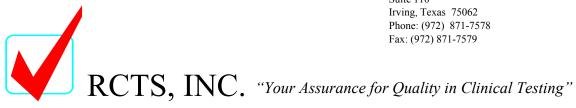
RCTS, Inc. Clinical Study Report

RCTS Study No.: 1837 Sponsor: Senetek, PLC

> 800 W. Airport Freeway Suite 110 Irving, Texas 75062

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## **RCTS STUDY NUMBER: 1837**

## A CLINICAL STUDY OF TOPICAL ZEATIN (0.10%, 0.025%) FOR IMPROVING THE APPEARANCE OF PHOTODAMAGED SKIN

Sponsor:	Senetek PLC 620 Airpark Road				
	Napa, CA 94558				
Sponsor's	Frank Massino Phone: 707-226-3900 ex	kt 109			
Representative:	E-Mail: Frank@senetek.				
Document Type:	Clinical Study Report				
Study Materials:	Zeatin (0.10%; Group A) Zeatin (0.025%; Group B)				
Type of Study:	Efficacy (12 Weeks)				
Medical Investigator:	Ponciano D. Cruz, Jr., MD Board Certified Dermatologist				
Sub Investigator:	Barry T. Reece, MS, MBA Vice President/Managing Partner, RCTS, Inc.				
Testing Facility:	RCTS, Inc. 800 W. Airport Freeway, #110 Irving, TX 75062				
First Subject Enrolled:	Completed:  Last Subject Completed:  12-July-2005				
Document Status:	Final Date: 06-September-2005				

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## **SIGNATURE**

I, the undersigned, certify that this document accurately describes the conduct and results of this investigation.

## Medical Investigator:

Ponciano D. Cruz, MD Medical Investigator Board Certified Dermatologist

signature

9-6-85

## Sub-Investigator:

Barry T. Reece, MS, MBA Sub-Investigator Vice President/Managing Partner RCTS, Inc.

signature

date

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#### STATEMENT OF QUALITY ASSURANCE

This study was conducted in accordance with the intent and purpose of Good Clinical Practice regulations described in CFR 21, Part 50 (Protection of Human Subjects - Informed Consent), Part 56 (Institutional Review Boards) and the International Conference on Harmonization -Good Clinical Practice Guidelines, May 9, 1997, Federal Register.

For Purposes of this clinical study:

Informed Consent was obtained.
Informed Consent was not obtained.
An IRB review was not required.
An IRB was convened and approval to conduct the proposed clinical research was granted.

This study report has been reviewed to ensure that it correctly describes the methods of testing and that the reported results accurately reflect the data obtained during the clinical study (RCTS Panel No. 1837; RCTS Test Article Code Nos.: 1837.7906, 1837.7907 and 1837.7908).

In addition, the Quality Assurance Department conducted in-study inspections on a random sampling of subjects during the study. Written status reports of inspections and findings were submitted to Management.

Date of Inspection	Type of Inspection	Date Reported to Management
4/04/05	Critical Phase Inspection: Study organization and management, screening procedures, informed consendermatologic medication and skin care/product history information.	
4/11/05	Critical Phase Inspection: Day 1 processincluding study organization and management and Self Evaluations, photograps and NOVA DPM measurements and disproduct and diary.	gement, hy, baseline TEWL

RCTS, Inc. Clinical Study Report Sponsor: Senetek, PLC	CONFIDENTIAL	Page 4 of 226 RCTS Study No.: 1837	
4/26/05	Critical Phase Inspection: Week 2 activities	4/26/05	
5/13/05	Critical Phase Inspection: Week 4 activities	5/17/05	
6/10/05	Critical Phase Inspection: Week 8 activities	6/13/05	
7/5/05	Critical Phase Inspection: Week 12 activities	7/5/05	
7/18/05	Review of Data Tables	8/1/05	
08/29/05	Review of Draft Final Report	8/30/05	
08/30/05	Review of Final Report	08/31/05	
09/02/05	Final Review of Final Report	09/06/05	

On the basis of the audits conducted, this report is considered to be a true and accurate reflection of the source data.

Laura O'Farrell, BS

Quality Assurance

9.6.00

Date

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#### STUDY SYNOPSIS

Study Title: A 12-Week Efficacy Evaluation of Topical Zeatin (0.10%, 0.025%) for

Improving the Appearance of Photodamaged Skin

Sponsor: Sentek PLC

620 Airpark Road Napa, CA 94558

Sponsor's

Representative: Frank Massino, Chief Executive Officer

**Contract Research** 

Organization (CRO): RCTS, Inc.

800 W. Airport Freeway, Suite 110

Irving, TX 75062

**RCTS Study #:** 1837

**Study Site:** Single centre:

RCTS, Inc.

800 W. Airport Freeway, Suite 110

Irving, TX 75062

**Dates of Study:** 04-April-2005 to 12-July-2005

Type of Study: Efficacy (12 week)

**Study Objectives:** The primary objective of this study was to compare the efficacy and tolerance

of topical Zeatin (0.10% and 0.025%) when applied twice daily for 12 consecutive weeks for improving the clinical signs of age-related changes in photodamaged facial skin. Additionally, to determine the effects of the test articles on skin tolerance (irritation) and acne (inflammatory and non-

inflammatory acne lesions).

**Study Design:** This was a 12 week, double-blinded study designed to determine the efficacy

and tolerance of two concentrations (0.10% and 0.025%) of Zeatin.

Approximately fifty female subjects between 30 to 65 years of age with mild to moderate signs of photodamaged facial skin were enrolled into this study. Twenty-five subjects were assigned to a group/cell which evaluated Zeatin at a concentration of 0.10% and 25 subjects were assigned to a group/cell which evaluated Zeatin at a concentration of 0.025%. Subjects were instructed to apply the test products to their face twice daily, in the early morning and in the evening (approximately 1 hour before bedtime), for 12

consecutive weeks. Subjects were instructed to follow the morning application with the Sponsor provided sunscreen (SPF 30). At baseline and at 2, 4, 8 and 12 weeks the subjects' faces were evaluated by the Sub-

Investigator for the following:

• Skin aging, including observations on wrinkles (coarse and fine), roughness, mottled hyperpigmentation and overall severity of skin aging;

• Presence of Irritation (i.e., tolerance);

 Presence of Acne (i.e., acne lesion counts) and the Overall Severity of Acne; and Clinical Study Report RCTS Study No.: 1837 Sponsor: Senetek, PLC

• Global assessment of improvement of skin aging (2, 4, 8, and 12 week visits only).

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Additionally, the following instrumental measurements were taken on the cheeks of each subject at baseline and weeks 2, 4, 8 and 12:

- Transepidermal water loss (TEWL);
- Skin moisture measurements (NOVA DPM); and
- Standard clinical photographs.

Finally, each subject was asked to evaluate themselves at the 2, 4, 8 and 12 week visits to determine the improvement over baseline in the following parameters:

- Texture
- Blotchiness (brown spots)
- Skin Color
- Fine Wrinkles
- Overall Improvement

#### **Study Population:**

Healthy female subjects, aged 30 to 65 years, fulfilling all of the inclusion, and none of the exclusion, criteria were eligible for participation in the study. The target was to complete 25 evaluable subjects for each cell. Actual enrollment was 73 subjects, of which 57 (Cell 1 = 30; Cell 2 = 27) completed the study.

## Investigational Products:

All test articles were provided by Senetek PLC.

#### **Dosage and Frequency:**

Subjects were instructed to use the test article twice daily for 12 weeks according to the following instructions:

- Wash your face with a mild cleanser and dry completely prior to application of the product to your face;
- Apply a liberal amount of the product to your face in the early morning and about one hour before bedtime;
- In the morning, after the product has absorbed into the skin, apply the sunscreen that was provided to you to your face;
- Other than the product being provided to you, do not introduce any new products into your skin care regimen;
- Do not apply any topical medications to your face;
- Do not take any steroid or retinoid medications; and
- Do not apply the test article or makeup to your face the morning of a scheduled visit.

# Evaluation of Efficacy:

Efficacy was determined by the following methods after two, four, eight and twelve weeks of product use:

 Expert Evaluation [Cutaneous Signs of Skin Aging (Fine Wrinkles, Coarse Wrinkles, Roughness and Mottled Hyperpigmentation), Overall Severity of Skin Aging, Global Assessment of Improvement of Skin RCTS, Inc. Clinical Study Report

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> Aging, Skin Irritation, Overall Severity of Acne, Count of Individual Acne Lesions (Inflammatory, Non-Inflammatory and Total Acne Lesions)];

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- Subject's Self Evaluation (Skin Texture, Skin Color, Blotchiness Brown Spots, Fine Wrinkles and Overall Improvement);
- Effect of the treatments on Transepidermal Water Loss (TEWL);
- Effect of the treatments on Skin Capacitance (NOVA DPM, an indirect measure of skin moisturization); and
- Digital Photographs (left and right facial profiles, full facial photo, and close-up photos of the right and left peri-orbital area).

**Adverse Events:** 

All local and systemic adverse events observed by or reported to the investigators were evaluated. The intensity, duration and causal relationship to the investigational test articles were rated for all adverse events.

**Adverse Event Results:** 

During this study, 34 adverse events were recorded. One (1) of the adverse events was considered serious. The breakdown for adverse events is as follows:

Type of Adverse Event	Frequency of Adverse Events
Blemishes (breakout)	11
Headache	1
Peeling/Sloughing	1
Swelling	1
Watery eye	1
Clogged pores	1
Hand Surgery (considered a serious adverse event unrelated to test article use)	1
Tightness	6
Redness	3
Redness with bumps	1
Dryness	2
Rash/bumps	1
Eyes Burning	2
Bronchitis	1
Bump	1

The relationship of the event to the test article can be found in Appendix 2, Data Listing 10.

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#### **Conclusions:**

Under the conditions of this study:

#### **Skin Aging**

#### • Fine Wrinkles

#### Sub-Investigator's Assessment of Skin Aging for Fine Wrinkles

 The Sub-Investigator noticed a significant improvement, relative to baseline, in the appearance of Fine Wrinkles for both Groups A and B after 4, 8 and 12 weeks of test article use. No significant difference in the appearance of Fine Wrinkles was observed at Week 2, regardless of the test group.

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 When comparing the Fine Wrinkle data generated by Group A to that generated by Group B, no significant difference between the groups was observed at any time point.

### Subject's Self Assessment for Fine Wrinkles

- Subjects in both Groups A and B noticed a significant improvement, relative to baseline, in the appearance of Fine Wrinkles at all time points.
- When comparing the changes observed in both groups, there was no significant difference in the data generated between Groups A and B at any time point.

#### • Coarse Wrinkles

#### Sub-Investigator's Assessment of Skin Aging for Coarse Wrinkles

- The Sub-Investigator noticed a significant improvement, relative to baseline, in the appearance of Coarse Wrinkles for subjects assigned to Group B values after 12 weeks of test article use. No other significant differences were observed at any time point.
- Subjects in Group A did not show a significant change, relative to baseline, in Coarse Wrinkle values; however, it was highly suggestive that reduction in Coarse Wrinkle values was observed at Week 12.
- When comparing the Coarse Wrinkle data generated by Group A to that generated by Group B, no significant difference between the groups was observed at any time point.

#### Roughness

#### Sub-Investigator's Assessment of Skin Aging for Roughness

- The Sub-Investigator noticed a significant improvement, relative to baseline, in the skin's Roughness for both Groups A and B at all time points.
- When comparing the Roughness data generated by Group A
  to that generated by Group B, no significant difference
  between the groups was observed at any time point.
  However, the data were highly suggestive that subjects in
  Group A had a greater improvement in Roughness values,
  relative to Group B, at the Week 12 time point.

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#### Subject's Self Assessment of Skin Texture

- Subjects in both Groups A and B noticed a significant improvement, relative to baseline, in their skin's texture at all time points.
- When comparing the Skin Texture data generated by Group A to that generated by Group B, no significant difference between the groups was observed at any time point.

#### · Overall Severity of Skin Aging

# <u>Sub-Investigator's Assessment of Skin Aging for Overall Severity of Skin Aging</u>

- The Sub-Investigator noticed a significant improvement, relative to baseline, in the Overall Severity of Skin Aging values for both Groups A and B at all time points.
- When comparing the Overall Severity of Skin Aging data generated by Group A to that generated by Group B, no significant difference between the groups was observed at any time point.

#### Global Assessment of Improvement

#### Sub-Investigator's Global Assessment of Improvement of Skin Aging

- The Sub-Investigator noticed a significant improvement, relative to baseline, in the Global Assessment of Improvement in Skin Aging values for both Groups A and B at all time points.
- When comparing the Global Assessment of Improvement in Skin Aging data generated by Group A to that generated by Group B, no significant difference between the groups was observed at any time point.

#### Subject's Self Assessment of Overall Improvement

- Subjects in both Groups A and B noticed a significant improvement, relative to baseline, in their skin at all time points.
- When comparing the Overall Improvement data generated by Group A to that generated by Group B, no significant difference between the groups was observed at any time point.

#### **Skin Color**

# <u>Sub-Investigator's Assessment of Skin Aging for Mottled Hyperpigmentation</u>

- The Sub-Investigator detected a significant improvement in Mottled Hyperpigmentation for subjects in Group A at Weeks 4, 8 and 12.
- The Sub-Investigator detected a significant improvement in Mottled Hyperpigmentation for subjects in Group B at all time points.
- It was highly suggestive that Group B performed better than Group A at Week 4.

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When comparing the Mottled Hyperpigmentation data generated by Group A to that generated by Group B, It was highly suggestive that Group B performed better than Group A at Week 4.

#### Subject's Self Assessment of Blotchiness – Brown Spots

- Subjects in both Groups A and B noticed a significant improvement, relative to baseline, in the Blotchiness-Brown Spots of their skin at Weeks 8 and 12.
- When comparing the Blotchiness-Brown Spots data generated by Group A to that generated by Group B, no significant difference between the groups was observed at any time point.

#### Subject's Self Assessment of Skin Color

- Subjects in both Groups A and B noticed a significant improvement, relative to baseline, in their Skin's Color at all time points.
- When comparing the Skin Color data generated by Group A to that generated by Group B, It was highly suggestive that Group B performed better than Group A at Weeks 4 and 8.

#### Skin Barrier Properties (TEWL) Moisturization (NOVA DPM)

#### **TEWL Measurements**

- Subjects in Group A produced significantly elevated TEWL values, relative to baseline, at Weeks 2 and 12.
- There was no significant difference in TEWL values, relative to baseline, detected for subjects in Group B at any time point.
- It was highly suggestive that subjects in Group B had lower TEWL values than subjects in Group A at the Week 8 time point.

#### **NOVA DPM Measurements**

- Subjects in Group A had significantly increased NOVA DPM values (an indirect measure of skin moisturization), relative to baseline, at Week 8.
- Group B had significantly increased NOVA DPM values at Weeks 8 and 12.
- There was no significant difference between Groups A and B at any time point.

#### Safety

## Sub-Investigator's Assessment of Skin Irritation

- The Sub-investigator detected a significant improvement, relative to baseline, in skin irritation for subjects in Group A at Weeks 4. 8 and 12.
- The Sub-investigator detected a significant improvement, relative to baseline, in skin irritation for subjects in Group B at all time points.

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> There was no significant difference between Groups A and B at any time point.

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#### Sub-Investigator's Assessment of Overall Severity of Acne

- Group A had significantly improved (reduced) values, relative to baseline, for Overall Severity of Acne at Week 8.
- No significant difference, relative to baseline, in the Overall Severity of Acne was observed at any time point for subjects in Group B.
- There was no significant difference between Groups A and B at any time point.

#### Count of Individual Acne Lesions

### **Inflammatory Acne Lesions**

- There were no significant changes in the inflammatory acne lesion counts, relative to baseline, for either group regardless of the time point.
- There was no significant difference between Groups A and B at any time point.

#### Non-Inflammatory Acne Lesions

- Group A had significantly decreased Non-Inflammatory Acne Lesion counts at Weeks 2, 8 and 12, relative to baseline.
- Subjects in Group B did not show a significant change, relative to baseline, in the presence of Non-Inflammatory Acne Lesions at any time point.
- Group A performed significantly better than Group B at decreasing the number of Non-Inflammatory Acne Lesions at Week 8.

#### Total Inflammatory & Non-Inflammatory Acne Lesions

- Group A had significantly lower Total Acne Lesion counts at Weeks 8 and 12, relative to baseline.
- Subjects in Group B did not show a significant change, relative to baseline, in the Total Inflammatory and Non-Inflammatory Acne Lesion counts at any time point.
- Group A performed significantly better than Group B at decreasing the number of Total Acne Lesion counts at Week 8.

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Therefore, in general, the test articles (0.10% and 0.025% Zeatin) performed at parity and helped to improve:

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- The appearance of Fine Wrinkles (Weeks 4, 8 and 12)
- Coarse Wrinkles (Group B at Week 12)
- Roughness (at all time points)
- Overall Severity of Skin Aging (at all time points)
- Mottled Hyperpigmentation (Group A at Weeks 4, 8 and 12; Group B at all time points)
- Blotchiness-Brown Spots (Weeks 8 and 12)
- Overall Skin Color (at all time points)

Additionally, the test articles were well tolerated with both the Sub-Investigator and Subjects not detecting any significant increase in irritation. In fact, the Sub-Investigator detected a significant improvement in the appearance of irritation, relative to baseline, after 4, 8 and 12 weeks of test article use (subjects in Group B actually showed a reduction in irritation at Week 2 as well).

Regarding the effect of the test articles on acne counts, while the test articles performed, in general, at parity (no significant difference between subjects who used the Zeatin at 0.10% and those that used Zeatin at 0.025%), subjects using Zeatin at 0.10% seemed to show a greater reduction, relative to baseline, in the presence of non-inflammatory and total acne lesions.

Finally, neither test article was effective at reducing TEWL. In fact, subjects in Group A (Zeatin at 0.10%) showed elevated TEWL values at Weeks 2 and 12. However, regarding NOVA DPM measurements, subjects in Group B (Zeatin at 0.025%) showed elevated NOVA DPM values at Weeks 8 and 12. Subjects in Group A showed elevated NOVA DPM values at Week 8 only.

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## STUDY PERSONNEL

## Key Senetek PLC Personnel:

Chief Executive Officer	Frank Massino
-------------------------	---------------

## Key RCTS, Inc., Personnel:

Medical Investigator	Ponciano D. Cruz, Jr., MD Board Certified Dermatologist
Sub-Investigator	Barry T. Reece, MS, MBA Vice President/Managing Partner RCTS, Inc.
Clinical Research Coordinator	Dorsi Simmons, BS
Quality Assurance	Laura O'Farrell, BS

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### **GLOSSARY OF ABBREVIATIONS AND TERMS**

AΕ Adverse event

ANOVA Analysis of Variance

**Arbitrary Units** ΑU

Code of Federal Regulations **CFR** 

Dermal Phase Meter DPM **GCP** Good Clinical Practice

International Conference on Harmonization **ICH** 

**IRB** Institutional Review Board Transepidermal Water Loss **TEWL** 

Quality Assurance QA

**RCTS** RCTS, Inc.

SAE Serious adverse event

Standard Operating Procedure SOP

Sun Protection Factor SPF VAS Visual Analog Scale

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#### 1 ETHICS AND GOOD CLINICAL PRACTICE

#### 1.1 Institutional Review Board

Prior to initiation of the study, the clinical study protocol (dated 03/17/05) and informed consent form were reviewed and approved on 03/28/2005 by an Institutional Review Board (IRB) operating in accordance with Title 21 of the Code of Federal Regulations (CFR), Part 56. Protocol amendment 1 was reviewed and approved on 07/15/2005. The clinical study site (RCTS, Inc.) and Principal Investigator were also approved by the IRB on 03/28/2005. The IRB that provided approval for all aspects of this study was the IntegReview Institutional Review Board. Further details on the IRB, including the IRB approval letter can be found in Appendix 1.2.

#### 1.2 ETHICAL CONDUCT OF THE STUDY

This study was carried out in compliance with the protocol and in accordance with RCTS, Inc.'s standard operating procedures (SOPs). These are designed to ensure adherence to Good Clinical Practices (GCPs), as described in:

- 1. International Conference on Harmonization (ICH) Harmonized Tripartite Guidelines for Good Clinical Practice 1996. Directive 91/507/EEC, The Rules Governing Medicinal Products in the European Community.
- 2. US 21 CFR dealing with clinical studies (including parts 50 and 56 concerning informed consent and IRB regulations).
- 3. Declaration of Helsinki, concerning medical research in humans (Recommendations Guiding Physicians in Biomedical Research Involving Human Subjects, Helsinki 1964, amended Tokyo 1975, Venice 1983, Hong Kong 1989, Somerset West 1996, Edinburgh, 2000).

The investigator agreed, when signing the protocol, to adhere to the instructions and procedures described in it, and thereby to adhere to the spirit of GCPs to which it conforms. A signed statement of Quality Assurance is included on Page 4.

#### 1.3 Subject Information and Consent

The investigator (or his designee) explained the nature of the study, its purpose and associated procedures, the expected duration and the potential benefits and risks of participation to each subject prior to her entry into the study (i.e., before procedures associated with selection for the study are performed). Each subject was provided a duplicate of the informed consent form, had ample opportunity to ask questions and was informed about the right to withdraw from the study at any time without any disadvantage and without having to provide reasons for this decision. No subject entered the study before her informed consent was obtained. A copy of the informed consent form presented for review and signature to all study subjects is provided in Appendix 1.3 of this report.

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#### 2 STUDY OBJECTIVES

Primary study objectives were as follows:

- 1) Observations by the sub-investigator to determine the improvement, relative to baseline, of wrinkles (coarse and fine), roughness, mottled hyperpigmentation, global assessment of overall severity and degree of improvement in skin aging as it relates to the face;
- 2) Subject self-assessment to determine the improvement of wrinkles, texture, blotchiness, color and perform a global assessment to document the overall improvement in their facial skin;
- 3) Effect of the treatment(s) on Transepidermal Water Loss (TEWL); and
- 4) Effect of the treatment(s) on Skin Capacitance (an indirect measure of skin moisturization).

Secondary study objectives were:

- 5) Observation by the sub-investigator for skin irritation and acne lesion counts; and
- 6) Subject self-assessment of skin tolerance.

#### 3 INVESTIGATIONAL PLAN

## 3.1 OVERALL STUDY DESIGN

This was a 12 week, double-blinded study designed to determine the efficacy and tolerance of two concentrations (0.10% and 0.025%) of Zeatin. Subjects were instructed to use the Zeatin (0.10%, 0.025%) cream twice a day for 12 weeks according to the instructions supplied to them. Evaluations occurred at baseline (prior to test article application) and after two, four, eight and twelve weeks of product use. At each visit the following measurements were performed:

- Sub-Investigator's Assessment of Cutaneous Signs of Skin Aging (Fine Wrinkles, Coarse Wrinkles, Roughness and Mottled Hyperpigmentation), Overall Severity of Skin Aging, Global Assessment of Improvement (2, 4, 8 and 12 week visits only), Skin Irritation, Overall Severity of Acne and a Count of Individual Acne Lesions (Inflammatory, Non-Inflammatory and Total Lesions);
- Subject's Self Assessment of Skin Texture, Skin Color, Blotchiness Brown Spots, Fine Wrinkles and Overall Improvement at the 2, 4, 8, and 12 week visits;
- Digital Photographs (left and right facial profiles, full facial photo, and close-up photos of the right and left peri-orbital area); and
- Instrumental Measurements (Transepidermal Water Loss and NOVA DPM).

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#### 3.2 DISCUSSION OF DESIGN

This was a 12 week, double-blinded study designed to determine the efficacy and tolerance of two concentrations (0.10% and 0.025%) of Zeatin. Fifty female subjects between the ages of 30 to 65 with mild to moderate signs of photodamaged facial skin were enrolled into this study. Twenty-five subjects were assigned to Group A which evaluated Zeatin at a concentration of 0.10% and 25 subjects were assigned to Group B which evaluated Zeatin at a concentration of 0.025%. Subjects applied the test products to their face twice daily, in the morning and in the evening (approximately 1 hour before bedtime), for 12 consecutive weeks. Subjects were instructed to follow the morning application with the Sponsor provided sunscreen (SPF 30). At baseline and after 2, 4, 8 and 12 weeks of test article application, the subjects' faces were evaluated by the sub-investigator for clinical signs of skin aging, including observations for wrinkles (coarse and fine), roughness, mottled hyperpigmentation, overall severity of skin aging, irritation, overall severity of acne and a count of individual acne lesions (inflammatory, noninflammatory lesions). Additionally at 2, 4, 8 and 12 weeks, the sub-investigator provided a global assessment of the overall improvement, relative to baseline, in skin aging. Furthermore, at each post-baseline visit, the subjects underwent a self assessment evaluation to determine the improvement in texture, blotchiness – brown spots, wrinkles and overall improvement. Finally, transepidermal water loss (TEWL) measurements, skin moisture measurements (NOVA DPM) and standard clinical photographs were taken at baseline and at weeks 2, 4, 8 and 12.

#### 3.3 STUDY PROCEDURES

## 3.3.1 Screening

Prior to study initiation, each subject was screened to ensure they met all of the inclusion, and none of the exclusion, criteria outlined in sections 3.4.1 and 3.4.2. Potential subjects were interviewed and examined by the Sub-Investigator or his designee to establish their eligibility for inclusion in the study. Subjects were given a full description of the nature and purpose of the study. If a subject was willing to participate, they had to provide written informed consent before proceeding with the study.

Screening procedures included the following activities for prospective participants:

- 1. Investigator, or designee, explaining the investigational study and eligibility requirements;
- 2. Subject signing an informed consent and photographic release form prior to any study-related procedures;
- 3. Recording of demographic information;
- 4. Subjects filling out a brief dermatologic, medication and skin care/cosmetic product history;
- 5. Administering a urine pregnancy test for those females of childbearing potential; and
- 6. Assigning a specific subject number to subjects admitted to the study.

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#### 3.3.2 Baseline Measurements

Upon arrival at the testing facility, qualified subjects were directed into an exam room where they were allowed to equilibrate for at least 15 minutes under controlled environmental conditions (70°F + 3°F; 45% + 10% relative humidity). During equilibration the subjects were interviewed regarding any changes to their medical history. Additionally, subjects were asked to provide a detailed account of all concomitant medications taken, and skin care products used on their face, since their screening visit. Subjects were also evaluated to ensure that no cuts, abrasions or other dermal deviations were present which might have prevented further participation on the clinical study. Following equilibration, each subject underwent a series of clinical measurements designed to assess the skin's overall condition (see 3.3.2.1 to 3.3.2.3).

#### 3.3.2.1 **Photography**

Digital photographs of both the left and right facial profiles (taken at an angle of 45 degrees) and a full face photo were taken of each subject using a Fuji S2 Pro digital camera attached to a Canfield Scientific VISIA CR Booth (Canfield Scientific, Fairfield, NJ). Photographs were taken under standard lighting, polarized lighting (crossed and parallel) and ultra violet lighting. Digital photographs were downloaded onto disks and were printed out and placed in a photo album.

Close-up digital photographs of both the left and right peri-orbital areas were taken using a digital camera (Fuji S2 Pro). The digital camera was fitted with a dual flash system and the subjects were placed in a facial positioning device (Canfield Scientific, New Jersey, USA). All photographs were stored on optical media until the end of the study. Digital photographs were downloaded onto disks and were printed out and placed in photo albums.

#### 3.3.2.2 **Sub-Investigator's Assessment of the Subjects' Faces**

At the Baseline (Day 1) visit the Sub-Investigator evaluated each subject's face for the presence of:

- Fine Wrinkles
- Coarse Wrinkles
- Roughness
- Mottled Hyperpigmentation

The Sub-Investigator used the following five-point scale to describe the above parameters:

0 = None

1 = Minimal

2 = Mild

3 = Moderate

4 = Severe

The Sub-Investigator evaluated the Overall Severity of Skin Aging using the 10 point scale below. The scale was an integrated assessment of all the signs of photoaging (wrinkles, roughness and mottled hyperpigmentation) previously evaluated.

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NONE	MILD			MODERATE			SEVERE		
0	1	2	3	4	5	6	7	8	9

Subjects with a baseline severity score greater than 6 were excluded from the study.

The Sub-Investigator proceeded to determine the baseline level of irritation present on the subjects' faces using the following four-point scale:

- 0: None
- 1: Mild
- 2: Moderate
- 3: Severe

In addition, individual acne lesions were counted on the subject's face and recorded on the subject's case report forms (CRF). The lesion counts were taken from the facial area: forehead, left and right cheeks, and chin above the jaw line (excluding the nose). The counts were added together to form three groups of lesion counts: inflammatory, non-inflammatory and total lesion counts. Open and closed comedones made up the non-inflammatory counts; papules and pustules made up the inflammatory counts and all of the lesions collectively composed the total lesion counts. The following are definitions of each lesion type counted:

- Open comedone A mass of sebaceous material that is impacted behind an open follicular orifice (blackhead).
- Closed comedone A mass of sebaceous material that is impacted behind a closed follicular orifice (whitehead).
- Papule A small, palpable, solid elevation less than 1 cm in diameter.
- Pustule A small, circumscribed elevation of the skin which contains yellow/yellowish-white exudates.

In addition to individual acne lesion counts, the overall severity of acne was determined using the same scale as described above for determining irritation.

#### 3.3.2.3 Instrumental Measurements

Following equilibration, Transepidermal Water Loss (TEWL) and Skin Capacitance Measurements (NOVA DPM) were taken at the center of both subjects' cheeks and recorded onto the subjects' CRF. TEWL measurements were taken in duplicate using a TEWA meter (Courage & Khazaka, Köln, Germany) and moisture measurements were taken in triplicate using the NOVA DPM 9003® (NOVA Technologies, Gloucester, MA, USA).

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## 3.3.2.4 Subjects' Test Article Use Instructions

Following baseline measurements, each subject was placed into one of two groups and provided with the test article and a sensitive skin sun block lotion. Subjects receiving the test article with 0.10% Zeatin were placed into Group A; subjects receiving the test article with 0.025% were placed into Group B. Subjects were instructed to use the test article and sunscreen in the following manner:

- 1. Wash your face with a mild cleanser and dry completely prior to application of the product to your face;
- 2. Apply a liberal amount of the product to your face in the early morning and about one hour before bedtime:
- 3. In the morning, after the product has absorbed into the skin, apply the sunscreen, which was provided to you, to your face. Avoid prolonged sun exposure;
- 4. Other than the product being provided to you, do not introduce any new products into your skin care regimen;
- 5. Do not apply any topical medications to your face;
- 6. Do not take any steroid or retinoid medications; and
- 7. Do not apply the test article or makeup to your face the morning of a scheduled visit.

Finally, all subjects were provided with a daily diary to record the dates and times of test article application and any observations or comments they felt pertinent to the study.

As an indication of compliance, weights of the test articles were determined at baseline and at all subsequent visits.

#### 3.3.3 Week 2, Week 4, Week 8 and Week 12 Visits

Subjects arriving after two, four, eight and twelve weeks of product use were directed into an environmentally controlled room  $(70^{\circ}\text{F} \pm 3^{\circ}\text{F}, 40\% \pm 15\% \text{ RH})$  where they were allowed to equilibrate for approximately 15 minutes. Following equilibration, the same measurements taken at baseline were repeated in the same manner with the following additions:

- Sub-Investigator's Assessment of Skin Aging: Global Assessment of Improvement; and
- Subject's Self Assessment (Skin Texture, Skin Color, Blotchiness Brown Spots, Fine Wrinkles and Overall Improvement).

The Sub-Investigator used the following six-point scale to describe the global improvement of the subject's skin relative to baseline:

- 1 = Excellent Improvement
- 2 = Marked Improvement
- 3 = Moderate Improvement
- 4 = Slight Improvement
- 5 = No Improvement
- 6 = Worse

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The Subjects used the following five-point scale to assess the change in Skin Texture, Skin Color, Blotchiness – Brown Spots, Fine Wrinkles and Overall Improvement:

- 1 = Much Improved
- 2 = Somewhat Improved
- 3 = No Change
- 4 = Somewhat Worse
- 5 = Much Worse

Subjects were also provided with a new daily diary at weeks 2, 4 and 8 to record the date and times of test article application and any observations or comments they felt pertinent to the study.

#### 3.3.4 Visit Schedule

The visit schedule and assessments are summarized in Text Table 3-1.

Text Table 3-1 Visit Schedule and Assessments

STUDY WEEK	0	2	4	8	12
Informed Consent	X				
Eligibility Criteria	X				
Dermatologic/Skin Care/Cosmetic Hx	X				
Laboratory Studies: Urine Pregnancy	X				$X^1$
Admission to Study	X				
Test Products/Diary Dispensed	X		X	X	
Test Products/Diary Collected			X	X	X
Twice Daily Application of Study Materials	X	X	X	X	X
Sub-Investigator Skin Evaluations (including acne lesion counts)	X	X	X	X	X
Subject Tolerance	X	X	X	X	X
Review of Concomitant Skin Care Products/Medications	X	X	X	X	X
TEWL/Moisture Measurements	X	X	X	X	X
Photography	X	X	X	X	X
End of Study Information/Exit Form <sup>1</sup>					X

<sup>&</sup>lt;sup>1</sup>Exit form and urine pregnancy test completed upon study completion or early discontinuation

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#### 3.4 SELECTION OF SUBJECTS

A sufficient number of subjects were enrolled to complete approximately 50 subjects (25 subjects per cell). An individual subject was allowed to participate in the study one time only.

### 3.4.1 Inclusion Criteria

Subjects included in the study:

- 1. Were female, ambulatory, 30 to 65 years of age and in reasonably good health;
- 2. Were postmenopausal, surgically sterile or were using a medically acceptable form of birth control with a negative urine pregnancy test;
- 3. Had mild to moderate changes associated with skin aging (1-6 overall severity score);
- 4. Were willing to refrain from using lotions, moisturizers, other skin care products (except those provided by the testing facility) or any medications on their facial area during the treatment period. Subjects were permitted to use their color cosmetics (e.g., foundation, blush) as long as the color cosmetics did not contain anti-aging ingredients;
- 5. Were willing to have clinical photographs taken to document their improvement;
- 6. Agreed to refrain from applying any products (including the test product) to their face the day of their visits. Subjects must have also agreed not to bathe or shower within two hours of their study visit (i.e., bathing or showering must have occurred no less than 2 hours before their study visits);
- 7. Agreed not to wear any facial makeup to any of their visits (lip and eye color were acceptable);
- 8. Indicated willingness to participate in the study by signing an informed consent document and a photo release document; and
- 9. Were Fitzpatrick Skin Types I III.

#### 3.4.2 Exclusion Criteria

Subjects excluded from the study:

- 1. Were pregnant or lactating;
- 2. Had a global severity score greater than 6 (see page 25);

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3. Had a history or evidence of any chronic or reoccurring skin disease or disorder (e.g., psoriasis, eczema, atopic dermatitis, mild to moderate acne, etc.) affecting the face;

- 4. Had a known allergy to any component of the study formulation or a proclivity to cutaneous hyper-reactivity;
- 5. Required the use of a tanning bed or participated in activities that involved excessive prolonged exposure to the sun;
- 6. Had used systemic retinoids within 6 months prior to study entry (e.g., acitretin, isotretinoin);
- 7. Had used topical retinoids within 2 months prior to study entry (e.g. tretinoin, adapalene);
- 8. Had received treatment with systemic corticosteroids within 6 months or topical corticosteroids to the face within 1 month prior to study entry;
- 9. Had used topical products containing 5% or more  $\alpha$ -hydroxy acids and/or  $\beta$ -hydroxy acids (e.g., Avon Anew, Olay BHA products, and any dermatologist products, such as the Murad line) within 1 month prior to study entry;
- 10. Had used peptide products (e.g., Olay Regenerist, Strivectin) within 1 month prior to study entry;
- 11. Had undergone phenol or trichloroacetic acid (TCA) deep peels within 1 year or medium to light peels within 3 months;
- 12. Had undergone facial cosmetic procedures such as dermabrasion, non-ablative laser rejuvenation or laser resurfacing within 1 year prior to study entry;
- 13. Had botulinum toxin injections or facial fillers (e.g., lipids, collagen, Restylane) within 6 months prior to study entry;
- 14. Had procedures of rhytidectomy (face-lifts), blepharoplasty, or had facial implants (silicone or Gore-Tex);
- 15. Were unwilling to use the SPF 30 sunscreen during the study;

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16. Had participated in any facial clinical trial involving an investigational drug or cosmetic product or procedure within the past 28 days; and

17. Had moderate to severe acne or other chronic recurring skin disorder.

## 3.4.3 Interruption or Discontinuation of Treatment

In accordance with legal requirements and ICH-GCP guidelines (see Section 1.2), every subject or her legal representative had the right to refuse further participation in the study at any time and without providing reasons (see also Section 1.3). A subject's participation was terminated immediately upon her request. The investigator made every attempt to obtain the reason and record this on the subject's data sheet.

The termination of an individual's participation was to be considered in the case of a serious adverse event (SAE). If the subject, during the course of the study, developed conditions which would have prevented her entry into the study according to the safety-related medical exclusion criteria, she was to be withdrawn immediately.

