Research Report S06-19

Confidential Material

A Randomized, Controlled 5 Day Pilot Study Assessing Topical Calcium Glycerophosphate as a Potential Agent for Minimizing Skin Damage Due to Adhesive Dressings

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I. OBJECTIVES

This study was designed to determine if pre-application of a test formulation reduces redness, stratum corneum disruption and pain/discomfort associated with adhesive damage to the skin. This was done using Expert Grader assessments of erythema, instrumental measurements of transepidermal water loss, skin surface hydration and skin surface redness and self-assessments of pain/discomfort.

II. EXPERIMENTAL DESIGN

A. General Considerations

This study was conducted under the supervision Gary Grove, Ph.D. and Charles Zerweck, Ph.D., at cyberDERM Clinical Studies in Broomall, Pennsylvania. A copy of each of their curriculum vitae is 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 March 27 to March 31, 2006. A calendar of events outlining the schedule of treatments and evaluative procedures that were followed during this study is attached as **Appendix A**.

This was a randomized, controlled study. Panelists were evaluated by the Expert Grader for erythema and had instrument measurements of skin water loss, hydration and redness on Day 1 (Baseline) prior to the product and tape application procedure. The test product was applied to 2 of the 4 test sites on the back and allowed to dry for 5 minutes. Medical grade adhesive tape (5cm x 5cm) was then applied to each of the 4 test sites and remained in place for 20-24 hours. The panelists returned on Day 2 and were asked to rate the difference in pain/discomfort between the sites upon tape removal. Thirty minutes later, the grades and instrument measurements were repeated. Immediately after the measurements were completed, the product was applied to the same 2 sites, allowed to dry and new tape strips were applied to all 4 sites and left in place for 20-24 hours. This procedure of applying the test product, allowing it to dry, applying a new tape strips and removing after 20-24 hours was repeated for a total of 5 days (apply Monday – Thursday and remove Tuesday – Friday). The result would be elevated transepidermal water loss and erythema associated with repeated adhesive tape trauma.

Irritation, stratum corneum disruption, and pain/discomfort relief was assessed daily (Monday – Friday) based on clinical observations, instrument measurements, and self-assessments. Instrumental assessments included the

cyberDERM Research Grade Evaporimeter, the Minolta Chromameter and DermaLab® Skin Sensor at Baseline and 30 minutes following each 24 hour tape removal cycle. Digital photographs were also taken on Day 5.

B. Panelist Selection

Six 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 range in age 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 and female, 18-55 years of age, and in good general health.
b. Agrees to discontinue use of all products except for cleansers on the back for 3 days prior to start of study (Day 1) and during the study.
c. Willing and able to follow all study directions and to commit to all follow-up visits for the duration of the study.
d. Must be willing to lie on stomach for time necessary to perform assessments.
e. 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.

During the study, the following restrictions were imposed:

- Female panelists were asked to wear a tank bathing suit or a type of top that has a low back (halter). They were also asked to bring a button-down shirt to wear over the front of them to keep warm and covered up.
- Panelists must not have any allergies or sensitivity to tapes or adhesives.
- Panelists may not have scars, moles, other blemishes on the back that would obscure grading or measuring of the test sites.
- Panelists may not be diabetic.
- Panelists may not be taking anti-inflammatories (Advil, Aleve, arthritis medications, etc.) except for acetaminophen (e.g. Tylenol).
- Panelists must be willing to lie on stomach for time necessary to perform assessments.
- Panelists may not exercise before each visit as this will affect the measurements
- Panelists may shower, but should not shower less than 1 hour before each visit.
- Panelists must stop the use of any products other than cleansers on their back during a 3 day pre-conditioning period prior to testing and during the 5 days of testing.

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, or 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 5 centimeter by 5 centimeter 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 (Baseline – prior to product and tape applications) and again approximately 30 minutes after the removal of the tapes on Days 2-5, 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. Water Loss Measurements with the cyberDERM, inc. Evaporimeter

All water loss measurements were taken following a 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.

On Day 1 (Baseline – prior to product applications and tape) and again approximately 30 minutes after the removal of the tapes on Days 2-5, evaporative water loss measurements were taken from each of the test sites as described below. Any individuals with water loss values outside the normal range (>10.0 gms/m^2hr) were excluded at that 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 (Broomall, PA) with TEWL Probes 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. Evaporimetery 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.

At each session, duplicate water loss readings were taken from each 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 serves as a back up in case there are 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 from all 4 sites on Day 1 (Baseline – prior to product and tape applications) and again approximately 30 minutes after the removal of the tapes on Days 2-5.

E. Minolta Chromameter a* Measurements

Skin surface color was measured instrumentally using reflectance techniques based on the standardized tristimulus system recommended by CIE. The specific model employed for such measurements was the Minolta CR-200 Chromameter that has an 8mm measuring area using the illuminant conditions of D_{65} which most closely approximates normal daylight conditions. This is a hand held device that is gently placed against the surface to be color characterized. When triggered, a pulsed xenon light source flashes and this light is reflected off the surface and measured back into the device. Within the device, there are 6 silicon photocells that are filtered to detect primary stimulus values for red, green and blue wavelengths of light. For color readings, the values are translated into the L*a*b* coordinates whose spacing correlates closely with color changes perceived by the human eye. This is an internationally recognized convention for numerically expressing color differences established by the C.I.E. (Commission International de L'Eclairage). The L* value represents the density value from black to white. The a* and b* values represent the color axes ranging from green to red and from blue to yellow, respectively. Higher a* values along the red-green axis are an indication that a treatment site is more irritated. [Babulak, S.W., Rhein, L.D., Scala, D.D., Simion, A.F. and Grove, G.L., Quantitation of Erythema in a Soap Chamber Test Using the Minolta Chroma (Reflectance)

Meter: Comparison of Instrumental Results with Visual Assessments, J. Soc. Cosmet. Chem. 37:475-479, 1986.]

Three sets of a* readings were taken from each of the test sites on Day 1 (Baseline – prior to product applications and tape) and again approximately 30 minutes after the removal of the tapes on Days 2-5, and the average value computed for each site.

F. DermaLab® Skin Sensor

The DermaLab® Skin Sensor is a new and unique device that is based on a patent issued to Procter & Gamble (Cincinnati, OH) that is now being produced by Cortex Technology and commercially available though cyberDERM, inc. who serves as their North American agent. The device consists of a multi-electrode sensing pad which is placed onto the skin surface. The circuitry is such that a DC voltage can be applied across the skin and the resulting current monitored in real time while the DC voltage is ramped up at a constant rate from 0 to a maximum of 80 volts. By plotting the resulting current as a function of the applied DC voltage, several parameters which are related to the basic electrical properties of the stratum corneum can be derived. These include the onset voltage at which current first begins to raise, the maximum voltage which is required to have the current reach a value of 2 microamps and the total charge under the curve. Preliminary studies have suggested that the onset voltage is related to skin surface hydration levels while maximum voltage and charge are more a measure of the barrier properties of the stratum corneum.

Three sets readings were taken from each of the test sites on Day 1 (Baseline – prior to product applications and tape) and again approximately 30 minutes after the removal of the tapes on Days 2-5 and the average value computed for each site.

G. Test Product and Treatment Procedures

The test product used in this study was supplied by Sponsor in individual squeeze bottles and labeled:

Cellerity Code 070605B
Investigational Use Only
Lab Control: 3-8-06

Two of the four test sites on the back were randomly assigned to the test product while two sites served as non-treated controls. The randomization was a balanced block design and is included in **Appendix C**.

After completing the visual grades and instrument measurements on Day 1 (Baseline), a technician applied approximately 0.10 cc of product using a clean finger cot to two of the four sites. The other two sites remained non-treated to serve as controls. The product was allowed to dry for 5 minutes before the tapes were applied.

H. Tape Strip Trauma – 24 Hour Dwell Time

On Day 1, after the Baseline measurements were completed and the product had been applied, 3M Cloth Adhesive Tape [Mfr #2950-2] (5cm x 5cm) was firmly applied to 4 test sites on the back (2 on each side) and allowed to remain in place for 20-24 hours. The panelists returned on Day 2 to have the tapes removed and evaluations completed.

After completing the evaluations, the test product was applied to the same test sites and allowed to dry for 5 minutes. New tape strips were applied and allowed to remain in place for 20-24 hours.

