Research Report S05-93

Confidential Material

CLINICAL STUDY REPORT: # TOPCGP-2005

TITLE OF STUDY:

A SINGLE-BLIND, RANDOMIZED, CONTROLLED PILOT STUDY WITH TOPICAL CALCIUM GLYCEROPHOSPHATE IN PATIENTS WITH TAPE-STRIP DAMAGED SKIN

Sponsor: **AkPharma, Inc.**
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Submitted By:

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I. OBJECTIVES

This study was designed to determine the effectiveness of test formulations in repairing damage to the skin and reducing redness as well as soothing irritation. We used an adhesive tape trauma wound healing test that included both Expert Grader assessments and instrument measurements of evaporative water loss. In addition, panelists were asked to provide a subjective sensory evaluation of the products applied to their damaged skin sites.

II. EXPERIMENTAL DESIGN

A. General Considerations

Prior to initiation of the study, the proposed protocol, the informed consent form and the product information were submitted to Allendale Investigational Review Board, which reviewed and approved this study on November 3, 2005 and Amendment I on November 17, 2005. This notification of the Board's approval along with a description by profession of the Board's composition was provided to the Sponsor prior to the initiation of the study.

This study was conducted under the supervision Gary Grove, Ph.D. and Charles Zerweck, Ph.D., at cyberDERM Clinical Studies in Broomall, Pennsylvania. Dr. Grove served as Principle Investigator and Dr. Zerweck served as the Sub-Investigator for this study. Copies of Drs. Grove's and Zerweck's curriculum vitae were provided to 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 pilot study was conducted on six (6) panelists from November 7, 2005 through November 18, 2005. The study was amended to add a second group of three (3) panelists and was conducted from November 28, 2005 through December 8, 2005 using a revised formulation. A calendar of events outlining the treatment schedule and evaluative procedures that were followed during the study is attached as **Appendix A**.

This was a single-blind, controlled, randomized study. Panelists were evaluated by the Expert Grader for erythema and had instrument measurements of skin water loss at Baseline (Day 1) prior to the tape trauma procedure. Adhesive tapes (1" x 3") were then applied to 4 test sites on the back (2 on each side) and removed. New tape samples were applied and removed repeatedly to disrupt the skin's stratum corneum barrier until "glistening". The result was significantly elevated transepidermal water loss and erythema associated with repetitive stratum corneum stripping. Relative uniformity

of traumatized sites (4 total, 2 on each side of the back) was assessed after the tape stripping procedure using the DermaLab TEWL Meter. After the tape trauma, a technician applied the test materials to 3 of the 4 test sites on the back according to a randomization schedule. The other tape traumatized site served as a non-treated control to follow the normal healing process for each individual. Panelists were also asked to rate the test products after application as to what degree the products caused burning/stinging or soothed the test sites. The evening product application was applied by a friend/partner of the panelist at home.

Irritation and healing rates were based on clinical observations and instrument measurements using the DermaLab® TEWL Meter daily (excluding weekends) on Days 2-5 and 8-11 prior to the morning treatment application. The evening and weekend product applications were applied by a friend/partner of the panelist at home. Panelists returned to the test facility on Day 12 for final Expert Grader assessments of erythema and DermaLab® TEWL measurements.

B. Panelist Selection

Volunteers for this project were recruited from a pool of healthy suburban Caucasian men and women who were willing to comply with the requirements of this experimental design. They were within the age range from 18 to 55 years and were interviewed to ascertain that they were not pregnant or nursing, had no medical problems, no known allergies to soaps or fragrances, and were not using concomitant medications that might interfere with the study results. The inclusion/exclusion criteria were as follows:

1. Inclusion Criteria

a. Male or female, 18-55 years of age, and in good general health.
b. Has a friend/partner willing to apply all evening and weekend treatments to their back.
c. Agrees to discontinue use of all products except for cleansers on the back for 3 days prior to start of study (Day 1).
d. Must agree to take showers during study (no tub bathing).
e. Agrees to not scrub the test sites with back brushes or loofahs, etc. or apply any other products to test sites.
f. Willing and able to follow all study directions and to commit to all follow-up visits for the duration of the study.
g. Agrees not to swim, use a sauna or tanning salon for the duration of study.
h. Must be willing to lie on stomach for time necessary to perform assessments.
i. Has read and completed the informed consent process.

2. Exclusion Criteria

a. Is pregnant or nursing.
b. Is taking anti-inflammatories (Advil, Aleve, arthritis medications, etc.) except for acetaminophen (e.g. Tylenol).
c. Has irritation, scars, moles, other blemishes on the back that would obscure grading or measuring of the test sites.
d. Has any allergy or sensitivity to tapes or adhesives.
e. Systemic or cutaneous disease that may interfere with study results.
f. Is diabetic.

All volunteers signed a consent form (**Appendix B**) after being informed as to their obligations and risks that they might encounter as a participant in this study. The selected panelists were advised of the general nature of this study and were instructed not to "tamper" with the sites in any way. Each candidate was instructed to stop the use of any products other than cleansers on their back during a 3 day pre-conditioning period prior to testing.

<u>During the study, the following restrictions were imposed:</u>

- Must have a friend/partner willing to apply all evening and weekend treatments to their back.
- Agreed to take showers during study (no tub bathing).
- Not scrub the test sites with back brushes or loofahs, etc. or apply any other products to test sites.
- Not have any allergies or sensitivity to tapes or adhesives.
- Not have scars, moles, other blemishes on the back that would obscure grading or measuring of the test sites.
- Not be diabetic.
- Not taking anti-inflammatories (Advil, Aleve, arthritis medications, etc.) except for acetaminophen (e.g. Tylenol).
- Not swim, use a sauna or tanning salon for the duration of study.
- Able to lie on stomach for time necessary to perform assessments.
- Not exercise before each visit as this would affect the measurements.
- Must shampoo prior to their evening applications.
- Must rinse their back thoroughly (1 minute or more) to remove residual product film in the shower. This must be at least 1 hour prior to morning visits so as not to influence any assessments.

Prior to testing, all candidates were assessed by Charles Zerweck, Ph.D., for suitability to be included on the panel. Any individuals with scars, moles, other blemishes on the back that would obscure grading or measuring of the test sites were excluded at that time. Qualified panelists were assigned a panelist number in the order of their admittance to the study panel. Dr. Zerweck logged each panelist in and outlined

four 1 inch by 3 inch test sites on the left and right sides of the back (two on each side) using a standard template.

C. Expert Grader Evaluations

Charles Zerweck, Ph.D., served as the Expert Grader for this study. On Day 1 (prior to tape trauma) and on Days 2-5 and 8-12, Dr. Zerweck was responsible for assessing the amount of erythema on the 4 test sites located on the back based on the following nine point grading scale:

Erythema	
0 =	None
2 =	Mild, erythema
4 =	Moderate, confluent erythema
6 =	Marked erythema with some edema
8 =	Intense erythema, edema, flare, possible erosion

Intermediate grade increments were used to denote intermediate levels of severity. The ties were broken by forcing the Expert Grader to add 0.1 to that site which he thought might be worse, except at Baseline.

D. Cortex Technology DermaLab Water Loss Meter

All water loss measurements were taken following a 15-30 minute acclimation period in a controlled environment with the relative humidity maintained at less than 50% and temperature maintained at 70 $\pm$ 2^{o}F.

Prior to the tape trauma, Baseline (Day 1) evaporative water loss measurements were obtained from each of the 4 test sites on the panelist's back as described below. Any individuals with water loss values outside the normal range (>10.0 gms/m^{2}hr) 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 DermaLab® Modular System with TEWL Probe that is manufactured by Cortex Technology (Hadsund, Denmark) and available in the US through cyberDERM, inc. (Media, 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.

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 DermaLab® Modular System is completely computerized and continuously communicates with its PC through a serial port using an RS-232C cable and associated cyberDERM, inc. software for the Evaporimeters. We use the application program entitled DLRUNONX that captures the water loss data from the attached evaporimeter at a sampling rate of 5 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.

At each session, duplicate water loss readings were taken from each test site and electronically recorded using a spreadsheet format based on Excel software that 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 there were problems with the computerized records.

Such measures provide a noninvasive method for determining the barrier function of the stratum corneum. Damage leads to a disruption of the barrier that is accompanied by elevated water loss rates.

Measurements were taken by Mr. Jonn Damia from all 4 sites at Baseline (Day 1) prior to the tape trauma and again immediately (10 minutes) after the tape trauma to determine if the 4 sites had achieved relatively uniform elevations in TEWL between the 4 sites. Measurements were also taken of the 4 sites located on the back prior to the morning applications on Days 2-5 and 8-11 and again on Day 12.

E. Repetitive Tape Strip Trauma

After the Baseline (Day 1) measurements were completed, Dr. Zerweck with the assistance of Mrs. Trish Alfano, applied adhesive tape (1” x 3”) to 4 test sites on the back (2 on each side). These were removed and new tape samples were applied and removed repeatedly to disrupt the stratum corneum barrier. Sites were stripped to “glistening” as visually determined by Dr. Zerweck. The result was significantly elevated transepidermal water loss and the eventual development of erythema associated with tape traumatized skin.

Using this technique we created (4) 1 inch x 2 inch irritated sites on the back (2 on each side). Our experience has been that normal Baseline TEWL values of 4-10

gm/m^2/hr can be easily elevated to within the range of 70-120 gm/m^2/hr. These test sites also developed moderate to marked confluent erythema.

Relative uniformity of tape traumatized sites was assessed after the procedure using the DermaLab® TEWL Meter and sites were tape stripped again if any sites had not attained the desired disruption of stratum corneum.

F. Test Supplies

The test materials were provided by the Sponsor in individual containers for each panelist and coded as follows:

GROUP 1 (N = 6)	
cyberDERM Code	**Sponsor Code**
Rx A	**AKP2930**
Rx B	**AKP4671**
Rx C	**AKP3578**

GROUP 2 (N=3)	
cyberDERM Code	**Sponsor Code**
Rx D	**AKP1491**
Rx E	**AKP5605**
Rx F	**AKP8937**

It should be noted that during the testing period for the first 6 panelists (Group 1), the Sponsor decided to make an adjustment to the formulations and these new formulations were then used to treat an additional 3 panelists (Group 2). Upon submission of the data to the Sponsor based on the above codes, the Sponsor provided the following Code Break:

GROUP 1 (N = 6)		
cyberDERM Code	**Sponsor Code**	**Code Break**
Rx A	**AKP2930**	**7.5% CGP; pH = 7.5-8.5**
Rx B	**AKP4671**	**7.5% CGP + 0.5% c.o.; pH = 7.5-8.5**
Rx C	**AKP3578**	**37% CGP; pH = 7.5-8.5**

GROUP 2 (N=3)		
cyberDERM Code	**Sponsor Code**	**Code Break**
Rx D	**AKP1491**	**37% CGP; pH = 5.5-5.8**
Rx E	**AKP5605**	**7.5% CGP + 0.5% c.o.; pH = 5.5-5.8**
Rx F	**AKP8937**	**7.5% CGP; pH = 5.5-5.8**

After completing the visual grades and instrument measurements on Day 1, the panelists had the test materials applied to 3 of the 4 sites twice daily for 11 days. The other tape traumatized site served as a non-treated control.

Three of the four test sites on the back were randomly assigned to the test products while one site served as a non-treated control according to the randomization schedules attached as **Appendix C**.

The morning treatments on Days 1-5 and 8-11 were performed by Mrs. Carol Cesari at the lab. The products were applied according to the Sponsor's instructions (**Appendix D**). The evening and weekend applications were performed by a friend/partner of the panelist at home.

The panelists were provided with a diary form to record the times of their applications. The diary also included a treatment map indicating the designated sites and instructions (**Appendix D**).

G. Self-Assessments

The panelists were asked to complete a self-assessment as to whether the products caused burning/stinging or were soothing prior to and after each morning application at the lab using the following scale:

Score	Burning/Stinging or Soothing?
-4	Burning/stinging is marked
-3	Burning/stinging is moderate
-2	Burning/stinging is mild
-1	Burning/stinging is barely perceptible
-0.1	Forced choice that site burns/stings
0.1	Forced choice that site is soothed
1	Barely soothing
2	Mildly soothing
3	Moderately soothing
4	Completely soothing/relief

H. Termination of a Site

All tape stripped sites were evaluated daily by the Expert Grader. If any site had been deemed to be substantially worsened during the course of treatment, that site would have been terminated and no further treatments with the study materials would have been made.

I. Adverse Reactions

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.

Non-Serious Adverse Event
All adverse events not classified as serious will be reported and 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.

J. Statistical Analysis

Dr. Grove was responsible for devising a sorting template that is based on Excel 2003 spreadsheet software and implemented on the IBM clone desktop computer. The sorted data for each parameter was tabulated and arranged in order of panelist number for every point of evaluation for each treatment group (Group 1 & Group 2 are reported separately). 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 ProStat software programs. The sorted data tables for each treatment group 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.

The approach used by Dr. Grove follows the general recommendations set forth by the International Federation of Society of Cosmetic Chemists in their Monograph on Principles of Product Evaluation: Objective Sensory Methods. In this approach various statistical tests were used as follows:

1. In the case of the instrumental measurements, a Paired T-Test was run on the net change from Baseline obtained at each point in time for each of the test products. The percent healing was also calculated. It should be noted that due to the panel sizes, this analysis was only done to show trends in the data for the pilot studies.

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

It should be noted that no attempt was made to compare the results of Group 1 and Group 2.