The subject may have been withdrawn from the study at any time at the discretion of the investigator for medical reasons and/or due to non-adherence to the treatment scheme and other duties stipulated in the study protocol. The reasons were to be fully documented on the subject's data sheet.

## 3.4.4 Withdrawals

The following medical and other reasons justified a premature termination (by subject or investigator) of the subject from the study:

- withdrawal of informed consent,
- serious adverse events.
- allergic reactions to the study materials,
- subject's request,
- the subject missed visits that exceeded what was outlined in the protocol.
- subject was lost to follow-up,
- investigator's judgment, and/or
- adverse event.

If a subject withdrew from the study, all efforts were made to complete a final evaluation, if possible. Subjects discontinued due to an adverse event (AE) were, in most cases, followed until the AE was resolved, a reasonable explanation was provided for the event, or the subject was referred to her primary medical doctor (PMD). The specific AE in question was recorded on the appropriate form.

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#### 3.5 TREATMENTS

## 3.5.1 Investigational Product

Text Table 3-2 Investigational Product Information

Identity	Client's Test Article Codes	RCTS Test Article Codes	Manufacturer	Date Received (and quantity received)	Physical Description
Group A Zeatin	Group A	1837.7906	Senetek PLC 620 Airpark Road Napa, CA 94558	4/8/2005 (100 tubes)	White Cream
Group B Zeatin	Group B	1837.7907	Senetek PLC 620 Airpark Road Napa, CA 94558	4/8/2005 (100 tubes)	White Cream
Sensitive Skin Sunblock	Sensitive Skin Sunblock	1837.7908	Senetek PLC 620 Airpark Road Napa, CA 94558	4/8/2005 (125 bottles) 6/2/05 (60 bottles)	White Cream

The investigational products were supplied to the study site by Senetek PLC and stored at room temperature,  $68^{\circ}$ - $77^{\circ}$ F ( $20^{\circ}$ - $25^{\circ}$ C). The product labels were printed in English and complied with RCTS Laboratory standards.

## 3.5.2 Handling of Study Products

The investigational products were supplied to the investigator by Senetek PLC. Study products were kept in an appropriate, secure area and stored according to the Sponsor's instructions. The study site confirmed receipt of the investigational products and used the investigational products only within the framework of this clinical study and in accordance with the study protocol.

All study products were used only for this protocol and not for any other purpose.

## 3.5.3 Assignment of Treatment Placement

Each subject who signed an informed consent and successfully completed the screening procedures was enrolled in the study. Upon enrollment, each subject was assigned a unique subject number.

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#### 3.5.4 Duration of Treatment

Each subject was instructed to apply Zeatin (0.10% or 0.025%) cream to their face twice daily, in the morning and evening, for twelve consecutive weeks. In the morning, after the Zeatin cream dried, the Sensitive Skin Sun block (SPF 30) was applied to the subject's entire face. In the evening the subject was instructed to wait an hour after application of the test article before retiring to bed.

#### 3.5.5 Treatment Compliance

Subjects documented use of the test articles by recording the time and date of application on their daily diaries. Additionally, at each scheduled visit (except the Week 2 visit) the test articles were weighed at the testing facility.

#### 3.6 BACKGROUND INFORMATION

Demographic data consisted of the age, gender and race of each subject. A summary of the demographics data is found in Post-Text Table I.

#### 3.7 EFFICACY VARIABLES

Efficacy assessments were performed using instrumental measurements (TEWL and NOVA DPM) and visual evaluations of the subjects' faces as outlined in 3.3.2.2. Data collected at post-baseline visits were compared to baseline visits to determine the significance of the measured changes.

#### 3.8 SAFETY VARIABLES

Safety assessments were performed using visual evaluations (Sub-Investigator's Evaluation of Skin Irritation, Overall Severity of Acne and Record of Individual Acne Lesions) and through anecdotal information (e.g., stinging, burning, itching) which was captured in the subjects' diaries.

#### 3.8.1 Adverse Events

Information about all local and systemic adverse events (AEs), whether volunteered by the subject, discovered by investigator questioning, or detected through other means was collected and recorded on Adverse Event forms and followed as appropriate.

An adverse event was defined as any untoward medical occurrence in a patient or clinical investigation subject administered a test article, which did not necessarily have a causal relationship with the study treatment. An AE could, therefore, refer to any unfavorable and unintended sign, symptom, or disease temporarily associated with the use of an investigational product, whether or not considered related to the investigational product.

Medical conditions/diseases present before starting study treatment were only considered AEs if they worsened after starting study treatment (i.e., after any procedures specified in the protocol had been initiated).

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Each adverse event was also described by:

- 1. its duration (start and end dates),
- 2. the severity grade (mild, moderate, severe),
- 3. its relationship to the study drug (definitely unrelated, unlikely, possible, probable, definitely related),
- 4. the action(s) taken, and
- 5. as relevant, the outcome.

## 3.8.2 Serious Adverse Events (SAEs)

Information about all SAEs was collected and recorded on the SAE Report form. To ensure patient safety, each SAE was reported to the Sponsor within 24 hours of learning of its occurrence. A serious adverse event was defined as any undesirable sign, symptom, or medical condition which:

- 1. was fatal or life-threatening,
- 2. required or prolonged hospitalization,
- 3. resulted in persistent or significant disability/incapacity,
- 4. constituted a congenital anomaly or a birth defect, or
- 5. was medically significant, may have jeopardized the subject, and may have required medical or surgical intervention to prevent one of the outcomes listed above.

Events **not** considered to be serious adverse events were:

- hospitalization for the treatment, which was elective or pre-planned, for a pre-existing condition that did not worsen, and
- treatment on an emergency, outpatient basis for an event **not** fulfilling any of the definitions of serious given above and **not** resulting in hospital admission.

Details pertaining to the relationship of an AE to study drug, severity of an AE, AE monitoring, documentation and SAE reporting are provided for in the clinical study protocol (Appendix 2, Data Listing 10 of this report).

## 3.8.3 Pregnancy Testing

A urine pregnancy test was required at study entry and exit for those female subjects who were not surgically sterile or post-menopausal.

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#### 4 PROTOCOL AMENDMENTS

• One (1) amendment was made to the original Protocol.

O Protocol Amendment 1 clarified that female subjects must be ambulatory, 30-65 years of age, in reasonably good health and Fitzpatrick Skin Types I-III. Additionally, it added to the exclusionary criteria that a panelist who had participated in a facial study in the past 28 days would not qualify for participation in this study.

#### 5 DATA MANAGEMENT

#### 5.1 DOCUMENTATION

The testing facility maintained detailed records on all study subjects. Data for this study was recorded on Case Report Forms (CRFs) provided by the Sponsor. All data were recorded completely, promptly, and legibly on the CRFs. Corrections were made in a manner that did not obscure or eliminate the original error, by striking through the original data with one line, and all corrections on the CRF were initialed and dated. The testing facility maintains a copy of all completed CRFs in its study files.

Originals and/or Certified copies of all data sheets, source documents, correspondence and study reports, etc. will be kept on hard-copy file by RCTS, Inc. for a minimum of two years from completion of the study. After two years, the investigator will obtain approval prior to any destruction. Storage is maintained at either the RCTS, Inc. facility at 800 W. Airport Freeway, Suite 110, Irving, TX 75062 in a secured room accessible only to RCTS employees, or at an offsite location that provides a secure environment with burglar/fire alarm systems, camera detection, and controlled temperature and humidity. Originals or copies of the source documents, correspondence, study reports, etc. will be available for the Sponsor's review on the premises of RCTS, Inc. or at a secure location off-site.

#### 5.2 DATA COLLECTION

Individual subject files were maintained. These files included the name or initials of the subject, any AEs encountered, and other notes, as appropriate. The data sheets were kept in order and current, so that they reflected the latest observations on the subjects enrolled in the study.

The original signed informed consent form was attached to each subject's file. When the study treatment was completed, the informed consent form was kept in the appropriate file folder; otherwise a note indicating where the records could be located was made. All records were kept in conformance to applicable national laws and regulations.

#### 5.3 QUALITY ASSURANCE

This study was conducted in accordance with the intent and purpose of Good Clinical Practice Regulations (21 CFR 50, 21 CFR 56 and 21 CFR 54). The study data and this Final Report was reviewed and signed by a representative of the Quality Assurance staff of RCTS, Inc. The investigator allowed representatives of the Sponsor's monitoring team (and, if necessary, city, state or federal regulating agencies) to inspect all study records, Case Report Forms at regular

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compliance with regulations.

intervals throughout the study. These inspections are for the purpose of verifying the adherence to the protocol, the completeness and exactness of the data being entered in the report form, and

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As a part of the quality assurance procedure, the Quality Assurance (QA) group performed instudy audits and assured that all data in the tables reflected what was on the source documents. Finally, the QA group audited this final report to ensure the accuracy in reporting of results.

#### 6 STATISTICAL METHODS

#### 6.1 SAMPLE SIZE ESTIMATION

The sample size of 50 subjects was agreed to by the Sponsor and the testing facility for determining the efficacy and subjects' tolerance of a facial skin care product.

#### 6.2 POPULATION

All subjects who completed a visit beyond the baseline visit were evaluable for efficacy.

#### 6.3 STATISTICAL AND ANALYTICAL PLAN

Only those subjects who satisfied the criteria for an evaluable subject were included in the statistical analysis of cosmetic efficacy. An evaluable subject was one who met all entry criteria, did not use any systemic or other unapproved topical skin care product or medication during the study, completed at least one post-baseline visit and evaluation, and complied with the treatment regimen.

The primary objective of this study was to determine the efficacy of topical Zeatin (0.10%, 0.025%) for improving the appearance of photodamaged skin when topically applied twice daily for up to 12 weeks. The primary efficacy endpoint was the change from baseline in the individual clinical signs of skin aging (wrinkles (coarse and fine), roughness and mottled hyperpigmentation). For the primary analysis of efficacy, the skin aging parameters at each follow-up visit (weeks 2, 4, 8 and 12) versus baseline scores were assessed using a Wilcoxon signed rank test. The Investigator's and subjects' global evaluations of efficacy were analyzed using a Wilcoxon signed rank test for all follow-up evaluations (weeks 2, 4, 8 and 12). The change from baseline in TEWL and skin moisture content were determined for each respective skin treatment site and analyzed using a paired difference t-test. Finally, Groups A and B were compared to each other using a one factor analysis of variance (ANOVA).

Data were analyzed with the confidence interval placed at 95% ( $p \le 0.05$ ) and performed using the SAS® system.

## 6.3.1 Analysis of Subject Demographics

Descriptive statistics were used to summarize demographic characteristics (age, gender and race). A summary of the demographics data is found in Post-Text Table I (page 80).

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#### 6.4 Changes in the Conduct of the Study or Planned Analysis

No changes in the conduct of the study or the planned analyses occurred.

#### 7 RESULTS

#### 7.1 SUBJECTS EVALUATED

Subjects' individual data tables are provided in Appendix 2 of this report. Diary comments, test article weights, and AEs can also be found in Appendix 2.

## 7.1.1 Subject Disposition

Seventy-three (73) subjects were enrolled in the study, of which 39 were enrolled in Group A and 34 were enrolled in Group B.

- Six (6) test subjects [Subject Nos.: 20, 22, 28, 34, 38 and 56] were dropped before their baseline visit due to reasons unrelated to the conduct of the study and, therefore, never received test article.
- Five (5) test subjects [Subject Nos.: 1, 9, 15, 33 and 63] were dropped after receiving test article; however, the reasons for discontinuation were unrelated to the conduct of the study.
- One (1) test subject [Subject No.: 61] was dropped due to violation of an exclusionary criteria (had been on a previous facial study within the last 28 days).
- Three (3) test subjects [Subject Nos.: 6, 54 and 73] were dropped due to non-serious adverse events (see Data Listing 10, Appendix 2, Page 221).
- One (1) test subject [Subject No.: 26] was discontinued due to a serious adverse event. Subject No.: 26, was admitted to the hospital for hand surgery (see Data Listing 10, Appendix 2, Page 221).

#### 7.1.2 Protocol Deviations

Deviations to the protocol can be found in Appendix 2, Data Listing 11 (Page 223).

#### 7.1.3 Baseline Demographic and Background Characteristics

All subjects enrolled met all of the inclusion, and none of the exclusion, requirements for study entry. Of the 73 subjects that were enrolled, 100% were female. Additionally, 39 subjects were assigned to Group A (0.10% Zeatin) and 34 subjects were assigned to Group B (0.025% Zeatin). The mean age of subjects enrolled into Group A was 49.9 years with a standard deviation of 7.0 years. The mean age of subjects enrolled into Group B was 50.2 years with a standard deviation of 8.1 years. Additionally, the ethnic composition of Group A was 87% Caucasian and 13% Hispanic. The ethnic composition of Group B was 85% Caucasian, 9% Hispanic, 3% Asian/pacific Islander and 3% Native American.

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Of the 57 subjects that completed the study, 30 subjects were assigned to Group A and 27 subjects to Group B. The mean age of subjects that completed Group A was 51.1 years with a standard deviation of 6.6 years. The mean age of subjects that completed Group B was 50.0 years with a standard deviation of 8.7 years. Additionally, the ethnic composition of Group A was 90% Caucasian and 10% Hispanic. The ethnic composition of Group B was 85% Caucasian, 11% Hispanic and 4% Native American.

A summary of demographic information is provided in Post-Text Table I (Page 80).

#### 7.2 **TEST ARTICLES**

#### 7.2.1 Study Test Articles

All enrolled subjects, up to the point of discontinuation, received the scheduled applications of the test articles, as specified by the protocol.

#### 7.3 **ASSESSMENT OF EFFICACY**

## 7.3.1 SUB-INVESTIGATOR'S ASSESSMENT OF SKIN AGING: FINE WRINKLES, COARSE WRINKLES, ROUGHNESS, MOTTLED HYPERPIGMENTATION, OVERALL SEVERITY OF SKIN AGING AND GLOBAL ASSESSMENT OF IMPROVEMENT

A summary of each assessment for each test article is located in Text Tables 7-1, 7-3, 7-5, 7-7, 7-9 and 7-11. Text Tables 7-2, 7-4, 7-6, 7-8, 7-10 and 7-12 provide a comparison of the baseline values to post-treatment values. A graphic representation of the data can be found in Text Figures 7-1 through 7-5.

Text Table 7-1 **Sub-Investigator's Assessment of Fine Wrinkles** 

			Visits					
	Descriptive Statistics	Baseline	Week 2	Week 4	Week 8	Week 12		
	Mean	2.61	2.45	2.17	1.90	1.73		
Group A	SD	0.62	0.62	0.79	0.88	0.91		
Gloup A	Median	3.00	2.00	2.00	2.00	1.00		
	N	31	31	30	30	30		
	Mean	2.55	2.45	2.21	1.96	1.93		
Group P	SD	0.87	0.91	0.99	0.92	0.96		
Group B	Median	3.00	3.00	2.00	2.00	2.00		
	N	29	29	28	28	27		

Scale:

0 = None; 1 = Minimal; 2 = Mild; 3 = Moderate; 4 = Severe

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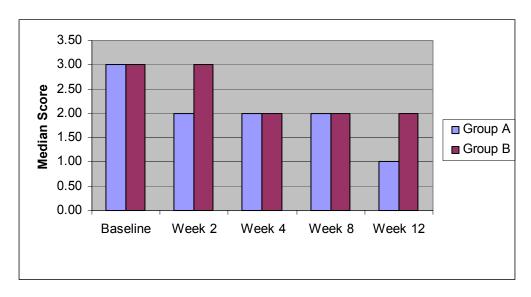
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Text Table 7-2 **Intra-Subject Change in Fine Wrinkles** 

			Intra-Subject Change**					
	Descriptive Statistics	Week 2 vs. Baseline	Week 4 vs. Baseline	Week 8 vs. Baseline	Week 12 vs. Baseline			
	Mean	-0.16	-0.47	-0.73	-0.90			
Croup	SD	0.37	0.51	0.58	0.61			
Group A	Median	0.00	0.00	-1.00	-1.00			
	N	31	30	30	30			
	P-Value*	0.063***	<0.001	<0.001	<0.001			
	Mean	-0.10	-0.32	-0.57	-0.67			
Group	SD	0.31	0.55	0.63	0.68			
В	Median	0.00	0.00	-0.50	-1.00			
	N	29	28	28	27			
	P-Value*	0.250	0.008	<0.001	<0.001			
	P-Value^: Group A vs. Group B	0.518	0.207	0.266	0.150			

<sup>\*</sup>P-values generated from a Wilcoxon Signed-Rank Test. Bolded values are significant at p≤0.05 \*\* Intra-subject change = Difference in values at two different time points (post-treatment minus baseline).

**Text Figure 7-1 Sub-Investigator's Assessment of Fine Wrinkles (Median Scores)** 



<sup>\*\*\*</sup>Although not less than or equal to 0.05, the data are highly suggestive of a difference.

<sup>^</sup>P-Value derived from One-Factor Analysis of Variance Test.

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The data in Text Table 7-2 show the results of subtracting baseline values for Fine Wrinkles (as determined by the Sub-Investigator) from post-treatment values for Fine Wrinkles. The p-values obtained as a result of the change (post-treatment minus baseline) were generated using a Wilcoxon Signed-Rank test. The p-values obtained when comparing Group A to Group B were derived from a One-Factor ANOVA test.

The results indicate that when the changes in post-baseline values for Fine Wrinkles were compared to baseline values:

- o There was a significant improvement (reduction), relative to baseline, in Fine Wrinkles at Weeks 4, 8 and 12 for Groups A and B.
- There was no significant difference, relative to baseline, in values for Fine Wrinkles at Week 2 for Groups A and B; however, it is highly suggestive (P Week 2 vs. Baseline = 0.063) that an improvement in Fine Wrinkles was observed for Group A at Week 2.

When comparing the two groups together, there was no evidence that the Fine Wrinkle values generated in Group A were significantly different from those generated in Group B, regardless of the time point.

Text Table 7-3 Sub-Investigator's Assessment of Coarse Wrinkles

			Visit					
	Descriptive Statistics	Baseline	Week 2	Week 4	Week 8	Week 12		
	Mean	1.97	1.97	1.97	1.83	1.77		
Group A	SD	1.17	1.08	1.13	1.15	1.22		
Gloup A	Median	2.00	2.00	2.00	2.00	2.00		
	N	31	31	30	30	30		
	Mean	1.83	1.76	1.71	1.68	1.70		
Group B	SD	1.42	1.43	1.51	1.54	1.49		
Group B	Median	1.00	1.00	1.00	1.00	1.00		
	N	29	29	28	28	27		

Scale:

0 = None; 1 = Minimal; 2 = Mild; 3 = Moderate; 4 = Severe

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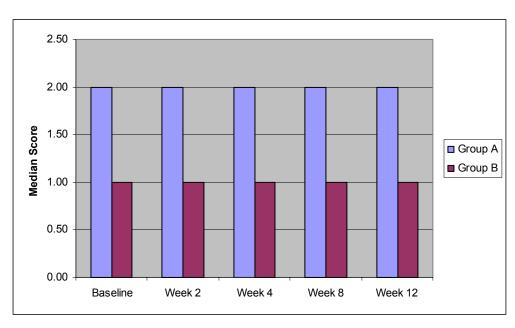
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Intra-Subject Change in Coarse Wrinkles Intra-Subject Change **Text Table 7-4** 

			Intra-Subject Change**					
	Descriptive	Week 2 vs.	Week 4 vs.	Week 8 vs.	Week 12 vs.			
	Statistics	Baseline	Baseline	Baseline	Baseline			
Group A	Mean SD Median	0.00 0.26 0.00	-0.03 0.18 0.00	-0.17 0.53 0.00	-0.23 0.57 0.00			
	N	31	30	30	30			
	P-Value*	1.000	1.000	0.188	0.063***			
Group	Mean	-0.07	-0.14	-0.18	-0.22			
	SD	0.26	0.36	0.39	0.42			
	Median	0.00	0.00	0.00	0.00			
В	N	29	28	28	27			
	P-Value*	0.500	0.125	0.063***	<b>0.031</b>			
	P-Value^: Group A vs. Group B	0.309	0.142	0.752	0.950			

<sup>\*</sup>P-values generated from a Wilcoxon Signed-Rank Test. Bolded values are significant at p<0.05 \*\* Intra-subject change = Difference in values at two different time points (post-treatment minus baseline).

**Text Figure 7-2 Expert Assessment of Coarse Wrinkles (Median Scores)** 



<sup>\*\*\*</sup>Although not less than or equal to 0.05, the data are highly suggestive of a difference.

<sup>^</sup>P-value derived from One-Factor Analysis of Variance Test.

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The data in Text Table 7-4 show the results of subtracting baseline values for Coarse Wrinkles (as determined by the Sub-Investigator) from post-treatment values for Coarse Wrinkles. The p-values obtained as a result of the change (post-treatment minus baseline) were generated using a Wilcoxon Signed-Rank test. The p-values obtained when comparing Group A to Group B were derived from a One-Factor ANOVA test.

The results indicate that when the changes in post-baseline values for Coarse Wrinkles were compared to baseline values:

- There was a significant improvement, relative to baseline, in Coarse Wrinkles at Week 12 for Group B. No other significant differences were observed at any other time points for Group B; however, it is highly suggestive (P Week 8 vs. Baseline = 0.063) that an improvement in Coarse Wrinkles was observed at Week 8.
- There were no significant differences at any time points, relative to baseline, in
   Coarse Wrinkle values for Group A; however, it is highly suggestive (P Week 12 vs. Baseline = 0.063) that an improvement in Coarse Wrinkles was observed at Week 12.

When comparing the two groups together, there was no evidence that the Coarse Wrinkle values generated in Group A were significantly different from those generated in Group B, regardless of the time point.

Text Table 7-5 Sub-Investigator's Assessment of Roughness

		Visit					
	Descriptive Statistics	Baseline	Week 2	Week 4	Week 8	Week 12	
	Mean	2.68	1.77	1.27	0.77	0.37	
Croup A	SD	0.48	0.96	0.83	0.77	0.49	
Group A	Median	3.00	2.00	1.00	1.00	0.00	
	N	31	31	30	30	30	
	Mean	2.41	1.59	1.07	0.82	0.44	
Group B	SD	0.68	0.91	0.72	0.77	0.64	
Gloup B	Median	3.00	2.00	1.00	1.00	0.00	
	N	29	29	28	28	27	

Scale:

0 = None; 1 = Minimal; 2 = Mild; 3 = Moderate; 4 = Severe

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baseline).

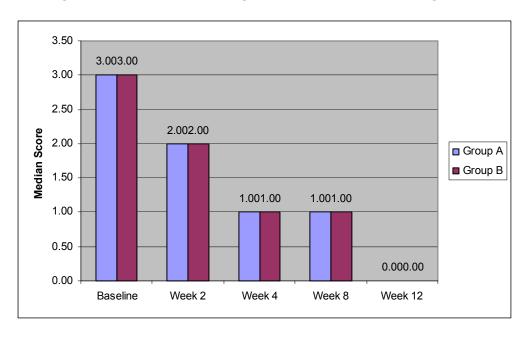
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**Text Table 7-6 Intra-Subject Change in Roughness** 

			Intra-Subject Change**					
	Descriptive Statistics	Week 2 vs. Baseline	Week 4 vs. Baseline	Week 8 vs. Baseline	Week 12 vs. Baseline			
	Mean	-0.90	-1.40	-1.90	-2.30			
Croup	SD	0.83	0.62	0.76	0.60			
Group A	Median	-1.00	-1.00	-2.00	-2.00			
	N	31	30	30	30			
	P-Value*	<0.001	<0.001	<0.001	<0.001			
	Mean	-0.83	-1.39	-1.64	-2.00			
Croup	SD	0.93	0.63	0.87	0.62			
Group B	Median	-1.00	-1.00	-2.00	-2.00			
	N	29	28	28	27			
	P-Value*	<0.001	<0.001	<0.001	<0.001			
	P-Value^: Group A vs. Group B	0.683	0.958	0.266	0.070***			

<sup>\*</sup>P-values generated from a Wilcoxon Signed-Rank Test. Bolded values are significant at p<0.05 \*\* Intra-subject change = Difference in values at two different time point (post-treatment minus

**Text Figure 7-3 Sub-Investigator's Assessment of Roughness (Median Scores)** 



<sup>\*\*\*</sup>Although not less than or equal to 0.05, the data are highly suggestive of a difference.

<sup>^</sup>P-value derived from One-Factor Analysis of Variance Test.

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The data in Text Table 7-6 show the results of subtracting baseline values for Roughness (as determined by the Sub-Investigator) from post-treatment values for Roughness. The p-values obtained as a result of the change (post-treatment minus baseline) were generated using a Wilcoxon Signed-Rank test. The p-values obtained when comparing Group A to Group B were derived from a One-Factor ANOVA test.

The results indicate that when the changes in post-baseline values for Roughness were compared to baseline values:

• There was a significant improvement, relative to baseline, in Roughness at all time points for Groups A and B.

When comparing the two groups together, there was no evidence of a significant difference at any time point. However, it is highly suggestive ( $P_{\text{Week }12 \text{ vs. Baseline}} = 0.070$ ) that Group A performed better than Group B at Week 12.

Text Table 7-7 Sub-Investigator's Assessment of Mottled Hyperpigmentation

				Visit		
	Descriptive Statistics	Baseline	Week 2	Week 4	Week 8	Week 12
	Mean	1.97	1.84	1.57	1.63	1.47
Croup A	SD	0.87	0.93	0.90	0.85	0.90
Group A	Median	2.00	2.00	1.50	2.00	1.00
	N	31	31	30	30	30
	Mean	1.86	1.62	1.25	1.29	1.26
Croup P	SD	0.92	1.01	0.70	0.81	0.71
Group B	Median	2.00	1.00	1.00	1.00	1.00
	N	29	29	28	28	27

Scale:

0 = None; 1 = Minimal; 2 = Mild; 3 = Moderate; 4 = Severe

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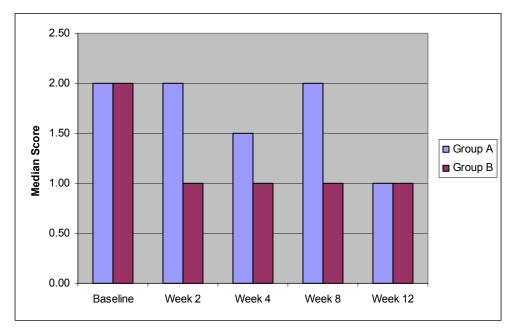
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**Text Table 7-8** Intra-Subject Change in Mottled Hyperpigmentation

			Intra-Subject Change**					
	Descriptive Statistics	Week 2 vs.Week 4 vs.Week 8 vs.Week 12BaselineBaselineBaselineBaseline						
	Mean	-0.13	-0.37	-0.30	-0.47			
0	SD	0.34	0.56	0.53	0.57			
Group A	Median	0.00	0.00	0.00	0.00			
	N	31	30	30	30			
	P-Value*	0.125	0.002	0.012	<0.001			
	Mean	-0.24	-0.57	-0.54	-0.59			
Craun	SD	0.51	0.50	0.64	0.80			
Group B	Median	0.00	-1.00	0.00	0.00			
	N	29	28	28	27			
	P-Value*	0.039	<0.001	<0.001	0.001			
	P-Value^: Group A vs. Group B	0.281	0.099***	0.196	0.591			

<sup>\*</sup>P-values generated from a Wilcoxon Signed-Rank Test. Bolded values are significant at p<0.05 \*\* Intra-subject change = Difference in values at two different time point (post-treatment minus baseline).

**Sub-Investigator's Assessment of Mottled Hyperpigmentation Text Figure 7-4** (Median Scores)



The data in Text Table 7-8 show the results of subtracting baseline values for Mottled Hyperpigmentation (as determined by the Sub-Investigator) from post-treatment values for

<sup>\*\*\*</sup>Although not less than or equal to 0.05, the data are highly suggestive of a difference.

<sup>^</sup>P-value derived from One-Factor Analysis of Variance Test.

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Mottled Hyperpigmentation. The p-values obtained as a result of the change (post-treatment minus baseline) were generated using a Wilcoxon Signed-Rank test. The p-values obtained when comparing Group A to Group B were derived from a One-Factor ANOVA test.

The results indicate that when the changes in post-baseline values for Mottled Hyperpigmentation were compared to baseline values:

- There was a significant improvement, relative to baseline, in Mottled Hyperpigmentation at all time points for Group B.
- O There was a significant improvement, relative to baseline, in Mottled Hyperpigmentation at Weeks 4, 8 and 12 for Group A; however, no significant difference was observed at Week 2.

When comparing the two groups together, there was no evidence of a significant difference at any time point; however it is highly suggestive ( $P_{\text{Week 4 vs. Baseline}} = 0.099$ ) that Group B performed better than Group A at Week 4.

Text Table 7-9 Sub-Investigator's Assessment of Overall Severity of Skin Aging

				Visits		
	Descriptive Statistics	Baseline	Week 2	Week 4	Week 8	Week 12
	Mean	3.97	3.55	3.07	2.90	2.70
Croup A	SD	1.17	1.26	1.31	1.42	1.47
Group A	Median	4.00	3.00	3.00	2.50	2.00
	N	31	31	30	30	30
	Mean	4.03	3.45	3.00	2.86	2.81
Group B	SD	1.43	1.70	1.49	1.58	1.57
Group B	Median	4.00	4.00	2.50	3.00	3.00
	N	29	29	28	28	27

Scale:

0 = None; 1-3 = Mild; 4-6 = Moderate; 7-9 = Severe

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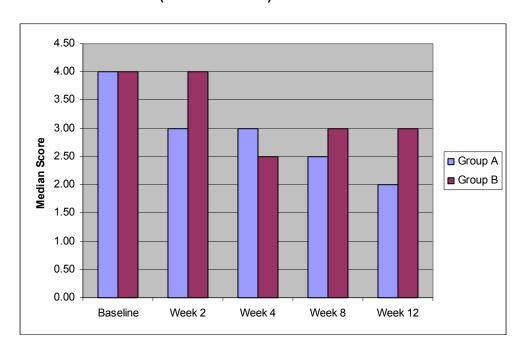
Text Table 7-10 Intra-Subject Change in Overall Severity of Skin Aging

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			Intra-Subject Change**					
	Descriptive Statistics	Week 2 vs. Baseline	Week 4 vs. Baseline	Week 8 vs. Baseline	Week 12 vs. Baseline			
	Mean	-0.42	-0.90	-1.07	-1.27			
Craun	SD	0.50	0.61	0.78	0.78			
Group A	Median	0.00	-1.00	-1.00	-1.00			
	N	31	30	30	30			
	P-Value*	<0.001	<0.001	<0.001	<0.001			
	Mean	-0.59	-1.00	-1.14	-1.30			
Croup	SD	0.57	0.54	0.80	0.72			
Group B	Median	-1.00	-1.00	-1.00	-1.00			
	N	29	28	28	27			
	P-Value*	<0.001	<0.001	<0.001	<0.001			
	P-Value^: Group A vs. Group B	0.267	0.504	0.987	0.720			

<sup>\*</sup>P-values generated from a Wilcoxon Signed-Rank Test. Bolded values are significant at p<0.05

Text Figure 7-5 Sub-Investigator's Assessment of Overall Severity of Skin Aging (Median Scores)



<sup>\*\*</sup> Intra-subject change = Difference in values at two different time points (Post-Treatment minus Baseline).

<sup>^</sup>P-value derived from One-Factor Analysis of Variance Test.

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The data in Text Table 7-10 show the results of subtracting baseline values for Overall Severity of Skin Aging (as determined by the Sub-Investigator) from post-treatment values for Overall Severity of Skin Aging. The p-values obtained as a result of the change (post-treatment minus baseline) were generated using a Wilcoxon Signed-Rank test. The p-values obtained when comparing Group A to Group B were derived from a One-Factor ANOVA test.

The results indicate that when the changes in post-baseline values for Overall Severity of Skin Aging were compared to baseline values:

• There was a significant improvement, relative to baseline, in Overall Severity of Skin Aging at all time points for both Groups A and B.

When comparing the two groups together, there was no evidence that the Overall Severity of Skin Aging values generated in Group A were significantly different from those generated in Group B, regardless of the time point.

Text Table 7-11 Sub-Investigator's Assessment of the Improvement of Skin Aging

			V	'isit	
	Descriptive Statistics	Week 2	Week 4	Week 8	Week 12
	Mean	4.74	4.23	4.23	4.23
Group A	SD	0.44	0.43	0.43	0.43
Gloup A	Median	5.00	4.00	4.00	4.00
	N	31	30	30	30
	Mean	4.66	4.39	4.32	4.26
Group B	SD	0.48	0.50	0.48	0.45
Group B	Median	5.00	4.00	4.00	4.00
	N	29	28	28	27

Scale:

<sup>1 =</sup> Excellent Improvement; 2 = Marked Improvement; 3 = Moderate Improvement; 4 = Slight Improvement; 5 = No Improvement; 6 = Worse

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Text Table 7-12 Intra-Subject Change in the Improvement of Skin Aging

			Intra-Subject Change**					
	Descriptive Statistics	Week 2	Week 4	Week 8	Week 12			
	Mean	0.26	0.77	0.77	0.77			
	SD	0.44	0.43	0.43	0.43			
Group A	Median	0.00	1.00	1.00	1.00			
	N	31	30	30	30.0			
	P-Value*	0.008	0.000	0.000	0.000			
	Mean	0.34	0.61	0.68	0.74			
	SD	0.48	0.50	0.48	0.45			
Group B	Median	0.00	1.00	1.00	1.00			
	N	29	28	28	27			
	P-Value*	0.002	0.000	0.000	0.000			
	P-Value^: Group A vs. Group B	0.472	0.196	0.462	0.824			

<sup>\*</sup>P-values generated from a Wilcoxon Signed-Rank Test. Bolded values are significant at p<0.05

The data in Text Table 7-12 show the results of subtracting baseline values for Improvement of Skin Aging (as determined by the Sub-Investigator) from post-treatment values for Improvement of Skin Aging. The p-values obtained as a result of the change (post-treatment minus baseline) were obtained using a Wilcoxon Signed-Rank test. The p-values obtained when comparing Group A to Group B were derived from a One-Factor ANOVA test. Additionally, the scores recorded at Weeks 2, 4, 8 and 12 were adjusted to reflect either a positive value, indicative of an improvement from baseline, or a negative value, indicative of a worsening from baseline.

The results indicate that when the changes in post-baseline values for Improvement of Skin Aging were compared to baseline values:

> o There was a significant improvement, relative to baseline, in Improvement of Skin Aging at all time points for both Groups A and B.

When comparing the two groups together, there was no evidence that the Improvement in Skin Aging values generated in Group A were significantly different from those generated in Group B, regardless of the time point.

<sup>\*\*</sup> The Intra-Subject Change scores recorded at Weeks 2, 4, 8 and 12 were adjusted to reflect either a positive value, indicative of an improvement from Baseline, or a negative value, indicative of a worsening from Baseline

<sup>^</sup>P-value derived from One-Factor Analysis of Variance Test.

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# 7.3.2 SUBJECT'S SELF ASSESSMENT: SKIN TEXTURE, SKIN COLOR, BLOTCHINESS - BROWN SPOTS, FINE WRINKLES AND OVERALL IMPROVEMENT

Subject self assessment summaries for each test article are located in Text Tables 7-13, 7-15, 7-17, 7-19 and 7-21. Text Tables 7-14, 7-16, 7-18, 7-20 and 7-22 provide a comparison of the change at Weeks 2, 4, 8 and 12 to baseline.

**Text Table 7-13 Subject Self Assessment of Skin Texture** 

			V	′isit	
	Descriptive Statistics	Week 2	Week 4	Week 8	Week 12
	Mean	2.48	2.27	1.97	1.83
Group A	SD	0.72	0.58	0.41	0.59
Group A	Median	2.00	2.00	2.00	2.00
	N	31	30	30	30
	Mean	2.24	2.25	1.79	1.78
Group B	SD	0.64	0.65	0.50	0.64
	Median	2.00	2.00	2.00	2.00
	N	29	28	28	27

### Scale:

<sup>1 =</sup> Much Improved; 2 = Somewhat Improved; 3 = No Change;

<sup>4 =</sup> Somewhat Worse; 5 = Much Worse

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Self Assessment of Skin Texture: Comparison of Post-Treatment to Text Table 7-14 **Baseline** 

		Intra-Subject Change**			
	Descriptive Statistics	Week 2	Week 4	Week 8	Week 12
	Mean	0.52	0.73	1.03	1.17
	SD	0.72	0.58	0.41	0.59
Group A	Median	1.00	1.00	1.00	1.00
	N	31	30	30	30
	P-Value*	0.001	0.000	0.000	0.000
	Mean	0.76	0.75	1.21	1.22
	SD	0.64	0.65	0.50	0.64
Group B	Median	1.00	1.00	1.00	1.00
	N	29	28	28	27
	P-Value*	0.000	0.000	0.000	0.000
	P-Value^: Group A vs. Group B	0.208	0.941	0.132	0.704

<sup>\*</sup>P-Values generated from the Wilcoxon Signed-Rank Test. Bolded values are significant at p≤0.05

The data in Text Table 7-14 show the results of subtracting baseline values for Skin Texture (as determined by the Subject) from post-treatment values for Skin Texture. The p-values obtained as a result of the change (post-treatment minus baseline) were generated using a Wilcoxon Signed-Rank test. The p-values obtained when comparing Group A to Group B were derived from a One-Factor ANOVA test. Additionally, the scores recorded at Weeks 2, 4, 8 and 12 were adjusted to reflect either a positive value, indicative of an improvement from baseline, or a negative value, indicative of a worsening from baseline.