This process of applying the test product, allowing it to dry for 5 minutes, applying new tape strips and removing them 20-24 hours later was repeated for a total of 5 days (apply Monday – Thursday and remove Tuesday – Friday). The result was elevated transepidermal water loss and the eventual development of erythema associated with tape traumatized skin.

Using this technique we created (4) 5 centimeter x 5 centimeter tape traumatized 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. These test sites were also likely to develop moderate to marked confluent erythema.

The tape traumatized sites were assessed daily (Monday – Friday) visually by the Expert Grader and instrumentally using the cyberDERM Research Grade Evaporimeter, Minolta Chromameter and DermaLab® Skin Sensor.

I. Panelist Self-Assessment of Discomfort/Pain

The Treatment Technician asked the panelists to rate if there is any difference in **discomfort/pain** between the sites when pulling off each set of tapes. During the assessments, the panelists first compared the removal of the 2 tapes from the upper sites and then compared the removal of the 2 tapes from the lower sites. The following scale was used:

0	No difference
1	Slightly more discomfort/pain
2	Moderately more discomfort/pain
3	Dramatically more discomfort/pain
MUST FORCE CHOICE FOR FINAL (if tied)	

The panelists were asked to make a forced choice between the sites on Day 5 if any sites were rated equal.

J. Digital Macrophotography

Standardized images were captured using a Canon EOS 10D digital camera with a 90 mm macro lens. Images were taken on Day 5 for all panelists.

This camera apparatus was configured by Faraghan Medical Camera systems. The design incorporates a pair of Twin Lite MT 24 EX strobes at fixed positions and inclinations.

All images were reviewed, stored and retrieved using Canon Utilities Zoom Browser EX software.

K. Termination of a Site

All tape stripped sites were evaluated daily by the Expert Grader. If any evaluated site progressed to a grade of 8 during the course of study, that site would be terminated and no further treatments with the study materials would be made. No sites were terminated during this study.

L. 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.

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.

There were no adverse reactions during this study.

M. 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. In creating these tables, column averages were computed in every case, but only to give a preliminary

look at the findings. A Paired T-Test was used to compare the net change in the tabulated results. This was a pilot study and employed only 6 panelists and thus extreme caution must be placed on the interpretation of these findings.

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

III. RESULTS

A. Panelist Accountability

Six panelists reported to the test facility for Baseline measurements, all of whom qualified for inclusion on the study panel. **Appendix D** contains a listing of each panelist's age and sex.

All 6 of the qualified panelists were able to successfully complete the entire course of the study.

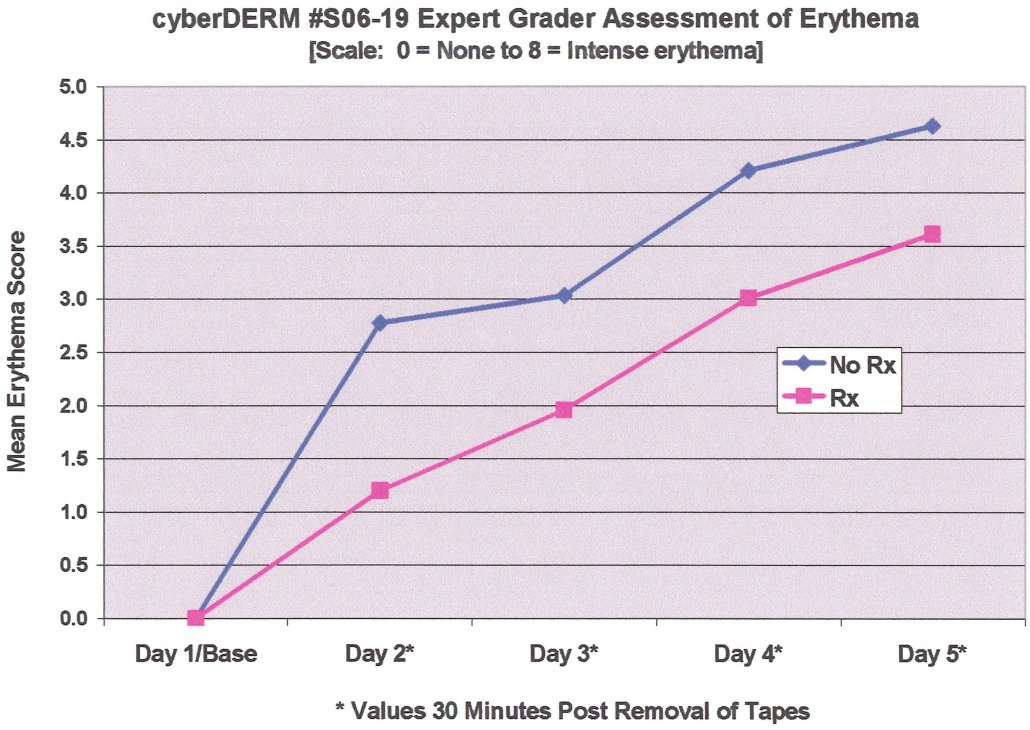
It should be noted that on Day 2, panelist #5 W030 arrived to have her tapes removed and it was discovered that additional tape had been applied over all 4 of her sites. Panelist #6 M130 reported for her Day 2 visit with additional tape applied to one edge of her upper right site and lower left site. All panelists had been instructed on Day 1 not to touch or otherwise tamper with the test sites. These panelists were further instructed on Day 2 to not tamper with the test sites. Below is a chart that lists for each panelist the sites that were tampered with or if the tape did not remain in place for the entire 24 hours.

#	ID	Day 2				Day 3				Day 4				Day 5			
		LU	RU	LL	RL	LU	RU	LL	RL	LU	RU	LL	RL	LU	RU	LL	RL
1	D082																
2	W011				¼ of tape adhered to site												
3	H027			Tape fell off							Tape fell off	Tape fell off				Tape fell off	
4	A002																
5	W030	Site taped over	Site taped over	Site taped over	Site taped over												
6	M130		Site taped on edge	Site taped on edge													

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

B. Expert Grader Evaluations

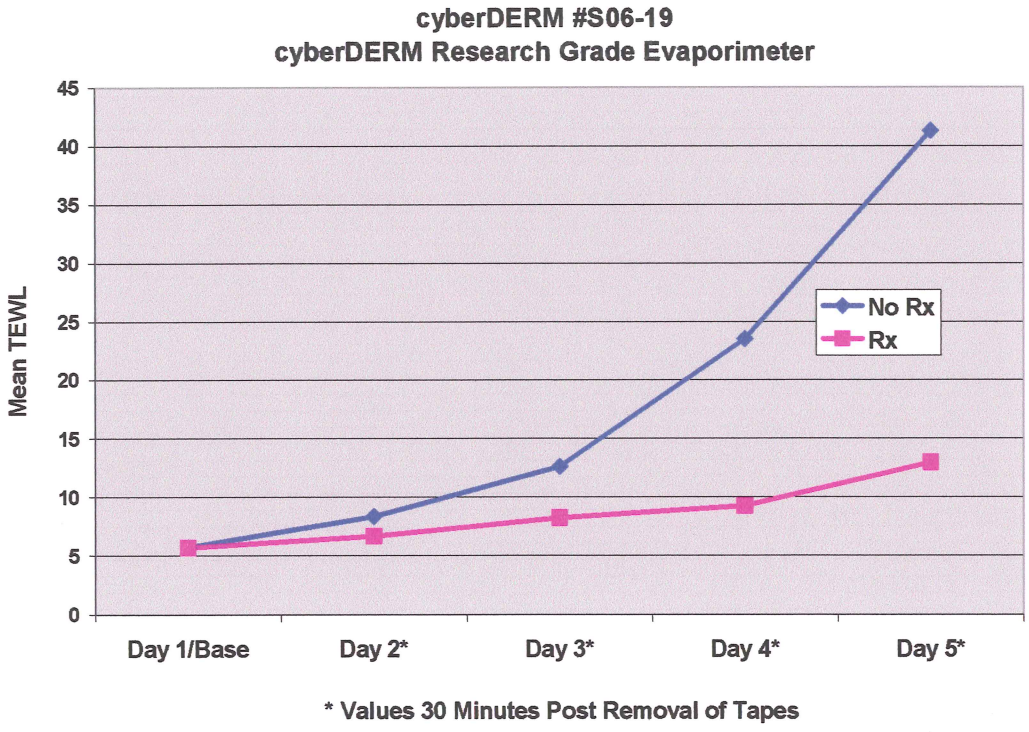
The decoded and sorted Expert Grader erythema data from the sessions at Baseline and 30 minutes post removal on Days 2, 3, 4 and 5 are attached as **Appendix E**. These results are also graphically summarized in the figure below:



Mean erythema scores for Cellerity treated sites were lower at every post challenge time point when compared to non-treated sites. These differences were significant ($p < 0.05$) on Days 2 and 4.