III. RESULTS

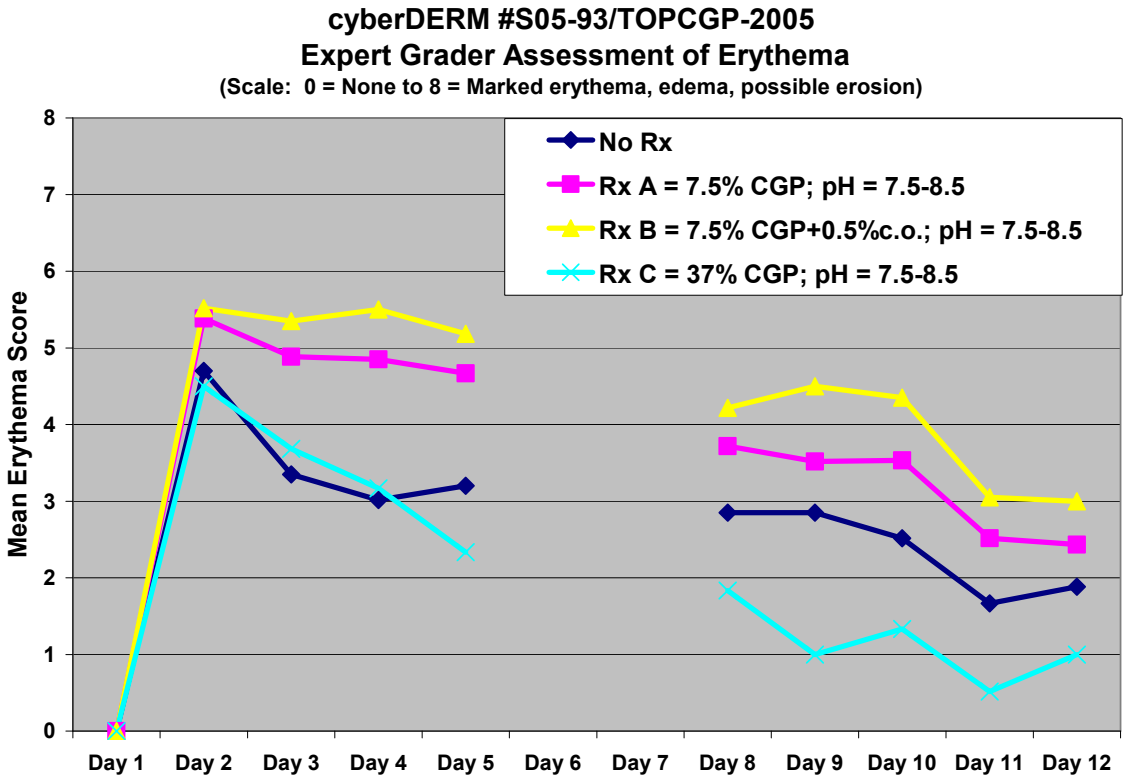
A. Panelist Accountability

Six panelists in Group 1 and three panelists in Group 2 reported to the test facility for Baseline assessments and were accepted onto the final panel. All panelists in Group 1 were able to successfully complete the entire study. In Group 2, panelist #8 F039 was not able to report for her Day 11 appointment due to a family emergency. In addition, all panelists in Group 2 had their final day's visit (Day 12) cancelled due to a snow storm. **Appendix E** contains a listing of each panelist's age and sex.

We have no reason to believe that these panelists were not otherwise fully compliant with the requirements of this study.

B. Group 1 – Expert Grader Erythema Data

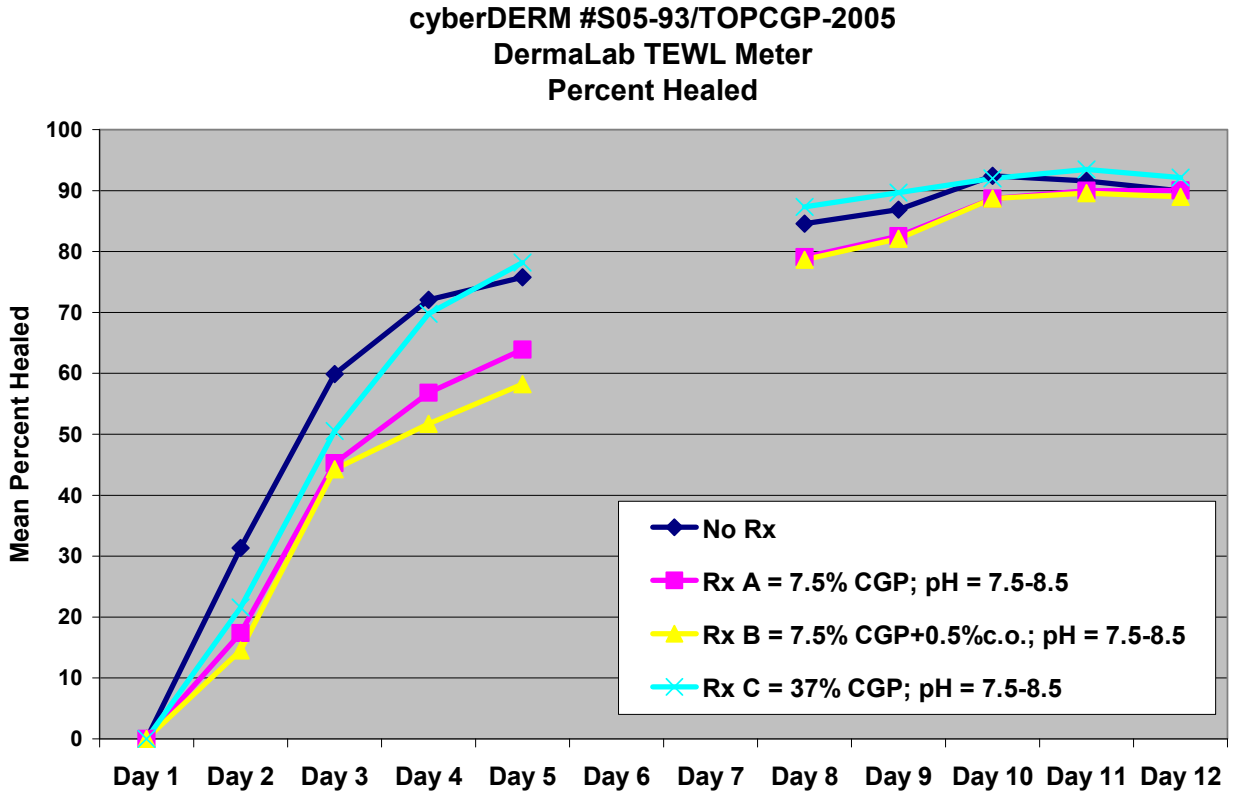
The sorted Expert Grader Erythema data for Group 1 are tabulated and attached as **Appendix F**. These tables record the data obtained at Baseline and at each follow-up time point for each of the panelists (#1-6). A summary of these values which represent skin surface redness and inflammation is graphically provided in the figure shown below:



Based on the results of expert grader assessments of erythema it appears that only sites treated with Product Code C (37% CGP; pH = 7.5-8.5) have returned more rapidly towards normal than the non-treated control.

C. Group 1 – DermaLab Water Loss Data

The sorted water loss data for Group 1 are tabulated and attached as **Appendix G**. These tables record the data obtained at Baseline and at each follow-up time point for each of the panelists (#1-6). These values were used to calculate the percentage return toward baseline value (assuming the range from baseline to immediate post trauma TEWL for each site could be normalized to 100%). A "percent healed" summary is graphically provided in the figure shown below:



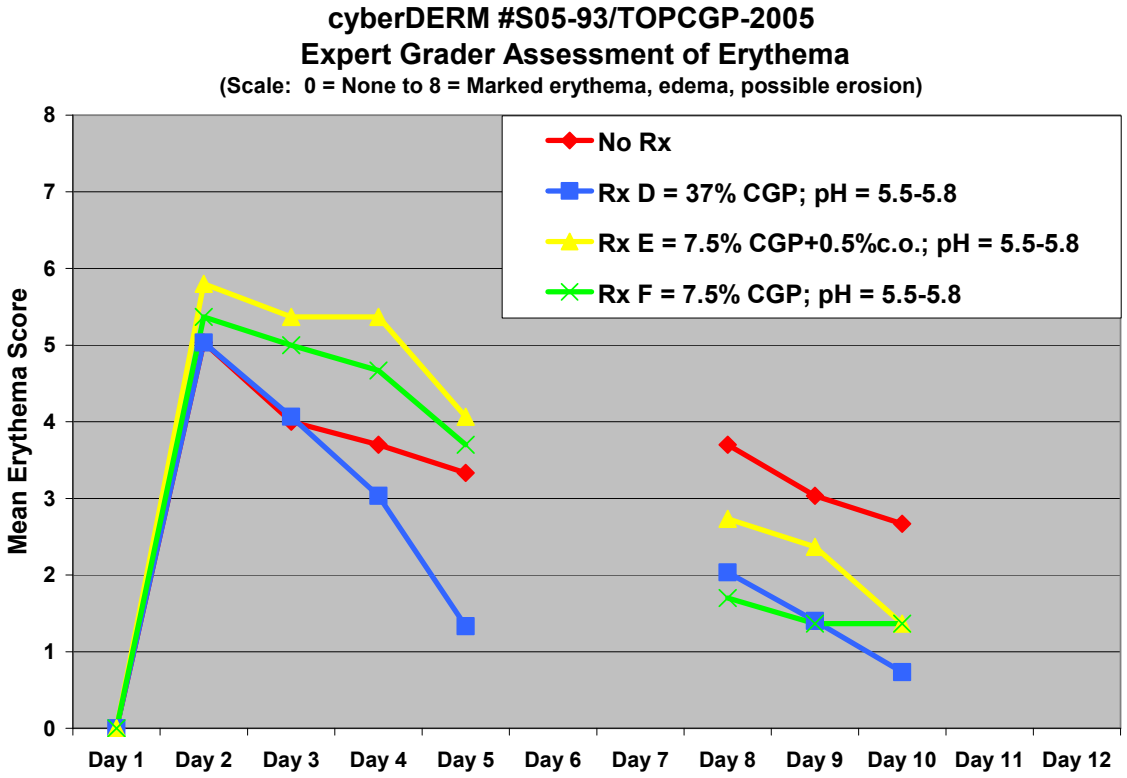
Based on evaporative water loss results it does not appear that any of the treatment regimens have significantly improved the rate at which the sites heal when compared to the non-treated control.

D. Group 1 – Self-Assessment Data

The sorted Self-Assessment data for Group 1 are tabulated and attached as **Appendix H**. These tables record the data obtained pre and post treatment during each session for the panelists (#1-6).

E. Group 2 – Expert Grader Erythema Data

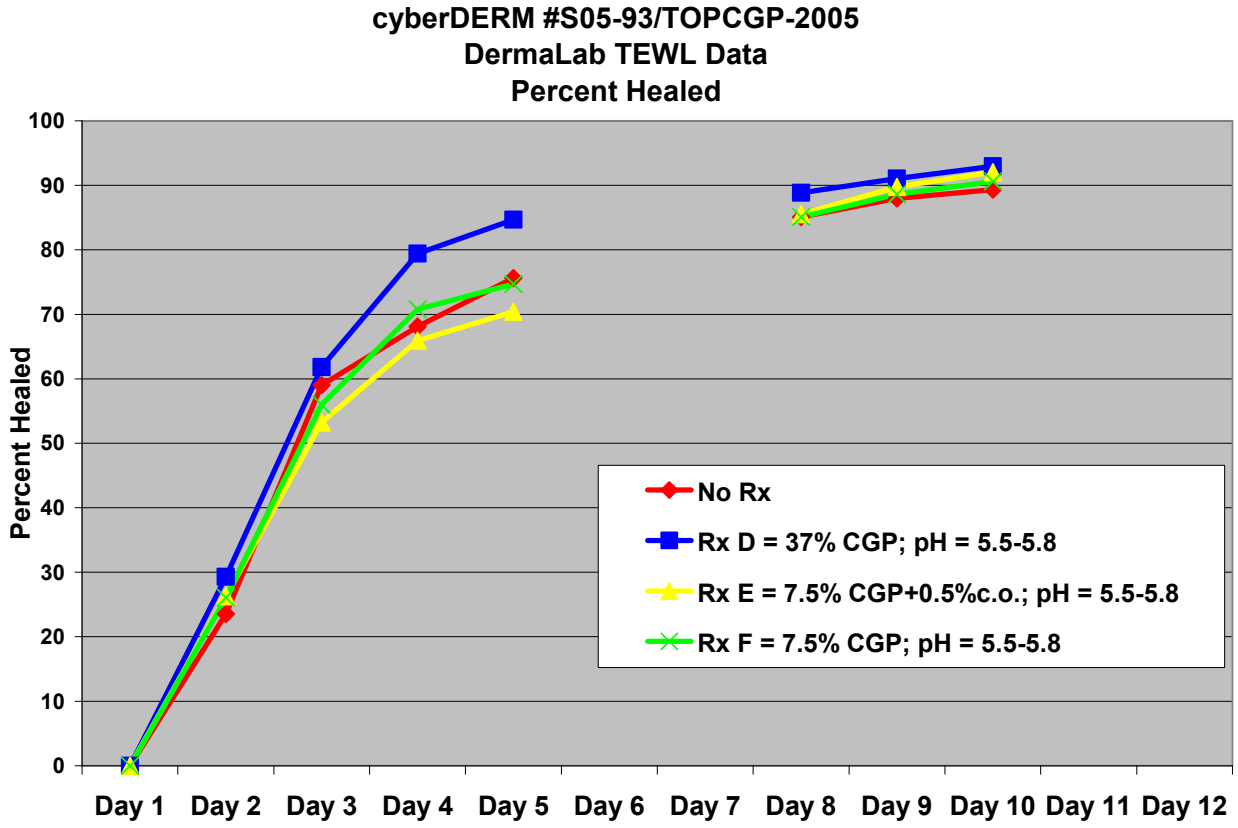
The sorted Expert Grader Erythema data for Group 2 are tabulated and attached as **Appendix I**. These tables record the data obtained at Baseline and at each follow-up time point for each of the panelists (#7-9). A summary of these values which represent skin surface redness and inflammation is graphically provided in the figure shown below:



Based on the mean erythema results for this small (n=3) sampling, it appears that all of the treatment regimens (D, E, and F) have returned more quickly toward baseline by Day 8 and onward. Product Code D (37% CGP; pH = 5.5-5.8) in particular appears to provide an earlier benefit in reducing erythema and is clearly superior on Day 5.

F. Group 2 – DermaLab Water Loss Data

The sorted water loss data for Group 2 are tabulated and attached as **Appendix J**. These tables record the data obtained at Baseline and at each follow-up time point for each of the panelists (#7-9). These values were used to calculate the percentage return toward baseline value (assuming the range from baseline to immediate post trauma TEWL for each site could be normalized to 100%). A "percent healed" summary is graphically provided in the figure shown below:



The results of the evaporative water loss data suggest that treatment with Product Code D (37% CGP; pH = 5.5-5.8) may accelerate repair of the stratum corneum barrier when compared to no treatment.

G. Group 2 – Self-Assessment Data

The sorted Self-Assessment data for Group 2 are tabulated and attached as **Appendix K**. These tables record the data obtained pre and post treatment during each session for the panelists (#7-9).

IV. CONCLUSIONS

In Group 1, (panelists 1-6) there was little suggestion that any of the product treatment regimens were resulting in enhanced skin repair. Three additional panelists were tested in Group II using modified test formulations. Based on the results of this second small sampling it appears that Product Code D (37% CGP; pH = 5.5-5.8) may in fact accelerate the rate of skin barrier repair and is a good candidate for further studies.