The results indicate that when the changes in post-baseline values for Skin Texture were compared to baseline values:

> o There was a significant improvement, relative to baseline, in Skin Texture at all time points for both Groups A and B.

When comparing the two groups together, there was no evidence that the Skin Texture values generated in Group A were significantly different from those generated in Group B, regardless of the time point.

<sup>^</sup>P-Value derived from a One-Factor Analysis of Variance Test.

<sup>\*\*</sup>Note: The Intra-Subject Scores recorded at Weeks 2, 4, 8 and 12 were adjusted to reflect either a positive value, indicative of an improvement from Baseline, or a negative value, indicative of a worsening from Baseline

<sup>\*\*\*</sup>Although not less than or equal to 0.05, the data are highly suggestive of a difference.

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Text Table 7-15 Subject Self Assessment of the Evaluation of Skin Color

			V	'isit	
Descriptiv Statistics		Week 2	Week 4	Week 8	Week 12
	Mean	2.74	2.67	2.37	2.27
Group A	SD	0.58	0.55	0.76	0.69
Gloup A	Median	3.00	3.00	2.00	2.00
	N	31	30	30	30
	Mean	2.72	2.39	2.07	2.19
Group B	SD	0.53	0.57	0.54	0.74
	Median	3.00	2.00	2.00	2.00
	N	29	28	28	27

Scale:

Text Table 7-16 Self Assessment of Skin Color: Comparison of Post-Treatment to Baseline

		Intra-Subject Change**				
	Descriptive Statistics	Week 2	Week 4	Week 8	Week 12	
	Mean	0.26	0.33	0.63	0.73	
	SD	0.58	0.55	0.76	0.69	
Group A	Median	0.00	0.00	1.00	1.00	
	N	31	30	30	30	
	P-Value*	0.035	0.006	0.000	0.000	
	Mean	0.28	0.61	0.93	0.81	
	SD	0.53	0.57	0.54	0.74	
Group B	Median	0.00	1.00	1.00	1.00	
	N	29	28	28	27	
	P-Value*	0.021	0.000	0.000	0.000	
	P-Value^: Group A vs. Group B	0.753	0.084***	0.077***	0.693	

<sup>\*</sup>P-Values generated from the Wilcoxon Signed-Rank Test. Bolded values are significant at p<0.05

<sup>1 =</sup> Much Improved; 2 = Somewhat Improved; 3 = No Change;

<sup>4 =</sup> Somewhat Worse; 5 = Much Worse

<sup>^</sup>P-Value derived from a One-Factor Analysis of Variance Test

<sup>\*\*</sup>Note: The Intra-Subject Scores recorded at Weeks 2, 4, 8 and 12 were adjusted to reflect either a positive value, indicative of an improvement from Baseline, or a negative value, indicative of a worsening from Baseline

<sup>\*\*\*</sup>Although not less than or equal to 0.05, the data are highly suggestive of a difference.

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The data in Text Table 7-16 show the results of subtracting baseline values for Skin Color (as determined by the Subject) from post-treatment values for Skin Color. The p-values obtained as a result of the change (post-treatment minus baseline) were generated using a Wilcoxon Signed-Rank test. The p-values obtained when comparing Group A to Group B were derived from a One-Factor Analysis of Variance test. Additionally, the scores recorded at Weeks 2, 4, 8 and 12 were adjusted to reflect either a positive value, indicative of an improvement from baseline, or a negative value, indicative of a worsening from baseline.

The results indicate that when the changes in post-baseline values for Skin Color were compared to baseline values:

• There was a significant improvement, relative to baseline, in Skin Color at all time points for both Groups A and B.

When comparing the two groups together, there was no evidence of a significant difference at any time point relative to baseline; however it is highly suggestive ( $P_{\text{Week 4 vs. Baseline}} = 0.084$  and  $P_{\text{Week 8 vs. Baseline}} = 0.077$ ) that Group B performed better than Group A at Weeks 4 and 8.

Text Table 7-17 Subject Self Assessment Evaluation of Blotchiness – Brown Spots

			V	isits	
Descriptiv Statistics		Week 2	Week 4	Week 8	Week 12
	Mean	3.00	2.90	2.50	2.57
Croup A	SD	0.37	0.48	0.68	0.63
Group A	Median	3.00	3.00	3.00	3.00
	N	31	30	30	30
	Mean	2.86	2.79	2.32	2.26
Group B	SD	0.44	0.50	0.77	0.76
Group B	Median	3.00	3.00	2.50	2.00
	N	29	28	28	27

Scale:

<sup>1 =</sup> Much Improved; 2 = Somewhat Improved; 3 = No Change;

<sup>4 =</sup> Somewhat Worse; 5 = Much Worse

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Text Table 7-18 **Self Assessment Evaluation of Blotchiness – Brown Spots: Comparison of Post-Treatment to Baseline** 

		Intra-Subject Change**				
	Descriptive Statistics	Week 2	Week 4	Week 8	Week 12	
	Mean	0.00	0.10	0.50	0.43	
Group A	SD	0.37	0.48	0.68	0.63	
	Median	0.00	0.00	0.00	0.00	
	N	31	30	30	30	
	P-Value*	1.000	0.453	0.001	0.002	
	Mean	0.14	0.21	0.68	0.74	
	SD	0.44	0.50	0.77	0.76	
Group B	Median	0.00	0.00	0.50	1.00	
	N	29	28	28	27	
	P-Value*	0.219	0.070***	0.000	0.000	
P-Value^: Group A vs. Group B		0.188	0.380	0.477	0.158	

<sup>\*</sup>P-Values generated from the Wilcoxon Signed-Rank Test. Bolded values are significant at p≤0.05 ^P-Value derived from a One-Factor Analysis of Variance Test

The data in Text Table 7-18 show the results of subtracting baseline values for Blotchiness (as determined by the Subject) from post-treatment values for Blotchiness. The p-values obtained as a result of the change (post-treatment minus baseline) were generated using a Wilcoxon Signed-Rank test. The p-values obtained when comparing Group A to Group B were derived from a One-Factor ANOVA test. Additionally, the scores recorded at Weeks 2, 4, 8 and 12 were adjusted to reflect either a positive value, indicative of an improvement from baseline, or a negative value, indicative of a worsening from baseline.

The results indicate that when the changes in post-baseline values for Blotchiness were compared to baseline values:

- o There was a significant improvement, relative to baseline, in Blotchiness at Weeks 8 and 12 for Group A. No other significant difference was observed at any other time point.
- There was a significant improvement, relative to baseline, in Blotchiness at Weeks 8 and 12 for Group B. No other significant difference was observed at any other time point; however, it is highly suggestive (P Week 4 vs. Baseline = 0.070) that the appearance of Blotchiness-Brown Spots was improved at Week 4.

When comparing the two groups together, there was no evidence that the Skin Blotchiness values generated in Group A were significantly different from those generated in Group B, regardless of the time point.

<sup>\*\*</sup>Note: The Intra-Subject Scores recorded at Week 2 were adjusted to reflect either a positive value, indicative of an improvement from Baseline, or a negative value, indicative of a worsening from Baseline

<sup>\*\*\*</sup>Although not less than or equal to 0.05, the data are highly suggestive of a difference.

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Text Table 7-19 Self Assessment of Fine Wrinkles

		Self A	Assessmen	t of Fine Wr	inkles
Descriptive Statistics		Week 2	Week 4	Week 8	Week 12
	Mean	2.61	2.30	2.07	2.10
Group A	SD	0.72	0.53	0.45	0.61
Gloup A	Median	3.00	2.00	2.00	2.00
	N	31	30	30	30
	Mean	2.41	2.29	2.07	1.93
Group B	SD	0.50	0.60	0.47	0.78
Gloup B	Median	2.00	2.00	2.00	2.00
	N	29	28	28	27

Scale:

Text Table 7-20 Self Assessment of Fine Wrinkles: Comparison of Post-Treatment to Baseline

		Intra-Subject Change**				
	Descriptive Statistics	Week 2	Week 4	Week 8	Week 12	
	Mean	0.39	0.70	0.93	0.90	
Group A	SD	0.72	0.53	0.45	0.61	
	Median	0.00	1.00	1.00	1.00	
	N	31	30	30	30	
	P-Value*	0.011	0.000	0.000	0.000	
	Mean	0.59	0.71	0.93	1.07	
	SD	0.50	0.6	0.47	0.78	
Group B	Median	1.00	1.00	1.00	1.00	
	N	29	28	28	27	
	P-Value*	0.000	0.000	0.000	0.000	
	P-Value^: Group A vs. Group B	0.248	0.782	0.965	0.253	

<sup>\*</sup>P-Values generated from the Wilcoxon Signed-Rank Test. Bolded values are significant at p≤0.05

The data in Text Table 7-20 show the results of subtracting baseline values for Fine Wrinkles (as determined by the Subject) from post-treatment values for Fine Wrinkles. The p-values obtained as a result of the change (post-treatment minus baseline) were generated using a Wilcoxon Signed-Rank test. The p-values obtained when comparing Group A to Group B were derived

<sup>1 =</sup> Much Improved; 2 = Somewhat Improved; 3 = No Change;

<sup>4 =</sup> Somewhat Worse; 5 = Much Worse

<sup>^</sup>P-Value derived from a One-Factor Analysis of Variance Test

<sup>\*\*</sup>Note: The Intra-Subject Scores recorded at Weeks 2, 4, 8 and 12 were adjusted to reflect either a positive value, indicative of an improvement from Baseline, or a negative value, indicative of a worsening from Baseline

<sup>\*\*\*</sup>Although not less than or equal to 0.05, the data are highly suggestive of a difference.

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from a One-Factor Analysis of Variance test. The values recorded at Weeks 2, 4, 8 and 12 were adjusted to reflect either a positive value, indicative of an improvement from baseline, or a negative value, indicative of a worsening from baseline.

The results indicate that when the changes in post-baseline values for Fine Wrinkles were compared to baseline values:

• There was a significant improvement, relative to baseline, in Fine Wrinkles at all time points for both Groups A and B.

When comparing the two groups together, there was no evidence that the Fine Wrinkle values generated in Group A were significantly different from those generated in Group B, regardless of the time point.

Text Table 7-21 Subject Self Assessment of Overall Improvement

			٧	'isit	
Descriptive Statistics		Week 2	Week 4	Week 8	Week 12
	Mean	2.58	2.23	2.00	1.87
Group A	SD	0.72	0.43	0.45	0.51
Gloup A	Median	3.00	2.00	2.00	2.00
	N	31	30	30	30
	Mean	2.34	2.18	2.00	1.89
Group B	SD	0.48	0.55	0.47	0.58
Group B	Median	2.00	2.00	2.00	2.00
	N	29	28	28	27

#### Scale:

<sup>1 =</sup> Much Improved; 2 = Somewhat Improved; 3 = No Change;

<sup>4 =</sup> Somewhat Worse; 5 = Much Worse

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**Self Assessment of Overall Improvement: Comparison of Post** Text Table 7-22 **Treatment to Baseline** 

		Intra-Subject Change**			
	Descriptive Statistics	Week 2	Week 4	Week 8	Week 12
	Mean	0.42	0.77	1.00	1.13
	SD	0.72	0.43	0.45	0.51
Group A	Median	0.00	1.00	1.00	1.00
	N	31	30	30	30
	P-Value*	0.007	0.000	0.000	0.000
	Mean	0.66	0.82	1.00	1.11
	SD	0.48	0.55	0.47	0.58
Group B	Median	1.00	1.00	1.00	1.00
	N	29	28	28	27
	P-Value*	0.000	0.000	0.000	0.000
P-Value^: Group A vs. Group B		0.168	0.511	1.000	0.906

<sup>\*</sup>P-Values generated from the Wilcoxon Signed-Rank Test. Bolded values are significant at p≤0.05

The data in Text Table 7-22 show the results of subtracting baseline values for Overall Improvement (as determined by the Subject) from post-treatment values for Overall Improvement. The p-values obtained as a result of the change (post-treatment minus baseline) were generated using a Wilcoxon Signed-Rank test. The p-values obtained when comparing Group A to Group B were derived from a One-Factor Analysis of Variance test. Additionally, the scores recorded at Weeks 2, 4, 8 and 12 were adjusted to reflect either a positive value, indicative of an improvement from baseline, or a negative value, indicative of a worsening from baseline.

The results indicate that when the changes in post-baseline values for Overall Improvement were compared to baseline values:

> o There was a significant improvement, relative to baseline, in Overall Improvement at all time points for both Groups A and B.

When comparing the two groups together, there was no evidence that the Overall Improvement values generated in Group A were significantly different from those generated in Group B, regardless of the time point.

<sup>^</sup>P-Value derived from a One-Factor Analysis of Variance Test

<sup>\*\*</sup>Note: The Intra-Subject Scores recorded at Weeks 2, 4, 8 and 12 were adjusted to reflect either a positive value, indicative of an improvement from Baseline, or a negative value, indicative of a worsening from Baseline.

<sup>\*\*\*</sup>Although not less than or equal to 0.05, the data are highly suggestive of a difference.

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# 7.3.3 Transepidermal Water Loss (TEWL) Measurements

A summary of the TEWL measurements for each test article is located in Text Table 7-23. Text Table 7-24 provides a comparison of the baseline values to post-treatment values. A graphic representation of the data can be found in Text Figure 7-6.

Text Table 7-23 TEWL Measurements

					TEWL Me	easurement	s (g/m²/hr)	
RCTS Test Article Codes	Client Test Article Codes	Site Measured	Descriptive Statistics	Baseline	Week 2	Week 4	Week 8	Week 12
			Mean	10.71	12.71	11.61	11.30	11.84
		Average of	SD	4.82	5.13	4.08	3.90	4.19
1837.7906	1837.7906 Group A	Right Cheek and Left Cheek	Median	8.68	11.20	10.49	10.51	10.65
			N	31	31	30	30	30
			% Change		19%	8%	6%	11%
			Mean	11.30	12.78	11.50	10.55	12.23
		Average of	SD	4.14	5.37	3.29	3.08	3.72
1837.7907	1837.7907 Group B	Right Cheek and	Median	11.10	12.00	11.85	10.90	12.00
		Left Cheek	N	29	29	28	28	27
			% Change		13%	2%	-7%	8%

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**Intra-Subject Change in TEWL Measurements** Text Table 7-24

#### Intra-Subject Change in TEWL Measurements (g/m²/hr)\*\* **RCTS Test** Descriptive Client Test Site Week 2 vs. Week 4 vs. Week 8 vs. Week 12 vs. Article Statistics Article Code Measured Baseline Baseline Baseline Baseline Code Mean 2.00 0.79 0.49 1.03 Average of SD 3.82 3.37 2.74 2.48 Right Cheek Group A 1837.7906 Median 1.85 0.31 0.54 1.11 and Left 30 30 31 30 Ν Cheek P-Value\* 0.090\*\*\* 0.007 0.431 0.049 1.48 -1.01 0.70 Mean -0.06 Average of SD 3.98 2.78 2.65 3.03 Right Cheek 1837.7907 Group B 0.38 1.05 0.48 -0.78 Median and Left Ν 29 28 28 27 Cheek 0.056\*\*\* 0.053\*\*\* P-Value\* 0.908 0.240 P-Value<sup>^</sup>: Group 0.066\*\*\* 0.605 0.221 0.672 A vs. Group B

<sup>\*</sup>P-values generated from a paired-difference t-test. Bolded values are significant at p<0.05

<sup>\*\*</sup> Intra-subject change = Difference in TEWL values at two different time points (Post-Baseline minus Baseline)

<sup>\*\*\*</sup>Although not less than or equal to 0.05, the data are highly suggestive of a difference.

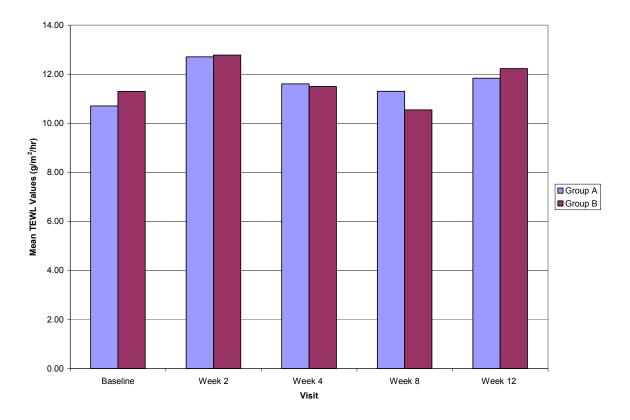
<sup>^</sup>P-Value derived from a One Factor Analysis of Variance Test

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The data in Text Table 7-24 show the results of subtracting baseline TEWL values from TEWL post-treatment values. The value obtained as a result of the change was compared to zero using a paired-difference t-test. The p-values obtained when comparing Group A to Group B were derived from a One-Factor Analysis of Variance test. Values were considered significant (P<0.05) if the change was significantly greater than zero (no change).

### The results indicate that:

- When the post-treatment TEWL values were compared to baseline, there were significant increases in TEWL values at Weeks 2 and 12 for Group A. No other significant differences were observed at any other time point; however it is highly suggestive (P Week  $_{4 \text{ vs. Baseline}} = 0.090$ ) that the Week 4 TEWL values were elevated over baseline. [An increase in TEWL values can indicate a disruption in the barrier properties of the skin].
- No significant differences were observed at any time point for Group B; however it is highly suggestive ( $P_{\text{Week 2 vs. Baseline}} = 0.056$  and  $P_{\text{Week 8 vs. Baseline}} = 0.053$ ) that at Week 2 TEWL values were elevated and at Week 8 the values were depressed over baseline. Group B's Week 2 TEWL values increased indicating the product induced skin barrier damage; however, Week 8 TEWL values decreased indicating the product improved the skin's barrier properties.
- When comparing the two groups together, there was no evidence of a significant difference at any time point; however, it is highly suggestive (P  $_{\text{Week 8 vs. Baseline}} = 0.066$ ) that Group B performed better (i.e., had lower TEWL values) than Group A at Week 8.

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## 7.3.4 SKIN MOISTURE MEASUREMENTS

A summary of the DPM measurements for each test article is located in Text Table 7-25. Text Table 7-26 provides a comparison of the baseline values to post-treatment values. A graphic representation of the data can be found in Text Figure 7-7.

Text Table 7-25 DPM Measurements

					DPM	Measureme	nts (au)	
RCTS Test Article Code	Client Test Article Code	Site Measured	Descriptive Statistics	Baseline	Week 2	Week 4	Week 8	Week 12
			Mean	121.88	121.40	122.07	137.53	121.98
		Average of	SD	23.36	26.28	27.33	39.31	21.52
1837.7906	1837.7906 Group A	Right Cheek and Left Cheek	Median	117.00	111.33	111.33	133.50	118.17
			N	31	31	30	30	30
			% Change		-0.40%	0.15%	12.84%	0%
			Mean	111.31	114.03	113.14	120.80	119.38
		Average of	SD	21.52	24.83	12.63	22.89	18.62
1837.7907 Group B	Right Cheek and	Median	102.67	106.33	110.50	119.17	112.00	
		Left Cheek	N	29	29	28	28	27
			% Change		2.45%	1.65%	8.52%	7%

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Text Table 7-26 Intra-Subject Change in DPM Measurements

				Intra-Subject Change in DPM Measurements (au)**			
RCTS Test Article Code	Client Test Article Code	Site Measured	Descriptive Statistics	Week 2 vs. Baseline	Week 4 vs. Baseline	Week 8 vs. Baseline	Week 12 vs. Baseline
1837.7906	Group A	Average of Right Cheek and Left Cheek	Mean SD Median N P-Value*	-0.48 28.43 0.00 31 0.925	-0.20 26.40 -4.67 30 0.967	15.27 34.97 9.33 30 <b>0.024</b>	-0.29 25.80 3.17 30 0.952
1837.7907	Group B	Average of Right Cheek and Left Cheek	Mean SD Median N P-Value*	2.72 17.80 4.00 29 0.417	3.95 16.82 4.84 28 0.225	11.61 24.26 13.67 28 <b>0.018</b>	9.78 24.31 9.33 27 <b>0.047</b>
			P-Value^: Group A vs. Group B	0.605	0.482	0.647	0.136

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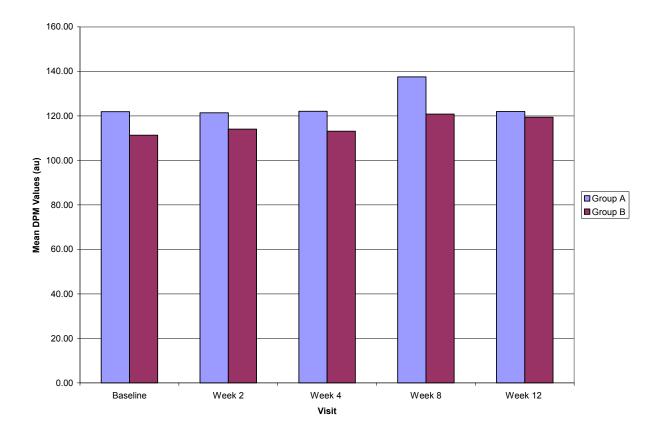
<sup>\*</sup>P-values generated from a paired-difference t-test. Bolded values are significant at p $\leq$ 0.05

<sup>\*\*</sup> Intra-subject change = Difference in NOVA DPM values at two different time points (Post-Baseline minus Baseline)

<sup>^</sup>P-Value derived from a One Factor Analysis of Variance Test

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The data in Text Table 7-26 reveal the following:

- When the post-treatment NOVA DPM values for Group A were compared to baseline values, a significant increase\* at Week 8 was measured. No other significant differences were observed at any other time point.
- When the post-treatment NOVA DPM values for Group B were compared to baseline values, there were significant increases at Weeks 8 and 12. No other significant differences were observed at any other time point.
- When comparing the two groups together, there was no evidence that the NOVA DPM values generated in Group A were significantly different from those generated in Group B, regardless of the time point.

<sup>\*</sup>An increase in NOVA DPM values indicates, indirectly, an increase in the skin's moisture properties.

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### 7.4 SAFETY RESULTS

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# 7.4.1 SUB-INVESTIGATOR'S ASSESSMENT OF SKIN IRRITATION, OVERALL SEVERITY OF ACNE AND RECORD OF INDIVIDUAL ACNE LESIONS

A summary of skin irritation, overall severity of acne and a count of the individual acne lesion for each test article is located in Text Tables 7-27, 7-29, 7-31, 7-33 and 7-35. Text Tables 7-28, 7-30, 7-32, 7-34 and 7-36 provide a comparison of the baseline values to post-treatment values. A graphic representation of the data (mean & median values) can be found in Text Figures 7-8 through 7-12.

Text Table 7-27 Sub-Investigator's Assessment of Skin Irritation

		Visit				
	Descriptive Statistics	Baseline	Week 2	Week 4	Week 8	Week 12
	Mean	1.10	0.94	0.67	0.33	0.43
Group A	SD	0.40	0.63	0.66	0.48	0.50
Gloup A	Median	1.00	1.00	1.00	0.00	0.00
	N	31	31	30	30	30
	Mean	0.97	0.69	0.43	0.32	0.15
Group B	SD	0.42	0.54	0.57	0.55	0.36
Group B	Median	1.00	1.00	0.00	0.00	0.00
	N	29	29	28	28	27

Scale:

0 = None; 1 = Mild; 2 = Moderate; 3 = Severe

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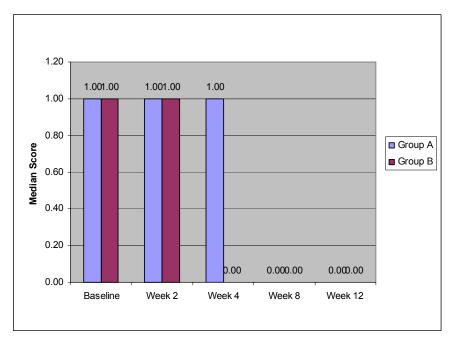
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**Text Table 7-28** Intra-Subject Change in Skin Irritation Data

		Intra-Subject Change**					
	Descriptive Statistics	Week 2 vs. Baseline	Week 4 vs. Baseline	Week 8 vs. Baseline	Week 12 vs. Baseline		
	Mean	-0.16	-0.43	-0.77	-0.67		
	SD	0.52	0.63	0.57	0.55		
Group A	Median	0.00	-0.50	-1.00	-1.00		
	N	31	30	30	30		
	P-Value*	0.180	0.002	<0.001	<0.001		
	Mean	-0.28	-0.54	-0.64	-0.78		
	SD	0.53	0.51	0.49	0.42		
Group B	Median	0.00	-1.00	-1.00	-1.00		
	N	29	28	28	27		
	P-Value*	0.021	<0.001	<0.001	<0.001		
	P-Value^: Group A vs. Group B	0.408	0.624	0.441	0.347		

<sup>\*</sup>P-values generated from a Wilcoxon Signed-Rank Test. Bolded values are significant at p≤0.05

**Text Figure 7-8 Sub-Investigator's Assessment of Skin Irritation (Median Scores)** 



The data in Text Table 7-28 show the results of subtracting baseline values for Skin Irritation (as determined by the Sub-Investigator) from post-treatment values for Skin Irritation. The p-values obtained as a result of the change (post-treatment minus baseline) were generated using a

<sup>\*\*</sup> Intra-Subject Change = Difference in values at two different time points (Post-Baseline Minus Baseline)

<sup>^</sup>P-value derived from One-Factor Analysis of Variance Test.

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Wilcoxon Signed-Rank test. The p-values obtained when comparing Group A to Group B were derived from a One-Factor ANOVA test. Values were considered significant ( $P \le 0.05$ ) if the change was significantly greater than zero (no change).

The results indicate that when the changes in post-baseline values for Skin Irritation were compared to baseline values:

- There was a significant improvement, relative to baseline, in Skin Irritation at all time points relative to baseline for Group B.
- There was a significant improvement, relative to baseline, in Skin Irritation at Weeks 4, 8 and 12 for Group A; however, no significant changes were observed at Week 2.

When comparing the two groups together, there was no evidence that the Skin Irritation values generated in Group A were significantly different from those generated in Group B, regardless of the time point.

Text Table 7-29 Sub-Investigator's Assessment of Overall Severity of Acne

		Visit					
	Descriptive Statistics	Baseline	Week 2	Week 4	Week 8	Week 12	
	Mean	0.81	0.84	0.90	0.50	0.70	
Group A	SD	0.48	0.37	0.40	0.51	0.53	
Gloup A	Median	1.00	1.00	1.00	0.50	1.00	
	N	31	31	30	30	30	
	Mean	0.66	0.66	0.57	0.57	0.56	
Group B	SD	0.48	0.48	0.57	0.50	0.51	
Group B	Median	1.00	1.00	1.00	1.00	1.00	
	N	29	29	28	28	27	

Scale:

0 = None; 1 = Mild; 2 = Moderate; 3 = Severe

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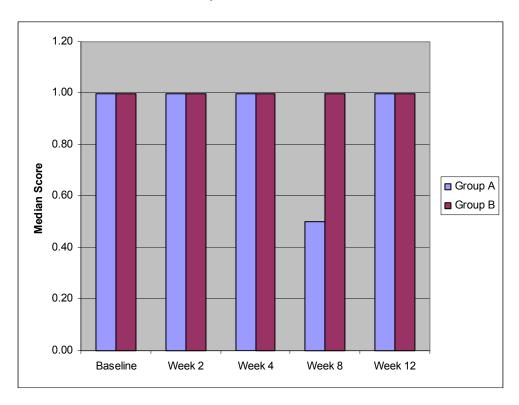
Text Table 7-30 Intra-Subject Change in Overall Severity of Acne Data

		Intra-Subject Change**					
	Descriptive Statistics	Week 2 vs. Baseline	Week 4 vs. Baseline	Week 8 vs. Baseline	Week 12 vs. Baseline		
	Mean	0.03	0.10	-0.30	-0.10		
Croun	SD	0.48	0.48	0.53	0.55		
Group A	Median	0.00	0.00	0.00	0.00		
'	N	31	30	30	30		
	P-Value*	1.000	0.453	0.012	0.508		
	Mean	0.00	-0.07	-0.07	-0.07		
Croun	SD	0.65	0.54	0.54	0.68		
Group B	Median	0.00	0.00	0.00	0.00		
	N	29	28	28	27		
	P-Value*	1.000	0.727	0.727	0.774		
	P-Value^: Group A vs. Group B	0.838	0.208	0.116	0.912		

<sup>\*</sup>P-values generated from a Wilcoxon Signed-Rank Test. Bolded values are significant at p<0.05

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Text Figure 7-9 Sub-Investigator's Assessment of Overall Severity of Acne (Median Scores)



<sup>\*\*</sup> Intra-Subject Change = Difference in values at two different time points (Post-Baseline Minus Baseline)

<sup>^</sup>P-value derived from One-Factor Analysis of Variance Test.

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The data in Text Table 7-30 show the results of subtracting baseline values for Overall Severity of Acne (as determined by the Sub-Investigator) from post-treatment values for Overall Severity of Acne. The p-values obtained as a result of the change (post-treatment minus baseline) were generated using a Wilcoxon Signed-Rank test. The p-values obtained when comparing Group A to Group B were derived from a One-Factor ANOVA test.

The results indicate that when the changes in post-baseline values for Overall Severity of Acne were compared to baseline values:

- There was a significant improvement, relative to baseline, in Overall Severity of Acne at Week 8 for Group A. No significant differences were observed at Weeks 2, 4 and 12.
- No significant changes, relative to baseline, were observed in Overall Severity of Acne at any time points for Group B.

When comparing the two groups together, there was no evidence that the Overall Severity of Acne values generated in Group A were significantly different from those generated in Group B, regardless of the time point.

Text Table 7-31 Sub-Investigator's Assessment of Inflammatory Acne Lesions

			Visit				
	Descriptive Statistics	Baseline	Week 2	Week 4	Week 8	Week 12	
	Mean	1.65	1.94	2.47	1.47	1.83	
Group A	SD	2.58	2.14	2.48	2.32	2.68	
Gloup A	Median	1.00	1.00	2.00	0.00	0.50	
	N	31	31	30	30	30	
	Mean	1.21	1.66	1.57	1.36	1.26	
Group B	SD	1.61	2.50	2.54	3.63	2.89	
Group B	Median	0.00	1.00	0.00	0.00	0.00	
	N	29	29	28	28	27	

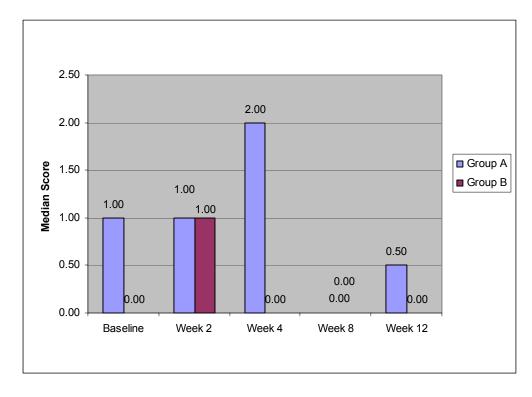
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Text Table 7-32 Intra-Subject Change in Inflammatory Acne Lesion Data

			Intra-Subject Change**					
	Descriptive	Week 2 vs.	Week 4 vs.	Week 8 vs.	Week 12 vs.			
	Statistics	Baseline	Baseline	Baseline	Baseline			
	Mean	0.29	0.77	-0.23	0.13			
	SD	3.05	3.28	3.08	3.06			
Group A	Median	0.00	0.00	0.00	0.00			
	N	31	30	30	30			
	P-Value*	0.407	0.165	0.891	0.941			
	Mean	0.45	0.46	0.25	0.15			
	SD	2.44	2.57	3.27	2.74			
Group	Median	0.00	0.00	0.00	0.00			
B	N	29	28	28	27			
	P-Value*	0.459	0.490	0.800	0.921			
	P-Value^: Group A vs. Group B	0.682	0.411	0.856	0.948			

<sup>\*</sup>P-values generated from a Wilcoxon Signed-Rank Test. Bolded values are significant at p<0.05

Text Figure 7-10 Sub-Investigator's Assessment of Inflammatory Acne Lesions (Median Scores)



<sup>\*\*</sup> Intra-Subject Change = Difference in values at two different time points (Post-Baseline Minus Baseline)

<sup>^</sup>P-value derived from One-Factor Analysis of Variance Test.

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The data in Text Table 7-32 show the results of subtracting baseline values for Inflammatory Acne Lesions (as determined by the Sub-Investigator) from post-treatment values for Inflammatory Acne Lesions. The p-values obtained as a result of the change (post-treatment minus baseline) were generated using a Wilcoxon Signed-Rank test. The p-values obtained when comparing Group A to Group B were derived from a One-Factor Analysis of Variance test.

The results indicate that when the changes in post-baseline values for Inflammatory Acne Lesions were compared to baseline values:

• There was no evidence of any significant changes in Inflammatory Acne Lesions at any time point, relative to baseline, for either Group A or Group B.

When comparing the two groups together, there was no evidence that the Inflammatory Acne Lesion values generated in Group A were significantly different from those generated in Group B, regardless of the time point.

Text Table 7-33 Sub-Investigator's Assessment of Non-Inflammatory Acne Lesions

		Visit					
	Descriptive Statistics	Baseline	Week 2	Week 4	Week 8	Week 12	
	Mean	8.19	4.23	6.20	2.63	4.67	
Croup A	SD	11.84	6.34	9.00	5.18	7.14	
Group A	Median	4.00	2.00	2.00	0.00	2.00	
	N	31	31	30	30	30	
	Mean	3.00	1.55	2.68	2.07	1.52	
Group B	SD	4.68	2.08	6.59	3.67	1.99	
	Median	2.00	0.00	0.00	0.00	0.00	
	N	29	29	28	28	27	

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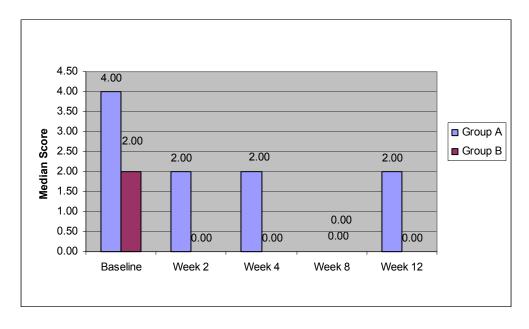
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Intra-Subject Change in Non-Inflammatory Acne Lesion Data **Text Table 7-34** 

		Intra-Subject Change*					
	Descriptive Statistics	Week 2 vs. Baseline	Week 4 vs. Baseline	Week 8 vs. Baseline	Week 12 vs. Baseline		
	Mean	-3.97	-1.83	-5.40	-3.37		
	SD	10.38	8.21	9.11	8.40		
Group A	Median	-1.00	0.00	-2.00	-2.00		
	N	31	30	30	30		
	P-Value*	0.048	0.396	<0.001	0.020		
	Mean	-1.45	-0.29	-0.89	-1.48		
	SD	4.48	7.53	3.49	5.18		
Group B	Median	-1.00	0.00	0.00	0.00		
	N	29	28	28	27		
	P-Value*	0.127	0.181	0.177	0.264		
	P-Value^: Group A vs. Group B	0.585	0.725	0.018	0.190		

<sup>\*</sup>P-values generated from a Wilcoxon Signed-Rank Test. Bolded values are significant at p≤0.05

**Text Figure 7-11** Sub-Investigator's Assessment of Non-Inflammatory Acne Lesions (Median Scores)



<sup>\*\*</sup> Intra-Subject Change = Difference in values at two different time points (Post-Baseline Minus Baseline)

<sup>^</sup>P-value derived from One-Factor Analysis of Variance Test.

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The data in Text Table 7-34 show the results of subtracting baseline values for Non-Inflammatory Acne Lesions (as determined by the Sub-Investigator) from post-treatment values for Non-Inflammatory Acne Lesions. The p-values obtained as a result of the change (post-treatment minus baseline) were generated using a Wilcoxon Signed-Rank test. The p-values obtained when comparing Group A to Group B were derived from a One-Factor ANOVA test.

The results indicate that when the changes in post-baseline values for Non-Inflammatory Acne Lesions were compared to baseline values:

- O There was a significant decrease, relative to baseline, in Non-Inflammatory Acne Lesions at Weeks 2, 8 and 12 for Group A. No evidence of a significant difference was observed at Week 4.
- o No evidence of a significant change, relative to baseline, was observed at any time point for Group B.

When comparing the two groups together, Group A performed significantly better (i.e., had a greater impact on reducing the appearance of non-inflammatory acne lesions) than Group B at the Week 8 visit. No other significant differences between the groups were observed, regardless of the time point.