C. Water Loss Measurements – cyberDERM, inc. Evaporimeter

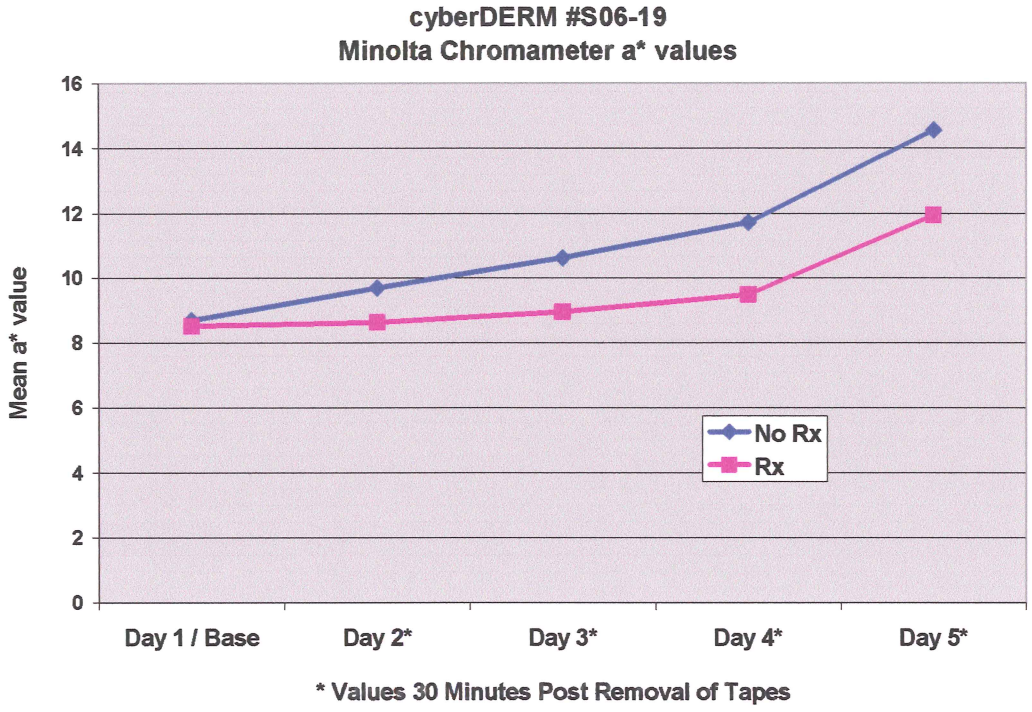
The decoded and sorted water loss measurement data from the sessions at Baseline and 30 minutes post removal on Days 2, 3, 4 and 5 are attached as **Appendix F**. These results are also graphically summarized in the figure below.



Mean TEWL values for Cellerity treated sites were significantly lower ($p < 0.05$) at every post challenge time point when compared to non-treated sites.

D. Minolta Chromameter a* Measurements

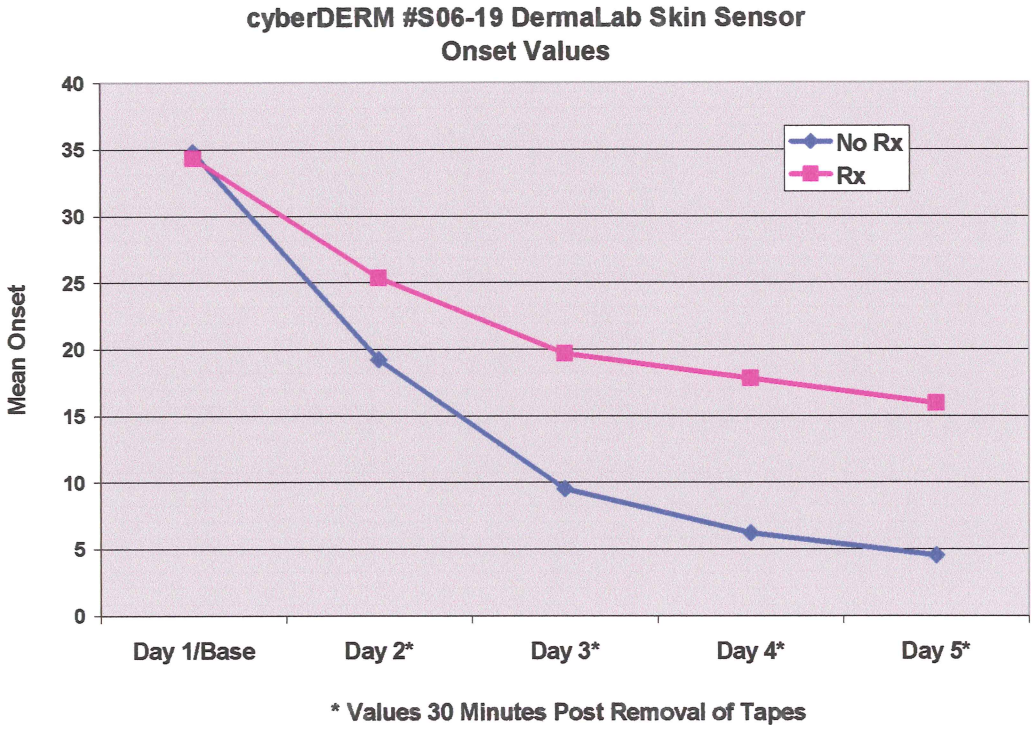
The decoded and sorted Chromameter a* data from the sessions at Baseline and 30 minutes post removal on Days 2, 3, 4 and 5 are attached as **Appendix G.** These results are also graphically summarized in the figure below:



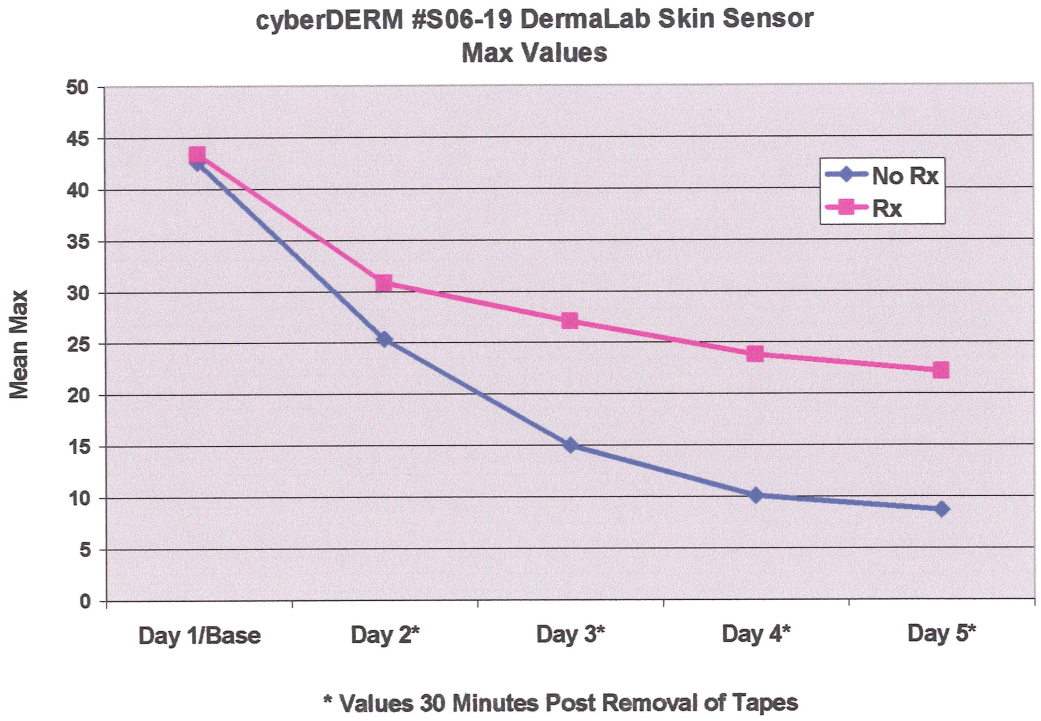
Mean Chromameter a* values for Cellerity treated sites were lower (less red) at every post challenge time point when compared to non-treated sites. These differences were significant ($p < 0.05$) at Days 2 and 3. However, because of the large individual variations, these differences were not found to be statistically significant at Days 4 and 5.

