberDERM Study S09-27
Mean Net Change in TEWL Treated Sites Only

Summary of Data

Group	Number of Points	Mean	Standard Deviation	Standard Error of Mean	Median
Rx A 10%	17	11.676	8.043	1.951	9.200
Rx B 2%	17	15.418	8.766	2.126	13.900
Rx C 0%	17	13.547	8.686	2.107	12.400
Rx D 4%	17	13.806	8.971	2.176	10.400

Repeated Measures Analysis of Variance

The P value is 0.0566, considered not quite significant.

Intermediate calculations. ANOVA Table:

Source of variation	Degrees of freedom	Sum of squares	Mean square
Treatment (between columns)	3	119.82	39.941
Individual (between rows)	16	4047.0	252.94
Random (residual)	48	712.40	14.842
Total	67	4879.2	

F = 2.691 =MStreatment/MSresidual

Assumption test: Was the matching effective?
This test uses a second value of F and a different P value.
F = 17.042 =(MSindividual/MSresidual)

The P value is < 0.0001, considered extremely significant.
Effective matching (or blocking) results in significant variation among means.
With these data, the matching appears to be effective.

Dunnett Multiple Comparisons Test

Control column: Rx C 0%

If the value of q is greater than 2.428 then the P value is less than 0.05.

Comparison	Mean Difference	q	P value
Rx C 0% vs Rx A 10%	1.871	1.416	ns P>0.05
Rx C 0% vs Rx B 2%	-1.871	1.416	ns P>0.05
Rx C 0% vs Rx D 4 %	-0.2588	0.1959	ns P>0.05

* * *

Comments: Although those sites treated with Rx A which contains CGP at 10% was the least damaged as assessed by elevated TEWL values, these differences did not reach significance at p <0.05.