Text Table 7-35 Sub-Investigator's Assessment of Total Acne Lesions (Inflammatory & Non-Inflammatory Lesions)

		Visit				
	Descriptive Statistics	Baseline	Week 2	Week 4	Week 8	Week 12
	Mean	9.84	6.16	8.67	4.10	6.50
Group A	SD	13.07	6.68	10.67	6.69	8.83
Group A	Median	7.00	4.00	4.50	1.00	3.00
	N	31	31	30	30	30
	Mean	4.21	3.21	4.25	3.43	2.59
Group B	SD	5.81	3.23	8.24	5.49	3.39
Group B	Median	3.00	3.00	1.00	1.50	2.00
	N	29	29	28	28	27

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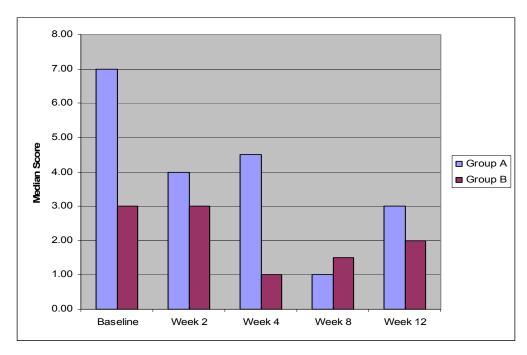
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Text Table 7-36 Intra-Subject Change in Total Acne Lesions (Inflammatory & Non-**Inflammatory Lesions)** 

			Intra-Subject Change**					
	Descriptive Statistics	Week 2 vs. Baseline	Week 4 vs. Baseline	Week 8 vs. Baseline	Week 12 vs. Baseline			
	Mean	-3.68	-1.07	-5.63	-3.23			
	SD	11.17	10.65	10.10	9.70			
Group A	Median	-1.00	0.00	-2.00	-1.50			
	N	31	30	30	30			
	P-Value*	0.116	0.814	0.001	0.044			
	Mean	-1.00	0.18	-0.64	-1.52			
	SD	4.99	8.90	4.34	5.83			
Group B	Median	0.00	0.00	0.00	0.00			
	N	29	28	28	27			
	P-Value*	0.466	0.446	0.401	0.237			
	P-Value^: Group A vs. Group B	0.503	0.715	0.032	0.360			

<sup>\*</sup>P-values generated from a Wilcoxon Signed-Rank Test. Bolded values are significant at p≤0.05

**Text Figure 7-12** Sub-Investigator's Assessment of Total Acne Lesions (Median Scores)



The data in Text Table 7-36 show the results of subtracting baseline values for Total Acne Lesions (as determined by the Sub-Investigator) from post-treatment values for Total Acne

<sup>\*\*</sup> Intra-Subject Change = Difference in values at two different time points (Post-Baseline Minus Baseline)

<sup>^</sup>P-value derived from One-Factor Analysis of Variance Test.

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Lesions. The p-values obtained as a result of the change (post-treatment minus baseline) were generated using a Wilcoxon Signed-Rank test. The p-values obtained when comparing Group A to Group B were derived from a One-Factor ANOVA test.

The results indicate that when the changes in post-baseline values for Total Acne Lesions were compared to baseline values:

- o There was a significant decrease, relative to baseline, in Total Acne Lesions at Weeks 8 and 12 for Group A. No evidence of a significant change was observed at Weeks 2 and 4.
- o No evidence of a significant change, relative to baseline, was observed at any time point for Group B.

When comparing the two groups together, Group A performed significantly better (i.e., had a greater impact on reducing the appearance of the total number of acne lesions) than Group B at the Week 8 visit. No other significant differences between the groups were observed, regardless of the time point.

#### 7.4.2 **Overall Experience of Adverse Events**

All treatment-emergent adverse events are listed in Data Listing 10 (Appendix 2).

During this study, 34 adverse events were recorded. One (1) of the adverse events was considered serious. The breakdown for adverse events is as follows:

Type of Adverse Event	Frequency of Adverse Events
Blemishes (breakout)	11
Headache	1
Peeling/Sloughing	1
Swelling	1
Watery eye	1
Clogged pores	1
Hand Surgery (considered a serious adverse event unrelated to test article use)	1
Tightness	6
Redness	3
Redness with bumps	1
Dryness	2
Rash/bumps	1
Eyes Burning	2
Bronchitis	1
Bump	1

The relationship of the event to the test article can be found in Appendix 2, Data Listing 10.

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### 8 DISCUSSION AND OVERALL CONCLUSIONS

#### **Conclusions:**

This was a 12 week, double blinded, single centre study designed to determine the efficacy and tolerance of two concentrations of Zeatin (0.10% and 0.025%). Under the conditions of this study:

### **Skin Aging**

#### • Fine Wrinkles

### Sub-Investigator's Assessment of Skin Aging for Fine Wrinkles

 The Sub-Investigator noticed a significant improvement, relative to baseline, in the appearance of Fine Wrinkles for both Groups A and B after 4, 8 and 12 weeks of test article use. No significant difference in the appearance of Fine Wrinkles was observed at Week 2, regardless of the test group.

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 When comparing the Fine Wrinkle data generated by Group A to that generated by Group B, no significant difference between the groups was observed at any time point.

### Subject's Self Assessment for Fine Wrinkles

- Subjects in both Groups A and B noticed a significant improvement, relative to baseline, in the appearance of Fine Wrinkles at all time points.
- When comparing the changes observed in both groups, there was no significant difference in the data generated between Groups A and B at any time point.

#### Coarse Wrinkles

#### Sub-Investigator's Assessment of Skin Aging for Coarse Wrinkles

- The Sub-Investigator noticed a significant improvement, relative to baseline, in the appearance of Coarse Wrinkles for subjects assigned to Group B values after 12 weeks of test article use. No other significant differences were observed at any time point.
- Subjects in Group A did not show a significant change, relative to baseline, in Coarse Wrinkle values; however, it was highly suggestive that reduction in Coarse Wrinkle values was observed at Week 12.
- When comparing the Coarse Wrinkle data generated by Group A to that generated by Group B, no significant difference between the groups was observed at any time point.

#### Roughness

### Sub-Investigator's Assessment of Skin Aging for Roughness

- The Sub-Investigator noticed a significant improvement, relative to baseline, in the skin's Roughness values for both Groups A and B at all time points.
- When comparing the Roughness data generated by Group A to that generated by Group B, no significant difference

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between the groups was observed at any time point.

between the groups was observed at any time point. However, the data were highly suggestive that subjects in Group A had a greater improvement in Roughness values, relative to Group B, at the Week 12 time point.

### Subject's Self Assessment of Skin Texture

- Subjects in both Groups A and B noticed a significant improvement, relative to baseline, in their skin's texture at all time points.
- When comparing the Skin Texture data generated by Group A to that generated by Group B, no significant difference between the groups was observed at any time point.

### Overall Severity of Skin Aging

<u>Sub-Investigator's Assessment of Skin Aging for Overall Severity of</u> Skin Aging

- The Sub-Investigator noticed a significant improvement, relative to baseline, in the Overall Severity of Skin Aging values for both Groups A and B at all time points.
- When comparing the Overall Severity of Skin Aging data generated by Group A to that generated by Group B, no significant difference between the groups was observed at any time point.

### Global Assessment of Improvement

Sub-Investigator's Global Assessment of Improvement of Skin Aging

- The Sub-Investigator noticed a significant improvement, relative to baseline, in the Global Assessment of Improvement in Skin Aging values for both Groups A and B at all time points.
- When comparing the Global Assessment of Improvement in Skin Aging data generated by Group A to that generated by Group B, no significant difference between the groups was observed at any time point.

### Subject's Self Assessment of Overall Improvement

- Subjects in both Groups A and B noticed a significant improvement, relative to baseline, in their skin at all time points.
- When comparing the Overall Improvement data generated by Group A to that generated by Group B, no significant difference between the groups was observed at any time point.

#### **Skin Color**

<u>Sub-Investigator's Assessment of Skin Aging for Mottled</u> Hyperpigmentation

 The Sub-Investigator detected a significant improvement in Mottled Hyperpigmentation for subjects in Group A at Weeks 4, 8 and 12. RCTS, Inc. CONFIDENTIAL Page 76 of 226
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> The Sub-Investigator detected a significant improvement in Mottled Hyperpigmentation for subjects in Group B at all time points.

- It was highly suggestive that Group B performed better than Group A at Week 4.
- When comparing the Mottled Hyperpigmentation data generated by Group A to that generated by Group B, It was highly suggestive that Group B performed better than Group A at Week 4.

### Subject's Self Assessment of Blotchiness – Brown Spots

- Subjects in both Groups A and B noticed a significant improvement, relative to baseline, in the Blotchiness-Brown Spots of their skin at Weeks 8 and 12.
- When comparing the Blotchiness-Brown Spots data generated by Group A to that generated by Group B, no significant difference between the groups was observed at any time point.

### Subject's Self Assessment of Skin Color

- Subjects in both Groups A and B noticed a significant improvement, relative to baseline, in their Skin's Color at all time points.
- When comparing the Skin Color data generated by Group A to that generated by Group B, It was highly suggestive that Group B performed better than Group A at Weeks 4 and 8.

### Skin Barrier Properties (TEWL) Moisturization (NOVA DPM)

#### **TEWL Measurements**

- Subjects in Group A produced significantly elevated TEWL values, relative to baseline, at Weeks 2 and 12.
- There was no significant difference in TEWL values, relative to baseline, detected for subjects in Group B at any time point.
- It was highly suggestive that subjects in Group B had lower TEWL values than subjects in Group A at the Week 8 time point.

#### **NOVA DPM Measurements**

- Subjects in Group A had significantly increased NOVA DPM values (an indirect measure of skin moisturization), relative to baseline, at Week 8.
- Group B had significantly increased NOVA DPM values at Weeks 8 and 12.
- There was no significant difference between Groups A and B at any time point.

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### Safety

# Sub-Investigator's Assessment of Skin Irritation

The Sub-investigator detected a significant improvement, relative to baseline, in skin irritation for subjects in Group A at Weeks 4, 8 and 12.

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- The Sub-investigator detected a significant improvement, relative to baseline, in skin irritation for subjects in Group B at all time points.
- There was no significant difference between Groups A and B at any time point.

### Sub-Investigator's Assessment of Overall Severity of Acne

- Group A had significantly improved (reduced) values, relative to baseline, for Overall Severity of Acne at Week 8.
- No significant difference, relative to baseline, in the Overall Severity of Acne was observed at any time point for subjects in Group B.
- There was no significant difference between Groups A and B at any time point.

### Count of Individual Acne Lesions

### Inflammatory Acne Lesions

- There were no significant changes in the inflammatory acne lesion counts, relative to baseline, for either group regardless of the time
- There was no significant difference between Groups A and B at any time point.

#### Non-Inflammatory Acne Lesions

- Group A had significantly decreased Non-Inflammatory Acne Lesion counts at Weeks 2, 8 and 12, relative to baseline.
- Subjects in Group B did not show a significant change, relative to baseline, in the presence of Non-Inflammatory Acne Lesions at any time point.
- Group A performed significantly better than Group B at decreasing the number of Non-Inflammatory Acne Lesions at Week 8.

### Total Inflammatory & Non-Inflammatory Acne Lesions

- Group A had significantly lower Total Acne Lesion counts at Weeks 8 and 12, relative to baseline.
- Subjects in Group B did not show a significant change, relative to baseline, in the Total Inflammatory and Non-Inflammatory Acne Lesion counts at any time point.

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> Group A performed significantly better than Group B at decreasing the number of Total Acne Lesion counts at Week 8.

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Therefore, in general, the test articles (0.10% and 0.025% Zeatin) performed at parity and helped to improve:

- The appearance of Fine Wrinkles (Weeks 4, 8 and 12)
- Coarse Wrinkles (Group B at Week 12)
- Roughness (at all time points)
- Overall Severity of Skin Aging (at all time points)
- Mottled Hyperpigmentation (Group A at Weeks 4, 8 and 12; Group B at all time points)
- Blotchiness-Brown Spots (Weeks 8 and 12)
- Overall Skin Color (at all time points)

Additionally, the test articles were well tolerated with both the Sub-Investigator and Subjects not detecting any significant increase in irritation. In fact, the Sub-Investigator detected a significant improvement in the appearance of irritation, relative to baseline, after 4, 8 and 12 weeks of test article use (subjects in Group B actually showed a reduction in irritation at Week 2 as well).

Regarding the effect of the test articles on acne counts, while the test articles performed, in general, at parity (no significant difference between subjects who used the Zeatin at 0.10% and those that used Zeatin at 0.025%), subjects using Zeatin at 0.10% seemed to show a greater reduction, relative to baseline, in the presence of non-inflammatory and total acne lesions.

Finally, neither test article was effective at reducing TEWL. In fact, subjects in Group A (Zeatin at 0.10%) showed elevated TEWL values at Weeks 2 and 12. However, regarding NOVA DPM measurements, subjects in Group B (Zeatin at 0.025%) showed elevated NOVA DPM values at Weeks 8 and 12. Subjects in Group A showed elevated NOVA DPM values at Week 8 only.

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#### 9 **POST-TEXT TABLES**

Follow:

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Table I
Demographics of Subjects

		Group A		Group B			
		Enrolled	Completed	mpleted Enrolled C			
	Mean	49.8	51.1	50.2	50.0		
	SD	7.0	6.6	8.1	8.7		
Age of Test Subjects	Median	50.0	51.5	52.0	52.0		
Subjects	Range	31-64	38-64	32-64	32-64		
	N	37	30	36	27		
Gender of Test Subjects	Female	100%	100%	100%	100%		
Ethnicity of Test Subjects	Caucasian	34 (87%)	27 (90%)	29 (85%)	24 (85%)		
	Hispanic	5 (13%)	3 (10%)	3 (9%)	3 (11%)		
	Native American	0 (0%)	0 (0%)	1 (3%)	1 (4%)		
	Asian/Pacific Islander	0 (0%)	0 (0%)	1 (3%)	0 (0%)		
Number of Completed Subjects	57						
Number of Discontinued Subjects	16						

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#### 10 **APPENDICES**

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# **APPENDIX 1 STUDY INFORMATION**

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# 1.1 Protocol and Protocol Amendment

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RCTS Protocol Number: 2005.091 March 17, 2005

### **CLINICAL PROTOCOL**

Title: A Clinical Study of Topical Zeatin (0.1%, 0.025%) for Improving

the Appearance of Photodamaged Skin

Date: March 17, 2005

RCTS Panel Number: 1837

Sponsor: Senetek PLC

620 Airpark Road Napa, CA 94558

Sponsor's Frank Massino

Representative: Phone: 707-226-3900 ext. 109

E Mail: Frank@senetek.net

Test Articles: Zeatin (0.1%)

Zeatin (0.025%)

Medical Investigator:

Ponciano Cruz, Jr., MD Date

**Board Certified Dermatologist** 

Address: RCTS, Inc.

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Phone: 972-871-7578 Fax: 214-441-2583 RCTS, Inc Confidential 2 of 35 RCTS Panel 1837 Protocol Version: Final

RCTS Protocol Number: 2005.091 March 17, 2005

Approvals:

Linh Kobylar, BA Date

Quality Assurance RCTS, Inc.

Barry T. Reece, MS, MBA Sub Investigator Date

Vice President/Managing Partner

RCTS, Inc.

Frank Massino Date

CEO

Senetek PLC

Protocol Version: Final RCTS Protocol Number: 2005.091 March 17, 2005

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	<u>S</u>	UMMARY	
Treatment Articles:	Zeatin (0.10%) Zeatin (0.025%)		
Control Articles:	Not Applicable		
Route of Administrat	ion: Topical applic	ation to the face	
applie		. •	atin (0.1% and 0.025%) inical signs of age-related
•	Enroll approximately 5	50 subjects (25 subjects i	n Cell I and 25 Subjects in
	Parallel Group Crossover	Duration of Treatment:	Approx. 12 Weeks
	Other (intra-individual)	Duration of Study:	Approximately 14 Weeks

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Multicenter:	Yes Number of Centers: 1 US site Common Training: X Yes No X No
Masking:	None Evaluator-Masked Patient-Masked Double-Masked Triple-Masked
Method of Patie	nt Assignment:
Randomization:	X Yes No
Concurrent Control:	X None No Treatment Placebo Active Specify: Other Specify:
Estimated Total	Sample Size: 25 subjects completed per cell
Efficacy Variable	es:
Primary:	
(coarse a	tions by the sub-investigator to determine the improvement of wrinkles and fine), roughness, mottled hyperpigmentation, global assessment of everity and degree of improvement relative to baseline;
Subject s     blotchine	self-assessment to determine the improvement of wrinkles, texture, ess, color and perform a global assessment to document the overall ment in their facial skin;
	the treatment(s) on Transepidermal Water Loss (TEWL); and the treatment(s) on Skin Capacitance (an indirect measure of skin ration)
Secondary:	
5. Observa	tion by the sub-investigator for skin irritation and acne lesion counts; and
6. Subject s	self-assessment of skin tolerance.

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### **Evaluability**

Only subjects who meet all of the inclusion and none of the exclusion criteria will be evaluable.

### **Analyses**

The primary statistical objectives of this study are to describe the efficacy of Zeatin (0.1% or 0.025%) with regard to the reduction in the signs of photoaging when used by a population of normal, healthy female subjects for 12 weeks. The test article(s) will be deemed effective if the post treatment data associated with the primary efficacy variables show a significant improvement relative to baseline values.

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### 1. INTRODUCTION

Kinetin is a cytokinin that regulates various aspects of plant growth and differentiation. The antiaging actions of kinetin on human skin were first demonstrated by Rattan and Clark (*Biochem. Biophys. Res. Commun.* 201:665-672, 1994) in cultured human fibroblasts, where the presence of kinetin delayed the onset and decreased the extent of many morphological and biochemical characteristics associated with serial passaging of cells. The effectiveness of kinetin in maintaining normal cell function in aging cells provides the basis for its use for preserving the vitality of aging skin.

Previous studies with a total of 96 subjects were conducted at the University of California, Irvine by Dr. Gerald Weinstein and Dr. Jerry McCullough (*Cosmetic Dermatology* 15: 29-32, 2003) to assess the tolerance and effectiveness of topical kinetin products ranging in concentration from 0.005% to 0.10% (Kinerase7) for the treatment of mild to moderately photodamaged facial skin. Treatments after 12 and 24 weeks produced significant improvement in the appearance of skin texture, mottled hyperpigmentation and fine wrinkles compared to baseline as assessed by both the physician and the subject. Treatments also produced an improvement in skin barrier function as assessed by a decrease in transepidermal water loss. Overall, the treatments were well tolerated by the subjects.

Zeatin, is cytokinin plant growth factor, 6-[4-hydroxy-3-methyl-but-2-enylamino] adenine, that like kinetin, also has growth modulatory, anti-oxidative and ant-senescence effects in human skin cells (Rattan and Sodagam, 2004). Zeatin is a plant cytokinin that has been identified to be present in the tRNA of a wide variety of organisms. There is a large body of information regarding the biosynthesis, activity and degradation of zeatin in bacteria, fungi and higher plants. The recent studies of Rattan and Sodagam have demonstrated several beneficial and youth-preserving effects of *trans*-zeatin on human cells (skin fibroblasts) undergoing aging *in vitro*. Although kinetin and zeatin are very much alike in their anti-aging effects on human skin cells, on a short-term basis, human skin fibroblasts can tolerate higher concentrations of zeatin. Kinetin is a DNA-based modified adenine, whereas, zeatin is a tRNA-based modified adenine.

### 2. OBJECTIVE

The primary objective of this study is to determine the cosmetic efficacy and subjects' tolerance of topical zeatin (0.10% and 0.025%) applied twice daily for 12 weeks for improving the clinical signs and symptoms of photodamaged facial skin.

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#### 3. TEST ARTICLES

### 3.1. Study Test Articles

Enough test articles will be supplied to evaluate approximately 25 subjects per cell. Depending on cell assignment, the subjects will receive one of the following test articles:

3.1.1. Zeatin (0.1%)

Lot Number TBD

Provided by Senetek PLC (Napa, CA)

Test article will be stored at room temperature (59-86°F, 15-30°C)

3.1.2. Zeatin (0.025%)

Lot Number TBD

Provided by Senetek PLC (Napa, CA)

Test article will be stored at room temperature (59-86°F, 15-30°C)

A certificate of analysis, or equivalent, for the Zeatin will be provided to the testing facility by the Sponsor. A copy of the certificate of analysis, or equivalent, will be provided in the final report.

Test articles will be coded by the Sponsor in a manner consistent with the study design.

### 3.2. Test Article Usage

Each subject will be randomly assigned to one of two cells and provided with the test article associated with their cell. Subjects will be instructed to use the test article twice daily for 12 weeks according to the following instructions:

- 1. Wash your face with a mild cleanser and dry completely prior to application of the product to your face;
- 2. Apply a liberal amount of the product to your face in the early morning and about one hour before bedtime;
- 3. In the morning, after the product has absorbed into the skin, apply the sunscreen that was provided to you to your face; and
- 4. Other than the product being provided to you, do not introduce any new products into your skin care regimen.

For test article accountability see 15.2

#### 4. SUBJECTS:

### 4.1. Subject Population

Subjects will be normal, healthy female volunteers between the ages of 30 and 65.

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### 4.2. Inclusion Criteria

Subjects must satisfy all of the following criteria:

1. Subjects must be ambulatory, 30 to 65 years of age and in reasonably good health;

- 2. Female subjects must be postmenopausal, surgically sterile or using a medically acceptable form of birth control with a negative urine pregnancy test;
- 3. Subjects must have mild to moderate changes associated with skin aging (1-6 overall severity score);
- 4. Subjects are willing to refrain from using lotions, moisturizers, or other skin care products (except those provided by the testing facility) or any medications on their facial area during the treatment period. Subjects are permitted to use their color cosmetics (e.g., foundation, blush) as long as the color cosmetics do not contain antiaging ingredients;
- 5. Subjects are willing to have clinical photographs taken to document their improvement;
- 6. All subjects must agree to refrain from applying any products (including the test product) to their face the day of their visits. Additionally, subjects must not have bathed or showered within two hours of their study visit (i.e., bathing or showering must have occurred no less than 2 hours before their study visits);
- 7. Subjects must agree not to wear any facial makeup to any of their visits (lip and eye color are acceptable); and
- 8. Subjects have indicated willingness to participate in the study by signing an informed consent document and a photo release document.

### 4.3. Exclusion Criteria

Subjects with any of the following conditions are not eligible for participation:

- 1. Subject is pregnant or lactating;
- 2. Subject with a global severity score greater than 6 (see section 5.1.2.3);
- 3. Subject has history or evidence of any chronic or reoccurring skin disease or disorder (e.g., psoriasis, eczema, atopic dermatitis, mild to moderate acne, etc.) affecting the face;
- 4. Subject has a known allergy to any component of study formulation or a proclivity to cutaneous hyper-reactivity;
- 5. Subject requires the use of a tanning bed or participates in activities that involve excessive prolonged exposure to the sun;

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- 6. Subject has used systemic retinoids within 6 months prior to study entry (e.g., acitretin, isotretinoin);
- 7. Subject has used topical retinoids within 2 months prior to study entry (e.g. tretinoin, adapalene);
- 8. Subject has received treatment with systemic corticosteroids within 6 months or topical corticosteroids to the face within 1 month prior to study entry;
- 9. Subject has used topical products containing 5% or more  $\alpha$ -hydroxy acids and/or  $\beta$ -hydroxy acids (e.g., Avon Anew, Olay BHA products, and any dermatologist products, such as the Murad line) within 1 month prior to study entry;
- 10. Subject has used peptide products (e.g., Olay Regenerist, Strivectin) within 1 month prior to study entry;
- 11. Subject has undergone phenol or trichloroacetic acid (TCA) deep peels within 1 year or medium to light peels within 3 months;
- 12. Subject has undergone facial cosmetic procedures such as dermabrasion, non-ablative laser rejuvenation or laser resurfacing within 1 year prior to study entry;
- 13. Subject has had botulinum toxin injections or facial fillers (e.g., lipids, collagen, Restylane) within 6 months prior to study entry;
- 14. Subject has ever had procedures of rhytidectomy (face-lifts), blepharoplasty, or had facial implants (silicone or Gore-Tex);
- 15. Subject is unwilling to use the SPF 30 sunscreen during the study;
- 16. Subject has participated in any clinical trial involving an investigational drug or cosmetic product or procedure within the past 30 days; and
- 17. Subjects with moderate to severe acne or other chronic recurring skin disorder.

#### 5. STUDY PROCEDURES

### 5.1. Study Design

This is a 12 week, double-blinded study designed to determine the efficacy of two concentrations (0.1% and 0.025%) of Zeatin. Fifty female volunteer subjects age 30 to 65 with mild to moderate signs of photodamaged facial skin will be enrolled into this study to evaluate the cosmetic efficacy and tolerance of topical zeatin (0.10% and 0.025%). Twenty-five subjects will be assigned to a cell which evaluates Zeatin at 0.10% and 25 subjects will be assigned to a cell which evaluates Zeatin at 0.025%. Subjects will apply the test products to the entire facial skin twice daily, in the early morning and in the evening (approximately 1 hour before bedtime) for 12 consecutive weeks. Subjects will be assessed for tolerance profile at weeks 2, 4, 8 and 12. At study entry (baseline), and at 2, 4, 8 and 12 weeks, the

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treated facial skin will be evaluated for clinical signs of skin aging, including observations by the sub-Investigator on wrinkles (coarse and fine), roughness, mottled hyperpigmentation, as well as subject self-assessment of improvement over baseline (wrinkles, texture, blotchiness, color and overall improvement). In addition, transepidermal water loss (TEWL) and skin moisture measurements will be taken on the cheeks of all subjects. Finally, standard clinical photographs of the face will be taken at baseline and at weeks 2, 4, 8 and 12.

### 5.1.1. Pre-Qualification of Test Subjects

Prior to study initiation, each subject will be screened to ensure they meet all of the inclusion and none of the exclusion criteria outlined above. Potential subjects will be interviewed and examined by the Sub-Investigator or his designee to establish their eligibility for inclusion in the study. Subjects will be given a full description of the nature and purpose of the study. If a subject is willing to participate, they must provide written informed consent before proceeding with the study.

Screening procedures will include the following activities for prospective participants:

- 1. Investigator, or designee, explains the investigational study and eligibility requirements;
- 2. Subject signs informed consent prior to any study-related procedures;
- 3. Record demographic information;
- 4. Brief dermatologic, medication and skin care/cosmetic product history:
- 5. Urine pregnancy test for females of childbearing potential; and
- 6. Subjects admitted to study will be assigned a specific subject number.

### 5.1.2. Day 0 (Baseline)

Qualified subjects arriving at the testing facility will be directed into an exam room where they will be allowed to equilibrate for at least 15 minutes under controlled environmental conditions ( $70^{\circ}F \pm 3^{\circ}F$ ;  $45\% \pm 10\%$  relative humidity). During equilibration the subjects will be interviewed regarding any changes to their medical history since their screening visit, asked to provide a detail account of all concomitant medications and skin care products and their face evaluated to ensure no cuts, abrasions or other dermal deviations are present which might prevent further participation on the clinical study. Following equilibration, each subject will undergo a series of clinical measurements designed to assess the skin's overall condition.

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### 5.1.2.1 Transepidermal Water Loss (TEWL)

TEWL refers to the amount of water vapor loss through the stratum corneum. If the water loss through the stratum corneum is altered, a corresponding change (increase or decrease) in TEWL will be observed. An observed increase in TEWL values can be a result of either Evaporative Water Loss (e.g. sweating or evaporation) or skin barrier damage. An observed decrease in TEWL values can be a result of either improvement in barrier function or the presence of a barrier over the skin.

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In this study, TEWL measurements will be taken using a TEWA meter (Courage & Khazaka, Köln, Germany). The TEWA meter is composed of a probe, containing two sensors (humidity and temperature), connected to a central processing unit. The probe will be placed in the center of both cheeks and measurements taken in duplicate. The corresponding data generated from the TEWL measurements will be entered onto the subject's case report form (CRF).

#### 5.1.2.2 Skin Moisture Measurements

Although a direct measurement of the skin's moisture content is possible, it is not practical. However, an indirect measure of the skin's moisture content is possible by measuring changes in the skin's electrical properties. Impedance based capacitance measurements can be taken on the skin using the NOVA DPM 9003® (NOVA Technologies, Gloucester, MA, USA). The instrument performs measurements at varying frequencies of the applied alternating current. The instrument takes a number of measurements at preselected frequencies up to 1 MHz. The actual calculation of the capacitance value is proprietary; however, the value displayed is directly related to capacitance and is displayed on the instrument in arbitrary units. A higher value indicates a greater capacitance which is indirectly related to the level of moisture at the test site.

In this study NOVA DPM measurements will be taken in the center of both cheeks. The probe will rest gently on the skin and measurements taken in triplicate. The corresponding data generated from the NOVA DPM measurements will be entered onto the subject's case report form (CRF).

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### 5.1.2.3 Expert Assessment of Subject's Facial Skin

At the baseline (Day 0) visit the Sub-Investigator will evaluate each subject's face for the presence of the following:

- Fine Wrinkles
- Coarse Wrinkles
- Roughness
- Mottled Hyperpigmentation

The Sub-Investigator will use the following five-point scale to describe the above parameters:

- 0 = None
- 1 = Minimal
- 2 = Mild
- 3 = Moderate
- 4 = Severe

Finally, the Sub-Investigator will evaluate the overall severity of skin photodamage using the 10 point scale below. The scale is an integrated assessment of all the signs of photoaging (wrinkles, roughness and mottled hyperpigmentation) previously evaluated.

#### **OVERALL SEVERITY SCORE**

NONE	N	/IILD		MODERATE		SEVERE			
0	1	2	3	4	5	6	7	8	9

Subjects with baseline severity scores greater than 6 will be excluded from the study.

### 5.1.2.4 Clinical Photography

Clinical photographs of each subject will be taken using a Fuji S2 digital camera attached to a Canfield Scientific VISIA CR Booth (Canfield Scientific, Fairfield, NJ). The subject will be positioned in the booth and photos taken of both the left and right profiles as well as a frontal photo. The profile photographs will be taken at an angle of 45°. Photographs will be taken using standard lighting, polarized lightening (crossed and parallel) and UV lightening. Additionally, close-up photographs of the peri-orbital area will be taken on both the left and right sides of the subject's face. No formal assessments or analysis of the photographs will be made. All subjects must sign a photographic consent form to participate in the study.

### 5.1.2.5 Irritation and the Overall Severity of Acne

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The baseline level of irritation will be assessed using the following four-point scale:

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- 0: None.
- 1: Mild.
- 2: Moderate.
- 3: Severe.

In addition, individual acne lesions will be recorded. The lesion counts will be taken from the facial area [forehead, left and right cheeks, and chin above the jaw line (excluding the nose)]. The counts will be added together to form three groups of lesion counts: inflammatory, non-inflammatory and total lesion counts. Open and closed comedones will make up the non-inflammatory group; papules and pustules will make up the inflammatory group and all of the lesions will compose the total lesion count group. The following are definitions of each lesion type counted:

- Open comedone A mass of sebaceous material that is impacted behind an open follicular orifice (blackhead)
- Closed comedone A mass of sebaceous material that is impacted behind a closed follicular orifice (whitehead)
- Papule A small, palpable, solid elevation less than 1 cm in diameter
- Pustule A small, circumscribed elevation of the skin which contains yellow /yellowish-white exudates.

### 5.1.2.6 Distribution of Test Article and Instructions to Subjects

Following baseline clinical measurements, subject will be provided with the test article and instructed to use the test article according to the following instructions:

- 1. Wash your face with a mild cleanser and dry completely prior to application of the product to your face;
- 2. Apply a liberal amount of the product to your face in the early morning and about one hour before bedtime;
- 3. In the morning, after the product has absorbed into the skin, apply the sunscreen, which was provided to you, to your face. Avoid prolonged sun exposure;
- 4. Other than the product being provided to, do not introduce any new products into your skin care regimen;
- 5. Do not apply any topical medications to your face;
- 6. Do not take any steroid or retinoid medications; and
- 7. Do not apply the test article or makeup to your face the morning of a scheduled visit.

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Finally, all subjects will be provided with a daily diary to record the dates and times of test article application and to record any observations or comments they feel pertinent to the study.

Following test article and diary distribution, each subject will be instructed to return to the testing facility at 2, 4, 8 and 12 weeks. Subjects will be instructed not to apply the test article the day of their visits.

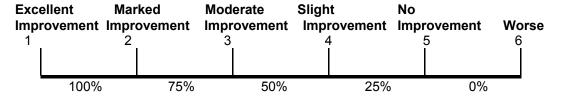
#### 5.1.3. Week 2

Subjects arriving at the testing facility on week 2 will be directed into an exam room where they will equilibrate for at least 15 minutes under controlled environmental conditions ( $70^{\circ}F \pm 3^{\circ}F$ ;  $45\% \pm 10\%$  relative humidity). During equilibration subjects will be queried for concomitant medication/skin care products/cosmetics and adverse events. Following equilibration, subjects will undergo the same measurements as described above (5.1.2.1 to 5.1.2.5). In addition to the measurements performed at baseline, the following additional measurements will be taken:

### 5.1.3.1 Global Assessment of Improvement

The sub-investigator will rate the overall improvement compared to baseline using a 6-point scale: (1) excellent improvement (100%); (2) marked improvement ( $\sim$ 75%); (3) moderate improvement ( $\sim$ 50%); (4) slight improvement ( $\sim$ 25%); (5) no improvement (0%); (6) worse. Color photographs taken at baseline will be used to assist the sub-investigator in the global evaluation.

#### **GLOBAL ASSESSMENT OF RESPONSE**



### 5.1.3.2 Subject's Perception of Efficacy

At each follow-up evaluation the subject will be asked to complete a self-assessment questionnaire to assess the improvement from baseline for each of the following:

Skin texture Skin color Blotchiness (brown spots)

Fine wrinkles Overall improvement

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Subjects will use the following five-point scale to document the changes on their face:

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- (1) = much improved;
- (2) = somewhat improved;
- (3) = no change;
- (4) = somewhat worse;
- (5) = much worse.

In addition to measurements, the diary distributed at the baseline visit will be collected and a new diary distributed to each subject. No new test article will be distributed at the week 2 visit.

### 5.1.4. Weeks 4, 8 and 12

Subjects arriving at the testing facility on weeks 4, 8 and 12 will be directed into an exam room where they will equilibrate for at least 15 minutes under controlled environmental conditions ( $70^{\circ}F \pm 3^{\circ}F$ ;  $45\% \pm 10\%$  relative humidity). During equilibration the subjects will be queried for concomitant medication/skin care products/cosmetics and adverse events. Following equilibration, subjects will undergo all measurements performed previously (see sections 5.1.2.1 to 5.1.2.5 and 5.1.3.1 to 5.1.3.2). Additionally, at Weeks 4 and 8 used test article will be exchanged for new and old diaries exchanged for new.

# 5.2. Duration of Study

Enrollment Phase: Approximately Two weeks to recruit 50 subjects

Total Duration of Subject Participation: Approximately 12 Weeks

Total Trial Duration: Approximately 15 weeks

### 5.3. Subject Population

Fifty evaluable female subjects with mild-to-moderate age-related changes in facial skin will participate in this clinical study. An evaluable subject is one who has passed the inclusion and exclusion criteria; given informed consent; received the assigned test formulation and applied the test article according to the treatment schedule, and has been adequately followed to establish valid endpoints of efficacy and tolerance. Replacement subjects may be enrolled with consent from the sponsor.

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### 5.3.1. Subject Numbering

Each subject who satisfies the inclusion and exclusion criteria will be assigned a number for treatment in accordance with their chronological order of qualification for the study. Once a treatment number has been assigned to a subject it cannot be re-assigned to any other subject.

#### 6. STATISTICAL METHODS

### 6.1. Sample Size Estimation

The sample size of 25 evaluable subjects per cell was requested by the Sponsor.

### 6.2. Population

All subjects who receive treatment and complete the study will be considered evaluable.

### 6.3. Statistical and Analytical Plan

Upon completion of the research study, the data will be analyzed by the Sponsor for tolerance and efficacy at each follow-up interval versus baseline. Only those subjects who satisfy the criteria for an evaluable subject will be included in the statistical analysis of cosmetic efficacy. An evaluable subject is one who meets all entry criteria, not used any systemic or other unapproved topical skin care product or medication during the study, completed at least one post-baseline visit and evaluation, and complied with the treatment regimen.

Skin irritation reactions during the study will be summarized using descriptive statistics and percentages whenever it is appropriate. The primary objective of this study is to determine the efficacy of topical zeatin (0.10%, 0.025%) for improving the appearance of skin aging when topically applied twice daily for up to 12 weeks. The primary efficacy endpoint is the change from baseline in the individual clinical signs of skin aging (wrinkles (coarse and fine), roughness and mottled hyperpigmentation). For the primary analysis for efficacy, the skin aging parameters at each follow-up visit (weeks 2, 4, 8 and 12) versus baseline scores will be assessed using a paired Student's *t*-test and a Wilcoxon signed rank test. The Investigator's and subject's global evaluation of efficacy will be summarized descriptively for all follow-up evaluations (weeks 2, 4, 8 and 12). The change from baseline in TEWL and skin moisture content will be determined for each respective skin treatment site and statistically analyzed.