E. DermaLab® Skin Sensor Measurements

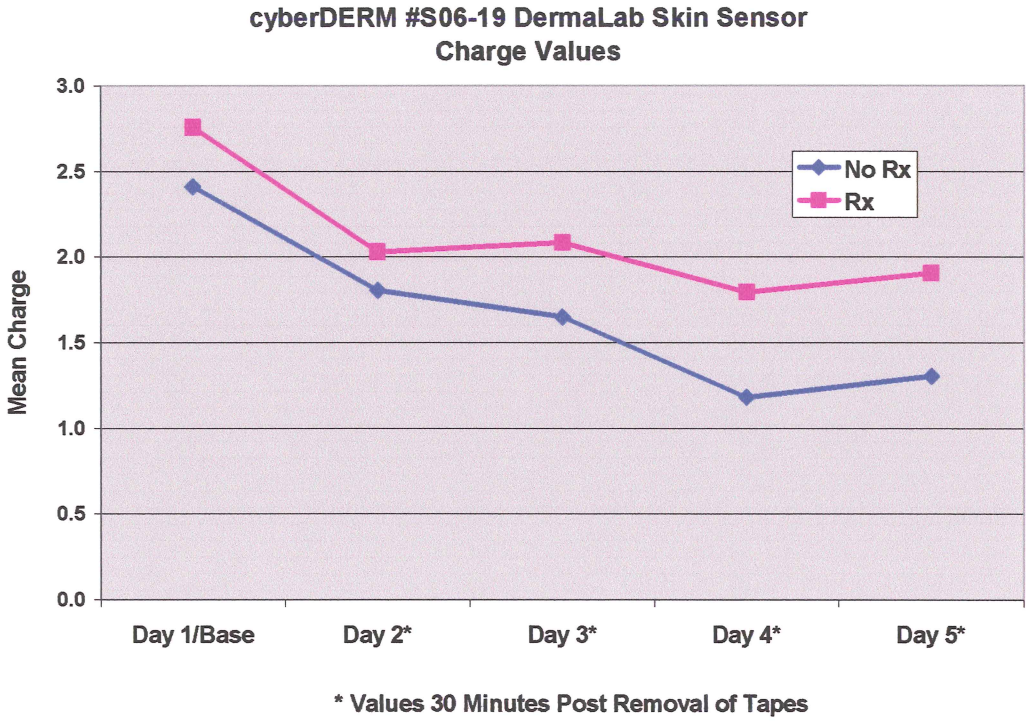
The decoded and sorted Skin Sensor measurement data from the sessions at Baseline and 30 minutes post removal on Days 2, 3, 4 and 5 are attached as **Appendix H.** These results are also graphically summarized in the figures below:



Mean Skin Sensor Onset values for Cellerity treated sites were significantly longer ($p < 0.05$) at all post challenge time points (indicating a drier skin surface) when compared to non-treated sites.



Mean Skin Sensor Max values for Cellerity treated sites were higher (indicating a drier stratum corneum) at all post challenge time points when compared to non-treated sites. These differences were statistically significant ($p < 0.01$) at Days 3 through 5.



Mean Skin Sensor Charge values for Cellerity treated sites were longer (indicating less stratum corneum disruption) at all post challenge time points when compared to non-treated sites. These differences were statistically significant ($p < 0.05$) at Days 4 and 5.

F. Self-Assessment of Discomfort/Pain upon Tape Removal

The decoded and sorted Self-Assessment data on Days 2, 3, 4 and 5 comparing the discomfort upon tape removal are attached as **Appendix I**.

Mean panelist ratings of discomfort favored the Cellerity treated sites at all post challenge time points when compared to the non-treated sites. Although this difference was statistically significant only at Day 5 there also appeared to be a tendency favoring Cellerity treated sites at both Days 3 and 4.

IV. CONCLUSIONS

Based on the results of this pilot study, we feel it is reasonable to draw certain conclusions that would likely be supported by a more expansive study. Both the Expert Grader assessments of erythema as well as Chromameter measurements of redness revealed that Cellerity treated sites were associated with less redness than non-treated sites due to adhesive stripping. Instrumental measures of both evaporative water loss and electrical properties of the skin also indicated that Cellerity treated sites exhibited significantly less disruption of the stratum corneum barrier than non-treated sites. In addition, there were indications from panelist self-assessments that removal of the adhesive dressing from Cellerity treated sites resulted in less discomfort than non-treated sites.

These results appear promising for this product as a skin protectant when used in conjunction with adhesive dressings. Further study is warranted to characterize the actual dressing adhesiveness with and without product pretreatment.

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 the 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

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CLINICAL STUDIES

cyberDERM #S06-19 CALENDAR OF EVENTS
A RANDOMIZED, CONTROLLED 5 DAY PILOT STUDY ASSESSING TOPICAL CALCIUM GLYCEROPHOSPHATE AS A POTENTIAL AGENT FOR MINIMIZING SKIN DAMAGE DUE TO ADHESIVE DRESSINGS

DAY 1 BASELINE ASSESSMENTS	DAYS 1-4 PRODUCT & TAPE APPLICATION PROCEDURE	DAYS 2-5
Expert Grader Erythema assessments	Product applied to 2 of 4 sites on back (randomized)	Remove tape
Minolta Chromameter a* measurements	Wait 5 minutes for product to dry	Self-Assessment of discomfort/pain
cyberDERM Research Grade Evaporimeter measurements	Apply tape to each site	Wait 30 minutes
DermaLab® Skin Sensor measurements	Leave tape in place for 20-24 hours	Expert Grader Erythema assessments
		Minolta Chromameter a* measurements
		cyberDERM Research Grade Evaporimeter measurements
		DermaLab® Skin Sensor measurements
		Digital Photography (Day 5 only)

CONDUCTION DATES: Monday, March 27, 2006 through Friday, March 31, 2006

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

PANEL:
N=6 Caucasian male or female panelists, ages 18 to 55

TEST SITES:
Four 5 x 5 cm test sites will be located on the back (2 on each side). Two of the four sites will be treated and two will remain non-treated to serve as controls using a balanced block randomization. All four sites will be tape stripped (1x daily).

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CLINICAL STUDIES

cyberDERM #S06-19 CALENDAR OF EVENTS
A RANDOMIZED, CONTROLLED 5 DAY PILOT STUDY ASSESSING TOPICAL CALCIUM GLYCEROPHOSPHATE AS A POTENTIAL AGENT FOR MINIMIZING SKIN DAMAGE DUE TO ADHESIVE DRESSINGS (continued)

TEST PRODUCT:
The test formulation to be used in this study will be supplied by the Sponsor

Approximately 0.10 cc of product will be applied by a technician using a clean finger cot to two of the four sites on Days 1-4. The product will be allowed to dry for 5 minutes before the surgical tapes are applied. The randomization will be a balanced block design.

TAPE PROCEDURE:
Following the product applications, 3M Cloth Adhesive Tape [Mfr #2950-2], which will be approximately 5 x 5 cm in size, will be applied firmly to each of the four test sites on the back (2 on each side) and allowed to remain in place for 20-24 hours before removal. The tape strips will be applied on Days 1-4 and removed on Days 2-5.

CLINICAL ASSESSMENTS:
Expert Grader assessments of erythema will be made of the 4 test sites prior to the first product application and again approximately 30 minutes after removing the tapes on Days 2-5. Ties will be broken by forcing the Expert Grader to add 0.1 to the site he thinks is worse, except at Baseline.

INSTRUMENTAL ASSESSMENTS:
The following measurements will be taken of the 4 test sites on Day 1 (Baseline) prior to the first product application and again approximately 30 minutes after removal of the tapes on Days 2-5:

- Measurements of skin surface redness using the Minolta Chromameter (a* values)
- Transepidermal water loss measurements using a cyberDERM Research Grade Evaporimeter
- Measurements using the DermaLab® Skin Sensor

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CLINICAL STUDIES

cyberDERM #S06-19 CALENDAR OF EVENTS
A RANDOMIZED, CONTROLLED 5 DAY PILOT STUDY ASSESSING TOPICAL CALCIUM GLYCEROPHOSPHATE AS A POTENTIAL AGENT FOR MINIMIZING SKIN DAMAGE DUE TO ADHESIVE DRESSINGS (continued)

SELF-ASSESSMENTS:
The Treatment Technician will ask the panelists to rate if there is any difference in **discomfort/pain** between the sites when pulling off each set of tapes. The following scale will be used:

0	No difference
1	Slightly more discomfort/pain
2	Moderately more discomfort/pain
3	Dramatically more discomfort/pain
MUST FORCE CHOICE FOR FINAL (if tied)	

The panelists will be asked to make a forced choice between the sites on Day 5 if any sites are rated equal.