In Group 1, no adjustment was made to the products to correct their pH levels toward that of the normal “protective acid mantle” (pH ~5.4). The acid mantle is very important to stratum corneum skin barrier repair / integrity and for restoration of healthy stratum corneum / epidermal function. The 37% CGP; pH = 7.5-8.5 (Rx C) seems to have overcome this problem. The most likely explanation is that it is delivering CGP into the epidermis and assisting the cellular differentiation process (precursor to the vital stratum corneum components) via nutritive needs of epidermal cells.

In Group 2, adjustment was made to the products to correct their pH levels. Based on the mean erythema results for this small (n=3) sampling, it appears that all of the treatment regimens (D, E, and F) returned more quickly toward baseline by Day 8 and onward. Product Code D (37% CGP; pH = 5.5-5.8) in particular appears to provide an earlier benefit in reducing erythema and is clearly superior on Day 5. In addition, the results of the evaporative water loss data suggest that treatment with Product Code D may accelerate repair of the stratum corneum barrier when compared to no treatment.

V. 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 #S05-93 CALENDAR OF EVENTS
A SINGLE-BLIND, RANDOMIZED, CONTROLLED PILOT STUDY WITH TOPICAL CALCIUM GLYCEROPHOSPHATE IN PATIENTS WITH WOUND-DAMAGED SKIN

Pre-Trial Conditioning: Panelists will stop the use of all moisturizing products on the back 3 days prior to study start.

MON. DAY 1	TUE.-FRI. DAYS 2-5	SAT.-SUN. DAY 6-7	MON.-THU. DAY 8-11	FRI. DAY 12
Expert Grader Erythema assessments	Expert Grader Erythema assessments		Expert Grader Erythema assessments	Expert Grader Erythema assessments
DermaLab® TEWL measurements	DermaLab® TEWL measurements		DermaLab® TEWL measurements	DermaLab® TEWL measurements
Tape Stripping of 4 sites on back				
DermaLab® TEWL measurements				
AM treatment **AT LAB**	AM treatment **AT LAB**		AM treatment **AT LAB**	Collect test products
Self-Assessment	Self-Assessment		Self-Assessment	
PM treatment at home	PM treatment at home	AM & PM treatment at home	PM treatment at home	

PANEL:
Male or female panelists, ages 18 to 55 without excessive hair on test sites

TEST SITES:
Four 1" x 2" test sites on the back (2 on each side); 3 of the 4 sites will be treated, 1 will remain non-treated to serve as a control.

TAPE STRIPPING PROCEDURE:
Adhesive tape will be applied and to 4 test sites on the back (2 on each side) and removed repeatedly to disrupt the stratum corneum barrier. Sites will be stripped to "glistening".

CLINICAL ASSESSMENTS:
Expert Grader erythema assessments of the 4 test sites on Days 1 (prior to tape stripping) and again on Days 2-5, and Days 8-12. Ties will be broken.

cyberDERM #S05-93 CALENDAR OF EVENTS
A SINGLE-BLIND, RANDOMIZED, CONTROLLED PILOT STUDY WITH TOPICAL CALCIUM GLYCEROPHOSPHATE IN PATIENTS WITH WOUND-DAMAGED SKIN

INSTRUMENTAL ASSESSMENTS:
DermaLab® TEWL Meter transepidermal water loss values of the 4 test sites on Days 1 (before and after tape stripping) and again on Days 2-5 and Days 8-12.

TEST PRODUCTS:
Test products supplied by Sponsor with dosage and use instructions. Products will be applied twice daily. Weekday morning applications will be applied at the lab following evaluations. Evening and weekend treatments will be applied by a friend/partner of the panelist at home.

SELF-ASSESSMENTS:
Panelists will be asked to assess the test sites for burning/stinging and soothing on a -4 (product burns/stings) to+4 (product soothes) scale on Day 1 immediately after product application and again on Days 2-5 and 8 and 10 prior to and following product application.

DATA ANALYSIS:
- A full statistical analysis is not warranted due to the small sample size; however, a Paired T-Test will be used to ascertain any trends in the data which would warrant further study. For all analyses, a two tailed $p < 0.05$ will be taken as the level of significance.

PANELIST RESTRICTIONS:
- Must have a friend/partner willing to apply all evening and weekend treatments to their back.
- Must agree to take showers during study (no tub bathing).
- May not scrub the test sites with back brushes or loofahs, etc. or apply any other products to test sites.
- Must not have any allergies or sensitivity to tapes or adhesives.
- May not have scars, moles, other blemishes on the back that would obscure grading or measuring of the test sites.
- May not be diabetic.
- May not be taking anti-inflammatories (Advil, Aleve, arthritis medications, etc.) except for acetaminophen (e.g. Tylenol).
- Must agree not to swim, use a sauna or tanning salon for the duration of study.
- Must be willing to lie on stomach for an extended period of time.
- The panelists may not exercise before each visit as this will affect the measurements.
- The panelists will be instructed to shampoo prior to their evening applications.
- Must rinse their back thoroughly (1 minute or more) to remove residual product film in the shower. This must be at least 1 hour prior to morning visits so as not to influence any assessments.

Appendix B: Consent Form

Subject Number: _____ CCS ID:_____

SUBJECT INFORMATION AND CONSENT FORM

TITLE: A Single-Blind, Randomized, Controlled Pilot Study With Topical Calcium Glycerophosphate In Patients With Wound-Damaged Skin

PROTOCOL NO.: cyberDERM #S05-93

INVESTIGATOR: Gary L. Grove, Ph.D.
Telephone: 610-325-0112 (Day)
610-358-2381 (Night)

CO-INVESTIGATOR: Charles R. Zerweck, Ph.D.
Telephone: 610-325-0112 (Day)
610-627-9236 (Night)

STUDY SITE: cyberDERM Clinical Studies
700 Parkway Drive
Broomall, Pennsylvania 19008
Telephone: 610-325-0112

This consent form may contain words that you do not understand. Please ask the study doctor or the study staff to explain any words or information that you do not clearly understand.

INTRODUCTION
Before agreeing to enroll in this research study, it is important that you read and understand the following explanation of the proposed procedures. This statement describes the purpose, procedures, benefits, risks, discomforts, and precautions of the study. It also describes the alternative procedures that are available to you and your right to withdraw from this study at any time. No guarantees or assurances can be made as to the results of the study.

This study is being conducted for a consumer product company. cyberDERM Clinical Studies is being paid by the study sponsor to conduct this study.

BACKGROUND AND PURPOSE OF STUDY

This study is designed to determine the effectiveness of test formulations in soothing irritation, reducing redness as well as repairing damage to the skin. We will use an adhesive tape trauma wound healing test to intentionally damage 4 sites on the back, each area being approximately 1 inch by 2 inches. This will be done by applying and removing adhesive tape multiple times until the skin surface is stripped to "glistening". The damage will be similar to a brush-burn.

This study is under the direction of Drs. Gary L. Grove and Charles R. Zerweck.

Approximately 6 volunteers will enroll in this study.

LENGTH OF STUDY AND PROCEDURES USED

Your participation in this study will last 12 days and involves 10 study visits. You will be asked to report to the testing facility at specific times during the study. It is important that you report at the designated times. Each of your visits will last approximately 1 hour. If you agree to participate, the following steps will occur:

Friday, 3 Days prior to testing start:

- You will begin a 3-day washout period. During this time, you must not use topical products (including moisturizing skin care products) on your back.

On Saturday through Sunday (The 2 days prior to testing start):

- Continue washout.

Monday, Day 1, start of testing:

- You will have 4 test sites mapped onto your back (2 on each side) with a skin-marking pen by the treatment technician. Each test site will be approximately 1 inch by 2 inches in size.
- You will then sit quietly and accommodate to the conditions of the test lab for approximately 15-20 minutes. During the accommodation and evaluations, your back must remain exposed to the air.
- You will have the test sites visually graded and instrumentally measured by technicians. The instrument measures Transepidermal Water Loss (referred to as "TEWL" or "TWL"), which is the amount of water evaporating from your skin. A probe is gently placed repeatedly against the skin for a few seconds or up to 1 minute while each non-invasive measurement is taken. You will lie face down on a padded exam table during the measurements.
- You will then have the 4 sites on your back "tape stripped" to intentionally damage the skin surface. This will involve a technician applying and removing adhesive tape multiple times until the skin surface is stripped to "glistening". The damage will be similar to a brush-burn.
- TEWL measurements will be taken of each test site to determine if the values are similar and in the desired range. If a site(s) is not in the desired range, it will be tape stripped additional times and the measurements will be

repeated to confirm damage.

- A technician will apply product to 3 of the 4 sites on your back. Three of the test sites will be treated with the test products and the other site will be left non-treated to serve as a control.
- You will be given products and instructions to take home for your partner to apply the evening treatments.
- You will be reminded to wear appropriate clothing to the lab for each visit so that the sites on the back can be treated and/or evaluated.

Tuesday, Day 2 through Friday, Day 5:

- You will report to the testing facility at a specific time to accommodate. The test site grading and instrumental measurements will be repeated.
- A technician will treat 3 of the 4 sites on your back.
- You will be given products and instructions to take home for the evening treatments.
- On Day 5, you will also be given product to take home for your partner to apply over the weekend.

Saturday, Day 6 and Sunday, Day 7:

- Your partner will apply both the morning and evening treatments.

Monday, Day 8 through Thursday, Day 11:

- You will report to the testing facility at a specific time to accommodate. The test site grading and instrumental measurements will be repeated.
- A technician will treat 3 of the 4 sites on your back.
- You will be given products and instructions to take home for the evening treatments.

Friday, Day 12:

- You will report to the testing facility at your designated time for the same skin grading and instrumental measurements.
- Your participation in this study will end.

During the visits the following instrument will be used:

For DermaLab TEWL measurements, you will lie face down on a padded exam table and the technician will gently hold the instrument probe against each site on your back to take measurements of how much moisture is evaporating from your skin.

STUDY REQUIREMENTS AND RESTRICTIONS

- Must have a friend/partner willing to apply all evening and weekend treatments to their back.
- Must agree to take showers during study (no tub bathing).
- May not scrub the test sites with back brushes or loofahs, etc. or apply any other products to test sites.
- Must not have any allergies or sensitivity to tapes or adhesives.
- May not have scars, moles, other blemishes on the back that would obscure grading or measuring of the test sites.
- May not be diabetic.
- May not be taking anti-inflammatories (Advil, Aleve, arthritis medications, etc.) except for acetaminophen (e.g. Tylenol).
- Must agree not to swim, use a sauna or tanning salon for the duration of study.
- Must be willing to lie on stomach for an extended period of time.
- The panelists may not exercise before each visit as this will affect the measurements.
- The panelists will be instructed to shampoo prior to their evening applications.
- Must rinse their back thoroughly (1 minute or more) to remove residual product film in the shower. This must be at least 1 hour prior to morning visits so as not to influence any assessments.

RISKS OR DISCOMFORTS

- The therapy and procedures to be followed in this study may involve the following foreseeable risks and discomforts. The tape stripping procedure will damage your skin. You may have possible lightening or darkening of the skin, skin irritation including, but not limited to, redness, dryness, itching, burning/stinging. This is usually temporary but could persist for a long time (even permanent). Your participation in this study may involve risks that are currently unforeseeable or unknown.
- You may experience momentary discomfort with one or more of the test materials (e.g. a mild to moderate stinging on application), a reddening of the skin, bumps or other changes in skin condition. These are usually temporary and may be caused by chemical irritation or mechanical trauma. These skin conditions should dissipate within one to two days after the materials are removed.
- 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 or are diabetic. You should also not participate in this study if you are sensitive to cosmetics, toiletries or any other skin care products.

If any of these should occur, the condition of your skin will be closely monitored until it returns to normal. Consultation with a physician will be made, if necessary.

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 that caused the allergic reaction in order that you may avoid contact with it in the future.

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.

NEW FINDINGS
Significant new findings that develop during the course of this study that may relate to your willingness to continue participation will be provided to you.

BENEFITS TO YOU OR TO OTHERS THAT MAY RESULT FROM THE RESEARCH STUDY
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.

SUBJECT COMPENSATION
You will be paid $225.00 to compensate you for your time and participation if you complete the entire study (Day 1 – Day 12). If you do not complete the study, either by choice (such as not attending a visit) or as instructed by the study investigator for any reason, you will be paid on a pro-rated basis, depending on the procedures you completed. Your payment will be provided after the end of the 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) and the Institutional Review Board (IRB) 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, the FDA, and the IRB.

COMPENSATION FOR STUDY-RELATED INJURY
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 by a physician at cyberDERM Clinical Studies at no cost to you. No additional compensation is available. You will not lose any of your legal rights as a research subject by signing this consent form.

EMERGENCY CONTACT/IRB CONTACT
If you have questions about this study, or in the event of a research-related injury or illness, you should call:

Gary L. Grove, Ph.D.		Charles R. Zerweck, Ph.D.
Investigator		Co-Investigator
Telephone:	610-325-0112 (Day)	610-325-0112 (Day)
	610-358-2381 (Night)	610-627-9236 (Night)

Project Coordinator: Danielle Fendrick
Telephone: cyberDERM Clinical Studies - 610-325-0112 (Day)

If you have any questions about your rights as a research participant, you should call Robert J. Staab, Ph.D. at Allendale Investigational Review Board [201-934-0995]. The review board is an independent committee established to help protect the rights of research subjects.

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 other 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 will be asked to return your unused study materials or have study ending tests and procedures for your safety.

ADDITIONAL COSTS THAT MAY RESULT FROM PARTICIPATION IN THE RESEARCH STUDY
You should incur no costs for participating in this research study. If you fully understand the details and possible risks of this study as outlined above and you still wish to participate, please read the section below carefully. This is important for your protection.

CONSENT

I have read and understand this informed subject consent and hereby consent to take part in the clinical research study. This study may involve some discomfort and there is a potential for adverse experiences. This and my part in the research study have been clearly explained to me, and I have had complete freedom to ask any questions about this study. All of my questions have been answered. I will be given a signed copy of this consent form to keep. I authorize the release of my study-related medical records to the sponsor, FDA, and Allendale Investigational Review Board.

Certain products in the study are highly proprietary to the Sponsor. Therefore, I agree to keep confidential the products and all information pertaining thereto. I understand that some individuals with health problems have a higher risk of developing adverse reactions to the test products. I have provided truthful information about my health status to the investigator's staff.

The telephone number listed below is a currently working number I can be reached. If I cannot be reached by telephone, I will be removed from the panel list. I must report to cyberDERM Clinical Studies for study visits as required. IF I DO NOT REPORT OR CALL IN, MY PARTICIPATION IN THIS STUDY MAY BE DISCONTINUED.

I will receive a signed and dated copy of the consent form for my files.