#### 7. STUDY COMPLETION STATUS

### 7.1. Normal Study Completion

Subjects who complete all visits of the study.

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# 7.2. Discontinued Subjects

The investigator (and/or sponsor) may discontinue the subject at any time based on his/her discretion. Reasons for discontinuation and forms required for each example are as follows:

#### 7.2.1. Adverse Events

Subjects may be discontinued because of adverse event(s) that, in the opinion of the investigator, present a significant risk to their safety or well-being.

### 7.2.2. Lost to Follow up

Subjects who fail to return for scheduled visits and who cannot be reached by phone (at least two documented phone calls must be completed), are considered Lost to Follow up. If the subject is reached by phone and explains the reason for not returning, then Lost to Follow up is NOT the reason for discontinuation.

### 7.2.3. Subject Decision Unrelated to Adverse Event

Subjects may be discontinued if they do not wish to continue due to scheduling conflicts or any other personal reason.

### 7.2.4. Noncompliance

Subjects that do not comply with the protocol requirements will be discontinued from the study. Examples of noncompliance include: uncooperative or unwilling to follow protocol.

#### 7.2.5. Inclusion/Exclusion Violation

Those subjects entered into the study and later found to be in violation of the inclusion/exclusion criteria will be discontinued.

### 7.2.6. Other

This category is to be used for any other discontinuation reason that may occur during the study.

#### 8. CONCOMITANT MEDICATIONS AND INTERFERING THERAPIES

Other than sunscreens or mild cleansers and use of color cosmetics, no topical skin care products or medications of any kind can be used on the face. Subjects will be instructed not to take any prescription medications (except those allowed by protocol), without prior consultation with the Investigator. If concomitant therapy must be added then the reason, the name of the drug, the daily dose, and date of initiation and/or discontinuation of therapy will be recorded on the Concomitant Medication Page of the Case Report Form.

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### 9. DATA ANALYSIS

### 9.1. Evaluability

Only subjects who meet all of the inclusion and none of the exclusion criteria, who miss no more than 1 visit (as long as the visit missed is not the first or last visit) and use the test article according to the Sponsor's instructions with the frequency outlined in the protocol will be considered evaluable.

### 9.2. Analysis

The primary objective of this study is to determine the efficacy of topical Zeatin (0.10%, 0.025%) for improving the appearance of skin aging when topically applied twice daily for up to 12 weeks. The primary efficacy endpoint is the change from baseline in the individual clinical signs of skin aging (wrinkles (coarse and fine), roughness and mottled hyperpigmentation). For the primary analysis for efficacy, the skin aging parameters at each follow-up visit (weeks 2, 4, 8 and 12) versus baseline scores will be assessed using a paired Student's t-test and a Wilcoxon signed rank test. The Investigator's and subject's global evaluation of efficacy will be summarized descriptively for all follow-up evaluations (weeks 2. 4, 8 and 12). The change from baseline in TEWL and skin moisture content will be determined for each respective skin treatment site and statistically analyzed.

#### 10. ADVERSE EVENTS

### 10.1. Introduction

All adverse events occurring during the course of a study will be documented on Adverse Event Forms. A separate Adverse Event Form will be filled out for each adverse event. All items on the form will be completed. For NONSERIOUS events, if information is missing at the initial visit and the subject will be returning for follow-up examination in a reasonably short period of time, the investigator may hold the Adverse Event Form until the scheduled follow-up examination. If the subject will not be returning in a reasonable period of time, the investigator will forward the form to the Sponsor and provide the missing information by letter or telephone call when the information is known. For SERIOUS adverse events, an Adverse Event Form will be returned to the Sponsor as soon as practical, even if it is incomplete, with new information submitted by telephone call as soon as it becomes known.

#### 10.2. Nonserious Adverse Event

An adverse event is defined as any untoward medical occurrence in a patient, or clinical investigation subject, administered a test product whether or not it is caused by this treatment. An adverse event can, therefore, be any unfavorable and unintended sign (including an abnormal laboratory finding, for example), symptom or disease temporarily associated with the use of a test product, whether or not considered related to the test product.

Events that occur prior to the administration of the investigational product are not considered adverse events.

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Possible expected occurrences due to the application of the test articles may be tingling, stinging, burning, dryness and/or itching. These reactions will not be reported as adverse events.

A non-serious adverse event is defined as a change in a subject's medical health, which is neither life-threatening, does not require hospitalization, does not prolong a current hospitalization, and is not disabling.

#### 10.3. Serious Adverse Event

Serious adverse events are defined as any finding which suggests a significant hazard, contraindication, side effect, or precaution. Additionally, any adverse event which results in a fatality, is life-threatening, is permanently disabling, requires inpatient hospitalization, prolongs a current hospitalization, or a congenital anomaly is also considered a serious adverse event.

A life-threatening adverse event means that the subject was, in the view of the investigator, at immediate risk of death from the reaction as it occurred. It does not include a reaction that, had it occurred in a more serious form, might have caused a death. Serious, alarming and/or unusual adverse events must be reported to the following individual within 24 hours of the investigator's knowledge of the event:

#### **SENETEK CONTACT:**

Frank Massino

Phone: 707-226-3900 ext. 109 E Mail: Frank@senetek.net

An Adverse Event Form will be completed for all serious adverse events and forwarded to the Sponsor within 24 hours. Additionally, a phone call will be made to confirm delivery of the report. When new significant information is obtained as well as when outcome of an event is known, the Sponsor will be informed by telephone call. Depending on the nature and seriousness of the adverse event, a copy of the medical record of the patient as well as results of laboratory tests performed may be requested. If the subject was hospitalized, a copy of the discharge summary may be forwarded to the Sponsor as soon as it is ready. In all instances, investigators will follow subjects until an outcome to the event is known.

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### 11. INFORMED CONSENT AND INSTITUTIONAL REVIEW BOARD

All subjects in this study will be completely informed, according to informed consent guidelines, about the pertinent details and purpose of the study. A written Informed Consent form will be understood and signed by each subject prior to enrollment into the study. The investigator or his designee will supply the consent form, approved by an Institutional Review Board, and a copy of such provided to the Sponsor. The study site will keep the original signed copies of all consent forms in its files and will provide the subject with a duplicate copy.

This study must be reviewed and approved by an appropriate Institutional Review Board (also known as an Ethics Committee). A copy of the letter indicating IRB approval will be provided to the Sponsor prior to study initiation. Annual updates will be provided to the IRB by the investigator for studies longer than a year.

### 12. SUBJECT IDENTIFICATION AND CONFIDENTIALITY

Subjects will be identified on the study CRFs by their Subject Number and their initials. CRFs are confidential documents and will only be available to the Investigator, the sponsor's representative and the IRB.

### 13. CONFIDENTIALITY/PUBLICATION OF THE STUDY

The existence of this clinical study is confidential and should not be discussed with persons outside of the study. Additionally, the information in this document and in the study contains commercially sensitive information that is confidential and may not be disclosed unless Federal or State law or regulations require such disclosure. Subject to the foregoing, this information may be disclosed only to those persons involved in the study who have a need to know, but all such persons must be instructed not to further disseminate this information to others. These restrictions of disclosure will apply equally to all future information supplied which is indicated as confidential.

### 14. STUDY MONITORING

The study may be monitored at any time. The monitor from the Sponsor will maintain a close liaison with the testing facility to clarify any problem(s) that may arise in the study and to ensure that the study is conducted according to the protocol. The liaison ordinarily consists of personal visits and/or frequent communications via telephone, fax and/or email.

The investigator will allow a Sponsor monitor to inspect all Case Report Forms and corresponding portions of a study subject's records, if necessary, to verify that the study was performed according to this protocol and that test results and collected data were faithfully and accurately recorded.

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### 15. STUDY MANAGEMENT

#### 15.1. Data Collection

The testing facility will maintain detailed records on all study subjects. Data for this study will be recorded on Case Report Forms (CRFs) provided by the Sponsor. All data will be recorded completely, promptly, and legibly on the CRFs. Corrections will be made in a manner that does not obscure or eliminate the original error, by striking through the original data with one line, and all corrections on the CRF should be initialed and dated. The testing facility will maintain a copy of all completed CRFs in its study files.

### 15.2. Test Article Accountability

The principal investigator or his designee, upon receipt of the clinical supplies, will conduct an inventory and complete and sign the Receipt of Clinical Supplies form (Supplied by the Sponsor), mailing it to the Sponsor. A copy will be maintained for the investigator's records.

The clinical staff will keep a current record of the inventory and dispensing of all test articles. All test articles will be weighed prior to distribution and upon collection from the subjects. Additionally, the clinical staff will confirm on the subject's data sheet (or CRF) dispensation of the test article. These records will be made available to the Sponsor's monitor for the purpose of accounting for all clinical supplies. Any significant discrepancy and/or deficiency will be recorded, with an explanation. All supplies sent to the investigator will be accounted for and in no case will the test articles be used in any unauthorized situation. After all subjects have completed the study, the testing facility will return the remaining test articles to the Sponsor with a copy of the inventory and dispensation log.

### 15.3. Record Retention

All records relating to the conduct of this study will be held by the investigator for a period of no less than two (2) years in a secure area. Additionally, the Sponsor will be contacted prior to the destruction of any study related records. Should the Sponsor require archiving for longer than 2 years, prior agreement between RCTS and the Sponsor must be obtained.

### 15.4. Quality Assurance

This study will be conducted in accordance with the intent and purpose of Good Clinical Practice Regulations (21 CFR 50, 21 CFR 56 and 21 CFR 54). The study data and Final Report will be reviewed and signed by a representative of the Quality Assurance staff of RCTS, Inc. The investigator will allow representatives of the Sponsor's monitoring team (and, if necessary, city, state or federal regulating agencies) to inspect all study records, Case Report Forms at regular intervals throughout the study. These inspections are for the purpose of verifying the adherence to the protocol, the completeness and exactness of the data being entered in the report form, and compliance with regulations.

\_\_\_\_\_

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# **16. STUDY PLAN**

STUDY WEEK	0	2	4	8	12
Informed Consent	Х				
Eligibility Criteria	Χ				
Dermatologic/Skin Care/Cosmetic Hx	Х				
Laboratory Studies: Urine Pregnancy	Х				X <sup>1</sup>
Admission to Study	Χ				
Test Products Dispensed	Χ		Χ	Χ	
Test Products Collected			Χ	Χ	Χ
Twice Daily Application of Study Materials	Х	Χ	Χ	Х	Х
Skin Evaluations	Х	Χ	Χ	Χ	Х
Subject Tolerance	Х	Χ	Χ	Χ	Х
Acne Lesion Counts	Х	Χ	Χ	Х	Х
Concomitant Skin Care Products/Medications	X	X	X	Х	Х
TEWL/Moisture Measurements	Χ	Χ	Х	Х	Х
Photography	Χ	Χ	Χ	Χ	Х
End of Study Information/Exit Form					Х

<sup>&</sup>lt;sup>4</sup>Exit form completed upon study completion or early discontinuation.

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### 17. APPENDICES

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### Appendix A

ADVERSE EVENTS – DEFINITION OF CAUSALITY

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### Adverse Events – Definition of Causality

1	-	Definitely -	Should be reserved for those events, which occur prior to test
		Unrelated	article administration (i.e., washout or single-masked placebo) or
			those events which cannot be even remotely related to study
			participation (e.g., injuries sustained in an automobile accident).

- Unlikely Whether or not there was a temporal relationship between the test article and the suspected adverse event, it is more likely than not that the event could have been produced by the subject's clinical state or other modes of therapy administered to the subject.
- 3 Possible The suspected adverse event may follow a reasonable temporal sequence from test article administration but could have been produced or mimicked by the subject's clinical state or by other modes of therapy concomitantly administered to the subject.
- 4 Probable The suspected adverse event follows a reasonable temporal sequence from test article administration, abates upon discontinuation of the test articles, and cannot be reasonably explained by the known characteristics of the subject's clinical state.
- 5 Definitely Should be reserved for those events which have no uncertainty in their relationship to test article administration (e.g., Positive Rechallenge).

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# Appendix B

**OBLIGATIONS OF INVESTIGATORS** 

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### Summary of Clinical Investigator Obligations

- Obtain approval from the Institutional Review Board (IRB) before enrolling any subjects; Submit verification of the approval to the Sponsor; Submit periodic progress reports to the IRB (at least annually); Obtain annual reapproval from the IRB; Submit a final report to the IRB and notification that the study is complete or was terminated early; Maintain records of all RB correspondence;
- 2. Obtain written informed consent from every subject (or legal representative) enrolled in the study and maintain records of consent as part of his/her study records;
- Approve the protocol and conduct the study according to the protocol and applicable regulations; Inform the Sponsor of all deviations from the protocol and immediately inform the IRB of any protocol deviation made to protect the safety of the subject; Approve all protocol amendments; Obtain-IRB approval of all amendments prior to their implementation;
- 4. Report all serious adverse events related to the test article (and for medical device studies, all adverse device effects) to the Sponsor and the IRB immediately; report all other adverse events to the Sponsor as specified in the protocol;
- 5. Maintain proper control and documentation of all test articles;
- 6. Keep careful and accurate records of all clinical study data which are generally more exact and complete than those kept in ordinary medical practice;
- Make study records available for inspection by the sponsor and representatives of relevant regulatory agencies; keep study records until approval for destruction has been obtained from the Sponsor;
- 8. Make the necessary arrangements, including emergency treatment, to ensure proper conduct of the investigation and the personal safety and well being of the subjects;
- 9. Submit the following records and reports to the Sponsor, if required:
  - a. Prior to the beginning of the Study
    - (1) A signed Investigator Agreement;
    - (2) A current CV and CVs for all sub-investigators listed in the Investigator Agreement;
    - (3) Approval letter from the IRB;
    - (4) IRB-approved consent form;
    - (5) Signed and dated copy of the approved Protocol Title page.

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- b. While Study is in Progress
  - (1) Signed receipt of the test articles (clinical supplies);
  - (2) Completed original Case Report Forms (including Adverse Event forms) for each subject enrolled in the study;
  - (3) Immediate notification of serious adverse events and protocol deviations;
  - (4) IRB annual re-approval letter;
  - (5) Signed protocol amendments; IRB approval of amendments and amended consent forms, if applicable;
- c. Once the Study is Completed
  - (1) Documentation of disposition of all test articles;
  - (2) A final study report or signature on the Clinical Study Report (CSR).

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# Appendix C

**ELEMENTS OF INFORMED CONSENT** 

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### **Elements of Informed Consent**

In conducting a clinical investigation, the Principal Investigator (PI) should adhere to the ethical principles which have their origin in the Declaration of Helsinki. The following information must be provided to each subject in obtaining informed consent. Informed consent must be documented in writing, using a form approved by the Independent Ethics Committee/Independent Review Board (IEC/IRB) which does not waive or appear to waive the subject's legal rights. This form should be signed and dated by the subject (or the subject's legal representative) and by the PI (or his designee) prior to the conduct of any study procedures. The subject (or representative) should be given a copy of the signed written informed consent. This information should be revised (and re-reviewed by the IRB) if new information becomes available that is relevant to the subject.

- 1. State that the study involves research.
  - a. Explain the purposes of the research.
  - b. State the expected duration of the subject's participation.
  - c. State the approximate number of subjects involved in the study
  - d. Describe the procedures to be followed.
  - e. Identify any experimental procedures.
- 2. Describe the subject's responsibilities.
  - a. Describe any anticipated prorated payments to be made to the subject for participating. [NOTE: In clinical studies on medical devices conducted in Europe, subjects who cannot be expected to derive any direct therapeutic benefit shall receive payments or inducements only for expense, time, and inconvenience].
  - b. Describe any anticipated expenses to the subject, if any.
- 3. Describe any reasonably foreseeable risks or discomforts to the subject.
- 4. Describe any benefits to the subject (or to others) which may reasonably be expected from the research.
- 5. Note available, appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
- 6. a. Note the extent to which confidentiality of records identifying the subject will be maintained.
  - b. Note that confidentiality of records that identify the subject will be maintained and will not be made publicly available to the extent permitted by the applicable laws and/or regulations.

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c. Note that relevant regulatory authorities (such as the Food and Drug Administration in the US), the sponsor's monitor(s), auditor(s), and the IEC/IRB may inspect the study records and will be granted access to the subject's original medical records for verification of the clinical trial procedures and/or data, without violating the confidentiality of the subject to the extent permitted by the applicable laws and regulations.

- d. Note that by signing the written informed consent form, the subject (or the subject's legal representative) is authorizing access to these records.
- 7. For research involving more than minimal risk, explain what compensation or medical treatments are available should a research-related injury occur. Explain what they consist of, or where further information may be obtained.
- 8. a. Tell whom to contact for answers to pertinent questions about
  - (i) the research, and
  - (ii) the research subjects' rights.
  - b. Tell whom to contact in the event of a research-related injury to the subject.
- 9. State that:
  - a. participation is voluntary, and
  - b. refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled.
- 10. a. Note that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
  - b. Describe the consequences of his/her withdrawal from the study and any procedures for orderly termination of participation by the subject.
  - c. Describe the circumstances under which the subject's participation may be terminated without the subject's consent.
- 11. State that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.

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RCTS, Inc. "Your Assurance for Quality in Clinical Testing"

### Protocol Amendment No.: 1 - RCTS Panel 1837

### Page No. 11 of 35

1. Original Protocol

Inclusion Criteria

- 1. Subjects must be ambulatory, 30 to 65 years of age and in reasonably good health;
- 1. Amended Protocol (amended language shown in italics)

Inclusion Criteria

- 1. Female subjects must be ambulatory, 30 to 65 years of age and in reasonably good health;
- 9. Fitzpatrick Skin Types ! III;

Reason for Amendment:

To add female subjects and Fitzpatrick Skin Types I-III to inclusion criteria.

2. Original Protocol

**Exclusion Criteria** 

- 16. Subject has participated in any clinical trial involving an investigational drug or cosmetic product or procedure within the past 30 days; and
- Amended Protocol (amended language shown in italics)

**Exclusion Criteria** 

16. Subject has participated in any facial clinical trial involving an investigational drug or cosmetic product or procedure within the past 30 days; and

Reason for Amendment:

To clarify the exclusion criteria.

Approvals:

For RCTS:

Vice President/Managing Partner

RCTS, Inc.

For the Sponsor:

Frank Massino

CEO

Senetek PLC

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### 1.2 IRB Approval Letter

IntegReview, Inc.

3001 S. Lamar Blvd., Suite 210

Austin, Texas 78704



Tel. 512.326.3001 Local Fax. 326.3446 http://www.integreview.com

IRB Registration Numbers: IRB00001035 and IRB0003657

March 28, 2005

Ponciano D. Cruz, Jr., M.D. RCTS, Inc. 800 W. Airport Freeway, Ste. 110 Irving, TX 75062

Re: Senetek PLC, Protocol Number 2005.091, Reliance Clinical Testing Services (RCTS) Study Number 1837, "A Clinical Study of Topical Zeatin (0.1%, 0.025%) for Improving the Appearance of Photodamaged Skin"

Dear Dr. Cruz:

The above-referenced study meets the requirements for a research study that may be reviewed through expedited review procedures set forth in FDA regulations. Therefore, utilizing the expedited review procedures authorized in 21 CFR 56.110, initial approval was granted by **Charles F. Ryan, Ph.D.** for IntegReview on the initial review of the above-referenced study.

### Approved:

Principal Investigator

Investigative site(s) as submitted with initial submission documents

Protocol dated March 17, 2005

Informed Consent, English language, dated March 28, 2005 (refer to IntegReview modifications as reflected on the following document containing revision marks)

Recruiting materials:

One print media advertisement

One Recruitment Sheet

The reviewer also reviewed the safety letter, for the test product, as appropriate.

Equipment required at study site(s) to treat life-threatening reactions for this study:
Injectable Epinephrine Injectable Benadryl
Crash cart Ambu bag Oxygen Other (describe):
No equipment required because subject will be dosed on an outpatient basis
No equipment required due to the non-invasive nature of this study

### **IMPORTANT**

- The following changes may not be implemented until you have received approval from IntegReview except where necessary to eliminate apparent immediate hazards to the human subjects:
  - > Protocol Amendments
  - > Change in the Principal Investigator and/or Sub Principal Investigators (only if the Sub PI's will be performing study-related procedures that the PI is not qualified through expertise to perform)
  - > Change in the address at the study site or the addition of a study site(s)
- Only Informed Consent documents <u>containing IntegReview's approval</u> stamp and recruiting materials <u>containing IntegReview's approval</u> stamp may be utilized.

- Only IntegReview staff may initiate modifications to Informed Consent documents. The Informed Consent document for your site will be maintained in our computer files, and IntegReview will make all revisions following IRB approval.
- Revision requests should be submitted on IntegReview's Request for Review/Approval Form, which can be obtained from our office or on our Website at www.integreview.com.

IntegReview approval for this study expires March 28, 2006. In order to obtain extended IRB approval, IntegReview must receive your form for continuing review four weeks prior to the IRB expiration date. Appropriate forms will be forwarded to you approximately 2 months prior to the approval expiration date. Should the study end before you receive notification, submit a Study Closure Notification form, which can be obtained from our office or on our Website at <a href="https://www.integreview.com">www.integreview.com</a>, to notify us of the study closure.

### REPORTING REQUIREMENTS

To ensure compliance with the Code of Federal Regulations (CFR), Parts 56.108 (a) (3), 312.32 (c) (1) (i) 312.66 as well as International Conference on Harmonisation (ICH), E6: Good Clinical Practice: Consolidated Guideline, IntegReview requires notification of the following for review/approval:

- Report within 10 working days:
  - > Unexpected adverse experience
  - > Any unanticipated problems involving risks to human subjects or others
  - All changes in research activity, including violations of the protocol (an act performed by the investigator and/or research staff of allowing or conducting activity inconsistent with the IRB approved protocol, such as allowing the enrollment of a subject who does not meet the inclusion/exclusion criteria, misdosing study subjects, incorrectly randomizing study drug, etc.) approved or not approved by the sponsor
- Submit prior to publication/distribution:
  - > Any modification(s) to the previously approved Informed Consent document
  - > New and/or modifications to previously approved recruiting materials
- Submit four weeks prior to IntegReview approval expiration date:
  - > Continuing review documents
- Submit upon completion of the study (that is when all data has been collected):
  - Notification of study closure upon completion of the study (study remains active only for data analysis) report on IntegReview's Study Closure Notification Form located on our Website or you may contact our office to request form.

NOTE: Requests for review/approval of modifications to study documents previously approved by IntegReview should be submitted on IntegReview's Request for Review/Approval Form.

At its discretion, IntegReview reserves the right to visit the study site.

IntegReview is organized and operates in accordance with Good Clinical Practices and International Conference of Harmonisation for IRB's as identified in Title 21 of the Code of Federal Regulations, Parts 50 and 56 and ICH Guidelines for Good Clinical Practices, E6. In addition, Standard Operating Procedures have been created to ensure compliance with these regulations and guidelines.

If you have any questions regarding these procedures or if you wish to appeal the decision, you may address your comments to IntegReview. Your comments will be reviewed, discussed and you will receive a response after your request has been considered.

Ponciano D. Cruz, Jr., M.D. Senetek PLC, Protocol No. 2005.091 Page 3

Failure to comply with the Code of Federal Regulations or the requirements or determinations of IntegReview can result in suspension or termination of IntegReview approval.

Sincerely,

Pricilla R. Gage, CIM

Compliance Coordinator

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### 1.3 Sample Informed Consent Form and Photographic Release Form

### INFORMED CONSENT AGREEMENT TO BE IN A RESEARCH STUDY

NAME OF TESTING COMPANY:

**CITY AND STATE:** 

RCTS, Inc. Irving, Texas

NUMBER AND NAME OF STUDY:

2005.091/1837; "A Clinical Study of Topical Zeatin (0.1%, 0.025%) for Improving the

Appearance of Photodamaged Skin"

NAME OF PERSON IN CHARGE OF

THE RESEARCH STUDY (INVESTIGATOR):

Ponciano D. Cruz, Jr., M.D.

ADDRESS OF STUDY SITE:

RCTS, Inc.

800 W. Airport Freeway, Suite 110

Irving, TX 75062

TELEPHONE NUMBERS, DAYTIME:

AFTER HOURS:

972-871-7578 972-572-3255

972-841-2916 (Cell number)

### INTRODUCTION

You are being asked to volunteer for a research experiment. Before agreeing to participate in this study, it is important that you read this form. This form, called a consent form, describes the purpose, procedures, benefits, financial payment, risks and discomforts of the study. It also describes the alternative procedures that are available to you and your right to withdraw from the study at any time. No promises or guarantees can be made as to the results of the research study. Please ask as many questions as you need to so that you can decide whether you want to be in the study.

The investigator is being paid to conduct this study.

If you are not completely truthful with the investigator and study staff regarding your health history, you may harm yourself by participating in this study.

### PURPOSE OF STUDY

This study is being done to see how safe and effective a facial cream will work to treat the appearance of photo-damaged skin.

If you qualify for the study, you will receive one of two different concentrations (0.1%) or 0.025% of the test product. You will be provided with the following instructions for use:

- Wash your face with a mild cleanser and dry completely prior to application of the test product to your face;
- Apply a liberal amount of the test product to your face in the early morning and about one hour before bedtime;
- In the morning, after the test product has absorbed into the skin, apply the sunscreen, which was provided to you, to your face. Avoid prolonged sun exposure;
- Other than the test product being provided to, do not introduce any new products into your skin care regimen;
- Do not apply any topical medications to your face;

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- Do not take any steroid or retinoid medications; and
- Do not apply the test product or makeup to your face the morning of a scheduled visit.

This is a double-blind study, which means that neither you nor the investigator will know which test product you are receiving. However, the study staff can get this information quickly if you have a problem.

The test product you receive will be assigned by chance, like the flip of a coin.

### HOW LONG THE STUDY WILL LAST AND THE NUMBER OF SUBJECTS EXPECTED TO PARTICIPATE

It is expected that the length of time you will participate in this study will be approximately twelve (12) weeks. Approximately fifty (50) female subjects, ages 30 to 65, are expected to participate in this study.

### TO BE IN THIS STUDY

You cannot be in this study if you are currently in any clinical study involving an investigational drug or if you have been in a study for cosmetic products or procedures in the last 30 days.

# WHAT WILL HAPPEN DURING THE STUDY

### Screening:

Before the study starts, you will be asked to sign this consent form, give your medical history, and to inform site personnel if you are taking any over-the-counter or prescription medications or vitamins.

As part of the screening and study process you will be required to undergo all of the tests listed below:

• Urine pregnancy tests for female subjects at screening and at the end of the study.

### **Study Procedures:**

Following the screening process, you will be directed into an environmentally controlled room where you will adjust to room temperature for approximately fifteen (15) minutes. During this time the following procedures will take place:

- During the fifteen (15) minute wait period, an expert grader will evaluate several aspects of your facial skin condition.
- Also during the wait period, a technician will take clinical photographs (front, left and right profiles) of your face.
- Following the fifteen (15) minute wait period, water loss measurements using a non-invasive (does not hurt) instrument called a TEWAMETER will be taken. The instrument's probe will rest gently on the center of your cheek and measurements will be taken two times on both sides of your face.
- Lastly, moisture measurements using an instrument called a NOVA DPM will also be taken non-invasively (does not hurt). The instrument's probe will rest gently on the center of your cheek and measurements will be taken three times on both sides of your face.

After all measurements and assessments are completed you will be given your test product and daily diary along with instructions for use.

It will be your responsibility to keep the test product out of the reach of children.

The same measurements and assessments completed at your baseline visit will be repeated at your 2, 4, 8 and 12 week visits. At each visit you and the expert grader will evaluate your skin to determine whether or not an

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### VERSION CONTROL

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improvement in your skin condition is noticeable. Additionally, you will be asked if you have taken any new medications. You are required to bring your test product and diary to each return visit.

### POSSIBLE SIDE EFFECTS AND RISKS OF THE STUDY TEST PRODUCT

It is possible you might experience the following side effects:

- Tingling
- Stinging
- Burning
- Dryness
- Itching

If you are not completely truthful with the investigator and study staff regarding any side effects, you may harm yourself by participating in this study.

# DANGERS OF PREGNANCY AND BIRTH CONTROL

If you are female, it is very important that you do not become pregnant during this study. The only certain way to prevent pregnancy is to not have sex. If you are a woman and choose to have sex during this study, you must use a medically proven type of birth control throughout the study.

Acceptable methods of birth control for this study include:

- Birth control pills
- Depo-Provera®
- IUD (intrauterine device)
- Diaphragm with spermicide
- Condom with spermicide
- Postmenopausal
- Surgically sterile

Even if you use a medically proven birth control method, there is a chance you could still become pregnant.

You will not be allowed to be in the study if you are pregnant or breastfeeding. The test product or procedures may involve currently unforeseeable risks to breast-fed babies. A pregnancy test could be wrong and if you become pregnant during the study you will be receiving the test product while pregnant. The effects of the test product on an unborn baby are unknown. If you become pregnant during study, stop using the test product and call the investigator at once.

### POSSIBLE BENEFITS OF THE STUDY

Since you do not require treatment with the test product, you will receive no medical benefit from this study, other than the benefit of free clinical tests.

## ALTERNATIVES TO PARTICIPATING IN THIS STUDY

Since this study is for research only, the alternative would be not to participate.

### RELEASE OF YOUR MEDICAL RECORDS AND PRIVACY (CONFIDENTIALITY)

Records of you being in this study will be kept confidential except as required by law. However, the investigator, the testing company and/or its representative will look at and copy information that is collected during the study. The following will be given a copy of this information:

- Testing company (RCTS, Inc.)
- Food and Drug Administration (FDA)
- Other government offices

### THIS IS AN IMPORTANT DOCUMENT - KEEP FOR FUTURE REFERENCE

### VERSION CONTROL

The Institutional Review Board (IRB), IntegReview, may inspect and copy your records, which will identify you by name. Therefore, absolute confidentiality cannot be guaranteed. By signing this consent form, you authorize the investigator to release your study-related medical records to the testing company and/or its representative, the FDA and the IRB. If the study results are presented at meetings or printed in publications, your name will not be used.

### PAYMENT FOR INJURY RELATED TO THE STUDY

There are no anticipated injuries associated with using this test product.

### **LEGAL RIGHTS**

You will not lose any of your legal rights as a research subject by signing this consent form.

### WHOM TO CONTACT

For answers to questions about this research or to report a research related injury, contact:

Barry Reece Office: 972-871-7578 After hours: 972-572-3255

Questions about your rights as a study subject as provided in the Experimental Subjects' Bill of Rights found in this informed consent form may be addressed to:

Chairperson
IntegReview
3001 S. Lamar Blvd., Suite 210
Austin, Texas 78704
512-326-3001 between 8 a.m. and 5 p.m.
Central Time (call collect)
integreview@integreview.com

Although IntegReview has approved the information provided in this informed consent form and has granted approval for the investigator to conduct the study this does not mean IntegReview has approved your participation in the study. You must evaluate the information in this informed consent form for yourself and decide whether or not you wish to participate.

### PAYMENT FOR BEING IN THE STUDY

If you leave the study before finishing all visits you will be paid \$20.00 for each completed visit. Upon successful completion you will be paid \$150.00. Payment will be available after your last scheduled study visit.

### YOUR PARTICIPATION IN THE STUDY

Your participation in this study is entirely voluntary. You cannot be forced to be in this study. You may not want to be in this study or you may leave the study at any time without penalty or loss of benefits to which you are otherwise entitled and without affecting your future medical care. The investigator, the testing company, IntegReview, or the FDA may take you out of the study without your permission at any time for the following reasons:

- If you do not follow the instructions of the investigator
- If it is discovered that you do not meet the study requirements
- If the study is cancelled
- If it appears to be medically harmful to you

If you leave the study or if you are taken out of the study for any reason, you may be asked to return to the investigator's office for a final visit. This is to make sure that you are in good health.

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### VERSION CONTROL

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### ADDITIONAL COSTS

You may be responsible for medical expenses that are not covered by your medical or hospital insurance or by third party or governmental programs providing such coverage.

### **NEW FINDINGS**

You will be told about any significant new findings developed during the course of the research about the test product. This information can help you decide if you wish to continue your participation in the study.

# EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

As a subject involved in an investigational research study, you have the following rights.

- 1. Be informed of the nature and purpose of the experiment.
- 2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be used.
- 3. Be given a description of any attendant discomforts and risk reasonably to be expressed from the experiment.
- 4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.
- 5. Be given a disclosure of any appropriate alternative procedures, drugs, or devices that might be advantageous to the subject, and their relative risks and benefits.
- Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.

- 7. Be given an opportunity to ask any questions concerning the experiment or the procedures involved.
- 8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time. The subject may discontinue participation in the medical experiment without prejudice.
- 9. Be given a copy of a signed and dated written consent form when one is required.
- 10. Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

# THE REASON FOR INSTITUTIONAL REVIEW BOARDS AND INFORMED CONSENT

### What is a consent form?

The Informed Consent document contains the required information as found in and required by the United States regulations regarding the protection of human subjects (Code of Federal Regulations, Title 21, Part 50-Protection of Human Subjects). As required by this regulation, the informed consent must be reviewed and approved by an Institutional Review Board (IRB).

### What is an Institutional Review Board (IRB)?

An Institutional Review Board (IRB) is any board, committee or other group, which reviews, approves, and does continuing review of biomedical research involving human subjects. The primary purpose of such review is to guarantee the protection of the rights and welfare of the human subjects.

IRBs were established as the result of unfair treatment of human subjects. Prior to this, other

### THIS IS AN IMPORTANT DOCUMENT - KEEP FOR FUTURE REFERENCE

### VERSION CONTROL

prg/3-28-05

committees existed as a requirement of the United States Public Health Service (USPHS) policy established in 1965. IRBs are regulated by the Food and Drug Administration and the Office for Human Research Protections (OHRP). The FDA and OHRP regulations require IRB review and approval of the study design (Protocol), Informed Consent form, and any recruiting materials prior to the enrollment of study subjects.

### What does an IRB mean to me?

The purpose of the IRB is to inform and protect human subjects through the information provided in the informed consent document. Therefore, the IRB is acting as a supporter for the research subject. This means that the IRB, during its review of the informed consent document, has the right and responsibility to ensure that the research subject is fully informed of the procedures involved in the study as well as the risks and other treatments that are available if participation in the study is refused.

# How can I tell that an IRB has reviewed and approved this study?

The date that IntegReview approved the study design as well as the information in this Informed Consent document is printed on the top of each page of this Informed Consent form.

### IntegReview, the IRB for this study

IntegReview is an independent IRB whose board members are individuals who work in the Austin community. IntegReview provides services nation-wide to research professionals.

FDA regulations require that the committee have at least five members with varying backgrounds to provide complete and adequate review of research activities.

To fulfill these requirements the IntegReview Board currently includes physicians, pharmacists, Ph.Ds., a toxicologist (someone who studies the harmful effects of chemicals), a psychologist, an oral surgeon, and lay members (non-scientific).

The telephone number of the Chair is available in every informed consent document in the contacts section. You may contact the Chair with concerns regarding your rights as a subject.

### THIS IS AN IMPORTANT DOCUMENT - KEEP FOR FUTURE REFERENCE

### AGREEMENT TO BE IN THE STUDY

you hav	onsent form contains important information to help you decide if you want to be in the stave any questions that are not answered in this consent form, ask one of the study staff. out "yes" or "no" in response to the following questions:	udy. If Please
A.	Do you understand the information in this consent form?	

B. Have you been able to ask questions and talk about the study?

C. Have all of your questions been answered to your satisfaction?

Do you think you received enough information about the study?

E. Do you understand that you can leave the study at any time without giving a reason and without affecting your medical care?

F. Do you understand that your medical records from this study may be reviewed by the testing company and by government authorities?

If you answered NO to any of these six questions, you should not sign this consent form.

When you sign this consent form you agree that:

- You have had a chance to ask questions
- You understand English
- You want to be in the study

You will not lose any of your legal rights by signing this consent fo	rm.	
Printed Name of Study Subject		
Signature of Study Subject DO NOT SIGN AFTER MARCH 28, 2006	Date	
Printed Name of Person Explaining Informed Consent		
Signature of Person Explaining Informed Consent	Date	-
You will be given a copy of this informed consent to keep.		

### THIS IS AN IMPORTANT DOCUMENT - KEEP FOR FUTURE REFERENCE

### VERSION CONTROL

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### PHOTOGRAPHIC INFORMED CONSENT FORM

You are being asked to allow photographs to be taken of your face. The photographs will be used for marketing purposes, training and scientific evaluation. Only the face will be photographed.

I, the undersigned, voluntarily consent to the taking and use of my picture by the sponsoring company, its affiliates, successors and assignees. All personal information and records will be kept confidential. The said photographs may be used for marketing (business), education, research, or informational purposes. It is understood that the sponsoring company shall make a decision as to how the said photographs are used or whether or not they are used at all. It is possible that the sponsoring company will use my photograph in company literature or other types of media to demonstrate the benefits of the products I am evaluating.