DIGITAL MACROPHOTOGRAPHY:
Digital images will be obtained of each panelist's back including all 4 test sites approximately 30 minutes after tape removal on Day 5 only.

DATA ANALYSIS & REPORT:
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. A final report will be completed by cyberDERM Clinical Studies.

PANELIST RESTRICTIONS:
- 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).
- The panelists may not exercise before their visit as this will affect the measurements.
- The panelists may shower, but should not shower less than 1 hour before each visit.
- The panelists will stop the use of all moisturizing products on the back 3 days prior to study start and during the 5 days of testing.

Appendix B: Consent Form
Subject Number: _____ CCS ID:_____

SUBJECT INFORMATION AND CONSENT FORM

TITLE: A Randomized, Controlled 5 Day Pilot Study Assessing Topical Calcium Glycerophosphate as a Potential Agent for Minimizing Skin Damage due to Adhesive Dressings

PROTOCOL NO.: cyberDERM #S06-19

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 a test formulation in reducing redness and working as a protective agent against adhesive tape damage to the skin, as well as relieving any pain/discomfort associated with adhesive tape damage. On Day 1 the test formulation will be applied to 2 of 4 sites on your back and allowed to dry. Each site will be approximately 5 centimeters by 5 centimeters. One piece of tape will

be applied to each site and will remain on the skin for 20-24 hours before being removed at the lab on the following day (Day 2). The process of applying the product, letting it dry, applying a piece of tape and removing it 20-24 hours later will be repeated for 5 days (apply Monday – Thursday, remove Tuesday – Friday). This will intentionally damage the non-treated sites and treated sites. The damage will be similar to a removing an aggressive adhesive bandage. We will use the measurement of skin water loss and electrical properties to assess the changes to the skin's barrier. Changes in skin redness will be assessed visually by an Expert Grader and instrumentally using the Minolta Chromameter. Digital images will also be taken of the test sites to capture any changes or differences in the test sites.

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 5 days and involves 5 study visits. You will be asked to report to the testing facility at a specific time for the study. It is important that you report at the designated time. Each visit will last approximately 1-1 ½ hours. 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 and Sunday (The 2 days prior to testing start):

- Continue washout.

Monday, Day 1 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 5 centimeters by 5 centimeters in size.
- You will then sit quietly and accommodate to the conditions of the test lab for approximately 30 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.
    - One 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 up to 1 minute while each non-invasive measurement is taken. You will lie face down on a padded exam table during the measurements.
    - Skin redness will be measured using the Minolta Chromameter. This will be done by gently placing the probe on each site for a few seconds. Three readings will be taken from each site.
    - Measurements will also be taken using the DermaLab® Skin Sensor

which measures the skin's hydration and barrier properties. The probe will be gently placed on each site for up to 1 minute while measurements are being taken.

- If the measurements are in the desired range and you are accepted onto the panel, you will then have the test formulation applied to 2 of the 4 sites. The product will be allowed to dry for 5 minutes.
- Cloth adhesive tape (5 centimeters by 5 centimeters) will be applied to each of the 4 sites on your back. They will remain on for 20-24 hours (until your next visit).
- You will then be allowed to leave the lab. You must not use topical products (including moisturizing skin care products) on your back. You may shower, but should not shower less than 1 hour before your next visit.

Tuesday through Thursday, Days 2-4 of testing:

- The tapes will be removed from each site and you will be asked to rate the difference in discomfort/pain between each pair of sites.
- After the tapes are removed from the last site, you will wait 30 minutes.
- The same assessments and measurements taken at Baseline will be repeated.
- You will then have the test formulation applied to same 2 sites. The product will be allowed to dry for 5 minutes
- Cloth adhesive tape (5 centimeters by 5 centimeters) will be applied to each of the 4 sites on your back. They will remain on for 20-24 hours (until your next visit).
- You will then be allowed to leave the lab. You must not use topical products (including moisturizing skin care products) on your back. You may shower, but should not shower less than 1 hour before your next visit.

Friday, Day 5 of testing:

- The tapes will be removed from each site and you will be asked to rate the difference in discomfort/pain between each pair of sites.
- After the tapes are removed from the last site, you will wait 30 minutes.
- The same assessments and measurements taken at Baseline will be repeated.
- Digital photographs will also be taken of the 4 test sites.
- Your participation in this study will end.

STUDY REQUIREMENTS AND RESTRICTIONS

- 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 be willing to lie on stomach for an extended period of time.
- You may not exercise before your visit as this will affect the measurements.

- You must not use topical products (including moisturizing skin care products) on your back. You may shower, but should not shower less than 1 hour before your next visit.

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 cause slight temporary 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 tape, 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 $____ to compensate you for your time and participation if you complete the entire study. 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) 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.

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
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)

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 may be asked to 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, the FDA.

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

S06-19 Consent v1.01

Appendix C: Randomization Schedule

Randomization Schedule

#	ID	Left		Right	
		Upper	Lower	Upper	Lower
1	D082	Rx	no Rx	no Rx	Rx
2	W011	Rx	no Rx	no Rx	Rx
3	H027	no Rx	Rx	Rx	no Rx
4	A002	Rx	no Rx	no Rx	Rx
5	W030	no Rx	Rx	Rx	no Rx
6	M130	no Rx	Rx	Rx	no Rx

Rx = Cellerity Code 070605B

Appendix D: Demographic Data

Demographic Data

#	ID	AGE	SEX
1	D082	39	F
2	W011	47	F
3	H027	38	F
4	A002	40	F
5	W030	30	F
6	M130	38	F

Decoded & Sorted Data

cyberDERM S06-19

Expert Grader Assessment of Erythema

[Scale: 0 = none to 8 = intense erythema]

Baseline - Day 1

		Rx		No Rx		Pooled	
#	ID	Left	Right	Left	Right	Rx	No Rx
1	D082	0	0	0	0	0	0
2	W011	0	0	0	0	0	0
3	H027	0	0	0	0	0	0
4	A002	0	0	0	0	0	0
5	W030	0	0	0	0	0	0
6	M130	0	0	0	0	0	0
					Mean	0.00	0.00
					SD	0.00	0.00
					paired t	1.0000	

Cellerity Code 070605B

Expert Grader Assessment of Erythema

[Scale: 0 = none to 8 = Intense erythema]

Day 2

(30 Minutes Post tape removal)

		Rx		No Rx		Pooled	
#	ID	Left	Right	Left	Right	Rx	No Rx
1	D082	2.2	2.0	2.1	3.0	2.1	2.6
2	W011	2.0	0.0	5.0	4.0	1.0	4.5
3	H027	1.0	3.0	4.0	3.1	2.0	3.6
4	A002	2.0	1.0	3.0	4.0	1.5	3.5
5	W030	0.0	1.1	2.0	1.0	0.6	1.5
6	M130	0.0	0.1	1.0	1.1	0.1	1.1
					Mean	1.20	2.78
					SD	0.82	1.32
					paired t	0.0162	

Cellerity Code 070605B

Expert Grader Assessment of Erythema

[Scale: 0 = none to 8 = Intense erythema]

Day 3

(30 Minutes Post tape removal)

		Rx		No Rx		Pooled	
#	ID	Left	Right	Left	Right	Rx	No Rx
1	D082	1	2.1	2.2	2	1.6	2.1
2	W011	3	1	5	4	2.0	4.5
3	H027	1	2.1	2	1.1	1.6	1.6
4	A002	3.1	2	4	3	2.6	3.5
5	W030	2.1	3.1	3	2	2.6	2.5
6	M130	1	2	4.1	4	1.5	4.1
					Mean	1.96	3.03
					SD	0.51	1.16
					paired t	0.0771	

Cellerity Code 070605B

Expert Grader Assessment of Erythema

[Scale: 0 = none to 8 = intense erythema]