_____	_____
Printed Name of Volunteer	Date
_____	_____
Signature of Volunteer	Date

_____	_____	_____	_____
Telephone Number	Birth date	Age	Sex

_____	_____
Person conducting consent discussion	Date

Appendix C: Randomization Schedule

Randomized Treatment Map

cyberDERM S05-93

#	ID	Left Back		Right Back	
		Upper	Lower	Upper	Lower
1	M036	A	No Rx	B	C
2	J007	No Rx	A	C	B
3	D054	C	No Rx	A	B
4	F010	A	B	No Rx	C
5	N001	B	A	C	No Rx
6	K011	C	B	A	No Rx
7	C032	E	F	No Rx	D
8	F039	D	No Rx	F	E
9	C038	No Rx	E	D	F

GROUP 1 (N = 6)

Rx A = AKP2930
Rx B = AKP4671
Rx C = AKP3578

GROUP 2 (N = 3)

Rx D = AKP1491
Rx E = AKP5605
Rx F = AKP8937

Appendix D: Treatment Instructions

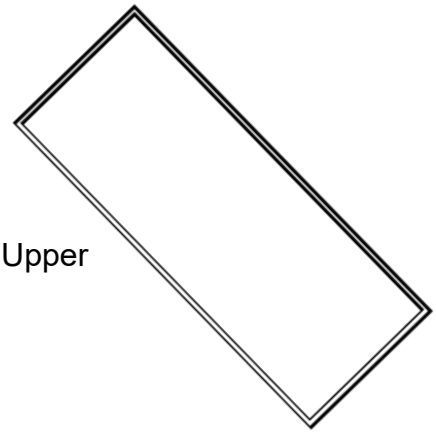
#: _____ ID: _____ cyberDERM #: S05-93

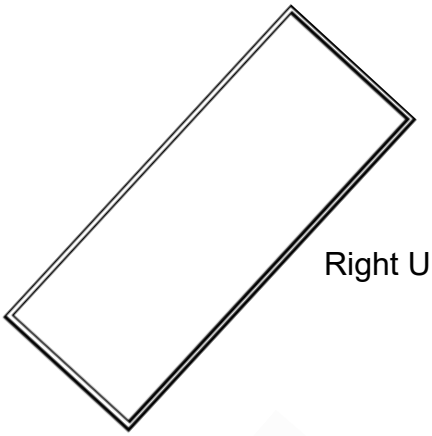
TREATMENT MAP

Left Side of Back

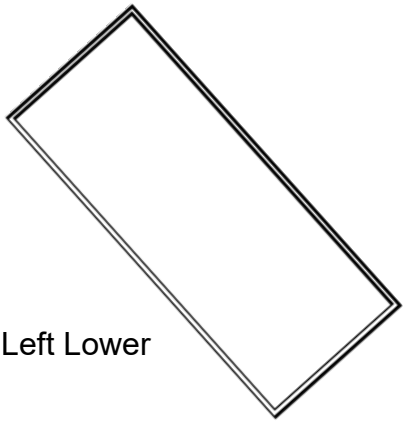
Right Side of Back

Left Upper

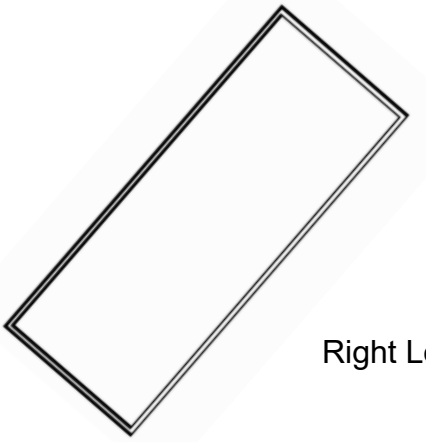




Right Upper



Left Lower



Right Lower

PLACE THIS PAPER IN FRONT OF YOU SO THAT YOU CAN READ THIS.

EACH PRODUCT IS LABELED WITH A DIFFERENT COLORED DOT.

PLACE PRODUCTS ON PAPER SO THAT COLORS MATCH.

APPLY PRODUCT FROM THE TUBE AS INSTRUCTED ONTO THE MATCHING SITE.
DO NOT APPLY PRODUCT TO THE SITE MARKED WITH AN "X"—THIS SITE WILL REMAIN NON-TREATED.

USE A DIFFERENT COT FOR EACH PRODUCT.

Application Instructions

1- Areas of skin to be treated should be clean.

2- Shake each TUBE several times in a direction from top to bottom prior to application.

3- Person applying treatment should use a new finger cot for each application. Apply the cream from the appropriate color-coded tube to fingertip, then directly to the assigned treatment area. Rub the cream gently but thoroughly into the assigned treatment area, using up and down, as well as circular motions. The amount of cream used should be a sufficient amount to cover over the entire treatment area. Be sure to apply an adequate amount! Allow treated skin to air dry – DO NOT OVER RUB.

4-Only 3 sites will receive a coded product. The fourth site will remain as a non-treated control.

5- When the products dry, you may or may not notice a slight whitish residue - Do not wash treated area until next application time.

6- Do not apply the products prior to bathing. We do not want you to wash the products off.

7- If you shower in the evening, please shower first and then apply your evening treatment.

8- Avoid contact with eyes. If product does get into eyes, rinse with water.

9- Please do not wash the test areas for at least five hours after applying the products.

10- On the morning of each visit to the lab, you must rinse your back thoroughly (1 minute or more) to remove residual product film in the shower. This must be at least 1 hour prior to morning visits so as not to influence any assessments. A.M. treatment applications will be done at the lab after your evaluations.

11- REMEMBER TO BRING YOU TEST PRODUCTS WITH YOU TO EACH VISIT.

12- If you have any questions please call our office: 610-325-0112.

Study Requirements and Restrictions:

- You must have a friend/partner willing to apply all evening and weekend treatments to their back.
- You must agree to take showers during study (no tub bathing).
- You may not scrub the test sites with back brushes or loofahs, etc. or apply any other products to test sites.
- You must not have any allergies or sensitivity to tapes or adhesives.
- You may not have scars, moles, other blemishes on the back that would obscure grading or measuring of the test sites.
- You may not be diabetic.
- You may not be taking anti-inflammatories (Advil, Aleve, arthritis medications, etc.) except for acetaminophen (e.g. Tylenol).
- You must agree not to swim, use a sauna or tanning salon for the duration of study.
- You must be willing to lie on stomach for time necessary to perform assessments.
- You may not exercise before each visit as this will affect the measurements
- You must rinse your back thoroughly (1 minute or more) to remove residual product film in the shower. This must be at least 1 hour prior to morning visits so as not to influence any assessments.

Appendix E: Demographic Data

cyberDERM #S05-93

Demographic Data

Group 1			
#	ID	AGE	SEX
1	M036	46	F
2	J007	39	F
3	D054	43	F
4	F010	41	F
5	N001	44	F
6	K011	48	F

Group 2			
#	ID	AGE	SEX
7	C032	43	F
8	F039	36	F
9	C038	34	F

Appendix F: Expert Grader Data – Group 1

Decoded & Sorted Data

cyberDERM #S05-93
TOPCGP-2005

Expert Grader Assessment
Erythema
Day 1 (Baseline)

(Scale: 0 = None to 8 = Marked erythema, edema, possible erosion)

#	ID	No Rx	Rx A	Rx B	Rx C
1	M036	0.0	0.0	0.0	0.0
2	J007	0.0	0.0	0.0	0.0
3	D054	0.0	0.0	0.0	0.0
4	F010	0.0	0.0	0.0	0.0
5	N001	0.0	0.0	0.0	0.0
6	K011	0.0	0.0	0.0	0.0
	Mean	**0.00**	**0.00**	**0.00**	**0.00**
	Std Dev	**0.00**	**0.00**	**0.00**	**0.00**

Rx A = AKP2930
Rx B = AKP4671
Rx C = AKP3578

Expert Grader Assessment
Erythema
Day 2

(Scale: 0 = None to 8 = Marked erythema, edema, possible erosion)

#	ID	No Rx	Rx A	Rx B	Rx C
1	M036	5.1	5.0	3.0	4.0
2	J007	4.0	5.1	6.0	5.0
3	D054	5.0	4.1	6.0	4.0
4	F010	4.1	6.0	5.0	4.0
5	N001	5.0	6.1	7.0	6.0
6	K011	5.0	6.0	6.1	4.0
	Mean	**4.70**	**5.38**	**5.52**	**4.50**
	Std Dev	**0.51**	**0.79**	**1.39**	**0.84**

Rx A = AKP2930
Rx B = AKP4671
Rx C = AKP3578

Expert Grader Assessment
Erythema
Day 3

(Scale: 0 = None to 8 = Marked erythema, edema, possible erosion)

#	ID	No Rx	Rx A	Rx B	Rx C
1	M036	3.0	4.1	5.0	4.0
2	J007	5.0	6.1	7.0	6.0
3	D054	2.0	4.0	5.0	2.1
4	F010	2.0	4.0	3.0	1.0
5	N001	4.0	5.1	6.0	5.0
6	K011	4.1	6.0	6.1	4.0
	Mean	**3.35**	**4.88**	**5.35**	**3.68**
	Std Dev	**1.22**	**0.99**	**1.38**	**1.84**

Rx A = AKP2930
Rx B = AKP4671
Rx C = AKP3578

Expert Grader Assessment
Erythema
Day 4

(Scale: 0 = None to 8 = Marked erythema, edema, possible erosion)

#	ID	No Rx	Rx A	Rx B	Rx C
1	M036	3.0	4.1	5.0	4.0
2	J007	2.0	4.0	5.0	3.0
3	D054	4.1	5.0	6.0	4.0
4	F010	2.0	4.0	3.0	1.0
5	N001	4.0	6.0	7.0	5.0
6	K011	3.0	6.0	7.0	2.0
	Mean	**3.02**	**4.85**	**5.50**	**3.17**
	Std Dev	**0.92**	**0.97**	**1.52**	**1.47**

Rx A = AKP2930
Rx B = AKP4671
Rx C = AKP3578

Expert Grader Assessment
Erythema
Day 5

(Scale: 0 = None to 8 = Marked erythema, edema, possible erosion)

#	ID	No Rx	Rx A	Rx B	Rx C
1	M036	4.0	5.0	6.0	3.0
2	J007	5.0	6.0	6.1	4.0
3	D054	3.0	4.0	6.0	2.0
4	F010	3.1	3.0	1.0	0.0
5	N001	3.0	5.0	6.0	4.0
6	K011	1.1	5.0	6.0	1.0
	Mean	**3.20**	**4.67**	**5.18**	**2.33**
	Std Dev	**1.29**	**1.03**	**2.05**	**1.63**

Rx A = AKP2930
Rx B = AKP4671
Rx C = AKP3578

Expert Grader Assessment
Erythema
Day 8

(Scale: 0 = None to 8 = Marked erythema, edema, possible erosion)

#	ID	No Rx	Rx A	Rx B	Rx C
1	M036	3.0	3.1	4.0	1.0
2	J007	5.0	6.0	6.1	3.0
3	D054	3.0	3.1	5.0	2.0
4	F010	1.0	1.1	0.1	0.0
5	N001	4.1	6.0	6.1	4.0
6	K011	1.0	3.0	4.0	1.0
	Mean	**2.85**	**3.72**	**4.22**	**1.83**
	Std Dev	**1.62**	**1.93**	**2.22**	**1.47**

Rx A = AKP2930
Rx B = AKP4671
Rx C = AKP3578

Expert Grader Assessment
Erythema
Day 9

(Scale: 0 = None to 8 = Marked erythema, edema, possible erosion)

#	ID	No Rx	Rx A	Rx B	Rx C
1	M036	3.0	2.0	4.0	0.0
2	J007	4.0	5.0	6.0	2.0
3	D054	3.0	2.0	4.0	1.0
4	F010	2.0	3.0	1.0	0.0
5	N001	3.1	6.1	6.0	3.0
6	K011	2.0	3.0	6.0	0.0
	Mean	**2.85**	**3.52**	**4.50**	**1.00**
	Std Dev	**0.76**	**1.67**	**1.97**	**1.26**

Rx A = AKP2930
Rx B = AKP4671
Rx C = AKP3578

Expert Grader Assessment
Erythema
Day 10

(Scale: 0 = None to 8 = Marked erythema, edema, possible erosion)

#	ID	No Rx	Rx A	Rx B	Rx C
1	M036	3.0	4.0	4.1	2.0
2	J007	2.0	6.0	5.0	1.0
3	D054	3.0	2.0	4.0	0.0
4	F010	1.0	0.1	2.0	0.0
5	N001	5.1	6.1	6.0	5.0
6	K011	1.0	3.0	5.0	0.0
	Mean	**2.52**	**3.53**	**4.35**	**1.33**
	Std Dev	**1.55**	**2.34**	**1.36**	**1.97**

Rx A = AKP2930
Rx B = AKP4671
Rx C = AKP3578

Expert Grader Assessment
Erythema
Day 11

(Scale: 0 = None to 8 = Marked erythema, edema, possible erosion)

#	ID	No Rx	Rx A	Rx B	Rx C
1	M036	1.0	2.0	3.0	0.0
2	J007	2.0	4.0	2.1	0.0
3	D054	2.0	1.0	4.0	0.0
4	F010	1.0	1.1	0.1	0.0
5	N001	3.0	5.0	5.1	3.1
6	K011	1.0	2.0	4.0	0.0
	Mean	**1.67**	**2.52**	**3.05**	**0.52**
	Std Dev	**0.82**	**1.63**	**1.77**	**1.27**

Rx A = AKP2930
Rx B = AKP4671
Rx C = AKP3578

Expert Grader Assessment
Erythema
Day 12

(Scale: 0 = None to 8 = Marked erythema, edema, possible erosion)

#	ID	No Rx	Rx A	Rx B	Rx C
1	M036	0.1	0.2	1.0	0.0
2	J007	4.1	5.0	4.0	2.0
3	D054	2.0	1.1	3.0	1.0
4	F010	0.1	0.2	1.0	0.0
5	N001	4.0	5.1	5.0	3.0
6	K011	1.0	3.0	4.0	0.0
	Mean	**1.88**	**2.43**	**3.00**	**1.00**
	Std Dev	**1.82**	**2.27**	**1.67**	**1.26**

Rx A = AKP2930
Rx B = AKP4671
Rx C = AKP3578

Appendix G: DermaLab Water Loss Measurements – Group 1

Decoded & Sorted Data

cyberDERM #S05-93
TOPCGP-2005

DermaLab TEWL Values
Day 1 Pre Stripping

#	ID	No Rx	Rx A	Rx B	Rx C
1	M036	5.9	8.2	7.0	4.2
2	J007	5.0	5.0	5.1	4.7
3	D054	5.5	4.7	5.2	5.9
4	F010	6.8	8.2	7.4	7.4
5	N001	3.8	5.0	5.1	3.9
6	K011	3.2	4.1	3.5	4.5
	Mean	**5.03**	**5.87**	**5.56**	**5.09**
	Std Dev	**1.35**	**1.83**	**1.41**	**1.30**