I hereby release the sponsoring company from any claim, demand, and cause of action or proceeding of whatever nature arising out of distribution of the said photographs in accordance with the terms of this release. This release also includes the officers, directors, employees, and agents of the sponsoring company.

Panelist's Signature	Date
Panelist's Name (Print)	
,	
Witness	 Date

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### APPENDIX 2 SUBJECT DATA LISTINGS

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### Expert Assessment of Fine Wrinkles

				Expert Assessment of Fine Wrinkles				
Subject No.	Subject Initials	Age	Sex	Baseline	Week 2	Week 4	Week 8	Week 12
4	SKH	46	Female	2	2	2	1	1
5	LMP	45	Female	3	2	2	2	1
6	PJW	43	Female	1	_	_	_	
10	JCL	41	Female	2	2	2	2	1
11	TLM	50	Female	3	3	3	2	1
13	DKS	38	Female	2	2	1	1	1
14	LKB	56	Female	4	4	4	4	3
15	NHK	56	Female	2	2			
16	VLH	57	Female	2	2	2	1	1
22	JKP	48	Female					
23	RMS	51	Female	3	2	2	2	2
25	TJJ	40	Female	3	2	2	2	2
29	DSE	59	Female	3	3	3	2	3
30	MMC	64	Female	3	3	3	3	3
33	J-G	47	Female					
34	LLL	31	Female					
35	DLM	52	Female	2	2	2	2	2
36	MAE	51	Female	2	2	1	1	1
37	GLJ	54	Female	2	2	1	1	1
38	KAS	42	Female					
41	E-N	61	Female	3	3	3	3	3
42	KAM	52	Female	3	3	2	2	2
43	CGC	48	Female	2	2	2	1	1
45	TDC	48	Female	2	2	1	1	1
48	JLL	47	Female	3	2	2	1	1
50	DKH	49	Female	2	2	1	1	1
52	CJL	53	Female	3	3	2	1	1
53	DSB	54	Female	3	3	2	2	2
55	SKR	57	Female	2	2	2	2	1
56	DAH	45	Female					
58	CZR	49	Female	2	2	2	1	1
62	KME	45	Female	3	3	2	2	2
63	MRG	51	Female	3				
68	SAM	53	Female	3	3	3	3	3
69	GHD	55	Female	3	3	3	3	3
70	CAC	62	Female	4	4	4	4	4
71	JAR	40	Female	2	2	2	2	1
72	NRC	56	Female	3	2	2	2	2
73	NLW	47	Female	1	1			
	Discontinu	led	Mean	2.61	2.45	2.17	1.90	1.73
			SD	0.62	0.62	0.79	0.88	0.91
			Median	3.00	2.00	2.00	2.00	1.00
			N	31	31	30	30	30

)	=	No	ne	

<sup>0 =</sup> None 1 = Minimal 2 = Mild 3 = Moderate 4 = Severe

				Expert Assessment of Fine Wrinkles Intra-Subject Change				
Subject	Subject		_	Week 2 Minus	Week 4 Minus	Week 8 Minus	Week 12 Minus	
No.	Initials	Age	Sex	Baseline	Baseline	Baseline	Baseline	
4	SKH	46	Female	0	0	-1	-1	
5	LMP	45	Female	-1	-1	-1	-2	
6	PJW	43	Female					
10	JCL	41	Female	0	0	0	-1	
11	TLM	50	Female	0	0	-1	-2	
13	DKS	38	Female	0	-1	-1	-1	
14	LKB	56	Female	0	0	0	-1	
15	NHK	56	Female	0				
16	VLH	57	Female	0	0	-1	-1	
22	JKP	48	Female					
23	RMS	51	Female	-1	-1	-1	-1	
25	TJJ	40	Female	-1	-1	-1	-1	
29	DSE	59	Female	0	0	-1	0	
30	MMC	64	Female	0	0	0	0	
33	J-G	47	Female					
34	LLL	31	Female					
35	DLM	52	Female	0	0	0	0	
36	MAE	51	Female	0	-1	-1	-1	
37	GLJ	54	Female	0	-1	-1	-1	
38	KAS	42	Female					
41	E-N	61	Female	0	0	0	0	
42	KAM	52	Female	0	-1	-1	-1	
43	CGC	48	Female	0	0	-1	-1	
45	TDC	48	Female	0	-1	-1	-1	
48	JLL	47	Female	-1	-1	-2	-2	
50	DKH	49	Female	0	-1	-1	-1	
52	CJL	53	Female	0	-1	-2	-2	
53	DSB	54	Female	0	-1	-1	-1	
55	SKR	57	Female	0	0	0	-1	
56	DAH	45	Female					
58	CZR	49	Female	0	0	-1	-1	
62	KME	45	Female	0	-1	-1	-1	
63	MRG	51	Female	-3				
68	SAM	53	Female	0	0	0	0	
69	GHD	55	Female	0	0	0	0	
70	CAC	62	Female	0	0	0	0	
71	JAR	40	Female	0	0	0	-1	
72	NRC	56	Female	-1	-1	-1	-1	
73	NLW	47	Female	0				
			Mean	-0.16	-0.47	-0.73	-0.90	
			SD	0.37	0.51	0.58	0.61	
			Median	0.00	0.00	-1.00	-1.00	
			N	31	30	30	30	

### Expert Assessment of Coarse Wrinkles

					Expert A	ssessment of Coars	e Wrinkles	
Subject No.	Subject Initials	Age	Sex	Baseline	Week 2	Week 4	Week 8	Week 12
4	SKH	46	Female	2	2	2	2	2
5	LMP	45	Female	2	2	2	2	2
6	PJW	43	Female	0				
10	JCL	41	Female	1	1	1	1	0
11	TLM	50	Female	2	2	2	2	2
13	DKS	38	Female	1	1	1	1	1
14 15	LKB NHK	56 56	Female	3 1	3 1	3	3	3
			Female					
16 22	VLH JKP	57 48	Female Female	1	1	1	1	1
23	RMS	51	Female	1	1	1	1	1
25	T.I.I	40	Female	1	1	1	1	1
25 29	DSE	40 59	Female	3	3	3	2	2
30	MMC	64	Female	4	4	4	4	4
33	J-G	47	Female	4	4	4	4	4
34	LLL	31	Female					
35	DLM	52	Female	3	3	3	3	3
36	MAE	51	Female	1	1	1	ő	0
37	GLJ	54	Female	3	3	3	3	3
38	KAS	42	Female		3	3	J	J
41	E-N	61	Female	3	3	3	3	3
42	KAM	52	Female	4	3	3	2	2
43	CGC	48	Female	3	3	3	2	2
45	TDC	48	Female	ō	1	ō	0	0
48	JLL	47	Female	1	1	1	1	1
50	DKH	49	Female	1	1	1	1	1
52	CJL	53	Female	1	1	1	2	2
53	DSB	54	Female	2	2	2	2	2
55	SKR	57	Female	1	1	1	1	1
56	DAH	45	Female					
58	CZR	49	Female	1	1	1	1	0
62	KME	45	Female	1	1	1	1	1
63	MRG	51	Female	1				
68	SAM	53	Female	2	2	2	2	2
69	GHD	55	Female	4	4	4	4	4
70	CAC	62	Female	4	4	4	4	4
71	JAR	40	Female	1	1	1	0	0
72	NRC	56	Female	3	3	3	3	3
73	NLW	47	Female	0	0			
	Discontinu	ued	Mean	1.97	1.97	1.97	1.83	1.77
			SD	1.17	1.08	1.13	1.15	1.22
			Median	2.00	2.00	2.00	2.00	2.00
			N	31	31	30	30	30

69	GHD	55	Female	4	4	4	4	4
70	CAC	62	Female	4	4	4	4	4
71	JAR	40	Female	1	1	1	0	0
72	NRC	56	Female	3	3	3	3	3
73	NLW	47	Female	0	0			
Discontinued		ıed	Mean	1.97	1.97	1.97	1.83	1.77
			SD	1.17	1.08	1.13	1.15	1.22
			Median	2.00	2.00	2.00	2.00	2.00
			N	31	31	30	30	30

				Expert Assessment of Coarse Wrinkles Intra-Subject Change				
Subject	Subject	Age	Sex	Week 2 Minus	Week 4 Minus	Week 8 Minus	Week 12 Minus	
No.	Initials SKH	46	Female	Baseline 0	Baseline 0	Baseline 0	Baseline 0	
5	IMP	45	Female	0	0	0	0	
6	PJW	43	Female	U	U	U	U	
10	JCL	43	Female	0	0	0	-1	
11	TLM	50	Female	0	0	0	0	
13	DKS	38	Female	0	0	0	0	
14	LKB	56	Female	0	0	0	0	
15	NHK	56	Female	0	U	U	U	
16	VIH	57	Female	0	0	0	0	
22	JKP	48	Female	U	U	U	U	
23	RMS	51	Female	0	0	0	0	
25	TJJ	40	Female	0	0	0	0	
29	DSF	59	Female	0	0	-1	-1	
30	MMC	64	Female	0	0	-1	0	
33	J-G	47	Female	U	U	U	U	
34	LLL	31	Female					
35	DLM	52	Female	0	0	0	0	
36	MAE	52	Female	0	0	-1	-1	
		51 54						
37 38	GLJ KAS	42	Female Female	0	0	0	0	
38 41	F-N	61	Female	0	0	0	0	
42	KAM	52	Female	-1	-1	-2	-2	
42	CGC	48	Female	0	0	-2 -1	-2 -1	
45	TDC	48	Female	1	0	-1	0	
48	JLL	46	Female	0	0	0	0	
50	DKH	49	Female	0	0	0	0	
52	CJL	53	Female	0	0	1	1	
53	DSB	54	Female	0	0	0	,	
55	SKR	57	Female	0	0	0	0	
56	DAH	45	Female	U	U	U	U	
58	CZR	49	Female	0	0	0	-1	
62	KMF	45	Female	0	0	0	0	
63	MRG	51	Female	-1	J	J	3	
68	SAM	53	Female	0	0	0	0	
69	GHD	55	Female	0	0	0	0	
70	CAC	62	Female	0	0	0	0	
71	JAR	40	Female	0	ő	-1	-1	
72	NRC	56	Female	0	0	0	0	
73	NLW	47	Female	0	, , , , , , , , , , , , , , , , , , ,	,		
			Mean	0.00	-0.03	-0.17	-0.23	
			SD	0.26	0.18	0.53	0.57	
			Median	0.00	0.00	0.00	0.00	
			N	31	30	30	30	
				٠.			50	

<sup>0 =</sup> None 1 = Minimal 2 = Mild 3 = Moderate 4 = Severe

### Expert Assessment of Roughness

				Expert Assessment of Roughnness					
Subject No.	Subject Initials	Age	Sex	Baseline	Week 2	Week 4	Week 8	Week 12	
4	SKH	46	Female	3	3	2	1	0	
5	LMP	45	Female	3	2	2	0	0	
6	PJW	43	Female	3					
10	JCL	41	Female	3	2	2	1	1	
11	TLM	50	Female	2	2	0	0	0	
13	DKS	38	Female	3	2	2	1	0	
14	LKB	56	Female	2	3	1	1	1	
15	NHK	56	Female	3	3				
16	VLH	57	Female	3	2	2	0	0	
22	JKP	48	Female						
23	RMS	51	Female	2	1	0	0	0	
25	TJJ	40	Female	3	3	2	1	1	
29	DSE	59	Female	2	1	0	0	0	
30	MMC	64	Female	3	2	1	1	0	
33	J-G	47	Female						
34	LLL	31	Female						
35	DLM	52	Female	3	1	1	0	0	
36	MAE	51	Female	3	2	2	1	0	
37	GLJ	54	Female	2	1	1	1	0	
38	KAS	42	Female						
41	E-N	61	Female	2	0	0	0	0	
42	KAM	52	Female	3	1	1	1	1	
43	CGC	48	Female	3	2	1	0	0	
45	TDC	48	Female	3	3	2 2	1	1	
48	JLL	47	Female	3	3	2	2	1	
50	DKH	49	Female	3	3	3	3	1	
52	CJL	53	Female	2	1	1	1	1	
53	DSB	54	Female	3	1	2	1	0	
55	SKR	57	Female	3	0	0	0	0	
56	DAH	45	Female						
58	CZR	49	Female	3	3	2	2	1	
62	KME	45	Female	3	2	2	2	1	
63	MRG	51	Female	2					
68	SAM	53	Female	2	0	0	0	0	
69	GHD	55	Female	2	1	1	0	0	
70	CAC	62	Female	2	1	1	1	0	
71	JAR	40	Female	3	2	1	0	0	
72	NRC	56	Female	3	2	1	1	1	
73	NLW	47	Female	2	2				
	Discontinued Mean			2.68	1.77	1.27	0.77	0.37	
SD			0.48	0.96	0.83	0.77	0.49		
			Median	3.00	2.00	1.00	1.00	0.00	
			N	31	31	30	30	30	

)	=	None
	_	Minimal

				Expert Assessment of Roughness Intra-Subject Change					
Subject	Subject		_	Week 2 Minus	Week 4 Minus	Week 8 Minus	Week 12 Minus		
No.	Initials	Age	Sex	Baseline	Baseline	Baseline	Baseline		
4	SKH	46	Female	0	-1	-2	-3		
5	LMP	45	Female	-1	-1	-3	-3		
6	PJW	43	Female						
10	JCL	41	Female	-1	-1	-2	-2		
11	TLM	50	Female	0	-2	-2	-2		
13	DKS	38	Female	-1	-1	-2	-3		
14	LKB	56	Female	1	-1	-1	-1		
15	NHK	56	Female	0					
16	VLH	57	Female	-1	-1	-3	-3		
22	JKP	48	Female						
23	RMS	51	Female	-1	-2	-2	-2		
25	TJJ	40	Female	0	-1	-2	-2		
29	DSE	59	Female	-1	-2	-2	-2		
30	MMC	64	Female	-1	-2	-2	-3		
33	J-G	47	Female						
34	LLL	31	Female						
35	DLM	52	Female	-2	-2	-3	-3		
36	MAE	51	Female	-1	-1	-2	-3		
37	GLJ	54	Female	-1	-1	-1	-2		
38	KAS	42	Female						
41	E-N	61	Female	-2	-2	-2	-2		
42	KAM	52	Female	-2	-2	-2	-2		
43	CGC	48	Female	-1	-2	-3	-3		
45	TDC	48	Female	0	-1	-2	-2		
48	JLL	47	Female	0	-1	-1	-2		
50	DKH	49	Female	0	0	0	-2		
52	CJL	53	Female	-1	-1	-1	-1		
53	DSB	54	Female	-2	-1	-2	-3		
55	SKR	57	Female	-3	-3	-3	-3		
56	DAH	45	Female						
58	CZR	49	Female	0	-1	-1	-2		
62	KME	45	Female	-1	-1	-1	-2		
63	MRG	51	Female	-2					
68	SAM	53	Female	-2	-2	-2	-2		
69	GHD	55	Female	-1	-1	-2	-2		
70	CAC	62	Female	-1	-1	-1	-2		
71	JAR	40	Female	-1	-2	-3	-3		
72	NRC	56	Female	-1	-2	-2	-2		
73	NLW	47	Female	0	4.40	4.00			
			Mean	-0.90	-1.40	-1.90	-2.30		
			SD Median	0.83	0.62	0.76	0.60		

<sup>1 =</sup> Minimal 2 = Mild 3 = Moderate 4 = Severe

## Data Listing 1 Panel 1837 A CLINICAL STUDY OF TOPICAL ZEATIN FOR IMPROVING THE APPEARANCE OF PHOTODAMAGED SKIN

### Expert Assessment of Mottled Hyperpigmentation

				Expert Assessment of Mottled Hyperpigmentation					
Subject No.	Subject Initials	Age	Sex	Baseline	Week 2	Week 4	Week 8	Week 12	
4	SKH	46	Female	2	2	2	2	2	
5	LMP	45	Female	2	2	2	2	2	
6	PJW	43	Female	1					
10	JCL	41	Female	1	1	1	1	1	
11	TLM	50	Female	3	3	2	2	2	
13	DKS	38	Female	1	1	0	0	0	
14	LKB	56	Female	3	3	3	3	3	
15	NHK	56	Female	3	3				
16	VLH	57	Female	2	2	1	1	1	
22	JKP	48	Female						
23	RMS	51	Female	1	1	1	1	1	
25	TJJ	40	Female	1	1	1	1	1	
29	DSE	59	Female	2	1	1	1	1	
30	MMC	64	Female	2	2	2	1	1	
33	J-G	47	Female						
34	LLL	31	Female						
35	DLM	52	Female	3	3	3	3	2	
36	MAE	51	Female	2	2	2	2	2	
37	GLJ	54	Female	3	3	2	2	2	
38	KAS	42	Female						
41	E-N	61	Female	1	1	1	2	1	
42	KAM	52	Female	3	3	3	3	3	
43	CGC	48	Female	1	1	1	1	0	
45	TDC	48	Female	2	1	1	1	1	
48	JLL	47	Female	1	0	0	1	0	
50	DKH	49	Female	0	0	0	0	0	
52	CJL	53	Female	2	2	1	1	1	
53	DSB	54	Female	3	3	3	3	3	
55	SKR	57	Female	1	1	1	1	1	
56	DAH	45	Female						
58	CZR	49	Female	2	2	2	2	2	
62	KME	45	Female	2	2	2	2	2	
63	MRG	51	Female	2					
68	SAM	53	Female	3	3	1	2	2	
69	GHD	55	Female	3	2	2	2	1	
70	CAC	62	Female	3	3	3	3	3	
71	JAR	40	Female	2	2	2	2	2	
72	NRC	56	Female	1	1	1	1	1	
73	NLW	47	Female	2	2				
	Discontinu	ued	Mean	1.97	1.84	1.57	1.63	1.47	
			SD	0.87	0.93	0.90	0.85	0.90	
			Median	2.00	2.00	1.50	2.00	1.00	
			N	31	31	30	30	30	
O - None									

							-
Subject	Subject	Age	Sex	Week 2 Minus	Week 4 Minus	Week 8 Minus	Week 12 Minus
No.	Initials			Baseline	Baseline	Baseline	Baseline
4	SKH	46	Female	0	0	0	0
5	LMP	45	Female	0	0	0	0
6	PJW	43	Female				
10	JCL	41	Female	0	0	0	0
11	TLM	50	Female	0	-1	-1	-1
13	DKS	38	Female	0	-1	-1	-1
14	LKB	56	Female	0	0	0	0
15	NHK	56	Female	0			
16	VLH	57	Female	0	-1	-1	-1
22	JKP	48	Female				
23	RMS	51	Female	0	0	0	0
25	TJJ	40	Female	0	0	0	0
29	DSE	59	Female	-1	-1	-1	-1
30	MMC	64	Female	0	0	-1	-1
33	J-G	47	Female				
34	LLL	31	Female				
35	DLM	52	Female	0	0	0	-1
36	MAE	51	Female	0	0	0	0
37	GLJ	54	Female	0	-1	-1	-1
38	KAS	42	Female				
41	E-N	61	Female	0	0	1	0
42	KAM	52	Female	0	0	0	0
43	CGC	48	Female	0	0	0	-1
45	TDC	48	Female	-1	-1	-1	-1
48	JLL	47	Female	-1	-1	0	-1
50	DKH	49	Female	0	0	0	0
52	CJL	53	Female	0	-1	-1	-1
53	DSB	54	Female	0	0	0	0
55	SKR	57	Female	0	0	0	0
56	DAH CZR	45	Female	0	0	0	0
58		49	Female	0	0	0	0
62 63	KME MRG	45 51	Female Female	-2	U	U	0
	SAM			-2 0	_		4
68		53	Female	-1	-2 -1	-1 -1	-1 -2
69	GHD CAC	55	Female	-1 0		-1 0	-2 0
70 71	JAR	62 40	Female Female	0	0	0	0
71 72	NRC	40 56	Female	0	0	0	0
73	NLW	47	Female	0	U	U	U
13	INLAA	41	Mean	-0.13	-0.37	-0.30	-0.47
			SD	0.34	0.56	0.53	0.57
			Median	0.34	0.56	0.00	0.00
			N	31	30	30	30
			.,	31	30	30	30

Expert Assessment of Mottled Hyperpigmentation Intra-Subject Change

<sup>0 =</sup> None 1 = Minimal 2 = Mild 3 = Moderate 4 = Severe

### Expert Assessment of Overall Severity of Skin Aging

				Expert Assessment of Overall Severity (Skin Aging)						
Subject No.	Subject Initials	Age	Sex	Baseline	Week 2	Week 4	Week 8	Week 12		
4	SKH	46	Female	4	4	3	2	2		
5	LMP	45	Female	4	3	3	2	2		
6	PJW	43	Female	2						
10	JCL	41	Female	4	3	3	2	2		
11	TLM	50	Female	5	4	3	3	3		
13	DKS	38	Female	2	2	1	1	1		
14	LKB	56	Female	6	6	5	5	5		
15	NHK	56	Female	4	4					
16	VLH	57	Female	4	3	3	2	2		
22	JKP	48	Female							
23	RMS	51	Female	3	2	2	3	2		
25	TJJ	40	Female	3	2	2	2	1		
29	DSE	59	Female	4	3	3	2	3		
30	MMC	64	Female	6	6	5	5	5		
33	J-G	47	Female							
34	LLL	31	Female							
35	DLM	52	Female	5	5	5	5	5		
36	MAE	51	Female	3	3	3	2	1		
37	GLJ	54	Female	4	4	4	4	4		
38	KAS	42	Female							
41	E-N	61	Female	4	4	4	5	5		
42	KAM	52	Female	5	5	5	4	4		
43	CGC	48	Female	3	3	2	2	2		
45	TDC	48	Female	3	3	2	1	1		
48	JLL	47	Female	3	2	2	1	1		
50	DKH	49	Female	2	2	2	2	2		
52	CJL	53	Female	3	3	2	2	2		
53	DSB	54	Female	5	4	3	3	3		
55	SKR	57	Female	2	1	1	1	1		
56	DAH	45	Female							
58	CZR	49	Female	4	4	3	3	2		
62	KME	45	Female	4	4	2	3	3		
63	MRG	51	Female	4						
68	SAM	53	Female	5	4	4	4	4		
69	GHD	55	Female	6	5	5	5	5		
70	CAC	62	Female	6	6	6	6	5		
71	JAR	40	Female	3	3	2	2	1		
72	NRC	56	Female	4	3	2	3	2		
73	NLW	47	Female	2	1					
	Discontinu	ıed	Mean	3.97 1.17	3.55	3.07	2.90	2.70		
	SD				1.26	1.31	1.42	1.47		
			Median	4.00	3.00	3.00	2.50	2.00		
			N	31	31	30	30	30		
0 = None										

0	=	Ν	one
1	-3	=	Mild
4	-6	=	Moderate
7	0	_	Covere

Subject   Subject   Subject   No.   Initials   Age   Sex   No.   Week 2 Minus Baseline   Week 4 Minus Baseline   Week 12 Minus Baseline   Age   Sex   SkH   46   Female   SkH   47   Female   SkH   48   SkH   48   SkH   58   SkH					Expert Asses	ssment of Overall Severity	(Skin Aging) Intra-Subject	t Change
S	No.	Initials	,					
6								
10					-1	-1	-2	-2
11								
13								
14								
15								
16						-1	-1	-1
22								
23					-1	-1	-2	-2
25								
29								
30								
33	29	DSE	59	Female	-1	-1	-2	-1
34	30	MMC	64	Female	0	-1	-1	-1
35	33	J-G	47	Female				
36	34	LLL	31	Female				
37   GLJ   54   Female   0   0   0   0   0   38   K8S   42   Female	35	DLM	52	Female	0	0	0	0
38	36	MAE	51	Female	0	0	-1	-2
41	37	GLJ	54	Female	0	0	0	0
42	38	KAS	42	Female				
43	41	E-N	61	Female	0	0	1	1
43	42	KAM	52	Female	0	0	-1	-1
45								
48								
50		JLI	47	Female	-1			
52   Call   53   Female   0   -1   -1   -1   -1   -1   -1   -1								
53         DSB         54         Female         -1         -2         -2         -2         -2         -5         SKR         57         Female         -1         -1         -1         -1         -1         -1         -1         -1         -1         -1         -1         -1         -1         -1         -1         -1         -2         -2         -1								
55         SKR         57         Female         -1         -1         -1         -1         -1         -1         -1         -1         -1         -1         -1         -1         -1         -2         -2         -1         -1         -1         -2         -2         -1 <t< td=""><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></t<>								
Section   Sect								
58         CZR         49         Female         0         -1         -1         -1         -2           62         KME         45         Female         0         -2         -1         -1         -1           63         MRG         51         Female            -1         -2         -1         -1								
62         KME         45         Female         0         -2         -1         -1           63         MRG         51         Female         -         -         -1         <					0	-1	-1	-2
63 MRG 51 Female -1 -1 -1 -1 -1 69 GHD 55 Female -1 -1 -1 -1 -1 -1 70 CAC 62 Female 0 0 0 -1 1 -1 -2 72 NRC 56 Female -1 -2 -1 -1 -2 -2								
68 SAM 53 Female -1 -1 -1 -1 -1 -1 -1 -1 -1 -1 -1 -1 -1					· ·	-2	-1	-1
69 GHD 55 Female -1 -1 -1 -1 -1 70 CAC 62 Female 0 0 0 -1 JAR 40 Female 0 -1 -1 -1 -2 72 NRC 56 Female -1 -2 -1 -2					-1	-1	-1	-1
70 CAC 62 Female 0 0 0 -1 71 JAR 40 Female 0 -1 -1 -2 72 NRC 56 Female -1 -2 -1 -2								
71 JAR 40 Female 0 -1 -1 -2 -2 -1 -2								
72 NRC 56 Female -1 -2 -1 -2								
					-1	-2	-1	-2
Mean -0.42 -0.90 -1.07 -1.27	13	INLAA	41		0.40	0.00	1.07	4.07
Mean -0.42 -0.90 -1.07 -1.27 SD 0.50 0.61 0.78 0.78								
Median 0.00 -1.00 -1.00 -1.00								
N 31 30 30 30								
N 31 30 30 30				IN	31	30	30	30

### Expert Assessment of Improvement of Skin Aging

Expert Assessment of Improvement (Skin Aging)								
Subject No.	Subject Initials	Age	Sex	Baseline	Week 2	Week 4	Week 8	Week 12
4	SKH	46	Female	N/A	5	4	4	4
5	LMP	45	Female	N/A	4	4	4	4
6	PJW	43	Female	N/A				
10	JCL	41	Female	N/A	5	4	4	4
11	TLM	50	Female	N/A	5	4	4	4
13	DKS	38	Female	N/A	5	4	4	4
14	LKB	56	Female	N/A	5	5	5	5
15	NHK	56	Female	N/A	5			
16	VLH	57	Female	N/A	5	4	4	4
22	JKP	48	Female	N/A				
23	RMS	51	Female	N/A	4	4	4	4
25	TJJ	40	Female	N/A	4	4	4	4
29	DSE	59	Female	N/A	4	4	4	5
30	MMC	64	Female	N/A	5	5	5	5
33	J-G	47	Female	N/A				
34	LLL	31	Female	N/A				
35	DLM	52	Female	N/A	5	5	5	5
36	MAE	51	Female	N/A	5	4	4	4
37	GLJ	54	Female	N/A	5	4	4	4
38	KAS	42	Female	N/A				
41	E-N	61	Female	N/A	5	5	5	5
42	KAM	52	Female	N/A	4	4	4	4
43	CGC	48	Female	N/A	5	4	4	4
45	TDC	48	Female	N/A	4	4	4	4
48	JLL	47	Female	N/A	4	4	4	4
50	DKH	49	Female	N/A	5	4	4	4
52	CJL	53	Female	N/A	5	4	4	4
53	DSB	54	Female	N/A	5	5	5	5
55	SKR	57	Female	N/A	5	4	4	4
56	DAH	45	Female	N/A				
58	CZR	49	Female	N/A	5	4	4	4
62	KME	45	Female	N/A	5	4	4	4
63	MRG	51	Female	N/A				
68	SAM	53	Female	N/A	5	4	4	4
69	GHD	55	Female	N/A	5	5	5	5
70	CAC	62	Female	N/A	5	5	5	4
71	JAR	40	Female	N/A	5	4	4	4
72	NRC	56	Female	N/A	4	4	4	4
73	NLW	47	Female	N/A	5			
	Discontinu	ued	Mean	•	4.74	4.23	4.23	4.23
			SD		0.44	0.43	0.43	0.43
			Median		5.00	4.00	4.00	4.00
			N		31	30	30	30

1	=	Ex	cell	ent	Improvement	(~100%)

<sup>1 =</sup> Excellent Improvement (~100%)
2 = Marked Improvement (~75%)
3 = Moderate Improvement (~50%)
4 = Slight Improvement (~25%)
5 = No Improvement (0%)
6 = Worse

				Expert Assessment of Improvement (Skin Aging) Intra-Subject Change						
				Expert Assessment o	f Improvement (Skin Agin	g) Intra-Subject Change				
Subject No.	Subject Initials	Age	Sex	Week 4 Minus Week 2	Week 8 Minus Week 2	Week 12 Minus Week 2				
4	SKH	46	Female	-1	-1	-1				
5	LMP	45	Female	0	0	0				
6	PJW	43	Female							
10	JCL	41	Female	-1	-1	-1				
11	TLM	50	Female	-1	-1	-1				
13	DKS	38	Female	-1	-1	-1				
14	LKB	56	Female	0	0	0				
15	NHK	56	Female							
16	VLH	57	Female	-1	-1	-1				
22	JKP	48	Female							
23	RMS	51	Female	0	0	0				
25	TJJ	40	Female	0	0	0				
29	DSE	59	Female	0	0	1				
30	MMC	64	Female	0	0	0				
33	J-G	47	Female							
34	LLL	31	Female							
35	DLM	52	Female	0	0	0				
36	MAE	51	Female	-1	-1	-1				
37	GLJ	54	Female	-1	-1	-1				
38	KAS	42	Female		·					
41	E-N	61	Female	0	0	0				
42	KAM	52	Female	Ō	Ō	0				
43	CGC	48	Female	-1	-1	-1				
45	TDC	48	Female	o o	o o	0				
48	JLL	47	Female	0	o O	Ö				
50	DKH	49	Female	-1	-1	-1				
52	CJL	53	Female	-i	-1	-1				
53	DSB	54	Female	o o	o o	0				
55	SKR	57	Female	-1	-1	-1				
56	DAH	45	Female	·	·					
58	CZR	49	Female	-1	-1	-1				
62	KMF	45	Female	-i	-1	-1				
63	MRG	51	Female	·	·					
68	SAM	53	Female	-1	-1	-1				
69	GHD	55	Female	0	0	0				
70	CAC	62	Female	0	o O	-1				
71	JAR	40	Female	-1	-1	-1				
72	NRC	56	Female	0	0	0				
73	NLW	47	Female			3				
. 0			Mean	-0.50	-0.50	-0.50				
			SD	0.51	0.51	0.57				
			Median	-0.50	-0.50	-1.00				
			N	30	30	30				
			IN	JU	JU	30				

### Expert Assessment of Skin Irritation

_					Expert Ass	sessment of Sk	in Irritation	
Subject No.	Subject Initials	Age	Sex	Baseline	Week 2	Week 4	Week 8	Week 12
4	SKH	46	Female	1	2	1	0	1
5	LMP	45	Female	1	1	1	0	1
6	PJW	43	Female	2				
10	JCL	41	Female	1	1	0	0	0
11	TLM	50	Female	1	1	1	0	0
13	DKS	38	Female	2	2	1	1	1
14	LKB	56	Female	1	1	1	1	1
15	NHK	56	Female				4	
16	VLH	57	Female	1	1	0	1	0
22 23	JKP RMS	48 51	Female Female	1	1	1	1	1
23 25		40		2	2	2	1	1
25 29	TJJ DSE	59	Female Female	1	0	0	0	0
30	MMC	64	Female	1	1	1	0	0
33	J-G	47	Female	-	-		U	U
34	J-G LLL	31	Female					
35	DLM	52	Female	1	1	0	0	0
36	MAE	51	Female	1	0	0	0	0
37	GLJ	54	Female	1	1	0	0	0
38	KAS	42	Female			U	U	U
41	E-N	61	Female	2	1	1	0	1
42	KAM	52	Female	1	Ö	Ö	0	ò
43	CGC	48	Female	1	ő	ő	Ö	ő
45	TDC	48	Female	1	1	2	1	ĭ
48	JLL	47	Female	1	1	1	1	0
50	DKH	49	Female	1	2	2	1	1
52	CJL	53	Female	i	0	1	Ö	i
53	DSB	54	Female	1	1	1	0	0
55	SKR	57	Female	1	0	0	0	0
56	DAH	45	Female		-		-	-
58	CZR	49	Female	1	1	0	0	0
62	KME	45	Female	0	0	0	0	0
63	MRG	51	Female	1				
68	SAM	53	Female	1	1	1	1	1
69	GHD	55	Female	1	1	0	0	0
70	CAC	62	Female	1	1	0	0	1
71	JAR	40	Female	1	1	1	1	1
72	NRC	56	Female	2	2	1	0	0
73	NLW	47	Female	2	3			
	Discontinued Mean			1.10	0.94	0.67	0.33	0.43
			SD	0.40	0.63	0.66	0.48	0.50
			Median	1.00	1.00	1.00	0.00	0.00
			N	31	31	30	30	30
0 = Nlong								

)	=	None	
•		140110	

_				Expert Asses	ssment of Skin II	ritation Intra-Sub	oject Change
Subject No.	Subject Initials	Age	Sex	Week 2 Minus Baseline	Week 4 Minus Baseline	Week 8 Minus Baseline	Week 12 Minus Baseline
4	SKH	46	Female	1	0	-1	0
5	LMP	45	Female	0	0	-1	0
6	PJW	43	Female				
10	JCL	41	Female	0	-1	-1	-1
11	TLM	50	Female	0	0	-1	-1
13	DKS	38	Female	0	-1	-1	-1
14	LKB	56	Female	0	0	0	0
15	NHK	56	Female	0			
16	VLH	57	Female	0	-1	0	-1
22	JKP	48	Female				
23	RMS	51	Female	0	0	0	0
25	TJJ	40	Female	0	0	-1	-1
29	DSE	59	Female	-1	-1	-1	-1
30	MMC	64	Female	0	0	-1	-1
33	J-G	47	Female				
34	LLL	31	Female				
35	DLM	52	Female	0	-1	-1	-1
36	MAE	51	Female	-1	-1	-1	-1
37	GLJ	54	Female	0	-1	-1	-1
38	KAS	42	Female				
41	E-N	61	Female	-1	-1	-2	-1
42	KAM	52	Female	-1	-1	-1	-1
43	CGC	48	Female	-1	-1	-1	-1
45	TDC	48	Female	0	1	0	0
48	JLL	47	Female	0	0	0	-1
50	DKH	49	Female	1	1	0	0
52	CJL	53	Female	-1	0	-1	0
53	DSB	54	Female	0	0	-1	-1
55	SKR	57	Female	-1	-1	-1	-1
56	DAH	45	Female				
58	CZR	49	Female	0	-1	-1	-1
62	KME	45	Female	0	0	0	0
63	MRG	51	Female				
68	SAM	53	Female	0	0	0	0
69	GHD	55	Female	0	-1	-1	-1
70	CAC	62	Female	0	-1	-1	0
71	JAR	40	Female	0	0	0	0
72	NRC	56	Female	0	-1	-2	-2
73	NLW	47	Female	1			
			Mean	-0.16	-0.43	-0.77	-0.67
			SD	0.52	0.63	0.57	0.55
			Median	0.00	-0.50	-1.00	-1.00
			N	31	30	30	30

<sup>0 =</sup> None 1 = Mild 2 = Moderate 3 = Severe

### Expert Assessment of Overall Severity of Acne

				Expert Assessment of Overall Severity (Acne)						
Subject No.	Subject Initials	Age	Sex	Baseline	Week 2	Week 4	Week 8	Week 12		
4	SKH	46	Female	1	1	1	1	1		
5	LMP	45	Female	1	1	1	1	1		
6	PJW	43	Female	1						
10	JCL	41	Female	1	1	1	0	1		
11	TLM	50	Female	1	1	1	1	1		
13	DKS	38	Female	1	1	1	1	1		
14	LKB	56	Female	1	1	1	0	1		
15	NHK	56	Female	1	1					
16	VLH	57	Female	1	1	1	0	1		
22	JKP	48	Female							
23	RMS	51	Female	0	1	0	0	0		
25	TJJ	40	Female	0	1	1	0	1		
29	DSE	59	Female	1	1	1	0	1		
30	MMC	64	Female	1	0	1	1	0		
33	J-G	47	Female							
34	LLL	31	Female							
35	DLM	52	Female	2	1	1	1	1		
36	MAE	51	Female	1	1	0	1	0		
37	GLJ	54	Female	1	1	1	0	0		
38	KAS	42	Female							
41	E-N	61	Female	0	0	0	0	0		
42	KAM	52	Female	1	0	1	0	1		
43	CGC	48	Female	1	1	1	1	1		
45	TDC	48	Female	1	1	1	0	1		
48	JLL	47	Female	1	1	1	1	1		
50	DKH	49	Female	1	1	1	1	2		
52	CJL	53	Female	1	1	1	1	1		
53	DSB	54	Female	1	1	1	0	1		
55	SKR	57	Female	1	1	1	1	0		
56	DAH	45	Female							
58	CZR	49	Female	1	1	1	0	1		
62	KME	45	Female	1	1	2	1	1		
63	MRG	51	Female	1						
68	SAM	53	Female	0	1	1	1	1		
69	GHD	55	Female	Ö	1	1	0	0		
70	CAC	62	Female	Ö	0	1	ō	Ö		
71	JAR	40	Female	1	1	1	1	Ö		
72	NRC	56	Female	0	0	0	0	0		
73	NLW	47	Female	2	0					
	Discontinu	ied	Mean	0.81	0.84	0.90	0.50	0.70		
			SD	0.48	0.37	0.40	0.51	0.53		
			Median	1.00	1.00	1.00	0.50	1.00		
			N	31	31	30	30	30		
0 = None										