Day 4

(30 Minutes Post tape removal)

		Rx		No Rx		Pooled	
#	ID	Left	Right	Left	Right	Rx	No Rx
1	D082	3	2	4	3.1	2.5	3.6
2	W011	4	2	5	5.1	3.0	5.1
3	H027	1	3	4	2	2.0	3.0
4	A002	4.1	4	5.1	5	4.1	5.1
5	W030	2	3	5	5.1	2.5	5.1
6	M130	3	5	3.1	4	4.0	3.6
					Mean	**3.01**	**4.21**
					SD	**0.85**	**0.94**
					paired t	**0.0364**	

Cellerity Code 070605B

Expert Grader Assessment of Erythema

[Scale: 0 = none to 8 = intense erythema]

Day 5

(30 Minutes Post tape removal)

		Rx		No Rx		Pooled	
#	ID	Left	Right	Left	Right	Rx	No Rx
1	D082	5	4	4.1	3	4.5	3.6
2	W011	5	3	5.1	6	4.0	5.6
3	H027	0	2	4	4.1	1.0	4.1
4	A002	4.1	4.2	5	4	4.2	4.5
5	W030	3	4	6	5	3.5	5.5
6	M130	4	5	4.1	5.1	4.5	4.6
					Mean	3.61	4.63
					SD	1.33	0.79
					paired t	0.1469	

Cellerity Code 070605B

Decoded & Sorted Data

cyberDERM S06-19

cyberDERM RG-1 Evaporimeter

Baseline - Day 1

		Rx		No Rx		Pooled	
#	ID	Left	Right	Left	Right	Rx	No Rx
1	D082	3.9	2.8	3.2	3.7	3.3	3.5
2	W011	5.0	3.6	4.4	4.2	4.3	4.3
3	H027	7.4	6.7	9.5	6.0	7.1	7.7
4	A002	7.6	7.4	5.4	8.1	7.5	6.7
5	W030	3.9	4.6	4.5	3.8	4.3	4.2
6	M130	7.3	8.1	8.1	7.9	7.7	8.0
					Mean	**5.70**	**5.73**
					SD	**1.94**	**2.01**
					paired t	**0.9042**	

Cellerity Code 070605B

cyberDERM RG-1 Evaporimeter

Day 2
(30 Minutes Post tape removal)

		Rx		No Rx		Pooled	
#	ID	Left	Right	Left	Right	Rx	No Rx
1	B082	4.8	3.8	4.8	5.0	4.3	4.9
2	W011	8.9	4.6	7.6	7.8	6.7	7.7
3	H027	7.2	8.7	11.4	9.0	7.9	10.2
4	A002	8.0	8.6	6.3	17.3	8.3	11.8
5	W030	5.0	6.1	5.5	5.3	5.5	5.4
6	M130	7.6	7.3	10.8	9.8	7.4	10.3
					Mean	**6.70**	**8.37**
					SD	**1.53**	**2.83**
					paired t	**0.0338**	

Cellerity Code 070605B

cyberDERM RG-1 Evaporimeter

Day 3
(30 Minutes Post tape removal)

		Rx		No Rx		Pooled	
#	ID	Left	Right	Left	Right	Rx	No Rx
1	D082	5.6	6.1	11.2	12.7	5.8	12.0
2	W011	10.9	10.0	9.7	9.2	10.5	9.5
3	H027	9.2	9.2	11.7	10.8	9.2	11.3
4	A002	8.4	8.4	13.3	18.7	8.4	16.0
5	W030	6.4	5.8	8.1	12.1	6.1	10.1
6	M130	9.3	9.4	20.4	13.4	9.4	16.9
					Mean	**8.23**	**12.62**
					SD	**1.87**	**3.11**
					paired t	**0.0248**	

Cellerity Code 070605B

cyberDERM RG-1 Evaporimeter

Day 4
(30 Minutes Post tape removal)

		Rx		No Rx		Pooled	
#	ID	Left	Right	Left	Right	Rx	No Rx
1	D082	6.1	5.9	32.4	22.0	6.0	27.2
2	W011	11.1	11.8	9.4	10.5	11.4	9.9
3	H027	7.0	8.2	11.7	13.9	7.6	12.8
4	A002	7.9	10.6	40.5	40.3	9.2	40.4
5	W030	8.2	8.2	17.7	28.8	8.2	23.3
6	M130	10.7	15.6	34.5	20.5	13.2	27.5
					Mean	**9.27**	**23.51**
					SD	**2.63**	**11.08**
					paired t	**0.0292**	

Cellerity Code 070605B

cyberDERM RG-1 Evaporimeter

Day 5
(30 Minutes Post tape removal)

		Rx		No Rx		Pooled	
#	ID	Left	Right	Left	Right	Rx	No Rx
1	D082	7.6	9.2	33.7	44.0	8.4	38.8
2	W011	12.1	10.4	17.2	17.5	11.3	17.3
3	H027	8.2	9.8	13.3	25.7	9.0	19.5
4	A002	12.2	14.8	58.1	58.2	13.5	58.1
5	W030	13.0	13.0	56.2	59.9	13.0	58.1
6	M130	16.1	28.8	57.6	53.7	22.5	55.7
					Mean	12.94	41.26
					SD	5.10	19.11
					paired t	0.0088	

Cellerity Code 070605B

Appendix G: Chromameter a* Data

Decoded & Sorted Data

cyberDERM S06-19

Minolta Chromameter a* Values

Baseline - Day 1

		Rx		No Rx		Pooled	
#	ID	Left	Right	Left	Right	Rx	No Rx
1	D082	6.6	7.3	6.4	7.1	6.9	6.8
2	W011	7.6	7.1	7.4	8.2	7.4	7.8
3	H027	9.0	10.1	9.6	8.4	9.6	9.0
4	A002	11.6	10.6	11.7	11.1	11.1	11.4
5	W030	8.3	9.7	10.0	8.9	9.0	9.4
6	M130	7.2	7.2	8.1	7.6	7.2	7.8
					Mean	8.53	8.70
					SD	1.65	1.63
					paired t	0.3904	

Cellerity Code 070605B

Minolta Chromameter a* Values

Day 2
(30 Minutes Post tape removal)

		Rx		No Rx		Pooled	
#	ID	Left	Right	Left	Right	Rx	No Rx
1	D082	6.5	5.5	7.2	6.9	6.0	7.1
2	W011	10.5	7.3	11.1	10.5	8.9	10.8
3	H027	9.1	10.4	11.4	10.3	9.7	10.8
4	A002	10.1	10.4	11.5	13.1	10.2	12.3
5	W030	9.0	9.4	11.1	8.1	9.2	9.6
6	M130	6.8	8.7	8.1	7.3	7.7	7.7
					Mean	**8.63**	**9.70**
					SD	**1.54**	**2.02**
					paired t	**0.0248**	

Cellerity Code 070605B

Minolta Chromameter a* Values

Day 3
(30 Minutes Post tape removal)

		Rx		No Rx		Pooled	
#	ID	Left	Right	Left	Right	Rx	No Rx
1	D082	6.6	7.1	8.5	7.4	6.8	8.0
2	W011	9.3	7.5	13.8	11.7	8.4	12.8
3	H027	7.5	8.7	9.2	8.9	8.1	9.1
4	A002	11.5	13.0	14.3	12.6	12.3	13.5
5	W030	10.0	10.0	12.9	8.9	10.0	10.9
6	M130	7.8	8.5	9.6	9.6	8.2	9.6
					Mean	8.95	10.62
					SD	1.91	2.16
					paired t	0.0282	

Cellerity Code 070605B

Minolta Chromameter a* Values

Day 4
(30 Minutes Post tape removal)

		Rx		No Rx		Pooled	
#	ID	Left	Right	Left	Right	Rx	No Rx
1	D082	6.1	5.2	7.4	6.8	5.7	7.1
2	W011	10.9	8.5	16.3	16.6	9.7	16.5
3	H027	8.1	10.5	11.3	8.9	9.3	10.1
4	A002	10.9	10.5	14.4	12.8	10.7	13.6
5	W030	9.5	12.0	13.6	12.5	10.8	13.1
6	M130	9.6	12.0	9.3	10.5	10.8	9.9
					Mean	**9.48**	**11.71**
					SD	**1.98**	**3.32**
					paired t	**0.0896**	

Cellerity Code 070605B

Minolta Chromameter a* Values

Day 5
(30 Minutes Post tape removal)