Rx A = AKP2930
Rx B = AKP4671
Rx C = AKP3578

DermaLab TEWL Values

Day 1 Immediately Post Stripping

#	ID	No Rx	Rx A	Rx B	Rx C
1	M036	79.6	85.2	84.4	71.9
2	J007	98.3	100.6	92.0	98.3
3	D054	99.5	95.9	99.5	98.3
4	F010	103.3	94.5	98.4	98.3
5	N001	94.6	97.3	95.6	96.8
6	K011	91.2	89.9	87.0	86.8
	Mean	**94.42**	**93.91**	**92.81**	**91.72**
	Std Dev	**8.35**	**5.52**	**6.13**	**10.72**

Net Change from Baseline

#	ID	No Rx	Rx A	Rx B	Rx C
1	M036	73.8	77.0	77.4	67.7
2	J007	93.3	95.7	86.8	93.6
3	D054	94.0	91.1	94.3	92.5
4	F010	96.4	86.3	91.1	90.9
5	N001	90.8	92.3	90.4	92.8
6	K011	88.0	85.8	83.5	82.3
	Mean	**89.38**	**88.03**	**87.25**	**86.63**
	Std Dev	**8.18**	**6.57**	**6.08**	**10.18**

Rx A = AKP2930
Rx B = AKP4671
Rx C = AKP3578

DermaLab TEWL Values
Day 2

#	ID	No Rx	Rx A	Rx B	Rx C
1	M036	49.8	65.0	67.1	45.9
2	J007	73.7	89.1	83.9	77.4
3	D054	71.4	69.6	79.6	89.3
4	F010	67.9	76.8	74.0	70.0
5	N001	70.8	80.3	82.6	78.0
6	K011	66.1	91.5	92.6	80.5
	Mean	**66.63**	**78.70**	**79.95**	**73.51**
	Std Dev	**8.69**	**10.48**	**8.76**	**14.91**
Paired T-Test vs Base		**0.0000**	**0.0000**	**0.0000**	**0.0001**

Net Change from Baseline

#	ID	No Rx	Rx A	Rx B	Rx C
1	M036	43.9	56.8	60.1	41.7
2	J007	68.7	84.1	78.8	72.7
3	D054	65.9	64.8	74.4	83.4
4	F010	61.1	68.6	66.6	62.6
5	N001	67.1	75.2	77.4	74.0
6	K011	62.9	87.4	89.1	76.0
	Mean	**61.60**	**72.83**	**74.40**	**68.42**
	Std Dev	**9.11**	**11.70**	**10.09**	**14.71**

% Recovery

#	ID	No Rx	Rx A	Rx B	Rx C
1	M036	40.5	26.3	22.4	38.4
2	J007	26.4	12.1	9.3	22.3
3	D054	29.9	28.9	21.1	9.8
4	F010	36.6	20.4	26.9	31.1
5	N001	26.1	18.5	14.4	20.2
6	K011	28.6	-1.9	-6.7	7.6
	Mean	**31.34**	**17.39**	**14.55**	**21.58**
	Std Dev	**5.90**	**11.15**	**12.12**	**11.92**

DermaLab TEWL Values
Day 3

#	ID	No Rx	Rx A	Rx B	Rx C
1	M036	35.3	44.5	43.8	33.4
2	J007	42.6	64.4	52.7	44.0
3	D054	36.3	47.3	50.5	59.7
4	F010	37.7	44.5	47.3	44.9
5	N001	54.8	65.4	58.2	56.1
6	K011	38.1	60.0	71.8	50.5
	Mean	**40.81**	**54.34**	**54.02**	**48.11**
	Std Dev	**7.30**	**9.97**	**9.97**	**9.46**
Paired T-Test vs Base		**0.0001**	**0.0001**	**0.0001**	**0.0001**

Net Change from Baseline

#	ID	No Rx	Rx A	Rx B	Rx C
1	M036	29.5	36.3	36.8	29.2
2	J007	37.7	59.4	47.6	39.3
3	D054	30.8	42.5	45.3	53.9
4	F010	30.8	36.3	39.9	37.6
5	N001	51.0	60.3	53.0	52.1
6	K011	34.9	55.9	68.2	46.0
	Mean	**35.78**	**48.47**	**48.47**	**43.02**
	Std Dev	**8.07**	**11.36**	**11.24**	**9.42**

% Recovery

#	ID	No Rx	Rx A	Rx B	Rx C
1	M036	60.1	52.9	52.5	56.8
2	J007	59.7	37.9	45.2	58.0
3	D054	67.2	53.3	51.9	41.8
4	F010	68.0	57.9	56.2	58.7
5	N001	43.8	34.6	41.4	43.8
6	K011	60.3	34.9	18.3	44.1
	Mean	**59.85**	**45.24**	**44.25**	**50.53**
	Std Dev	**8.71**	**10.56**	**13.81**	**8.05**

DermaLab TEWL Values
Day 4

#	ID	No Rx	Rx A	Rx B	Rx C
1	M036	25.4	37.1	42.0	21.6
2	J007	35.1	57.9	42.5	37.0
3	D054	27.7	38.9	49.1	32.4
4	F010	30.7	32.5	34.2	26.5
5	N001	33.1	44.6	38.3	39.7
6	K011	27.9	53.7	77.5	31.5
	Mean	**29.98**	**44.11**	**47.27**	**31.45**
	Std Dev	**3.67**	**9.94**	**15.63**	**6.66**
Paired T-Test vs Base		**0.0000**	**0.0004**	**0.0017**	**0.0003**

Net Change from Baseline

#	ID	No Rx	Rx A	Rx B	Rx C
1	M036	19.6	28.9	35.0	17.4
2	J007	30.1	53.0	37.4	32.4
3	D054	22.2	34.1	43.9	26.6
4	F010	23.9	24.3	26.8	19.2
5	N001	29.3	39.5	33.1	35.7
6	K011	24.6	49.5	74.0	27.0
	Mean	**24.95**	**38.23**	**41.72**	**26.36**
	Std Dev	**4.10**	**11.36**	**16.77**	**7.17**

% Recovery

#	ID	No Rx	Rx A	Rx B	Rx C
1	M036	73.5	62.5	54.8	74.3
2	J007	67.7	44.6	57.0	65.4
3	D054	76.4	62.5	53.4	71.3
4	F010	75.2	71.9	70.5	78.9
5	N001	67.7	57.2	63.4	61.5
6	K011	72.0	42.2	11.3	67.2
	Mean	**72.09**	**56.81**	**51.73**	**69.78**
	Std Dev	**3.71**	**11.42**	**20.78**	**6.33**

DermaLab TEWL Values
Day 5

#	ID	No Rx	Rx A	Rx B	Rx C
1	M036	26.0	33.8	42.9	18.6
2	J007	38.8	50.3	46.1	32.1
3	D054	21.6	35.0	40.2	22.9
4	F010	24.4	23.7	25.0	21.1
5	N001	30.1	37.2	35.4	26.0
6	K011	18.8	46.9	59.5	23.5
	Mean	**26.58**	**37.82**	**41.53**	**24.03**
	Std Dev	**7.09**	**9.59**	**11.46**	**4.66**
Paired T-Test vs Base		**0.0007**	**0.0009**	**0.0009**	**0.0003**

Net Change from Baseline

#	ID	No Rx	Rx A	Rx B	Rx C
1	M036	20.1	25.6	35.9	14.4
2	J007	33.8	45.3	41.0	27.4
3	D054	16.1	30.3	35.0	17.0
4	F010	17.6	15.5	17.7	13.8
5	N001	26.3	32.2	30.3	22.1
6	K011	15.5	42.7	55.9	19.0
	Mean	**21.55**	**31.95**	**35.97**	**18.94**
	Std Dev	**7.15**	**11.02**	**12.59**	**5.15**

% Recovery

#	ID	No Rx	Rx A	Rx B	Rx C
1	M036	72.8	66.8	53.6	78.8
2	J007	63.8	52.6	52.8	70.7
3	D054	82.9	66.8	62.8	81.6
4	F010	81.8	82.0	80.6	84.8
5	N001	71.1	65.1	66.5	76.2
6	K011	82.3	50.2	33.0	76.9
	Mean	**75.78**	**63.91**	**58.23**	**78.17**
	Std Dev	**7.80**	**11.50**	**15.99**	**4.85**

DermaLab TEWL Values
Day 8

#	ID	No Rx	Rx A	Rx B	Rx C
1	M036	17.3	19.4	25.6	12.8
2	J007	21.9	34.7	29.2	22.0
3	D054	20.0	23.4	24.2	16.1
4	F010	14.4	15.4	15.0	14.2
5	N001	25.8	34.9	32.3	16.8
6	K011	13.3	20.2	18.4	14.5
	Mean	**18.78**	**24.67**	**24.10**	**16.09**
	Std Dev	**4.74**	**8.26**	**6.50**	**3.23**
	Paired T-Test vs Base	**0.0013**	**0.0045**	**0.0012**	**0.0008**

Net Change from Baseline

#	ID	No Rx	Rx A	Rx B	Rx C
1	M036	11.5	11.2	18.6	8.7
2	J007	17.0	29.8	24.0	17.3
3	D054	14.5	18.6	19.1	10.2
4	F010	7.5	7.2	7.6	6.8
5	N001	22.0	29.9	27.2	12.9
6	K011	10.1	16.1	14.9	10.0
	Mean	**13.75**	**18.80**	**18.55**	**11.00**
	Std Dev	**5.22**	**9.41**	**6.90**	**3.69**

% Recovery

#	ID	No Rx	Rx A	Rx B	Rx C
1	M036	84.5	85.5	76.0	87.2
2	J007	81.8	68.9	72.3	81.5
3	D054	84.6	79.6	79.8	89.0
4	F010	92.2	91.6	91.7	92.5
5	N001	75.8	67.6	70.0	86.1
6	K011	88.5	81.3	82.2	87.8
	Mean	**84.57**	**79.07**	**78.66**	**87.34**
	Std Dev	**5.64**	**9.37**	**7.82**	**3.61**

DermaLab TEWL Values
Day 9

#	ID	No Rx	Rx A	Rx B	Rx C
1	M036	15.8	18.2	22.2	11.1
2	J007	19.3	29.1	24.1	17.0
3	D054	17.3	22.4	25.8	15.2
4	F010	13.7	14.7	13.6	12.4
5	N001	25.2	31.7	27.3	17.1
6	K011	9.1	13.4	14.2	11.7
	Mean	**16.75**	**21.58**	**21.19**	**14.08**
	Std Dev	**5.44**	**7.54**	**5.90**	**2.68**
Paired T-Test vs Base		**0.0040**	**0.0060**	**0.0016**	**0.0010**

Net Change from Baseline

#	ID	No Rx	Rx A	Rx B	Rx C
1	M036	10.0	10.0	15.2	7.0
2	J007	14.4	24.2	18.9	12.3
3	D054	11.8	17.7	20.6	9.3
4	F010	6.9	6.5	6.3	5.0
5	N001	21.5	26.7	22.2	13.2
6	K011	5.9	9.3	10.6	7.2
	Mean	**11.72**	**15.71**	**15.63**	**8.99**
	Std Dev	**5.70**	**8.41**	**6.18**	**3.22**

% Recovery

#	ID	No Rx	Rx A	Rx B	Rx C
1	M036	86.5	87.0	80.4	89.7
2	J007	84.6	74.8	78.2	86.8
3	D054	87.5	80.6	78.2	89.9
4	F010	92.9	92.5	93.1	94.5
5	N001	76.4	71.1	75.5	85.8
6	K011	93.3	89.2	87.3	91.3
	Mean	**86.86**	**82.53**	**82.10**	**89.68**
	Std Dev	**6.22**	**8.45**	**6.71**	**3.12**

DermaLab TEWL Values
Day 10

#	ID	No Rx	Rx A	Rx B	Rx C
1	M036	9.4	11.4	13.9	6.9
2	J007	13.1	21.1	14.5	10.0
3	D054	12.4	15.3	16.5	10.1
4	F010	9.9	13.2	12.0	11.6
5	N001	18.9	25.4	21.5	13.3
6	K011	7.5	10.4	14.4	20.2
	Mean	**11.86**	**16.13**	**15.46**	**12.00**
	Std Dev	**3.98**	**5.92**	**3.27**	**4.55**
Paired T-Test vs Base		**0.0136**	**0.0140**	**0.0018**	**0.0176**

Net Change from Baseline

#	ID	No Rx	Rx A	Rx B	Rx C
1	M036	3.5	3.2	6.9	2.7
2	J007	8.1	16.1	9.4	5.4
3	D054	6.9	10.6	11.3	4.2
4	F010	3.1	5.0	4.7	4.2
5	N001	15.1	20.4	16.3	9.3
6	K011	4.3	6.2	10.8	15.7
	Mean	**6.83**	**10.26**	**9.90**	**6.91**
	Std Dev	**4.49**	**6.80**	**4.01**	**4.86**

% Recovery

#	ID	No Rx	Rx A	Rx B	Rx C
1	M036	95.2	95.9	91.1	96.1
2	J007	91.3	83.2	89.2	94.3
3	D054	92.7	88.4	88.0	95.5
4	F010	96.8	94.2	94.9	95.4
5	N001	83.4	77.9	82.0	90.0
6	K011	95.1	92.7	87.0	80.9
	Mean	**92.42**	**88.70**	**88.69**	**92.01**
	Std Dev	**4.83**	**7.00**	**4.31**	**5.86**

DermaLab TEWL Values
Day 11

#	ID	No Rx	Rx A	Rx B	Rx C
1	M036	10.4	12.5	13.9	8.0
2	J007	14.4	16.9	16.0	12.7
3	D054	12.1	14.6	16.0	10.9
4	F010	10.0	11.2	11.0	10.2
5	N001	18.1	21.8	17.7	12.2
6	K011	10.6	12.3	13.2	10.7
	Mean	**12.60**	**14.87**	**14.63**	**10.78**
	Std Dev	**3.14**	**3.95**	**2.42**	**1.67**
	Paired T-Test vs Base	**0.0054**	**0.0075**	**0.0010**	**0.0015**

Net Change from Baseline

#	ID	No Rx	Rx A	Rx B	Rx C
1	M036	4.5	4.2	6.9	3.8
2	J007	9.4	12.0	10.9	8.1
3	D054	6.6	9.9	10.8	5.1
4	F010	3.2	3.0	3.6	2.8
5	N001	14.3	16.8	12.6	8.2
6	K011	7.4	8.2	9.7	6.2
	Mean	**7.57**	**9.00**	**9.07**	**5.69**
	Std Dev	**3.96**	**5.09**	**3.27**	**2.21**