0	=	None
1	=	Mild

				Expert Assessment of Overall Severity (Acne) Intra-Subject Change						
Subject No.	Subject Initials	Age	Sex	Week 2 Minus Baseline	Week 4 Minus Baseline	Week 8 Minus Baseline	Week 12 Minus Baseline			
4	SKH	46	Female	0	0	0	0			
5	LMP	45	Female	0	0	0	0			
6	PJW	43	Female							
10	JCL	41	Female	0	0	-1	0			
11	TLM	50	Female	0	0	0	0			
13	DKS	38	Female	0	0	0	0			
14	LKB	56	Female	0	0	-1	0			
15	NHK	56	Female	0						
16	VLH	57	Female	0	0	-1	0			
22	JKP	48	Female							
23	RMS	51	Female	1	0	0	0			
25	TJJ	40	Female	1	1	0	1			
29	DSE	59	Female	0	0	-1	0			
30	MMC	64	Female	-1	0	0	-1			
33	J-G	47	Female							
34	LLL	31	Female							
35	DLM MAF	52 51	Female Female	-1 0	-1 -1	-1	-1 -1			
36 37	GLJ	54	Female	0	0	0 -1	-1 -1			
38	KAS	42	Female	U	U	-1	-1			
41	E-N	61	Female	0	0	0	0			
42	KAM	52	Female	-1	0	-1	0			
43	CGC	48	Female	0	0	0	0			
45	TDC	48	Female	0	ő	-1	Ö			
48	JH	47	Female	0	ő	0	Ö			
50	DKH	49	Female	0	Ö	Ö	1			
52	CJL	53	Female	0	Ö	Ö	Ö			
53	DSB	54	Female	0	Ō	-1	Ö			
55	SKR	57	Female	0	Ō	0	-1			
56	DAH	45	Female							
58	CZR	49	Female	0	0	-1	0			
62	KME	45	Female	0	1	0	0			
63	MRG	51	Female							
68	SAM	53	Female	1	1	1	1			
69	GHD	55	Female	1	1	0	0			
70	CAC	62	Female	0	1	0	0			
71	JAR	40	Female	0	0	0	-1			
72	NRC	56	Female	0	0	0	0			
73	NLW	47	Female	-2						
			Mean	0.03	0.10	-0.30	-0.10			
			SD	0.48	0.48	0.53	0.55			
			Median	0.00	0.00	0.00	0.00			
			N	31	30	30	30			

<sup>2 =</sup> Moderate 3 = Severe

### Inflammatory Lesion Count

Subject   Subject   No.   Initialis   Age   Sex   Baseline   Week 2   Week 4   Week 8   Week 12						Inflammatory	Lesion Cour	it (Forehead)	
Section   Sect			Age	Sex	Baseline	Week 2	Week 4	Week 8	Week 12
6									
10						1	0	0	1
11									
13									
14									
15								-	
16							1	0	0
22									
Page 25					0	4	2	0	2
25									
29									
30								-	
33									
State					0	0	0	0	0
35									
36 MAE 51 Female 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0									
37									
38									
Heat   Care   Heat   Care					3	0	0	0	0
42									
43									
45	42		52	Female	1				
48 JLL 47 Female 0 1 0 0 0 0 3 3 5 2 CJL 53 Female 0 0 1 4 0 0 3 3 5 5 2 CJL 53 Female 0 0 0 0 0 0 0 0 0 5 5 5 SKR 57 Female 0 1 0 0 0 0 0 0 5 5 5 SKR 57 Female 0 1 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	43	CGC	48	Female	0		0	2	
50         DKH         49         Female         0         1         4         0         3           52         CJL         53         Female         0         1         0         0         0         1         0         0         1         0         0         1         0         0         1         0         0         1         1         0         0         2         1         1         0         0         2         1         1         4         0			48	Female	0				
S2				Female		1	0		
53         DSB         54         Female         3         2         4         0         0         0           56         DAH         45         Female         0         1         0         0         0         0         0         0         1         0         0         1         0         0         1         0         0         1         0         0         1         0         0         1         0         0         1         0         0         2         1         4         0			49	Female	0				
SKR   S7   Female   O	52	CJL	53	Female	0	0	0	0	0
S6	53	DSB	54	Female	3	2	4	0	0
Female	55	SKR	57	Female	0	1	0	0	0
62         KME         45         Female         1         0         0         2         1           63         MRG         51         Female         1         -	56	DAH	45	Female					
63 MRG 51 Female 1 2 1 4 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0									
68 SAM 53 Female 0 2 1 4 0 0 6 6 9 GHD 55 Female 0 0 0 0 0 0 0 0 0 0 7 0 0 0 0 0 0 0 0						0	0	2	1
69         GHD         55         Female         0         0         0         0         0         0           70         CAC         62         Female         0         0         1         0					1				
70									
71 JAR 40 Female 0 0 1 1 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0		GHD		Female					
72         NRC         56         Female         0         0         0         0         0           73         NLW         47         Female         4         0	70	CAC	62	Female	0	0	1	0	0
73 NLW 47 Female 4 0	71	JAR	40	Female	0	0		0	0
Mean         0.26         0.68         0.83         0.30         0.47           SD         0.77         0.98         1.29         0.88         0.78           Median         0.00         0.00         0.00         0.00         0.00	72	NRC	56	Female			0	0	0
SD 0.77 0.98 1.29 0.88 0.78 Median 0.00 0.00 0.00 0.00 0.00	73	NLW	47	Female					
Median 0.00 0.00 0.00 0.00 0.00									
							1.29		
N 31 31 30 30 30									
14 51 51 50 50 50				N	31	31	30	30	30

				Inflammator	ry Lesion Count (Fo	orehead) Intra-Sub	ject Change
Subject No.	Subject Initials	Age	Sex	Week 2 Minus Baseline	Week 4 Minus Baseline	Week 8 Minus Baseline	Week 12 Minus Baseline
4	SKH	46	Female	0	0	0	1
5	LMP	45	Female	1	0	0	1
6	PJW	43	Female		_	_	
10	JCL	41	Female	1	2	0	1
11	TLM DKS	50	Female Female	1 0	2	0	0
13 14	LKB	38 56	Female	0	1	0	0
15	NHK	56	Female	1	1	U	U
16	VLH	57	Female	4	2	0	2
22	JKP	48	Female	4		U	2
23	RMS	51	Female	1	0	0	0
25	TJJ	40	Female	3	2	Ö	1
29	DSE	59	Female	0	0	Ö	1
30	MMC	64	Female	0	0	0	0
33	J-G	47	Female				
34	LLL	31	Female				
35	DLM	52	Female	1	0	0	0
36	MAE	51	Female	0	0	1	0
37	GLJ	54	Female	-3	-3	-3	-3
38	KAS	42	Female				
41	E-N	61	Female	0	0	0	0
42	KAM	52	Female	-1	0	-1	-1
43	CGC	48 48	Female	1	0	2	2
45 48	TDC JLL	48 47	Female Female	0 1	0	0	0
48 50	DKH	47	Female	1	4	0	3
52	CJL	53	Female	0	0	0	0
53	DSB	54	Female	-1	1	-3	-3
55	SKR	57	Female	1	0	0	0
56	DAH	45	Female		Ü		Ů
58	CZR	49	Female	0	4	0	1
62	KME	45	Female	-1	-1	1	0
63	MRG	51	Female				
68	SAM	53	Female	2	1	4	0
69	GHD	55	Female	0	0	0	0
70	CAC	62	Female	0	1	0	0
71	JAR	40	Female	0	1	0	0
72	NRC	56	Female	0	0	0	0
73	NLW	47	Female	-4	0.57	0.02	0.00
			Mean SD	0.42 1.23	0.57 1.36	0.03 1.19	0.20 1.19
			SD Median	0.00	1.36 0.00	1.19 0.00	1.19 0.00
			N	31	30	30	30
			14	31	30	30	30

Discontinued

### Inflammatory Lesion Count

				Inflammatory Lesion Count (Left Cheek)						
Subject No.	Subject Initials	Age	Sex	Baseline	Week 2	Week 4	Week 8	Week 12		
4	SKH	46	Female	5	0	2	0	1		
5	LMP	45	Female	0	0	0	0	0		
6	PJW	43	Female	2						
10	JCL	41	Female	0	0	1	0	0		
11	TLM	50	Female	1	1	0	0	0		
13	DKS	38	Female	0	0	0	0	1		
14	LKB	56	Female	1	0	0	0	0		
15	NHK	56	Female	0	4					
16	VLH	57	Female	6	0	0	0	0		
22	JKP	48	Female							
23	RMS	51	Female	0	0	0	0	0		
25	TJJ	40	Female	0	0	0	0	0		
29	DSE	59	Female	0	1	1	0	0		
30	MMC	64	Female	0	0	0	0	0		
33	J-G	47	Female							
34	LLL	31	Female							
35	DLM	52	Female	2	0	0	2	0		
36	MAE	51	Female	0	0	0	0	0		
37	GLJ	54	Female	3	0	1	0	0		
38	KAS	42	Female							
41	E-N	61	Female	0	0	0	0	0		
42	KAM	52	Female	0	0	2	0	0		
43	CGC	48	Female	1	1	1	1	3		
45	TDC	48	Female	0	0	0	0	0		
48	JLL	47	Female	1	1	1	0	0		
50	DKH	49	Female	0	2	0	2	4		
52	CJL	53	Female	0	2	0	0	0		
53	DSB	54	Female	0	0	0	0	0		
55	SKR	57	Female	0	0	0	2	0		
56	DAH	45	Female							
58	CZR	49	Female	0	1	3	0	0		
62	KME	45	Female	1	0	0	0	0		
63	MRG	51	Female	0						
68	SAM	53	Female	0	0	0	0	0		
69	GHD	55	Female	0	1	1	0	0		
70	CAC	62	Female	0	0	0	0	0		
71	JAR	40	Female	0	0	0	0	0		
72	NRC	56	Female	0	0	0	0	0		
73	NLW	47	Female	1	0					
			Mean	0.68	0.45	0.43	0.23	0.30		
			SD	1.47	0.89	0.77	0.63	0.92		
			Median	0.00	0.00	0.00	0.00	0.00		
			N	31	31	30	30	30		

				Inflammator	y Lesion Count (Le	ft Cheek) Intra-Sub	oject Change
Subject No.	Subject Initials	Age	Sex	Week 2 Minus Baseline	Week 4 Minus Baseline	Week 8 Minus Baseline	Week 12 Minus Baseline
4	SKH	46	Female	-5	-3	-5	-4
5	LMP	45	Female	0	0	0	0
6	PJW	43	Female				
10	JCL	41	Female	0	1	0	0
11	TLM	50	Female	0	-1	-1	-1
13	DKS	38	Female	0	0	0	1
14	LKB	56	Female	-1	-1	-1	-1
15	NHK	56	Female	4		_	_
16	VLH	57	Female	-6	-6	-6	-6
22	JKP	48	Female				
23	RMS	51 40	Female Female	0	0	0	0
25	TJJ			0	0	0	0
29	DSE	59 64	Female Female	1 0	1 0	0	0
30 33	MMC J-G	47	Female	0	0	U	0
33	J-G	31	Female				
35	DLM	52	Female	-2	-2	0	-2
36	MAE	51	Female	0	0	0	0
37	GLJ	54	Female	-3	-2	-3	-3
38	KAS	42	Female	-3	-2	-5	-5
41	E-N	61	Female	0	0	0	0
42	KAM	52	Female	0	2	Ö	Ö
43	CGC	48	Female	0	0	Ö	2
45	TDC	48	Female	0	Ō	Ö	0
48	JLL	47	Female	0	Ō	-1	-1
50	DKH	49	Female	2	0	2	4
52	CJL	53	Female	2	0	0	0
53	DSB	54	Female	0	0	0	0
55	SKR	57	Female	0	0	2	0
56	DAH	45	Female				
58	CZR	49	Female	1	3	0	0
62	KME	45	Female	-1	-1	-1	-1
63	MRG	51	Female				
68	SAM	53	Female	0	0	0	0
69	GHD	55	Female	1	1	0	0
70	CAC	62	Female	0	0	0	0
71	JAR	40	Female	0	0	0	0
72	NRC	56	Female	0	0	0	0
73	NLW	47	Female	-1	0.07	0.47	0.40
			Mean SD	-0.23 1.84	-0.27 1.55	-0.47 1.61	-0.40
			SD Median	0.00	1.55 0.00	0.00	1.71 0.00
			N	31	30	30	30
			IN	31	30	30	30

Discontinued

### Inflammatory Lesion Count

				Inflammatory Lesion Count (Right Cheek)						
Subject No.	Subject Initials	Age	Sex	Baseline	Week 2	Week 4	Week 8	Week 12		
4	SKH	46	Female	4	3	0	4	3		
5	LMP	45	Female	0	0	1	0	2		
6	PJW	43	Female	1		_	_			
10	JCL	41	Female	0	1	0	0	1		
11 13	TLM DKS	50 38	Female	0	0	0	1 0	0 2		
13	LKB	38 56	Female Female	0	0	0	0	0		
15	NHK	56	Female	0	1	U	U	U		
16	VLH	57	Female	3	0	3	0	3		
22	JKP	48	Female	3	U	3	U	3		
23	RMS	51	Female	0	1	0	0	0		
25	TJJ	40	Female	0	Ö	2	0	ő		
29	DSE	59	Female	0	ő	0	0	0		
30	MMC	64	Female	0	ő	0	0	0		
33	J-G	47	Female	, and the second	, and the second	, i		ŭ		
34	LLL	31	Female							
35	DLM	52	Female	0	2	0	0	0		
36	MAE	51	Female	0	0	0	0	0		
37	GLJ	54	Female	1	0	1	0	0		
38	KAS	42	Female							
41	E-N	61	Female	0	0	0	0	0		
42	KAM	52	Female	0	0	0	0	0		
43	CGC	48	Female	0	2	0	2	1		
45	TDC	48	Female	0	0	0	0	1		
48	JLL	47	Female	1	0	2	1	0		
50	DKH	49	Female	1	4	1	3	1		
52	CJL	53	Female	1	0	0	0	1		
53	DSB	54	Female	0	0	1	0	0		
55	SKR	57	Female	0	0	0	0	0		
56	DAH	45	Female							
58	CZR	49	Female	0	0	3	0	0		
62	KME	45	Female	0	0	3	1	0		
63	MRG	51	Female	0						
68	SAM	53	Female	0	2	1	1	0		
69	GHD	55	Female	0	0	0	0	0		
70	CAC	62	Female	0	0	0	0	0		
71 72	JAR NRC	40	Female	0	0	3 0	0	0		
72	NEC	56 47	Female Female	2	0	U	U	U		
/3	IAFAA	4/	Mean	0.35	0.52	0.70	0.43	0.50		
			SD	0.33	1.03	1.09	0.43	0.90		
			Median	0.00	0.00	0.00	0.00	0.90		
			N	31	31	30	30	30		
					٠.		20			

				Inflammatory	Lesion Count (Rig	ht Cheek) Intra-Su	bject Change
Subject No.	Subject Initials	Age	Sex	Week 2 Minus Baseline	Week 4 Minus Baseline	Week 8 Minus Baseline	Week 12 Minus Baseline
4	SKH	46	Female	-1	-4	0	-1
5	LMP	45	Female	0	1	0	2
6	PJW	43	Female				
10	JCL	41	Female	1	0	0	1
11	TLM	50	Female	0	0	1	0
13	DKS	38	Female	0	0	0	2
14	LKB	56	Female	0	0	0	0
15	NHK	56	Female	1			
16	VLH	57	Female	-3	0	-3	0
22	JKP	48	Female				
23	RMS	51	Female	1	0	0	0
25	TJJ	40	Female	0	2	0	0
29	DSE	59	Female	0	0	0	0
30	MMC	64	Female	0	0	0	0
33	J-G	47	Female				
34	LLL	31	Female				
35	DLM	52	Female	2	0	0	0
36	MAE	51	Female	0	0	0	0
37	GLJ	54	Female	-1	0	-1	-1
38	KAS	42	Female				
41	E-N	61	Female	0	0	0	0
42	KAM	52	Female	0	0	0	0
43	CGC	48	Female	2	0	2	1
45	TDC	48	Female	0	0	0	1
48	JLL	47	Female	-1	1	0	-1
50	DKH	49	Female	3	0	2 -1	0
52	CJL	53	Female	-1	-1		0
53	DSB	54	Female	0	1 0	0	0
55	SKR	57	Female	0	0	0	0
56	DAH	45 49	Female Female	0	2	0	
58 62	CZR KMF	49 45	Female	0	3	0 1	0
62	MRG	45 51	Female	U	3	1	U
68	SAM	53	Female	2	1	1	0
69	GHD	55	Female	0	0	0	0
70	CAC	62	Female	0	0	0	0
70 71	JAR	40	Female	0	3	0	0
72	NRC	56	Female	0	0	0	0
73	NLW	47	Female	-2	U	U	J
, 3	IACAA	71	Mean	0.16	0.33	0.07	0.13
			SD	1.10	1.30	0.87	0.68
			Median	0.00	0.00	0.00	0.00
			N	31	30	30	30
			•••	٠.		20	50

Discontinued

Inflammatory Lesion Count

					Inflammato	ory Lesion Co	ount (Chin)	
Subject No.	Subject Initials	Age	Sex	Baseline	Week 2	Week 4	Week 8	Week 12
4	SKH	46	Female	1	0	1	2	1
5	LMP	45	Female	0	0	1	3	1
6	PJW	43	Female	2				
10	JCL	41	Female	1	1	0	0	2
11	TLM	50	Female	0	0	1	1	1
13 14	DKS LKB	38	Female	1 0	1 0	0	0	2
14 15	NHK	56 56	Female Female	0	0	0	0	0
16	VLH	57	Female	0	0	0	0	0
22	JKP	48	Female	U	U	U	U	U
23	RMS	51	Female	0	0	0	0	0
25	TJJ	40	Female	0	0	1	0	2
29	DSE	59	Female	2	ő	Ö	0	0
30	MMC	64	Female	0	0	ő	ő	0
33	J-G	47	Female			, and the second	, and the second	Ü
34	LLL	31	Female					
35	DLM	52	Female	0	0	0	0	2
36	MAE	51	Female	0	0	0	0	0
37	GLJ	54	Female	0	0	0	0	0
38	KAS	42	Female					
41	E-N	61	Female	0	0	0	0	0
42	KAM	52	Female	0	0	0	0	0
43	CGC	48	Female	0	0	0	1	2
45	TDC	48	Female	0	0	0	0	0
48	JLL	47	Female	0	3	0	3	0
50	DKH	49	Female	1	2	4	1	2
52	CJL	53	Female	1	0	0	0	0
53	DSB	54	Female	0	1	1	0	0
55	SKR	57	Female	0	0	0	0	0
56 58	DAH CZR	45 49	Female Female	0	0	0	0	0
62	KME	49	Female	1	0	4	4	2
63	MRG	51	Female	1	U	4	4	2
68	SAM	53	Female	0	0	0	0	0
69	GHD	55	Female	0	0	0	0	0
70	CAC	62	Female	0	ő	1	0	0
71	JAR	40	Female	3	1	1	0	0
72	NRC	56	Female	0	0	o O	ő	Ö
73	NLW	47	Female	1	0			
	Discontinu	ied	Mean	0.35	0.29	0.50	0.50	0.57
			SD	0.71	0.69	1.04	1.07	0.86
			Median	0.00	0.00	0.00	0.00	0.00
			N	31	31	30	30	30

				Inflamma	atory Lesion Count	(Chin) Intra-Subject	t Change
Subject No.	Subject Initials	Age	Sex	Week 2 Minus Baseline	Week 4 Minus Baseline	Week 8 Minus Baseline	Week 12 Minus Baseline
4	SKH	46	Female	-1	0	1	0
5	LMP	45	Female	0	1	3	1
6	PJW	43	Female				_
10 11	JCL TLM	41 50	Female Female	0	-1 1	-1 1	1
13	DKS	38	Female	0	-1	-1	
14	LKB	56	Female	0	0	0	Ö
15	NHK	56	Female	0	U	U	U
16	VLH	57	Female	ő	0	0	0
22	JKP	48	Female	, and the second	ŭ	, and the second	
23	RMS	51	Female	0	0	0	0
25	TJJ	40	Female	0	1	0	2
29	DSE	59	Female	-2	-2	-2	-2
30	MMC	64	Female	0	0	0	0
33	J-G	47	Female				
34	LLL	31	Female				
35	DLM	52	Female	0	0	0	2
36	MAE	51	Female	0	0	0	0
37 38	GLJ	54	Female	0	0	0	0
38 41	KAS E-N	42 61	Female Female	0	0	0	0
42	KAM	52	Female	0	0	0	0
43	CGC	48	Female	0	0	1	2
45	TDC	48	Female	ő	ő	Ö	0
48	JLL	47	Female	3	Ö	3	ő
50	DKH	49	Female	1	3	Ō	1
52	CJL	53	Female	-1	-1	-1	-1
53	DSB	54	Female	1	1	0	0
55	SKR	57	Female	0	0	0	0
56	DAH	45	Female				
58	CZR	49	Female	0	0	0	0
62	KME	45	Female	-1	3	3	1
63	MRG	51	Female				
68	SAM	53	Female	0	0	0	0
69 70	GHD CAC	55 62	Female Female	0	0 1	0	0
70	JAR	40	Female	-2	-2	-3	-3
72	NRC	56	Female	0	0	-3	0
73	NLW	47	Female	-1	,		0
			Mean	-0.06	0.13	0.13	0.20
			SD	0.85	1.07	1.25	1.03
			Median	0.00	0.00	0.00	0.00
			N	31	30	30	30

#### Non-Inflammatory Lesion Count

Subject No.   Subject No.   Initials   Age					١	Ion-Inflammato	ory Lesion Co	unt (Forehea	d)
6         LMP         45         Female         1         2         0         0         0           6         PJW         43         Female         1			Age	Sex	Baseline	Week 2	Week 4	Week 8	Week 12
Female				Female	11				
10						2	0	0	0
111 TLM 50 Female 4 2 0 1 1 0 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1									
13									
14									
15									
16			56				0	0	1
22									
RMS				Female	0	3	0	0	3
25									
29						-			
33									
33	29	DSE	59	Female	4				0
34	30	MMC	64	Female	0	0	3	2	0
35	33	J-G	47	Female					
36	34	LLL	31	Female					
37	35	DLM	52	Female	0	0	5	0	4
38	36	MAE	51	Female	5	1	0	2	0
1	37	GLJ	54	Female	0	0	0	0	0
42	38	KAS	42	Female					
A3	41	E-N	61	Female	0	0	0	0	0
A5	42	KAM	52	Female	3	0	1	0	4
48	43	CGC	48	Female	0	0	0	0	1
Female	45	TDC	48	Female	0	0	0	0	0
S2	48	JLL	47	Female	0	0	0	0	0
53         DSB         54         Female         0         0         2         0         2           55         SKR         57         Female         2         0         1         0         0           56         DAH         45         Female         0         2         3         0         0           58         CZR         49         Female         0         2         3         0         0           62         KME         45         Female         0         2         3         0         0           63         MRG         51         Female         0         0         0         0         0           68         SAM         53         Female         0         2         0         0         0         0         0           69         GHD         55         Female         0	50	DKH	49	Female	0	0	2	0	6
55         SKR         57         Female         2         0         1         0         0           56         DAH         45         Female         -	52	CJL	53	Female	1	4	3	3	1
56         DAH         45         Female         0         2         3         0         0           58         CZR         49         Female         0         2         3         0         0           62         KME         45         Female         4         3         8         1         0           63         SAM         53         Female         0         0         0         0         0           68         SAM         53         Female         0         2         0         0         0         0           70         CAC         62         Female         0	53	DSB	54	Female	0	0	2	0	2
58         CZR         49         Female         0         2         3         0         0           62         KME         45         Female         4         3         8         1         0           63         MRG         51         Female         0         -         -         -         -           68         SAM         53         Female         0         2         0         0         0         0           70         CAC         62         Female         0<	55	SKR	57	Female	2	0	1	0	0
62         KME         45         Female         4         3         8         1         0           63         MRG         51         Female         0         -         -         0	56	DAH	45	Female					
63 MRG 51 Female 0 2 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	58	CZR	49	Female	0			0	0
68         SAM         53         Female         0         2         0         0         0         0           69         GHD         55         Female         0	62	KME	45	Female	4	3	8	1	0
69         GHD         55         Female         0         0         0         0         0           70         CAC         62         Female         0         0         0         0         0         0           71         JAR         40         Female         1         2         0         6         0           72         NRC         56         Female         0         0         0         0         0         0           73         NLW         47         Female         16         0	63	MRG	51	Female	0				
70         CAC         62         Female         0         0         0         0         0           71         JAR         40         Female         1         2         0         6         0           72         NRC         56         Female         0         0         0         0         0           73         NLW         47         Female         16         0         0         0         0         0           Mean         1.16         0.81         1.10         0.60         1.03           SD         2.37         1.22         1.84         1.30         1.88           Median         0.00         0.00         0.00         0.00         0.00         0.00	68	SAM	53	Female	0	2	0	0	0
71 JAR 40 Female 1 2 0 6 0 0 7 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	69	GHD	55	Female	0	0	0	0	0
72 NRC 56 Female 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	70	CAC	62	Female	0	0	0	0	0
73 NLW 47 Female 16 0	71	JAR	40	Female	1		0	6	0
Mean         1.16         0.81         1.10         0.60         1.03           SD         2.37         1.22         1.84         1.30         1.88           Median         0.00         0.00         0.00         0.00         0.00         0.00	72	NRC	56	Female	0	0	0	0	0
SD 2.37 1.22 1.84 1.30 1.88 Median 0.00 0.00 0.00 0.00 0.00	73	NLW	47	Female	16	0			
Median 0.00 0.00 0.00 0.00 0.00				Mean	1.16	0.81	1.10	0.60	1.03
				SD	2.37	1.22	1.84	1.30	1.88
N 31 31 30 30 30				Median					
				N	31	31	30	30	30

Subject No.   Subject Initials   Age   Sex   Week 2 Minus   Baseline   Week 4 Minus   Baseline   Baseline   Baseline   Baseline   Baseline   Compared to the	Week 12 Minus Baseline -4 -1 1 -4 0
5 LMP 45 Female 1 -1 -1 6 PJW 43 Female	-1 1 -4
6 PJW 43 Female	1 -4
	-4
10 JCL 41 Female 0 0 0	-4
44   TIM   50   Family   0   4   0	
11 TLM 50 Female -2 -4 -3 13 DKS 38 Female 0 1 2	
13 DKS 38 Female 0 1 2 14 LKB 56 Female 0 0 0	1
	1
16 VLH 57 Female 3 0 0 22 JKP 48 Female	3
22 JKP 48 Female 0 0 0	0
23 RMS 51 Female 0 0 0 0 0	1
25   133   40   Female   0   0   0   0   29   DSE   59   Female   -4   -2   -4	-4
30 MMC 64 Female 0 3 2	0
30 Minic 64 Female 0 3 2	U
34 LLL 31 Female	
35 DLM 52 Female 0 5 0	4
36 MAF 51 Female -4 -5 -3	-5
36 MAE 51 Female -4 -5 -3 37 GLJ 54 Female 0 0 0	-5 0
38 KAS 42 Female 0 0 0	U
41 E-N 61 Female 0 0 0	0
42 KAM 52 Female -3 -2 -3	1
43 CGC 48 Female 0 0 0	1
45 TDC 48 Female 0 0 0	0
48 JLL 47 Female 0 0 0	0
50 DKH 49 Female 0 2 0	6
50   DKH   49   Fellale   0   2   0   1   1   1   1   1   1   1   1   1	0
53 DSB 54 Female 0 2 0	2
55 SKR 57 Female -2 -1 -2	-2
56 DAH 45 Female	-2
58 CZR 49 Female 2 3 0	0
62 KME 45 Female -1 4 -3	-4
63 MRG 51 Female	·
68 SAM 53 Female 2 0 0	0
69 GHD 55 Female 0 0 0	ő
70 CAC 62 Female 0 0 0	Ö
71 JAR 40 Female 1 -1 5	-1
72 NRC 56 Female 0 0 0	0
73 NLW 47 Female -16	
Mean -0.35 -0.10 -0.60	-0.17
SD 2.15 2.66 2.51	2.38
Median 0.00 0.00 0.00	0.00
N 31 30 30	30

#### Non-Inflammatory Lesion Count

				N	on-Inflammato	ry Lesion Cou	unt (Left Che	ek)
Subject No.	Subject Initials	Age	Sex	Baseline	Week 2	Week 4	Week 8	Week 12
4	SKH	46	Female	12	3	9	8	9
5	LMP	45	Female	1	0	0	0	0
6	PJW	43	Female	1				
10	JCL	41	Female	0	0	0	0	0
11	TLM	50	Female	2	5	0	0	0
13	DKS	38	Female	1	0	3	0	0
14	LKB	56	Female	1	1	0	0	2
15	NHK	56	Female	6	0			
16	VLH	57	Female	0	0	2	0	2
22	JKP	48	Female					
23	RMS	51	Female	0	1	0	0	0
25	TJJ	40	Female	0	0	0	0	ō
29	DSE	59	Female	2	1	0	0	1
30	MMC	64	Female	2	o o	ő	ő	ó
33	J-G	47	Female	_				Ů
34	LLL	31	Female					
35	DLM	52	Female	18	0	11	0	6
36	MAF	51	Female	3	1	0	0	0
37	GLJ	54	Female	0	ó	0	0	0
38	KAS	42	Female	U	U	U	U	U
41	E-N	61	Female	0	0	0	0	0
42	KAM	52	Female	0	0	0	0	5
43	CGC	48	Female	1	0	0	0	1
						2		
45	TDC	48	Female	1	1		0	0
48	JLL	47	Female	0	0	0	0	0
50	DKH	49	Female	7	5	4	1	7
52	CJL	53	Female	17	4	5	4	7
53	DSB	54	Female	4	1	5	0	0
55	SKR	57	Female	0	0	1	0	0
56	DAH	45	Female					
58	CZR	49	Female	0	0	2	0	2
62	KME	45	Female	9	15	18	13	5
63	MRG	51	Female	1				
68	SAM	53	Female	0	0	1	0	2
69	GHD	55	Female	0	0	0	0	0
70	CAC	62	Female	0	0	0	0	0
71	JAR	40	Female	3	0	4	0	0
72	NRC	56	Female	0	0	0	0	0
73	NLW	47	Female	0	0			
			Mean	2.90	1.23	2.23	0.87	1.63
			SD	4.87	2.94	4.07	2.80	2.65
			Median	1.00	0.00	0.00	0.00	0.00
			N	31	31	30	30	30

				Non-Inflammatory Lesion Count (Left Cheek) Intra-Subject Change					
Subject No.	Subject Initials	Age	Sex	Week 2 Minus Baseline	Week 4 Minus Baseline	Week 8 minus Baseline	Week 12 Minus Baseline		
4	SKH	46	Female	-9	-3	-4	-3		
5 6	LMP	45 43	Female	-1	-1	-1	-1		
	PJW	43	Female				_		
10 11	JCL TLM	50	Female Female	0 3	0 -2	0 -2	0 -2		
13	DKS	38	Female	-1	2	-2 -1	-2 -1		
13	LKB	56	Female	0	-1	-1 -1	1		
15	NHK	56	Female	-6	-1	-1	'		
16	VLH	57	Female	0	2	0	2		
22	JKP	48	Female	U		U			
23	RMS	51	Female	1	0	0	0		
25	TJJ	40	Female	Ö	0	0	0		
29	DSE	59	Female	-1	-2	-2	-1		
30	MMC	64	Female	-2	-2	-2	-2		
33	J-G	47	Female	_	_	_	_		
34	LLL	31	Female						
35	DLM	52	Female	-18	-7	-18	-12		
36	MAE	51	Female	-2	-3	-3	-3		
37	GLJ	54	Female	0	0	0	0		
38	KAS	42	Female						
41	E-N	61	Female	0	0	0	0		
42	KAM	52	Female	0	0	0	5		
43	CGC	48	Female	-1	-1	-1	0		
45	TDC	48	Female	0	1	-1	-1		
48	JLL	47	Female	0	0	0	0		
50	DKH	49	Female	-2	-3	-6	0		
52	CJL	53	Female	-13	-12	-13	-10		
53	DSB	54	Female	-3	1	-4	-4		
55	SKR	57	Female	0	1	0	0		
56	DAH	45	Female						
58	CZR	49	Female	0	2	0	2		
62	KME	45	Female	6	9	4	-4		
63	MRG	51	Female						
68	SAM	53	Female	0	1	0	2		
69	GHD	55	Female	0	0	0	0		
70	CAC	62	Female	0	0	0	0		
71	JAR	40	Female	-3 0	1 0	-3 0	-3 0		
72 73	NRC NLW	56 47	Female Female	0	U	U	U		
13	INLVV	4/	Mean	-1.68	-0.57	-1.93	-1.17		
			SD	4.48	3.34	4.15	3.28		
			Median	0.00	0.00	-0.50	0.00		
			N	31	30	30	30		
			. 4	01	50	50	50		

#### Non-Inflammatory Lesion Count

				No	n-Inflammator	y Lesion Cou	nt (Right Che	eek)
Subject No.	Subject Initials	Age	Sex	Baseline	Week 2	Week 4	Week 8	Week 12
4	SKH	46	Female	9	2	5	4	5
5	LMP	45	Female	0	0	0	1	0
6	PJW	43	Female	5				
10	JCL	41	Female	1	2	1	0	1
11	TLM	50	Female	2	1	1	1	1
13	DKS	38	Female	2	3	3	0	0
14	LKB	56	Female	5	4	4	0	1
15	NHK	56	Female	5	0			
16	VLH	57	Female	2	1	0	0	1
22	JKP	48	Female					
23	RMS	51	Female	0	0	0	0	0
25	TJJ	40	Female	0	0	0	0	0
29	DSE	59	Female	3	0	0	0	0
30	MMC	64	Female	2	0	0	1	0
33	J-G	47	Female					
34	LLL	31	Female					
35	DLM	52	Female	26	0	9	5	4
36	MAE	51	Female	3	0	0	0	0
37	GLJ	54	Female	1	6	3	0	0
38	KAS	42	Female					
41	E-N	61	Female	0	0	0	0	0
42	KAM	52	Female	5	0	3	0	6
43	CGC	48	Female	1	0	0	0	0
45	TDC	48	Female	2	0	0	0	0
48	JLL	47	Female	2	2	0	1	2
50	DKH	49	Female	3	2	8	2	10
52	CJL	53	Female	15	16	8	6	5
53	DSB	54	Female	1	2	3	0	1
55	SKR	57	Female	0	0	0	0	0
56	DAH	45	Female					
58	CZR	49	Female	0	0	4	0	0
62	KME	45	Female	10	3	6	6	4
63	MRG	51	Female	0				
68	SAM	53	Female	0	2	1	1	3
69	GHD	55	Female	0	0	0	0	0
70	CAC	62	Female	0	0	0	0	0
71	JAR	40	Female	0	0	1	0	0
72	NRC	56	Female	0	0	0	0	0
73	NLW	47	Female	8	0			
			Mean	3.23	1.48	2.00	0.93	1.47
			SD	5.44	3.08	2.77	1.82	2.43
			Median	2.00	0.00	0.50	0.00	0.00
			N	31	31	30	30	30