		Rx		No Rx		Pooled	
#	ID	Left	Right	Left	Right	Rx	No Rx
1	D082	10.3	9.1	10.0	9.8	9.7	9.9
2	W011	16.6	9.7	17.5	17.9	13.2	17.7
3	H027	8.7	10.3	12.5	14.2	9.5	13.3
4	A002	13.2	14.3	15.6	14.6	13.8	15.1
5	W030	11.7	12.1	20.4	16.2	11.9	18.3
6	M130	12.2	15.0	12.1	13.9	13.6	13.0
					Mean	**11.94**	**14.55**
					SD	**1.93**	**3.15**
					paired t	**0.0642**	

Cellerity Code 070605B

Decoded & Sorted Data

cyberDERM S06-19

DermaLab® Skin Sensor
Onset

Baseline - Day 1

		Rx		No Rx		Pooled	
#	ID	Left	Right	Left	Right	Rx	No Rx
1	D082	43.27	35.34	39.54	45.42	39.31	42.48
2	W011	25.09	8.07	19.62	31.23	16.58	25.43
3	H027	69.15	58.00	68.67	60.96	63.58	64.82
4	A002	28.10	23.39	29.02	13.80	25.75	21.41
5	W030	44.33	34.49	28.84	40.08	39.41	34.46
6	M130	22.93	19.93	16.61	23.55	21.43	20.08
					Mean	**34.34**	**34.78**
					SD	**17.09**	**16.99**
					paired t	**0.8441**	

Cellerity Code 070605B

DermaLab® Skin Sensor
Onset

Day 2
(30 Minutes Post tape removal)

		Rx		No Rx		Pooled	
#	ID	Left	Right	Left	Right	Rx	No Rx
1	D082	28.10	34.67	20.54	25.52	31.39	23.03
2	W011	18.76	24.73	16.85	12.51	21.75	14.68
3	H027	34.37	22.96	27.30	24.78	28.67	26.04
4	A002	20.42	16.81	14.58	9.11	18.62	11.85
5	W030	35.41	19.32	22.81	32.05	27.37	27.43
6	M130	22.83	25.89	11.88	12.55	24.36	12.22
					Mean	**25.36**	**19.21**
					SD	**4.71**	**7.11**
					paired t	**0.0175**	

Cellerity Code 070605B

DermaLab® Skin Sensor
Onset

Day 3
(30 Minutes Post tape removal)

		Rx		No Rx		Pooled	
#	ID	Left	Right	Left	Right	Rx	No Rx
1	D082	26.81	31.73	10.48	7.64	29.27	9.06
2	W011	15.08	10.28	12.98	10.04	12.68	11.51
3	H027	27.60	20.48	21.21	19.49	24.04	20.35
4	A002	13.04	17.22	2.61	2.24	15.13	2.43
5	W030	15.44	17.90	9.42	7.48	16.67	8.45
6	M130	14.83	25.71	3.52	7.10	20.27	5.31
					Mean	**19.68**	**9.52**
					SD	**6.17**	**6.18**
					paired t	**0.0178**	

Cellerity Code 070605B

DermaLab® Skin Sensor
Onset

Day 4
(30 Minutes Post tape removal)

		Rx		No Rx		Pooled	
#	ID	Left	Right	Left	Right	Rx	No Rx
1	D082	11.76	8.81	1.68	1.86	10.29	1.77
2	W011	20.30	21.96	7.34	16.92	21.13	12.13
3	H027	21.16	28.40	17.10	12.68	24.78	14.89
4	A002	14.86	11.32	0.64	1.50	13.09	1.07
5	W030	18.02	12.02	4.40	2.44	15.02	3.42
6	M130	27.30	17.77	2.66	5.06	22.54	3.86
					Mean	**17.81**	**6.19**
					SD	**5.81**	**5.83**
					paired t	**0.0006**	

Cellerity Code 070605B

DermaLab® Skin Sensor
Onset

Day 5
(30 Minutes Post tape removal)

		Rx		No Rx		Pooled	
#	ID	Left	Right	Left	Right	Rx	No Rx
1	D082	10.30	20.91	1.37	1.37	15.61	1.37
2	W011	23.73	20.24	6.35	10.78	21.99	8.57
3	H027	35.84	17.35	12.32	10.40	26.60	11.36
4	A002	9.91	5.12	0.46	0.64	7.52	0.55
5	W030	20.17	13.53	3.97	1.75	16.85	2.86
6	M130	10.04	3.89	2.66	2.04	6.97	2.35
					Mean	**15.92**	**4.51**
					SD	**7.78**	**4.39**
					paired t	**0.0015**	

Cellerity Code 070605B

DermaLab® Skin Sensor
Max

Baseline - Day 1

		Rx		No Rx		Pooled	
#	ID	Left	Right	Left	Right	Rx	No Rx
1	D082	47.12	53.35	49.73	50.40	50.24	50.07
2	W011	41.13	27.50	25.52	40.38	34.32	32.95
3	H027	71.35	60.40	69.69	65.33	65.88	67.51
4	A002	35.59	29.02	40.46	23.55	32.31	32.01
5	W030	51.94	48.56	43.27	50.40	50.25	46.84
6	M130	31.05	23.68	23.06	29.46	27.37	26.26
					Mean	**43.39**	**42.60**
					SD	**14.57**	**15.27**
					paired t	**0.2989**	

Cellerity Code 070605B

DermaLab® Skin Sensor
Max

Day 2
(30 Minutes Post tape removal)

		Rx		No Rx		Pooled	
#	ID	Left	Right	Left	Right	Rx	No Rx
1	D082	31.60	41.74	25.39	32.95	36.67	29.17
2	W011	30.62	37.57	23.68	21.73	34.10	22.71
3	H027	39.83	31.72	31.13	27.87	35.78	29.50
4	A002	23.49	25.52	24.10	14.59	24.51	19.35
5	W030	22.04	28.84	29.45	36.09	25.44	32.77
6	M130	26.62	30.68	16.36	20.97	28.65	18.67
					Mean	**30.86**	**25.36**
					SD	**5.35**	**5.91**
					paired t	**0.1005**	

Cellerity Code 070605B

DermaLab® Skin Sensor
Max

Day 3
(30 Minutes Post tape removal)

		Rx		No Rx		Pooled	
#	ID	Left	Right	Left	Right	Rx	No Rx
1	D082	32.40	34.37	15.01	13.97	33.39	14.49
2	W011	26.38	21.77	20.18	18.16	24.08	19.17
3	H027	35.48	31.11	24.90	22.94	33.30	23.92
4	A002	18.95	22.63	7.14	6.61	20.79	6.88
5	W030	23.25	24.59	14.77	12.93	23.92	13.85
6	M130	20.91	33.09	9.73	13.54	27.00	11.64
					Mean	**27.08**	**14.99**
					SD	**5.23**	**5.93**
					paired t	**0.0019**	

Cellerity Code 070605B

DermaLab® Skin Sensor
Max

Day 4
(30 Minutes Post tape removal)

		Rx		No Rx		Pooled	
#	ID	Left	Right	Left	Right	Rx	No Rx
1	D082	21.42	14.77	5.61	6.29	18.10	5.95
2	W011	27.30	29.94	11.88	20.17	28.62	16.03
3	H027	28.03	33.52	21.59	15.92	30.78	18.76
4	A002	21.89	15.26	3.40	4.63	18.58	4.02
5	W030	22.47	19.62	8.99	6.84	21.05	7.92
6	M130	31.98	19.07	6.66	8.93	25.53	7.80
					Mean	**23.77**	**10.08**
					SD	**5.33**	**5.91**
					paired t	**0.0000**	

Cellerity Code 070605B

DermaLab® Skin Sensor
Max

Day 5
(30 Minutes Post tape removal)

		Rx		No Rx		Pooled	
#	ID	Left	Right	Left	Right	Rx	No Rx
1	D082	16.63	25.64	4.88	4.69	21.14	4.79
2	W011	28.11	30.13	11.96	17.66	29.12	14.81
3	H027	45.89	21.22	18.63	14.04	33.56	16.34
4	A002	16.05	9.67	2.78	3.16	12.86	2.97
5	W030	22.87	20.60	8.31	4.99	21.74	6.65
6	M130	18.33	10.55	6.71	6.05	14.44	6.38
					Mean	**22.14**	**8.66**
					SD	**8.07**	**5.54**
					paired t	**0.0003**	