% Recovery

#	ID	No Rx	Rx A	Rx B	Rx C
1	M036	93.9	94.5	91.0	94.4
2	J007	89.9	87.5	87.4	91.4
3	D054	93.0	89.2	88.6	94.5
4	F010	96.7	96.5	96.0	96.9
5	N001	84.2	81.8	86.1	91.1
6	K011	91.6	90.5	88.4	92.5
	Mean	**91.55**	**90.00**	**89.61**	**93.47**
	Std Dev	**4.24**	**5.23**	**3.55**	**2.21**

DermaLab TEWL Values
Day 12

#	ID	No Rx	Rx A	Rx B	Rx C
1	M036	13.3	14.6	16.1	9.2
2	J007	13.4	15.4	14.9	11.2
3	D054	14.4	15.7	17.1	17.5
4	F010	10.7	12.2	12.8	11.5
5	N001	23.0	20.3	18.6	11.9
6	K011	9.1	10.5	11.6	10.5
	Mean	**13.98**	**14.78**	**15.18**	**11.95**
	Std Dev	**4.81**	**3.36**	**2.63**	**2.86**
	Paired T-Test vs Base	**0.0093**	**0.0031**	**0.0004**	**0.0015**

Net Change from Baseline

#	ID	No Rx	Rx A	Rx B	Rx C
1	M036	7.4	6.4	9.1	5.0
2	J007	8.5	10.4	9.8	6.5
3	D054	8.9	10.9	11.9	11.6
4	F010	3.9	4.0	5.4	4.1
5	N001	19.2	15.3	13.4	8.0
6	K011	5.9	6.4	8.1	6.0
	Mean	**8.95**	**8.91**	**9.62**	**6.86**
	Std Dev	**5.33**	**4.10**	**2.83**	**2.66**

% Recovery

#	ID	No Rx	Rx A	Rx B	Rx C
1	M036	89.9	91.7	88.2	92.6
2	J007	90.9	89.1	88.8	93.0
3	D054	90.6	88.0	87.4	87.5
4	F010	96.0	95.4	94.0	95.5
5	N001	78.9	83.4	85.1	91.4
6	K011	93.3	92.5	90.3	92.7
	Mean	**89.94**	**90.03**	**88.98**	**92.12**
	Std Dev	**5.86**	**4.15**	**3.01**	**2.63**

Self-Assessment
Is the site burning/stinging or soothing?
Day 1 (Baseline)

(Scale: -4 = Burning/stinging is marked to 4 = Completely soothing/relief)

		BEFORE TREATMENT				AFTER TREATMENT				NET CHANGE			
#	ID	No Rx	Rx A	Rx B	Rx C	No Rx	Rx A	Rx B	Rx C	No Rx	Rx A	Rx B	Rx C
1	M036	-2.0	-2.0	-3.0	-3.0	-2.0	-3.0	-4.0	-3.0	0.0	-1.0	-1.0	0.0
2	J007	-2.0	-1.0	-0.1	-3.0	-2.0	-1.0	-0.1	-2.0	0.0	0.0	0.0	1.0
3	D054	-1.0	-2.0	-2.0	-1.0	-1.0	2.0	2.0	-0.1	0.0	4.0	4.0	0.9
4	F010	-3.0	-0.1	-0.1	-2.0	-4.0	2.0	2.0	1.0	-1.0	2.1	2.1	3.0
5	N001	-4.0	-2.0	-2.0	-2.0	-4.0	-2.0	-1.0	-2.0	0.0	0.0	1.0	0.0
6	K011	-0.1	-0.1	-0.1	-1.0	4.0	0.1	-3.0	-3.0	4.1	0.2	-2.9	-2.0
	Mean	**-2.02**	**-1.20**	**-1.22**	**-2.00**	**-1.50**	**-0.32**	**-0.68**	**-1.52**	**0.52**	**0.88**	**0.53**	**0.48**
	Std Dev	**1.39**	**0.94**	**1.28**	**0.89**	**2.95**	**2.07**	**2.50**	**1.63**	**1.80**	**1.83**	**2.41**	**1.64**

Rx A = AKP2930
Rx B = AKP4671
Rx C = AKP3578

Self-Assessment
Is the site burning/stinging or soothing?
Day 2

(Scale: -4 = Burning/stinging is marked to 4 = Completely soothing/relief)

		BEFORE TREATMENT				AFTER TREATMENT				NET CHANGE			
#	ID	No Rx	Rx A	Rx B	Rx C	No Rx	Rx A	Rx B	Rx C	No Rx	Rx A	Rx B	Rx C
1	M036	-2.0	-1.0	-1.0	-2.0	-2.0	-2.0	-2.0	-3.0	0.0	-1.0	-1.0	-1.0
2	J007	-1.0	0.1	-2.0	-1.0	-1.0	-2.0	-3.0	-2.0	0.0	-2.1	-1.0	-1.0
3	D054	-1.0	-1.0	-1.0	-1.0	-1.0	2.0	1.0	-3.0	0.0	3.0	2.0	-2.0
4	F010	-2.0	-1.0	-1.0	-0.1	-2.0	2.0	3.0	-3.0	0.0	3.0	4.0	-2.9
5	N001	1.0	1.0	1.0	1.0	-1.0	-2.0	-1.0	-3.0	-2.0	-3.0	-2.0	-4.0
6	K011	1.0	1.0	1.0	-2.0	1.0	2.0	-3.0	-3.0	0.0	1.0	-4.0	-1.0
	Mean	**-0.67**	**-0.15**	**-0.50**	**-0.85**	**-1.00**	**0.00**	**-0.83**	**-2.83**	**-0.33**	**0.15**	**-0.33**	**-1.98**
	Std Dev	**1.37**	**0.99**	**1.22**	**1.16**	**1.10**	**2.19**	**2.40**	**0.41**	**0.82**	**2.58**	**2.88**	**1.25**

Rx A = AKP2930
Rx B = AKP4671
Rx C = AKP3578

Self-Assessment
Is the site burning/stinging or soothing?
Day 3

(Scale: -4 = Burning/stinging is marked to 4 = Completely soothing/relief)

		BEFORE TREATMENT				AFTER TREATMENT				NET CHANGE			
#	ID	No Rx	Rx A	Rx B	Rx C	No Rx	Rx A	Rx B	Rx C	No Rx	Rx A	Rx B	Rx C
1	M036	1.0	1.0	1.0	1.0	1.0	-1.0	-1.0	1.0	0.0	-2.0	-2.0	0.0
2	J007	0.1	1.0	-0.1	-2.0	0.1	1.0	-1.0	-2.0	0.0	0.0	-0.9	0.0
3	D054	-1.0	-2.0	-1.0	-1.0	-1.0	1.0	1.0	-2.0	0.0	3.0	2.0	-1.0
4	F010	0.1	-0.1	0.1	0.1	0.1	-2.0	-1.0	1.0	0.0	-1.9	-1.1	0.9
5	N001	1.0	1.0	1.0	1.0	1.0	-2.0	-1.0	-2.0	0.0	-3.0	-2.0	-3.0
6	K011	4.0	4.0	4.0	4.0	4.0	2.0	-1.0	-2.0	0.0	-2.0	-5.0	-6.0
	Mean	**0.87**	**0.82**	**0.83**	**0.52**	**0.87**	**-0.17**	**-0.67**	**-1.00**	**0.00**	**-0.98**	**-1.50**	**-1.52**
	Std Dev	**1.70**	**1.95**	**1.72**	**2.07**	**1.70**	**1.72**	**0.82**	**1.55**	**0.00**	**2.18**	**2.26**	**2.57**

Rx A = AKP2930
Rx B = AKP4671
Rx C = AKP3578

Self-Assessment
Is the site burning/stinging or soothing?
Day 4

(Scale: -4 = Burning/stinging is marked to 4 = Completely soothing/relief)

		BEFORE TREATMENT				AFTER TREATMENT				NET CHANGE			
#	ID	No Rx	Rx A	Rx B	Rx C	No Rx	Rx A	Rx B	Rx C	No Rx	Rx A	Rx B	Rx C
1	M036	1.0	-1.0	1.0	1.0	1.0	-0.1	-2.0	1.0	0.0	0.9	-3.0	0.0
2	J007	0.1	1.0	-1.0	-2.0	0.1	0.1	-1.0	-1.0	0.0	-0.9	0.0	1.0
3	D054	-1.0	-1.0	-1.0	-1.0	-1.0	2.0	-1.0	1.0	0.0	3.0	0.0	2.0
4	F010	1.0	-0.1	1.0	1.0	1.0	1.0	2.0	2.0	0.0	1.1	1.0	1.0
5	N001	1.0	1.0	-0.1	1.0	-1.0	-1.0	-2.0	-1.0	-2.0	-2.0	-1.9	-2.0
6	K011	4.0	4.0	2.0	4.0	4.0	4.0	2.0	-1.0	0.0	0.0	0.0	-5.0
	Mean	**1.02**	**0.65**	**0.32**	**0.67**	**0.68**	**1.00**	**-0.33**	**0.17**	**-0.33**	**0.35**	**-0.65**	**-0.50**
	Std Dev	**1.66**	**1.87**	**1.22**	**2.07**	**1.86**	**1.79**	**1.86**	**1.33**	**0.82**	**1.74**	**1.49**	**2.59**

Rx A = AKP2930
Rx B = AKP4671
Rx C = AKP3578

Self-Assessment
Is the site burning/stinging or soothing?
Day 5

(Scale: -4 = Burning/stinging is marked to 4 = Completely soothing/relief)

		BEFORE TREATMENT				AFTER TREATMENT				NET CHANGE			
#	ID	No Rx	Rx A	Rx B	Rx C	No Rx	Rx A	Rx B	Rx C	No Rx	Rx A	Rx B	Rx C
1	M036	0.1	0.1	-0.1	-0.1	0.1	-1.0	-2.0	1.0	0.0	-1.1	-1.9	1.1
2	J007	-0.1	-0.1	-0.1	-2.0	-0.1	0.1	0.1	-1.0	0.0	0.2	0.2	1.0
3	D054	-0.1	-0.1	-0.1	-0.1	-0.1	-0.1	0.1	-1.0	0.0	0.0	0.2	-0.9
4	F010	1.0	-0.1	0.1	1.0	1.0	1.0	1.0	2.0	0.0	1.1	0.9	1.0
5	N001	1.0	1.0	0.1	1.0	1.0	-1.0	-2.0	-1.0	0.0	-2.0	-2.1	-2.0
6	K011	1.0	1.0	0.1	0.1	1.0	-0.1	-0.1	-1.0	0.0	-1.1	-0.2	-1.1
	Mean	**0.48**	**0.30**	**0.00**	**-0.02**	**0.48**	**-0.18**	**-0.48**	**-0.17**	**0.00**	**-0.48**	**-0.48**	**-0.15**
	Std Dev	**0.57**	**0.55**	**0.11**	**1.10**	**0.57**	**0.75**	**1.24**	**1.33**	**0.00**	**1.12**	**1.23**	**1.35**

Rx A = AKP2930
Rx B = AKP4671
Rx C = AKP3578

Self-Assessment
Is the site burning/stinging or soothing?
Day 8

(Scale: -4 = Burning/stinging is marked to 4 = Completely soothing/relief)

		BEFORE TREATMENT				AFTER TREATMENT				NET CHANGE			
#	ID	No Rx	Rx A	Rx B	Rx C	No Rx	Rx A	Rx B	Rx C	No Rx	Rx A	Rx B	Rx C
1	M036	2.0	2.0	2.0	2.0	2.0	2.0	-0.1	1.0	0.0	0.0	-2.1	-1.0
2	J007	0.1	0.1	0.1	0.1	0.1	0.1	0.1	-1.0	0.0	0.0	0.0	-1.1
3	D054	0.1	0.1	0.1	0.1	0.1	2.0	2.0	2.0	0.0	1.9	1.9	1.9
4	F010	1.0	1.0	-0.1	2.0	1.0	1.0	-0.1	2.0	0.0	0.0	0.0	0.0
5	N001	1.0	1.0	-0.1	0.1	1.0	-2.0	-1.0	-1.0	0.0	-3.0	-0.9	-1.1
6	K011	3.0	-0.1	3.0	2.0	3.0	2.0	3.0	3.0	0.0	2.1	0.0	1.0
	Mean	**1.20**	**0.68**	**0.83**	**1.05**	**1.20**	**0.85**	**0.65**	**1.00**	**0.00**	**0.17**	**-0.18**	**-0.05**
	Std Dev	**1.13**	**0.80**	**1.33**	**1.04**	**1.13**	**1.59**	**1.52**	**1.67**	**0.00**	**1.84**	**1.31**	**1.27**

Rx A = AKP2930
Rx B = AKP4671
Rx C = AKP3578

Self-Assessment
Is the site burning/stinging or soothing?
Day 9

(Scale: -4 = Burning/stinging is marked to 4 = Completely soothing/relief)

		BEFORE TREATMENT				AFTER TREATMENT				NET CHANGE			
#	ID	No Rx	Rx A	Rx B	Rx C	No Rx	Rx A	Rx B	Rx C	No Rx	Rx A	Rx B	Rx C
1	M036	2.0	2.0	2.0	2.0	2.0	-0.1	-0.1	2.0	0.0	-2.1	-2.1	0.0
2	J007	0.1	1.0	2.0	0.1	0.1	1.0	2.0	2.0	0.0	0.0	0.0	1.9
3	D054	4.0	-0.1	4.0	4.0	4.0	3.0	2.0	2.0	0.0	3.1	-2.0	-2.0
4	F010	1.0	-0.1	-0.1	2.0	1.0	1.0	1.0	3.0	0.0	1.1	1.1	1.0
5	N001	1.0	1.0	-0.1	1.0	1.0	-1.0	-1.0	-1.0	0.0	-2.0	-0.9	-2.0
6	K011	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	0.0	0.0	0.0	0.0
	Mean	**1.85**	**1.13**	**1.80**	**2.02**	**1.85**	**1.15**	**1.15**	**1.83**	**0.00**	**0.02**	**-0.65**	**-0.18**
	Std Dev	**1.45**	**1.21**	**1.65**	**1.39**	**1.45**	**1.62**	**1.49**	**1.47**	**0.00**	**1.96**	**1.26**	**1.58**

Rx A = AKP2930
Rx B = AKP4671
Rx C = AKP3578

Self-Assessment
Is the site burning/stinging or soothing?
Day 10

(Scale: -4 = Burning/stinging is marked to 4 = Completely soothing/relief)