Cellerity Code 070605B

DermaLab® Skin Sensor
Charge

Baseline - Day 1

		Rx		No Rx		Pooled	
#	ID	Left	Right	Left	Right	Rx	No Rx
1	D082	0.96	5.62	2.59	1.41	3.29	2.00
2	W011	5.68	5.69	2.04	3.44	5.68	2.74
3	H027	0.63	0.48	0.28	1.23	0.55	0.75
4	A002	2.04	2.03	4.00	3.32	2.03	3.66
5	W030	2.01	4.38	3.95	3.38	3.19	3.66
6	M130	2.57	1.01	1.88	1.43	1.79	1.65
					Mean	**2.76**	**2.41**
					SD	**1.75**	**1.16**
					paired t	**0.6148**	

Cellerity Code 070605B

DermaLab® Skin Sensor
Charge

Day 2
(30 Minutes Post tape removal)

		Rx		No Rx		Pooled	
#	ID	Left	Right	Left	Right	Rx	No Rx
1	D082	1.18	1.88	1.59	2.11	1.53	1.85
2	W011	3.46	3.99	2.01	2.56	3.72	2.28
3	H027	1.32	2.48	1.01	1.11	1.90	1.06
4	A002	0.92	2.68	2.67	1.71	1.80	2.19
5	W030	1.54	2.50	2.03	1.07	2.02	1.55
6	M130	1.16	1.28	1.45	2.36	1.22	1.90
					Mean	**2.03**	**1.80**
					SD	**0.88**	**0.45**
					paired t	**0.5348**	

Cellerity Code 070605B

DermaLab® Skin Sensor
Charge

Day 3
(30 Minutes Post tape removal)

		Rx		No Rx		Pooled	
#	ID	Left	Right	Left	Right	Rx	No Rx
1	D082	1.61	0.85	1.49	1.73	1.23	1.61
2	W011	3.27	3.30	2.10	2.37	3.28	2.23
3	H027	2.22	3.12	1.03	0.91	2.67	0.97
4	A002	1.66	1.21	1.45	1.50	1.43	1.47
5	W030	2.22	1.89	1.55	1.57	2.05	1.56
6	M130	1.88	1.82	1.99	2.14	1.85	2.06
					Mean	**2.08**	**1.65**
					SD	**0.77**	**0.45**
					paired t	**0.2472**	

Cellerity Code 070605B

DermaLab® Skin Sensor
Charge

Day 4
(30 Minutes Post tape removal)

		Rx		No Rx		Pooled	
#	ID	Left	Right	Left	Right	Rx	No Rx
1	D082	3.12	1.99	1.31	1.43	2.55	1.37
2	W011	2.16	2.51	1.47	0.89	2.33	1.18
3	H027	2.33	1.19	1.04	0.93	1.76	0.98
4	A002	1.99	1.15	0.87	0.97	1.57	0.92
5	W030	1.04	2.28	1.39	1.42	1.66	1.41
6	M130	1.25	0.53	1.25	1.21	0.89	1.23
					Mean	**1.79**	**1.18**
					SD	**0.59**	**0.20**
					paired t	**0.0494**	

Cellerity Code 070605B

DermaLab® Skin Sensor
Charge

Day 5
(30 Minutes Post tape removal)

		Rx		No Rx		Pooled	
#	ID	Left	Right	Left	Right	Rx	No Rx
1	D082	2.20	1.33	1.13	1.06	1.77	1.09
2	W011	1.18	2.91	1.80	2.24	2.04	2.02
3	H027	2.88	1.11	2.00	0.90	1.99	1.45
4	A002	1.89	1.43	0.78	0.85	1.66	0.81
5	W030	0.95	2.30	1.37	1.05	1.62	1.21
6	M130	2.57	2.13	1.23	1.28	2.35	1.26
					Mean	**1.90**	**1.30**
					SD	**0.28**	**0.41**
					paired t	**0.0103**	

Cellerity Code 070605B

Appendix I: Self-Assessment Data

Decoded & Sorted Data **cyberDERM S06-19**

SELF-ASSESSMENT OF DISCOMFORT/PAIN

[Scale: 0 = No difference to 3 = Dramatically more discomfort/pain]

Day 2

		Rx		No Rx		Pooled		
#	ID	Left	Right	Left	Right	Rx	No Rx	
1	D082	0	3	0	2	1.5	1	
2	W011	0	**0**	1	0	0	0.5	*
3	H027	*	0	0	*	0	0	
4	A002	0	1	0	1	0.5	0.5	
5	W030	*	*	*	*	*	*	
6	M130	**0**	**0**	3	3	0	3	*
					Mean	**0.40**	**1.00**	
					SD	**0.65**	**1.17**	
					paired t	**0.3883**		

A = Cellerity Code 070605B

* 2 W011: 3/4 of RL (Rx site) tape was not adhered to site.

3 H027: The tape fell off of LL (Rx site). LL & RL self-assessment data not applicable.

5 W030: Panelist applied additional tapes over sites and self-assessment data was not applicable.

6 M130: Panelist applied additional tape to edge of RU & LL (both Rx sites).

SELF-ASSESSMENT OF DISCOMFORT/PAIN

[Scale: 0 = No difference to 3 = Dramatically more discomfort/pain]

Day 3

		Rx		No Rx		Pooled	
#	ID	Left	Right	Left	Right	Rx	No Rx
1	D082	0	1	0	1	0.5	0.5
2	W011	0	0	1	1	0	1
3	H027	0	0	1	1	0	1
4	A002	0	1	0	1	0.5	0.5
5	W030	0	1	0	1	0.5	0.5
6	M130	0	0	1	1	0	1
					Mean	0.25	0.75
					SD	0.27	0.27
					paired t	0.0756	

A = Cellerity Code 070605B

SELF-ASSESSMENT OF DISCOMFORT/PAIN

[Scale: 0 = No difference to 3 = Dramatically more discomfort/pain]

Day 4

		Rx		No Rx		Pooled	
#	ID	Left	Right	Left	Right	Rx	No Rx
1	D082	0	0	1	1	0	1
2	W011	0	0	1	0	0	0.5
3	H027	*	*	*	*	*	*
4	A002	0	1	0	1	0.5	0.5
5	W030	0	1	0	1	0.5	0.5
6	M130	0	1	0	3	0.5	1.5
					Mean	**0.30**	**0.80**
					SD	**0.27**	**0.45**
					paired t	**0.0890**	

A = Cellerity Code 070605B

* 3 H027: Tape fell off of RU & LL (both Rx sites). Self-assessment data not applicable.

SELF-ASSESSMENT OF DISCOMFORT/PAIN

[Scale: 0 = No difference to 3 = Dramatically more discomfort/pain]

Day 5

		Rx		No Rx		Pooled	
#	ID	Left	Right	Left	Right	Rx	No Rx
1	D082	0	0	2	2	0	2
2	W011	0	0	1	1	0	1
3	H027	*	0	1	*	0	1
4	A002	0	0	1	1	0	1
5	W030	0	1	0	1	0.5	0.5
6	M130	0	1	0	3	0.5	1.5
					Mean	0.17	1.17
					SD	0.26	0.52
					paired t	0.0117	

A = Cellerity Code 070605B

* 3 H027: Tape fell off of LL (Rx site). LL & RL self-assessment data not applicable.

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RECORD RETENTION FORM

cyberDERM #: Sa6-19 SPONSOR #: _____

STUDY TITLE: 5 Day Pilot Topical Calcium Glycerophosphate - Adhesive Dressing

SPONSOR: AK Pharma, Inc

ADDRESS: 6840 Old Egg Harbor Road
Pleasantville NJ

CONTACT: Charles L Bove ACRP DATE: 21 June 2006

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 this form which accompanies the final report. **It is the sole responsibility of the Sponsor to ensure that the completed form is promptly returned to cyberDERM Clinical Studies.**

☐ I authorize the study records to be destroyed:

Printed Name of Sponsor	Signature of Sponsor	Date

☒ I request the study records to be forwarded to:

Name: AK Pharma

Address: (same as above)

Telephone: _____

Method of Shipping: ☐ UPS (acct. #)_____ ☐ FedEx (acct. #)_____

☒ Other Pick-up

Printed Name of Sponsor	Signature of Sponsor	Date
AK Pharma/Charles L-Bove	Charles L Bove	6/28/06

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To carol Cesari
6/28/06