		BEFORE TREATMENT				AFTER TREATMENT				NET CHANGE			
#	ID	No Rx	Rx A	Rx B	Rx C	No Rx	Rx A	Rx B	Rx C	No Rx	Rx A	Rx B	Rx C
1	M036	2.0	3.0	3.0	3.0	2.0	0.1	-0.1	1.0	0.0	-2.9	-3.1	-2.0
2	J007	-0.1	-0.1	1.0	2.0	-0.1	0.1	2.0	2.0	0.0	0.2	1.0	0.0
3	D054	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	0.0	0.0	0.0	0.0
4	F010	1.0	0.1	1.0	2.0	1.0	1.0	2.0	2.0	0.0	0.9	1.0	0.0
5	N001	1.0	1.0	0.1	1.0	1.0	-0.1	-0.1	-0.1	0.0	-1.1	-0.2	-1.1
6	K011	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	0.0	0.0	0.0	0.0
	Mean	**1.82**	**1.83**	**2.02**	**2.50**	**1.82**	**1.35**	**1.80**	**1.98**	**0.00**	**-0.48**	**-0.22**	**-0.52**
	Std Dev	**1.50**	**1.72**	**1.52**	**1.05**	**1.50**	**1.74**	**1.65**	**1.44**	**0.00**	**1.35**	**1.51**	**0.85**

Rx A = AKP2930
Rx B = AKP4671
Rx C = AKP3578

Self-Assessment
Is the site burning/stinging or soothing?
Day 11

(Scale: -4 = Burning/stinging is marked to 4 = Completely soothing/relief)

		BEFORE TREATMENT				AFTER TREATMENT				NET CHANGE			
#	ID	No Rx	Rx A	Rx B	Rx C	No Rx	Rx A	Rx B	Rx C	No Rx	Rx A	Rx B	Rx C
1	M036	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	0.0	0.0	0.0	0.0
2	J007	-0.1	3.0	3.0	3.0	-0.1	1.0	3.0	3.0	0.0	-2.0	0.0	0.0
3	D054	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	0.0	0.0	0.0	0.0
4	F010	2.0	1.0	1.0	3.0	2.0	2.0	2.0	4.0	0.0	1.0	1.0	1.0
5	N001	2.0	2.0	0.1	2.0	2.0	3.0	3.0	3.0	0.0	1.0	2.9	1.0
6	K011	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	0.0	0.0	0.0	0.0
	Mean	**2.48**	**2.83**	**2.52**	**3.17**	**2.48**	**2.83**	**3.17**	**3.50**	**0.00**	**0.00**	**0.65**	**0.33**
	Std Dev	**1.55**	**1.17**	**1.61**	**0.75**	**1.55**	**1.17**	**0.75**	**0.55**	**0.00**	**1.10**	**1.17**	**0.52**

Rx A = AKP2930
Rx B = AKP4671
Rx C = AKP3578

Self-Assessment
Is the site burning/stinging or soothing?
Day 12

(Scale: -4 = Burning/stinging is marked to 4 = Completely soothing/relief)

		BEFORE TREATMENT				AFTER TREATMENT				NET CHANGE			
#	ID	No Rx	Rx A	Rx B	Rx C	No Rx	Rx A	Rx B	Rx C	No Rx	Rx A	Rx B	Rx C
1	M036	4.0	4.0	4.0	4.0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
2	J007	1.0	3.0	3.0	1.0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
3	D054	4.0	4.0	4.0	4.0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
4	F010	3.0	2.0	3.0	4.0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
5	N001	3.0	3.0	3.0	3.0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
6	K011	4.0	4.0	4.0	4.0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Mean	**3.17**	**3.33**	**3.50**	**3.33**								
	Std Dev	**1.17**	**0.82**	**0.55**	**1.21**								

Rx A = AKP2930
Rx B = AKP4671
Rx C = AKP3578

Appendix I: Expert Grader Data – Group 2

Decoded & Sorted Data cyberDERM #S05-93A
TOPCGP-2005

Expert Grader Assessment
Erythema
Day 1 (Baseline)

(Scale: 0 = None to 8 = Marked erythema, edema, possible erosion)

#	ID	No Rx	Rx D	Rx E	Rx F
7	C032	0.0	0.0	0.0	0.0
8	F039	0.0	0.0	0.0	0.0
9	C038	0.0	0.0	0.0	0.0
	Mean	**0.00**	**0.00**	**0.00**	**0.00**
	Std Dev	**0.00**	**0.00**	**0.00**	**0.00**

Rx D = AKP1491
Rx E = AKP5605
Rx F = AKP8937

Expert Grader Assessment
Erythema
Day 2

(Scale: 0 = None to 8 = Marked erythema, edema, possible erosion)

#	ID	No Rx	Rx D	Rx E	Rx F
7	C032	5.1	6.0	6.1	5.0
8	F039	5.0	5.1	5.2	6.0
9	C038	5.0	4.0	6.1	5.1
	Mean	**5.03**	**5.03**	**5.80**	**5.37**
	Std Dev	**0.06**	**1.00**	**0.52**	**0.55**

Rx D = AKP1491
Rx E = AKP5605
Rx F = AKP8937

Expert Grader Assessment
Erythema
Day 3

(Scale: 0 = None to 8 = Marked erythema, edema, possible erosion)

#	ID	No Rx	Rx D	Rx E	Rx F
7	C032	5.0	4.1	6.0	4.0
8	F039	4.0	4.1	5.0	6.0
9	C038	3.0	4.0	5.1	5.0
	Mean	**4.00**	**4.07**	**5.37**	**5.00**
	Std Dev	**1.00**	**0.06**	**0.55**	**1.00**

Rx D = AKP1491
Rx E = AKP5605
Rx F = AKP8937

Expert Grader Assessment
Erythema
Day 4

(Scale: 0 = None to 8 = Marked erythema, edema, possible erosion)

#	ID	No Rx	Rx D	Rx E	Rx F
7	C032	5.1	4.1	5.0	4.0
8	F039	4.0	2.0	6.0	5.0
9	C038	2.0	3.0	5.1	5.0
	Mean	**3.70**	**3.03**	**5.37**	**4.67**
	Std Dev	**1.57**	**1.05**	**0.55**	**0.58**

Rx D = AKP1491
Rx E = AKP5605
Rx F = AKP8937

Expert Grader Assessment
Erythema
Day 5

(Scale: 0 = None to 8 = Marked erythema, edema, possible erosion)

#	ID	No Rx	Rx D	Rx E	Rx F
7	C032	3.0	1.0	3.1	2.0
8	F039	4.0	2.0	5.0	5.1
9	C038	3.0	1.0	4.1	4.0
	Mean	**3.33**	**1.33**	**4.07**	**3.70**
	Std Dev	**0.58**	**0.58**	**0.95**	**1.57**

Rx D = AKP1491
Rx E = AKP5605
Rx F = AKP8937

Expert Grader Assessment
Erythema
Day 8

(Scale: 0 = None to 8 = Marked erythema, edema, possible erosion)

#	ID	No Rx	Rx D	Rx E	Rx F
7	C032	3.1	2.0	3.0	1.0
8	F039	5.0	2.0	3.0	2.1
9	C038	3.0	2.1	2.2	2.0
	Mean	**3.70**	**2.03**	**2.73**	**1.70**
	Std Dev	**1.13**	**0.06**	**0.46**	**0.61**

Rx D = AKP1491
Rx E = AKP5605
Rx F = AKP8937

Expert Grader Assessment
Erythema
Day 9

(Scale: 0 = None to 8 = Marked erythema, edema, possible erosion)

#	ID	No Rx	Rx D	Rx E	Rx F
7	C032	3.0	1.0	2.1	2.0
8	F039	4.0	1.0	3.0	1.1
9	C038	2.1	2.2	2.0	1.0
	Mean	**3.03**	**1.40**	**2.37**	**1.37**
	Std Dev	**0.95**	**0.69**	**0.55**	**0.55**

Rx D = AKP1491
Rx E = AKP5605
Rx F = AKP8937

Expert Grader Assessment
Erythema
Day 10

(Scale: 0 = None to 8 = Marked erythema, edema, possible erosion)

#	ID	No Rx	Rx D	Rx E	Rx F
7	C032	3.0	0.0	2.0	1.0
8	F039	3.0	1.0	1.1	2.0
9	C038	2.0	1.2	1.0	1.1
	Mean	**2.67**	**0.73**	**1.37**	**1.37**
	Std Dev	**0.58**	**0.64**	**0.55**	**0.55**

Rx D = AKP1491
Rx E = AKP5605
Rx F = AKP8937

Appendix J: DermaLab Water Loss Measurements – Group 2

Decoded & Sorted Data

cyberDERM #S05-93A
TOPCGP-2005

DermaLab TEWL Values
Day 1 Pre Stripping

#	ID	No Rx	Rx D	Rx E	Rx F
7	C032	7.1	7.3	7.7	7.2
8	F039	10.2	6.0	11.2	5.6
9	C038	5.6	4.5	4.4	4.3
	Mean	**7.62**	**5.93**	**7.74**	**5.72**
	Std Dev	**2.32**	**1.40**	**3.39**	**1.46**

Rx D = AKP1491
Rx E = AKP5605
Rx F = AKP8937

DermaLab TEWL Values

Day 1 Immediately Post Stripping

#	ID	No Rx	Rx D	Rx E	Rx F
7	C032	88.0	89.4	81.8	83.5
8	F039	86.9	89.7	89.7	90.7
9	C038	82.1	87.2	87.7	90.4
	Mean	**85.66**	**88.72**	**86.37**	**88.21**
	Std Dev	**3.14**	**1.37**	**4.13**	**4.04**

Net Change from Baseline

#	ID	No Rx	Rx D	Rx E	Rx F
7	C032	80.9	82.0	74.1	76.3
8	F039	76.7	83.7	78.6	85.1
9	C038	76.5	82.6	83.3	86.0
	Mean	**78.05**	**82.79**	**78.63**	**82.49**
	Std Dev	**2.51**	**0.84**	**4.61**	**5.36**

Rx D = AKP1491
Rx E = AKP5605
Rx F = AKP8937

DermaLab TEWL Values
Day 2

#	ID	No Rx	Rx D	Rx E	Rx F
7	C032	67.1	67.6	56.0	60.2
8	F039	67.0	63.7	71.2	69.5
9	C038	67.7	62.1	70.7	70.8
	Mean	**67.27**	**64.46**	**65.93**	**66.83**
	Std Dev	**0.33**	**2.83**	**8.63**	**5.77**
	Paired T-Test vs Base	**0.0006**	**0.0002**	**0.0081**	**0.0045**

Net Change from Baseline

#	ID	No Rx	Rx D	Rx E	Rx F
7	C032	60.1	60.3	48.3	53.0
8	F039	56.9	57.7	60.0	63.9
9	C038	62.0	57.6	66.3	66.5
	Mean	**59.66**	**58.53**	**58.18**	**61.12**
	Std Dev	**2.60**	**1.51**	**9.15**	**7.15**

% Recovery

#	ID	No Rx	Rx D	Rx E	Rx F
7	C032	25.8	26.5	34.8	30.6
8	F039	25.9	31.0	23.6	25.0
9	C038	18.9	30.3	20.4	22.7
	Mean	**23.52**	**29.29**	**26.28**	**26.08**
	Std Dev	**4.01**	**2.42**	**7.57**	**4.04**

Rx D = AKP1491
Rx E = AKP5605
Rx F = AKP8937

DermaLab TEWL Values
Day 3

#	ID	No Rx	Rx D	Rx E	Rx F
7	C032	37.7	33.9	32.9	32.3
8	F039	42.8	38.9	55.6	50.0
9	C038	38.2	40.0	45.8	44.8
	Mean	**39.56**	**37.56**	**44.76**	**42.36**
	Std Dev	**2.82**	**3.24**	**11.42**	**9.12**
	Paired T-Test vs Base	**0.0004**	**0.0069**	**0.0252**	**0.0250**

Net Change from Baseline

#	ID	No Rx	Rx D	Rx E	Rx F
7	C032	30.7	26.6	25.2	25.0
8	F039	32.6	32.9	44.5	44.4
9	C038	32.5	35.4	41.4	40.5
	Mean	**31.95**	**31.63**	**37.01**	**36.64**
	Std Dev	**1.12**	**4.57**	**10.38**	**10.24**

% Recovery

#	ID	No Rx	Rx D	Rx E	Rx F
7	C032	62.1	67.6	66.0	67.2
8	F039	57.5	60.7	43.4	47.8
9	C038	57.4	57.1	50.3	52.9
	Mean	**59.01**	**61.81**	**53.23**	**55.99**
	Std Dev	**2.69**	**5.34**	**11.60**	**10.03**

Rx D = AKP1491
Rx E = AKP5605
Rx F = AKP8937

DermaLab TEWL Values
Day 4

#	ID	No Rx	Rx D	Rx E	Rx F
7	C032	24.5	22.4	20.5	22.8
8	F039	46.1	22.9	48.5	37.1
9	C038	26.6	23.7	35.5	30.4
	Mean	**32.39**	**22.97**	**34.83**	**30.10**
	Std Dev	**11.94**	**0.66**	**13.98**	**7.18**
	Paired T-Test vs Base	**0.0488**	**0.0048**	**0.0664**	**0.0351**

Net Change from Baseline

#	ID	No Rx	Rx D	Rx E	Rx F
7	C032	17.4	15.0	12.8	15.5
8	F039	36.0	16.9	37.3	31.5
9	C038	20.9	19.2	31.1	26.1
	Mean	**24.78**	**17.04**	**27.09**	**24.38**
	Std Dev	**9.85**	**2.06**	**12.74**	**8.12**

% Recovery

#	ID	No Rx	Rx D	Rx E	Rx F
7	C032	78.5	81.7	82.7	79.7
8	F039	53.1	79.8	52.5	63.0
9	C038	72.6	76.8	62.6	69.6
	Mean	**68.08**	**79.42**	**65.93**	**70.76**
	Std Dev	**13.26**	**2.44**	**15.36**	**8.38**

Rx D = AKP1491
Rx E = AKP5605
Rx F = AKP8937

DermaLab TEWL Values
Day 5

#	ID	No Rx	Rx D	Rx E	Rx F
7	C032	21.0	19.9	17.9	20.4
8	F039	32.6	17.5	42.0	31.6
9	C038	26.1	18.5	34.2	28.5
	Mean	**26.55**	**18.61**	**31.36**	**26.82**
	Std Dev	**5.81**	**1.21**	**12.31**	**5.77**
	Paired T-Test vs Base	**0.0178**	**0.0032**	**0.0724**	**0.0340**

Net Change from Baseline

#	ID	No Rx	Rx D	Rx E	Rx F
7	C032	13.9	12.6	10.2	13.2
8	F039	22.4	11.5	30.9	26.0
9	C038	20.4	14.0	29.8	24.1
	Mean	**18.93**	**12.67**	**23.62**	**21.10**
	Std Dev	**4.43**	**1.24**	**11.65**	**6.92**

% Recovery

#	ID	No Rx	Rx D	Rx E	Rx F
7	C032	82.8	84.7	86.3	82.7
8	F039	70.8	86.3	60.7	69.5
9	C038	73.3	83.1	64.2	71.9
	Mean	**75.61**	**84.69**	**70.39**	**74.71**
	Std Dev	**6.33**	**1.58**	**13.85**	**7.05**

Rx D = AKP1491
Rx E = AKP5605
Rx F = AKP8937

DermaLab TEWL Values
Day 8

#	ID	No Rx	Rx D	Rx E	Rx F
7	C032	15.3	16.1	13.9	15.1
8	F039	24.1	15.3	21.7	17.7
9	C038	18.1	14.1	22.4	21.7
	Mean	**19.18**	**15.16**	**19.33**	**18.18**
	Std Dev	**4.48**	**1.04**	**4.72**	**3.30**
	Paired T-Test vs Base	**0.0209**	**0.0005**	**0.0784**	**0.0450**

Net Change from Baseline

#	ID	No Rx	Rx D	Rx E	Rx F
7	C032	8.3	8.8	6.2	7.9
8	F039	13.9	9.3	10.6	12.1
9	C038	12.5	9.6	18.0	17.4
	Mean	**11.57**	**9.23**	**11.58**	**12.46**
	Std Dev	**2.94**	**0.37**	**5.97**	**4.74**

% Recovery

#	ID	No Rx	Rx D	Rx E	Rx F
7	C032	89.8	89.2	91.6	89.6
8	F039	81.9	88.9	86.6	85.8
9	C038	83.6	88.4	78.4	79.8
	Mean	**85.10**	**88.85**	**85.53**	**85.07**
	Std Dev	**4.16**	**0.41**	**6.69**	**4.95**

Rx D = AKP1491
Rx E = AKP5605
Rx F = AKP8937

DermaLab TEWL Values
Day 9

#	ID	No Rx	Rx D	Rx E	Rx F
7	C032	12.6	13.2	11.3	12.1
8	F039	23.9	13.4	17.9	15.4
9	C038	14.3	13.5	18.8	18.3
	Mean	**16.95**	**13.34**	**15.99**	**15.27**
	Std Dev	**6.06**	**0.14**	**4.09**	**3.12**
	Paired T-Test vs Base	**0.0586**	**0.0140**	**0.1234**	**0.0685**

Net Change from Baseline

#	ID	No Rx	Rx D	Rx E	Rx F
7	C032	5.6	5.9	3.6	4.9
8	F039	13.7	7.4	6.8	9.8
9	C038	8.7	8.9	14.4	14.0
	Mean	**9.33**	**7.41**	**8.25**	**9.56**
	Std Dev	**4.10**	**1.54**	**5.55**	**4.57**

% Recovery

#	ID	No Rx	Rx D	Rx E	Rx F
7	C032	93.1	92.8	95.1	93.6
8	F039	82.1	91.2	91.4	88.5
9	C038	88.6	89.2	82.7	83.7
	Mean	**87.95**	**91.06**	**89.75**	**88.61**
	Std Dev	**5.51**	**1.83**	**6.37**	**4.95**

Rx D = AKP1491
Rx E = AKP5605
Rx F = AKP8937

DermaLab TEWL Values
Day 10

#	ID	No Rx	Rx D	Rx E	Rx F
7	C032	10.2	10.7	9.9	10.6
8	F039	24.1	13.2	17.1	15.5
9	C038	13.3	11.5	15.4	14.7
	Mean	**15.85**	**11.79**	**14.17**	**13.61**
	Std Dev	**7.33**	**1.25**	**3.76**	**2.63**
	Paired T-Test vs Base	**0.1199**	**0.0415**	**0.1278**	**0.0730**

Net Change from Baseline

#	ID	No Rx	Rx D	Rx E	Rx F
7	C032	3.1	3.4	2.3	3.4
8	F039	14.0	7.2	6.0	9.9
9	C038	7.6	7.0	11.1	10.4
	Mean	**8.24**	**5.86**	**6.43**	**7.89**
	Std Dev	**5.44**	**2.13**	**4.42**	**3.91**

% Recovery

#	ID	No Rx	Rx D	Rx E	Rx F
7	C032	96.1	95.9	97.0	95.6
8	F039	81.8	91.4	92.4	88.4
9	C038	90.0	91.6	86.7	87.9
	Mean	**89.32**	**92.94**	**92.02**	**90.62**
	Std Dev	**7.19**	**2.53**	**5.13**	**4.29**

Rx D = AKP1491
Rx E = AKP5605
Rx F = AKP8937

Appendix K: Self-Assessment Data – Group 2

Decoded & Sorted Data

cyberDERM #S05-93A
TOPCGP-2005

Self-Assessment
Is the site burning/stinging or soothing?
Day 1 (Baseline)

(Scale: -4 = Burning/stinging is marked to 4 = Completely soothing/relief)

		BEFORE TREATMENT				AFTER TREATMENT				NET CHANGE			
#	ID	No Rx	Rx D	Rx E	Rx F	No Rx	Rx D	Rx E	Rx F	No Rx	Rx D	Rx E	Rx F
7	C032	-3.0	-3.0	-3.0	-3.0	-4.0	-4.0	-4.0	-4.0	-1.0	-1.0	-1.0	-1.0
8	F039	-3.0	-2.0	-4.0	-4.0	-3.0	-4.0	-4.0	-3.0	0.0	-2.0	0.0	1.0
9	C038	-2.0	-2.0	-3.0	-3.0	-2.0	-3.0	-4.0	-2.0	0.0	-1.0	-1.0	1.0
	Mean	**-2.67**	**-2.33**	**-3.33**	**-3.33**	**-3.00**	**-3.67**	**-4.00**	**-3.00**	**-0.33**	**-1.33**	**-0.67**	**0.33**
	Std Dev	**0.58**	**0.58**	**0.58**	**0.58**	**1.00**	**0.58**	**0.00**	**1.00**	**0.58**	**0.58**	**0.58**	**1.15**

Rx D = AKP1491
Rx E = AKP5605
Rx F = AKP8937

Self-Assessment
Is the site burning/stinging or soothing?
Day 2

(Scale: -4 = Burning/stinging is marked to 4 = Completely soothing/relief)

		BEFORE TREATMENT				AFTER TREATMENT				NET CHANGE			
#	ID	No Rx	Rx D	Rx E	Rx F	No Rx	Rx D	Rx E	Rx F	No Rx	Rx D	Rx E	Rx F
7	C032	-1.0	-1.0	-1.0	-1.0	-1.0	-1.0	-1.0	-1.0	0.0	0.0	0.0	0.0
8	F039	-1.0	-2.0	-1.0	-2.0	-1.0	-2.0	-3.0	-2.0	0.0	0.0	-2.0	0.0
9	C038	-0.1	1.0	-1.0	-1.0	-0.1	-2.0	-1.0	0.1	0.0	-3.0	0.0	1.1
	Mean	**-0.70**	**-0.67**	**-1.00**	**-1.33**	**-0.70**	**-1.67**	**-1.67**	**-0.97**	**0.00**	**-1.00**	**-0.67**	**0.37**
	Std Dev	**0.52**	**1.53**	**0.00**	**0.58**	**0.52**	**0.58**	**1.15**	**1.05**	**0.00**	**1.73**	**1.15**	**0.64**

Rx D = AKP1491
Rx E = AKP5605
Rx F = AKP8937

Self-Assessment
Is the site burning/stinging or soothing?
Day 3

(Scale: -4 = Burning/stinging is marked to 4 = Completely soothing/relief)

		BEFORE TREATMENT				AFTER TREATMENT				NET CHANGE			
#	ID	No Rx	Rx D	Rx E	Rx F	No Rx	Rx D	Rx E	Rx F	No Rx	Rx D	Rx E	Rx F
7	C032	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	0.0	0.0	0.0	0.0
8	F039	-1.0	-1.0	-1.0	-1.0	-1.0	-1.0	-2.0	-1.0	0.0	0.0	-1.0	0.0
9	C038	1.0	-1.0	-2.0	-2.0	1.0	1.0	0.1	1.0	0.0	2.0	2.1	3.0
	Mean	**1.33**	**0.67**	**0.33**	**0.33**	**1.33**	**1.33**	**0.70**	**1.33**	**0.00**	**0.67**	**0.37**	**1.00**
	Std Dev	**2.52**	**2.89**	**3.21**	**3.21**	**2.52**	**2.52**	**3.04**	**2.52**	**0.00**	**1.15**	**1.58**	**1.73**

Rx D = AKP1491
Rx E = AKP5605
Rx F = AKP8937

Self-Assessment
Is the site burning/stinging or soothing?
Day 4

(Scale: -4 = Burning/stinging is marked to 4 = Completely soothing/relief)

		BEFORE TREATMENT				AFTER TREATMENT				NET CHANGE			
#	ID	No Rx	Rx D	Rx E	Rx F	No Rx	Rx D	Rx E	Rx F	No Rx	Rx D	Rx E	Rx F
7	C032	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	0.0	0.0	0.0	0.0
8	F039	-1.0	-1.0	-2.0	-2.0	-1.0	-1.0	-4.0	-3.0	0.0	0.0	-2.0	-1.0
9	C038	-0.1	1.0	-1.0	-1.0	-0.1	2.0	1.0	1.0	0.0	1.0	2.0	2.0
	Mean	**0.97**	**1.33**	**0.33**	**0.33**	**0.97**	**1.67**	**0.33**	**0.67**	**0.00**	**0.33**	**0.00**	**0.33**
	Std Dev	**2.67**	**2.52**	**3.21**	**3.21**	**2.67**	**2.52**	**4.04**	**3.51**	**0.00**	**0.58**	**2.00**	**1.53**

Rx D = AKP1491
Rx E = AKP5605
Rx F = AKP8937

Self-Assessment
Is the site burning/stinging or soothing?
Day 5

(Scale: -4 = Burning/stinging is marked to 4 = Completely soothing/relief)

		BEFORE TREATMENT				AFTER TREATMENT				NET CHANGE			
#	ID	No Rx	Rx D	Rx E	Rx F	No Rx	Rx D	Rx E	Rx F	No Rx	Rx D	Rx E	Rx F
7	C032	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	0.0	0.0	0.0	0.0
8	F039	-0.1	-1.0	-1.0	-2.0	-0.1	-1.0	-2.0	-1.0	0.0	0.0	-1.0	1.0
9	C038	1.0	0.1	-1.0	-1.0	1.0	2.0	0.1	0.1	0.0	1.9	1.1	1.1
	Mean	**1.63**	**1.03**	**0.67**	**0.33**	**1.63**	**1.67**	**0.70**	**1.03**	**0.00**	**0.63**	**0.03**	**0.70**
	Std Dev	**2.12**	**2.63**	**2.89**	**3.21**	**2.12**	**2.52**	**3.04**	**2.63**	**0.00**	**1.10**	**1.05**	**0.61**

Rx D = AKP1491
Rx E = AKP5605
Rx F = AKP8937

Self-Assessment
Is the site burning/stinging or soothing?
Day 8

(Scale: -4 = Burning/stinging is marked to 4 = Completely soothing/relief)

		BEFORE TREATMENT				AFTER TREATMENT				NET CHANGE			
#	ID	No Rx	Rx D	Rx E	Rx F	No Rx	Rx D	Rx E	Rx F	No Rx	Rx D	Rx E	Rx F
7	C032	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	0.0	0.0	0.0	0.0
8	F039	-0.1	-0.1	-1.0	-0.1	-0.1	-0.1	-1.0	-1.0	0.0	0.0	0.0	-0.9
9	C038	4.0	4.0	4.0	4.0	4.0	2.0	2.0	2.0	0.0	-2.0	-2.0	-2.0
	Mean	**2.63**	**2.63**	**2.33**	**2.63**	**2.63**	**1.97**	**1.67**	**1.67**	**0.00**	**-0.67**	**-0.67**	**-0.97**
	Std Dev	**2.37**	**2.37**	**2.89**	**2.37**	**2.37**	**2.05**	**2.52**	**2.52**	**0.00**	**1.15**	**1.15**	**1.00**

Rx D = AKP1491
Rx E = AKP5605
Rx F = AKP8937

Self-Assessment
Is the site burning/stinging or soothing?
Day 9

(Scale: -4 = Burning/stinging is marked to 4 = Completely soothing/relief)

		BEFORE TREATMENT				AFTER TREATMENT				NET CHANGE			
#	ID	No Rx	Rx D	Rx E	Rx F	No Rx	Rx D	Rx E	Rx F	No Rx	Rx D	Rx E	Rx F
7	C032	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	0.0	0.0	0.0	0.0
8	F039	0.1	0.1	-0.1	0.1	0.1	-0.1	-1.0	0.1	0.0	-0.2	-0.9	0.0
9	C038	4.0	4.0	4.0	4.0	4.0	3.0	3.0	3.0	0.0	-1.0	-1.0	-1.0
	Mean	**2.70**	**2.70**	**2.63**	**2.70**	**2.70**	**2.30**	**2.00**	**2.37**	**0.00**	**-0.40**	**-0.63**	**-0.33**
	Std Dev	**2.25**	**2.25**	**2.37**	**2.25**	**2.25**	**2.14**	**2.65**	**2.03**	**0.00**	**0.53**	**0.55**	**0.58**

Rx D = AKP1491
Rx E = AKP5605
Rx F = AKP8937

Self-Assessment
Is the site burning/stinging or soothing?
Day 10

(Scale: -4 = Burning/stinging is marked to 4 = Completely soothing/relief)

		BEFORE TREATMENT				AFTER TREATMENT				NET CHANGE			
#	ID	No Rx	Rx D	Rx E	Rx F	No Rx	Rx D	Rx E	Rx F	No Rx	Rx D	Rx E	Rx F
7	C032	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	0.0	0.0	0.0	0.0
8	F039	1.0	1.0	-0.1	1.0	1.0	1.0	1.0	1.0	0.0	0.0	1.1	0.0
9	C038	4.0	4.0	4.0	4.0	4.0	3.0	3.0	3.0	0.0	-1.0	-1.0	-1.0
	Mean	**3.00**	**3.00**	**2.63**	**3.00**	**3.00**	**2.67**	**2.67**	**2.67**	**0.00**	**-0.33**	**0.03**	**-0.33**
	Std Dev	**1.73**	**1.73**	**2.37**	**1.73**	**1.73**	**1.53**	**1.53**	**1.53**	**0.00**	**0.58**	**1.05**	**0.58**

Rx D = AKP1491
Rx E = AKP5605
Rx F = AKP8937