				Non-Inflammatory Lesion Count (Right Cheek) Intra-Subject Change					
Subject No.	Subject Initials	Age	Sex	Week 2 Minus Baseline	Week 4 Minus Baseline	Week 8 minus Baseline	Week 12 Minus Baseline		
4	SKH	46	Female	-7	-4	-5	-4		
5	LMP	45	Female	0	0	1	0		
6	PJW	43	Female		_				
10	JCL	41	Female	1	0	-1	0		
11	TLM	50	Female	-1	-1	-1	-1		
13	DKS	38	Female	1	1	-2	-2		
14	LKB	56	Female	-1	-1	-5	-4		
15	NHK	56	Female	-5					
16	VLH	57	Female	-1	-2	-2	-1		
22	JKP	48	Female						
23	RMS	51	Female	0	0	0	0		
25	TJJ	40	Female	0	0	0	0		
29	DSE	59	Female	-3	-3	-3	-3		
30	MMC	64	Female	-2	-2	-1	-2		
33	J-G	47	Female						
34	LLL	31	Female						
35	DLM	52	Female	-26	-17	-21	-22		
36	MAE	51	Female	-3	-3	-3	-3		
37	GLJ	54	Female	5	2	-1	-1		
38	KAS	42	Female						
41	E-N	61	Female	0	0	0	0		
42	KAM	52	Female	-5	-2	-5	1		
43	CGC	48	Female	-1	-1	-1	-1		
45	TDC	48	Female	-2	-2	-2	-2		
48	JLL	47	Female	0	-2	-1	0		
50	DKH	49	Female	-1	5	-1	7		
52	CJL	53	Female	1	-7	-9	-10		
53	DSB	54	Female	1	2	-1	0		
55	SKR	57	Female	0	0	0	0		
56	DAH	45	Female						
58	CZR	49	Female	0_	4	0	0		
62	KME	45	Female	-7	-4	-4	-6		
63	MRG	51	Female						
68	SAM	53	Female	2	1	1	3		
69	GHD	55	Female	0	0	0	0		
70	CAC	62	Female	0	0	0	0		
71	JAR	40	Female	0	1	0	0		
72	NRC	56	Female	0	0	0	0		
73	NLW	47	Female	-8 -1.74	-1.17	-2.23	1.70		
			Mean SD		-1.17 3.82		-1.70		
			Median	5.14 0.00	0.00	4.17 -1.00	4.76 0.00		
			N	31	30	-1.00 30	30		
			14	31	30	30	30		

#### Non-Inflammatory Lesion Count

				Non-Inflammatory Lesion Count (Chin)						
Subject No.	Subject Initials	Age	Sex	Baseline	Week 2	Week 4	Week 8	Week 12		
4	SKH	46	Female	11	0	0	0	2		
5	LMP	45	Female	2	0	0	0	0		
6	PJW	43	Female	1						
10	JCL	41	Female	0	1	0	0	0		
11	TLM	50	Female	2	1	0	1	0		
13	DKS	38	Female	0	0	0	0	0		
14	LKB	56	Female	0	0	0	0	0		
15	NHK	56	Female	2	0					
16	VLH	57	Female	0	2	0	0	2		
22	JKP	48 51	Female Female	0	1	0	0	_		
23 25	RMS TJJ	40	Female	0	0	0	0	0		
29	DSF	59	Female	0	0	0	0	1		
30	MMC	64	Female	0	0	0	0	0		
33	J-G	47	Female	U	U	U	U	U		
34	LLL	31	Female							
35	DLM	52	Female	0	0	1	1	3		
36	MAF	51	Female	0	0	0	0	0		
37	GLJ	54	Female	0	o o	0	0	0		
38	KAS	42	Female							
41	F-N	61	Female	0	0	0	0	0		
42	KAM	52	Female	ő	ő	0	ő	ő		
43	CGC	48	Female	0	0	0	0	0		
45	TDC	48	Female	1	2	Ö	Ö	2		
48	JLL	47	Female	0	0	4	0	0		
50	DKH	49	Female	0	0	3	0	2		
52	CJL	53	Female	0	0	0	0	0		
53	DSB	54	Female	0	0	0	0	0		
55	SKR	57	Female	0	0	0	0	0		
56	DAH	45	Female							
58	CZR	49	Female	10	10	14	0	0		
62	KME	45	Female	0	5	3	3	3		
63	MRG	51	Female	0						
68	SAM	53	Female	0	0	0	2	1		
69	GHD	55	Female	0	0	0	0	0		
70	CAC	62	Female	0	0	0	0	0		
71	JAR	40	Female	0	0	1	0	0		
72	NRC	56	Female	0	0	0	0	0		
73	NLW	47	Female	0	0					
	Discontinu	ned	Mean	0.90	0.71	0.87	0.23	0.53		
			SD	2.64	2.00	2.69	0.68	0.97		
			Median	0.00	0.00	0.00	0.00	0.00		
			N	31	31	30	30	30		

_				Non-Inflammat	ory Lesion Cour	nt (Chin) Intra-Su	, ,
Subject No.	Subject Initials	Age	Sex	Week 2 Minus Baseline	Week 4 Minus Baseline	Week 8 minus Baseline	Week 12 Minus Baseline
4	SKH	46	Female	-11	-11	-11	-9
5	LMP	45	Female	-2	-2	-2	-2
6	PJW	43	Female				
10	JCL	41	Female	1	0	0	0
11	TLM	50	Female	-1	-2	-1	-2
13	DKS	38	Female	0	0	0	0
14	LKB	56	Female	0	0	0	0
15	NHK	56	Female	-2			
16	VLH	57	Female	2	0	0	2
22	JKP	48	Female				
23	RMS	51	Female	1	0	0	0
25	TJJ	40	Female	0	0	0	0
29	DSE	59	Female	0	0	0	1
30	MMC	64	Female	0	0	0	0
33	J-G	47	Female				
34	LLL	31	Female	_			_
35	DLM	52	Female	0	1	1	3
36	MAE	51	Female	0	0	0	0
37	GLJ	54	Female	0	0	0	0
38	KAS	42	Female	_	_		
41	E-N	61	Female	0	0	0	0
42	KAM	52	Female	0	0	0	0
43	CGC	48	Female	0	0 -1	0	0 1
45 48	TDC JLL	48 47	Female	1 0	-1 4	-1 0	0
			Female	-	3		2
50 52	DKH CJL	49 53	Female	0	0	0	0
52	DSB	53 54	Female Female	0	0	0	0
55	SKR	54 57	Female	0	0	0	0
55 56	DAH	45	Female	U	U	U	U
58	CZR	49	Female	0	4	-10	-10
62	KME	45	Female	5	3	3	3
63	MRG	51	Female		,	J	,
68	SAM	53	Female	0	0	2	1
69	GHD	55	Female	0	0	0	Ö
70	CAC	62	Female	Ö	Ö	Ö	0
71	JAR	40	Female	Ö	1	Ö	0
72	NRC	56	Female	ő	Ö	ő	Ö
73	NLW	47	Female	0	-	-	-
			Mean	-0.19	0.00	-0.63	-0.33
			SD	2.32	2.51	2.81	2.72
			Median	0.00	0.00	0.00	0.00
			N	31	30	30	30
					<del>-</del>	- <del>-</del>	· <del>-</del>

### Total Inflammatory Lesion Count

					Total Les	ion Count (Infla	mmatory)	
Subject No.	Subject Initials	Age	Sex	Baseline	Week 2	Week 4	Week 8	Week 12
4	SKH	46	Female	10	3	3	6	6
5	LMP	45	Female	0	1	2	3	4
6	PJW	43	Female					
10	JCL	41	Female	1	3	3	0	4
11	TLM	50	Female	1	2	3	2	1
13	DKS	38	Female	1	1	0	0	5
14	LKB	56	Female	1	0	1	0	0
15	NHK	56	Female	0	6			
16	VLH	57	Female	9	4	5	0	5
22	JKP	48	Female	_	_	_	_	_
23	RMS	51	Female	0	2	0	0	0
25	TJJ	40	Female	0	3	5	0	3
29	DSE	59	Female	2	1	1	0	1
30	MMC	64	Female	0	0	0	0	0
33	J-G	47	Female					
34	LLL	31	Female	_	_	_	_	_
35	DLM	52	Female	2	3	0	2	2
36	MAE	51	Female	0	0	0	1	0
37	GLJ	54	Female	7	0	2	0	0
38	KAS	42	Female					
41	E-N	61	Female	0	0	0	0	0
42	KAM	52	Female	1	0	3	0	0
43	CGC	48	Female	1	4	1	6	8
45	TDC	48	Female	0	0	0	0	1
48	JLL	47	Female	2	5	3	4	0
50	DKH	49	Female	2	9	9	6	10
52	CJL	53 54	Female	2	2	0	0	1
53 55	DSB	54 57	Female Female	3	3 1	6	0	0
56	SKR DAH	45	Female	U	1	U		U
58	CZR	45	Female	0	1	10	0	1
58 62	KME	49 45	Female	0 3	0	10 7	7	3
63	MRG	51	Female	2	U	,	,	3
68	SAM	53	Female	0	4	2	5	0
69	GHD	55	Female	0	1	1	0	0
70	CAC	62	Female	0	0	2	0	0
71	JAR	40	Female	3	1	5	0	0
72	NRC	56	Female	0	0	0	0	0
73	NLW	47	Female	8	0	U	U	U
70	Discontinu		Mean	1.65	1.94	2.47	1.47	1.83
	D. GOOTHIIL	.ou	SD	2.58	2.14	2.78	2.32	2.68
			Median	1.00	1.00	2.00	0.00	0.50

				Total Les	sion Count (Inflamm	natory) Intra-Subjec	ct Change
Subject No.	Subject Initials	Age	Sex	Week 2 Minus Baseline	Week 4 Minus Baseline	Week 8 Minus Baseline	Week 12 Minus Baseline
4	SKH	46	Female	-7	-7	-4	-4
5	LMP	45	Female	1	2	3	4
6	PJW JCL	43 41	Female Female	0		-1	3
10 11	TLM	50	Female	2 1	2 2	1	0
13	DKS	38	Female	0	-1	-1	4
14	LKB	56	Female	-1	0	-1	-1
15	NHK	56	Female	6	, and the second		
16	VLH	57	Female	-5	-4	-9	-4
22	JKP	48	Female				
23	RMS	51	Female	2	0	0	0
25	TJJ	40	Female	3	5	0	3
29	DSE	59	Female	-1	-1	-2	-1
30	MMC	64	Female	0	0	0	0
33 34	J-G LLL	47 31	Female Female				
35	DLM	52	Female	1	-2	0	0
36	MAE	51	Female	0	0	1	0
37	GLJ	54	Female	-7	-5	-7	-7
38	KAS	42	Female				
41	E-N	61	Female	0	0	0	0
42	KAM	52	Female	-1	2	-1	-1
43	CGC	48	Female	3	0	5	7
45	TDC	48	Female	0	0	0	1
48	JLL	47	Female	3	1_	2	-2
50	DKH	49	Female	7 0	7	4	8 -1
52 53	CJL DSB	53 54	Female Female	0	-2 3	-2 -3	-1 -3
55	SKR	57	Female	1	0	2	-3
56	DAH	45	Female		U		U U
58	CZR	49	Female	1	10	0	1
62	KME	45	Female	-3	4	4	Ö
63	MRG	51	Female				
68	SAM	53	Female	4	2	5	0
69	GHD	55	Female	1	1	0	0
70	CAC	62	Female	0	2	0	0
71	JAR	40	Female	-2	2	-3	-3
72 73	NRC NLW	56 47	Female Female	0 -8	0	0	0
13	INLVV	41	Mean	0.29	0.77	-0.23	0.13
			SD	3.05	3.28	3.08	3.06
			Median	0.00	0.00	0.00	0.00
			N	31	30	30	30
					- <del>-</del>	<del>-</del>	· -

Total Non-Inflammatory Lesion Count

					Total Lesion	n Count (Non-Ir	flammatory)	
Subject No.	Subject Initials	Age	Sex	Baseline	Week 2	Week 4	Week 8	Week 12
4	SKH	46	Female	43	8	16	13	23
5 6	LMP PJW	45 43	Female Female	4	2	0	1	0
10	JCL	43	Female	1	3	1	0	2
11	TLM	50	Female	10	9	1	3	1
13	DKS	38	Female	3	3	7	2	o o
14	LKB	56	Female	6	5	4	0	4
15	NHK	56	Female	13	1			
16	VLH	57	Female	2	6	2	0	8
22	JKP	48	Female					
23	RMS	51	Female	0	2	0	0	0
25	TJJ	40	Female	0	0	0 2	0	1 2
29 30	DSE MMC	59 64	Female Female	9	1 0	3	0	0
33	J-G	47	Female	4	U	3	3	U
34	LLL	31	Female					
35	DLM	52	Female	44	0	26	6	17
36	MAE	51	Female	11	2	0	2	0
37	GLJ	54	Female	1	6	3	0	0
38	KAS	42	Female	_		_		
41	E-N	61	Female	0	0	0	0	0
42 43	KAM CGC	52 48	Female Female	8 2	0	4 0	0	15 2
43 45	TDC	48	Female	4	3	2	0	2
48	JLL	47	Female	2	2	4	1	2
50	DKH	49	Female	10	7	17	3	25
52	CJL	53	Female	33	24	16	13	13
53	DSB	54	Female	5	3	10	0	3
55	SKR	57	Female	2	0	2	0	0
56	DAH	45	Female					
58	CZR	49	Female	10	12	23	0	2
62	KME	45	Female	23	26	35	23	12
63	MRG	51	Female	1	4	2	2	
68 69	SAM GHD	53 55	Female Female	0	4 0	2	3 0	6
70	CAC	62	Female	0	0	0	0	0
71	JAR	40	Female	4	2	6	6	0
72	NRC	56	Female	o O	0	ő	ő	Ö
73	NLW	47	Female	24	0			
	Discontinu	ıed	Mean	8.19	4.23	6.20	2.63	4.67
			SD	11.84	6.34	9.00	5.18	7.14
			Median	4.00	2.00	2.00	0.00	2.00
			N	31	31	30	30	30

				Total Lesion	n Count (Non-Inflar	nmatory) Intra-Sub	ject Change
Subject No.	Subject Initials	Age	Sex	Week 2 Minus Baseline	Week 4 Minus Baseline	Week 8 Minus Baseline	Week 12 Minus Baseline
4	SKH	46	Female	-35	-27	-30	-20
5	LMP	45	Female	-2	-4	-3	-4
6	PJW	43	Female				
10	JCL	41	Female	2	0	-1	1
11	TLM	50	Female	-1	-9	-7	-9
13	DKS	38	Female	0	4	-1	-3
14	LKB	56	Female	-1	-2	-6	-2
15	NHK	56	Female	-12	_	_	_
16	VLH	57	Female	4	0	-2	6
22	JKP	48	Female	_	_	_	_
23	RMS	51	Female	2	0	0	0
25	TJJ	40	Female	0	0_	0	1_
29	DSE	59	Female	-8	-7	-9	-7
30	MMC	64	Female	-4	-1	-1	-4
33 34	J-G LLL	47 31	Female Female				
35	DLM	52	Female	-44	-18	-38	-27
36	MAE	52 51	Female	- <del>44</del> -9	-18 -11	-38 -9	-27 -11
37	GLJ	54	Female	-9 5	2	-9 -1	-11
38	KAS	42	Female	5	2	-1	-1
41	E-N	61	Female	0	0	0	0
42	KAM	52	Female	-8	-4	-8	7
43	CGC	48	Female	-2	-2	-2	ó
45	TDC	48	Female	-1	-2	-4	-2
48	JLL	47	Female	o .	2	-1	0
50	DKH	49	Female	-3	7	-7	15
52	CJL	53	Female	-9	-17	-20	-20
53	DSB	54	Female	-2	5	-5	-2
55	SKR	57	Female	-2	ō	-2	-2
56	DAH	45	Female				
58	CZR	49	Female	2	13	-10	-8
62	KME	45	Female	3	12	0	-11
63	MRG	51	Female	-1			
68	SAM	53	Female	4	2	3	6
69	GHD	55	Female	0	0	0	0
70	CAC	62	Female	0	0	0	0
71	JAR	40	Female	-2	2	2	-4
72	NRC	56	Female	0	0	0	0
73	NLW	47	Female	-24			
			Mean	-3.97	-1.83	-5.40	-3.37
			SD	10.38	8.21	9.11	8.40
			Median	-1.00	0.00	-2.00	-2.00
			N	31	30	30	30

Total Lesion Count (Inflammatory and Non-Inflammatory)

				Total Le	sion Count (I	nflammatory	& Non-Inflam	matory)
Subject No.	Subject Initials	Age	Sex	Baseline	Week 2	Week 4	Week 8	Week 12
4	SKH	46	Female	53	11	19	19	29
5	LMP	45	Female	4	3	2	4	4
6	PJW	43	Female					
10	JCL	41	Female	2	6	4	0	6
11	TLM	50	Female	11	11	4	5	2
13	DKS	38	Female	4	4	7	2	5
14	LKB	56	Female	7	5	5	0	4
15	NHK	56	Female	13	7			
16	VLH	57	Female	11	10	7	0	13
22	JKP	48	Female					
23	RMS	51	Female	0	4	0	0	0
25	TJJ	40	Female	0	3	5	0	4
29	DSE	59	Female	11	2	3	0	3
30	MMC	64	Female	4	0	3	3	0
33	J-G	47	Female					
34	LLL	31	Female					
35	DLM	52	Female	46	3	26	8	19
36	MAE	51	Female	11	2	0	3	0
37	GLJ	54	Female	8	6	5	0	0
38	KAS	42	Female					
41	E-N	61	Female	0	0	0	0	0
42	KAM	52	Female	9	0	7	0	15
43	CGC	48	Female	3	4	1	6	10
45	TDC	48	Female	4	3	2	0	3
48	JLL	47	Female	4	7	7	5	2
50	DKH	49	Female	12	16	26	9	35
52	CJL	53	Female	35	26	16	13	14
53	DSB	54	Female	8	6	16	0	3
55	SKR	57	Female	2	1	2	2	0
56	DAH	45	Female					
58	CZR	49	Female	10	13	33	0	3
62	KME	45	Female	26	26	42	30	15
63	MRG	51	Female	3				
68	SAM	53	Female	0	8	4	8	6
69	GHD	55	Female	0	1	1	0	0
70	CAC	62	Female	0	0	2	0	0
71	JAR	40	Female	7	3	11	6	0
72	NRC	56	Female	0	0	0	0	0
73	NLW	47	Female	32	0			
Discontinued		Mean	9.84	6.16	8.67	4.10	6.50	

6.16 6.68 4.00 31

9.84 13.07 7.00 31

Mean SD Median N

8.67 10.67 4.50 30

4.10 6.69 1.00 30

6.50 8.83 3.00 30

				Total Lesion Count (Inflammatory & Non-Inflammatory) Intra-Subject Change				
Subject No.	Subject Initials	Age	Sex	Week 2 Minus Baseline	Week 4 Minus Baseline	Week 8 Minus Baseline	Week 12 Minus Baseline	
4	SKH	46	Female	-42	-34	-34	-24	
5	LMP	45	Female	-1	-2	0	0	
6	PJW	43	Female		_		-	
10	JCL	41	Female	4	2	-2	4	
11	TLM	50	Female	0	-7	-6	-9	
13	DKS	38	Female	Ö	3	-2	1	
14	LKB	56	Female	-2	-2	-7	-3	
15	NHK	56	Female	-6	_			
16	VLH	57	Female	-1	-4	-11	2	
22	JKP	48	Female					
23	RMS	51	Female	4	0	0	0	
25	TJJ	40	Female	3	5	0	4	
29	DSE	59	Female	-9	-8	-11	-8	
30	MMC	64	Female	-4	-1	-1	-4	
33	J-G	47	Female					
34	LLL	31	Female					
35	DLM	52	Female	-43	-20	-38	-27	
36	MAE	51	Female	-9	-11	-8	-11	
37	GLJ	54	Female	-2	-3	-8	-8	
38	KAS	42	Female					
41	E-N	61	Female	0	0	0	0	
42	KAM	52	Female	-9	-2	-9	6	
43	CGC	48	Female	1	-2	3	7	
45	TDC	48	Female	-1	-2	-4	-1	
48	JLL	47	Female	3	3	1	-2	
50	DKH	49	Female	4	14	-3	23	
52	CJL	53	Female	-9	-19	-22	-21	
53	DSB	54	Female	-2	8	-8	-5	
55	SKR	57	Female	-1	0	0	-2	
56	DAH	45	Female					
58	CZR	49	Female	3	23	-10	-7	
62	KME	45	Female	0	16	4	-11	
63	MRG	51	Female					
68	SAM	53	Female	8	4	8	6	
69	GHD	55	Female	1	1	0	0	
70	CAC	62	Female	0	2	0	0	
71	JAR	40	Female	-4	4	-1	-7	
72	NRC	56	Female	0	0	0	0	
73	NLW	47	Female	-32				
			Mean	-3.68	-1.07	-5.63	-3.23	
			SD	11.17	10.65	10.10	9.70	
			Median	-1.00	0.00	-2.00	-1.50	
			N	31	30	30	30	

### Subject's Self Assessment of Skin Texture

				Subject's	s Self Assessn	nent of Skin Te	xture
Subject No.	Subject Initials	Age	Sex	Week 2	Week 4	Week 8	Week 12
4	SKH	46	Female	2	2	3	2
5	LMP	45	Female	2	2	2	2
6	PJW	43	Female				
10	JCL	41	Female	3	3	2	2
11	TLM	50	Female	3	3	2	2
13	DKS	38	Female	3	3	1	1
14	LKB	56	Female	3	3	2	2
15	NHK	56	Female	4			
16	VLH	57	Female	3	2	2	1
22	JKP	48	Female				
23	RMS	51	Female	2	2	2	2
25	TJJ	40	Female	3	2	2	2
29	DSE	59	Female	2	2	1	2
30	MMC	64	Female	1	3	2	2
33	J-G	47	Female				
34	LLL	31	Female				
35	DLM	52	Female	2	2	2	2
36	MAE	51	Female	2	1	1	1
37	GLJ	54	Female	2	2	2	1
38	KAS	42	Female				
41	E-N	61	Female	3	2	2	1
42	KAM	52	Female	2	2	2	2
43	CGC	48	Female	3	2	2	2
45	TDC	48	Female	2	2	2	2
48	JLL	47	Female	4	2	3	3
50	DKH	49	Female	2	2	2	2
52	CJL	53	Female	1	2	2	2
53	DSB	54	Female	2	4	2	1
55	SKR	57	Female	3	2	2	1
56	DAH	45	Female				
58	CZR	49	Female	2	3	2	2
62	KME	45	Female	3	2	2	2
63	MRG	51	Female				
68	SAM	53	Female	3	2	2	2
69	GHD	55	Female	3	3	2	3
70	CAC	62	Female	2	2	2	3
71	JAR	40	Female	2	2	2	1
72	NRC	56	Female	3	2	2	2
73	NLW	47	Female				
	Discontinu	ıed	Mean	2.48	2.27	1.97	1.83
			SD	0.72	0.58	0.41	0.59
			Median N	2.00 31	2.00 30	2.00 30	2.00 30

				Subject's Self Asse	essment of Skin Texture Intr	a-Subject Change
Subject No.	Subject Initials	Age	Sex	Week 4 Minus Week 2	Week 8 Minus Week 2	Week 12 Minus Week 2
4	SKH	46	Female	0	1	0
5	LMP	45	Female	0	0	0
6	PJW	43	Female			
10	JCL	41	Female	0	-1	-1
11	TLM	50	Female	0	-1	-1
13	DKS	38	Female	0	-2	-2
14	LKB	56	Female	0	-1	-1
15	NHK	56	Female			
16	VLH	57	Female	-1	-1	-2
22	JKP	48	Female			
23	RMS	51	Female	0	0	0
25	TJJ	40	Female	-1	-1	-1
29	DSE	59	Female	0	-1	0
30	MMC	64	Female	2	1	1
33	J-G	47	Female			
34	LLL	31	Female			
35	DLM	52	Female	0	0	0
36	MAE	51	Female	-1	-1	-1
37	GLJ	54	Female	0	0	-1
38	KAS	42	Female			
41	E-N	61	Female	-1	-1	-2
42	KAM	52	Female	0	0	0
43	CGC	48	Female	-1	-1	-1
45	TDC	48	Female	0	0	0
48	JLL	47	Female	-2	-1	-1
50	DKH	49	Female	0	0	0
52	CJL	53	Female	1 2	1	1
53	DSB	54	Female	2 -1	0 -1	-1 -2
55 56	SKR DAH	57 45	Female Female	-1	-1	-2
58	CZR	45	Female	1	0	0
62	KME	49 45	Female	-1	-1	-1
63	MRG	51	Female	-1	-1	-1
68	SAM	53	Female	-1	-1	-1
69	GHD	55	Female	0	-1	0
70	CAC	62	Female	0	0	1
71	JAR	40	Female	0	0	-1
72	NRC	56	Female	-1	-1	-1
73	NLW	47	Female	-1	-1	-1
			Mean	-0.17	-0.47	-0.60
			SD	0.87	0.73	0.86
			Median	0.00	-1.00	-1.00
			N	30	30	30

<sup>1 =</sup> Much Improved 2 = Somewhat Improved 3 = No Change 4 = Somewhat Worse 5 = Much Worse

### Subject's Self Assessment of Skin Color

				Subject's	s Self Asses	ssment of S	kin Color
Subject No.	Subject Initials	Age	Sex	Week 2	Week 4	Week 8	Week 12
4	SKH	46	Female	3	3	3	3
5	LMP	45	Female	2	3	2	2
6	PJW	43	Female				
10	JCL	41	Female	3	3	2	2
11	TLM	50	Female	3	3	3	3
13	DKS	38	Female	2	2	1	1
14	LKB	56	Female	3	3	3	2
15	NHK	56	Female	3	_	_	_
16	VLH	57	Female	3	2	2	2
22	JKP	48	Female				
23	RMS	51	Female	3	2	3	2
25	TJJ	40	Female	4	3	3	3
29	DSE	59	Female	3	2	1	3
30	MMC	64	Female	2	3	3	3
33	J-G	47	Female				
34	LLL	31	Female				
35	DLM	52	Female	3	3	3	3
36	MAE	51	Female	3	3	2	2
37	GLJ	54	Female	3	2	1	2
38	KAS	42	Female				
41	E-N	61	Female	3	2	2	2
42	KAM	52	Female	2	2	2	1
43	CGC	48	Female	3	3	3	2
45	TDC	48	Female	3	4	3	3
48	JLL	47	Female	3	2	4	3
50	DKH	49	Female	3	3	3	3
52	CJL	53	Female	3	3	2	2
53	DSB	54	Female	1	2	1	1
55	SKR	57	Female	3	3	2	1
56	DAH	45	Female				
58	CZR	49	Female	3	3	3	3
62	KME	45	Female	3	3	2	2
63	MRG	51	Female	2	2	2	,
68	SAM	53	Female	2	2	2	3
69	GHD	55	Female	2	2	3	2
70	CAC	62	Female	3	3	3	3
71	JAR	40	Female	2	3	2	2
72	NRC	56	Female	3	3	2	2
73	NLW	47	Female	2.74	2.67	2.27	2.27
	Discontinu	iea	Mean	2.74	2.67	2.37	2.27
			SD	0.58	0.55	0.76	0.69
			Median	3.00	3.00	2.00	2.00
			N	31	30	30	30

1 = Much Improved
2 = Somewhat Improved
3 = No Change
4 = Somewhat Worse
5 = Much Worse

				Subject's Self Asse	essment of Skin Texture In	tra-Subject Change
Subject No.	Subject Initials	Age	Sex	Week 4 Minus Week 2	Week 8 Minus Week 2	Week 12 Minus Week 2
4	SKH	46	Female	0	0	0
5	LMP	45	Female	1	0	0
6	PJW	43	Female			
10	JCL	41	Female	0	-1	-1
11	TLM	50	Female	0	0	0
13	DKS	38	Female	0	-1	-1
14	LKB	56	Female	0	0	-1
15	NHK	56	Female			
16	VLH	57	Female	-1	-1	-1
22	JKP	48	Female			
23	RMS	51	Female	-1	0	-1
25	TJJ	40	Female	-1	-1	-1
29	DSE	59	Female	-1	-2	0
30	MMC	64	Female	1	1	1
33	J-G	47	Female			
34	LLL	31	Female		_	
35	DLM	52	Female	0	0	0
36	MAE	51	Female	0	-1	-1
37	GLJ	54	Female	-1	-2	-1
38	KAS	42	Female	4	4	
41 42	E-N KAM	61 52	Female Female	-1 0	-1 0	-1 -1
42	CGC	48	Female	0	0	-1 -1
45	TDC	48	Female	1	0	0
48	JLL	46	Female	-1	1	0
50	DKH	49	Female	0	0	0
52	CJL	53	Female	Ö	-1	-1
53	DSB	54	Female	1	o o	0
55	SKR	57	Female	0	-1	-2
56	DAH	45	Female			_
58	CZR	49	Female	0	0	0
62	KME	45	Female	0	-1	-1
63	MRG	51	Female			
68	SAM	53	Female	0	0	1
69	GHD	55	Female	0	1	0
70	CAC	62	Female	0	0	0
71	JAR	40	Female	1	0	0
72	NRC	56	Female	0	-1	-1
73	NLW	47	Female			
			Mean	-0.07	-0.37	-0.47
			SD	0.64	0.76	0.68
			Median	0.00	0.00	-0.50
			N	30	30	30

Subject's Self Assessment of Skin Blotchiness - Brown Spots

Subject   No.   Subject   No.   Subject   No.   Subject   Initials   Age   Sex   Week 2   Week 4   Week 8   Week 12					Subject's Self	Assessment o Spo		ness - Browr
Second Page			Age	Sex	Week 2	Week 4	Week 8	Week 12
Fig.   Female	4	SKH	46	Female	3	2	3	3
10	5	LMP	45	Female	3	3	2	2
11				Female				
13				Female				
14         LKB         56         Female         3         2         2           16         NLHK         56         Female         4				Female				
15				Female				
16	14	LKB	56	Female	3	3	2	2
22	15	NHK	56	Female	4			
23	16	VLH	57	Female	3	2	2	2
25	22	JKP	48	Female				
29	23	RMS	51	Female	3	3	3	3
30	25	TJJ	40	Female	3	3	3	3
33	29	DSE	59	Female	3	3	2	2
State	30	MMC	64	Female	3	3	3	3
35	33	J-G	47	Female				
35	34	111	31	Female				
36         MAE         51         Female         3         2         2         2         2           38         KAS         42         Female         4         4         2         2         2           41         E-N         61         Female         3         2         2         2         4         4         2         4         2         2					3	3	3	3
37								
38								
Head					·			
42					3	3	3	3
43								
45								
48 J.L. 47 Female 2 2 4 4 2 50 DKH 49 Female 3 3 3 3 3 3 52 C.J. 53 Female 2 3 3 2 2 53 DSB 54 Female 2 3 3 2 2 55 SKR 57 Female 3 3 3 2 2 2 56 DAH 45 Female 3 3 3 2 2 2 56 DAH 45 Female 3 3 3 3 3 3 3 58 C2R 49 Female 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3								
50         DKH         49         Female         3         3         3         3         3         2         2         2           53         DSB         54         Female         2         3         2         2         2         2         5         5         SKR         57         Female         3         3         2<								
52         CJL         53         Female         3         3         2         2         2           53         DSB         54         Female         2         3         2         2         2           55         SKR         57         Female         3         3         2         2         2           56         DAH         45         Female         3								
53         DSB         54         Female         2         3         2         2         2           56         DAH         45         Female         3         3         2         2         2           58         CZR         49         Female         3								
SKR   ST   Female   3   3   2   2								
56								
58         CZR         49         Female         3					3	3		2
62 KME 45 Female 3 3 3 3 3 6 6 6 6 6 6 5 6 6 6 6 6 6 6 6					2	_	_	2
63								
68 SAM 53 Female 3 3 2 3 3 6 9 GHD 55 Female 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3					3	3	3	3
69 GHD 55 Female 3 3 3 3 3 3 3 3 3 7 1 1 2								
70 CAC 62 Female 3 3 3 3 3 3 7 7 1 JAR 40 Female 3 3 3 3 3 3 3 3 2 7 2 NRC 56 Female 3 3 3 1 2 2 7 3 NLW 47 Female 50 SD 0.37 0.48 0.68 0.63 Median 3.00 3.00 3.00 3.00 3.00 3.00 3.00 3.0								
71 JAR 40 Female 3 3 3 1 2 72 NRC 56 Female 3 3 1 2 73 NLW 47 Female  Discontinued Mean 3.00 2.90 2.50 2.57 SD 0.37 0.48 0.68 0.63 Median 3.00 3.00 3.00 3.00 N 31 30 30 30 30								
72 NRC 56 Female 3 3 1 2  73 NLW 47 Female  Discontinue Mean 3.00 2.90 2.50 2.57 SD 0.37 0.48 0.68 0.63 Median 3.00 3.00 3.00 3.00 N 31 30 30 30								
73 NLW 47 Female  Discontinued Mean 3.00 2.90 2.50 2.57 SD 0.37 0.48 0.68 0.63 Median 3.00 3.00 3.00 3.00 3.00 N 31 30 30 30								
Discontinued   Mean   3.00   2.90   2.50   2.57     SD   0.37   0.48   0.68   0.63   Median   3.00   3.00   3.00   3.00   N   31   30   30   30					3	3	1	2
SD 0.37 0.48 0.68 0.63 Median 3.00 3.00 3.00 N 31 30 30 30	73							
Median 3.00 3.00 3.00 3.00 N 31 30 30 30		Discontini	ued					
N 31 30 30 30								
1 = Much Improved				N	31	30	30	30
2 = Somewhat Improved			oved					
3 = No Change 4 = Somewhat Worse								

1	=	Much Improved
2	=	Somewhat Improved

s	=	No Change
4	=	Somewhat Worse
5	=	Much Worse

				Subject's Self Assessment of Skin Blotchiness - Brown Spots Intra-Subject Change				
Subject No.	Subject Initials	Age	Sex	Week 4 Minus Week 2	Week 8 Minus Week 2	Week 12 Minus Week 2		
4	SKH	46	Female	-1	0	0		
5	LMP	45	Female	0	-1	-1		
6	PJW	43	Female					
10	JCL	41	Female	0	0	0		
11	TLM	50	Female	0	0	0		
13	DKS	38	Female	-1	-2	-2		
14	LKB	56	Female	0	-1	-1		
15	NHK	56	Female					
16	VLH	57	Female	-1	-1	-1		
22	JKP	48	Female	·				
23	RMS	51	Female	0	0	0		
25	TJJ	40	Female	0	ő	0		
29	DSF	59	Female	0	-1	-1		
30	MMC	64	Female	0	0	0		
33	J-G	47	Female		Ŭ	Ü		
34	111	31	Female					
35	DLM	52	Female	0	0	0		
36	MAE	51	Female	-1	-1	-1		
37	GLJ	54	Female	0	-1	-1		
38	KAS	42	Female	0	-2	-2		
41	E-N	61	Female	0	0	0		
41	E-IN KAM	52	Female	0	-1	-1		
			Female					
43	CGC	48		0	0	0		
45	TDC	48	Female	1	-1	1		
48	JLL	47	Female	0	2	0		
50	DKH	49	Female	0	0	0		
52	CJL	53	Female	0	-1	-1		
53	DSB	54	Female	1	0	0		
55	SKR	57	Female	0	-1	-1		
56	DAH	45	Female					
58	CZR	49	Female	0	0	0		
62	KME	45	Female	0	0	0		
63	MRG	51	Female					
68	SAM	53	Female	0	-1	0		
69	GHD	55	Female	0	0	0		
70	CAC	62	Female	0	0	0		
71	JAR	40	Female	0	0	0		
72	NRC	56	Female	0	-2	-1		
73	NLW	47	Female					
			Mean	-0.07	-0.47	-0.40		
			SD	0.45	0.82	0.67		
			Median	0.00	0.00	0.00		
			N	30	30	30		

### Subject's Self Assessment of Fine Wrinkles

				Subject's Self Assessment of Fine Wrinkles					
Subject No.	Subject Initials	Age	Sex	Week 2	Week 4	Week 8	Week 12		
4	SKH	46	Female	2	2	2	3		
5	LMP	45	Female	3	2	2	2		
6	PJW	43	Female						
10	JCL	41	Female	3	3	3	2		
11	TLM	50	Female	3	3	3	3		
13	DKS	38	Female	4	2	2	1		
14	LKB	56	Female	3	3	2	2		
15	NHK	56	Female	2					
16	VLH	57	Female	3	2	2	2		
22	JKP	48	Female						
23	RMS	51	Female	2	2	2	2		
25	TJJ	40	Female	4	2	3	2		
29	DSE	59	Female	2	2	1	2		
30	MMC	64	Female	2	3	2	3		
33	J-G	47	Female						
34	LLL	31	Female						
35	DLM	52	Female	2	2	2	2		
36	MAE	51	Female	2	2	1	1		
37	GLJ	54	Female	3	2	2	2		
38	KAS	42	Female						
41	E-N	61	Female	3	3	2	2		
42	KAM	52	Female	2	2	2	2		
43	CGC	48	Female	2	2	2	2		
45	TDC	48	Female	3	3	2	3		
48	JLL	47	Female	2	1	2	2		
50	DKH	49	Female	2	2	2	3		
52	CJL	53	Female	2	2	2	2		
53	DSB	54	Female	1	3	2	1		
55	SKR	57	Female	3	2	2	1		
56	DAH	45	Female						
58	CZR	49	Female	2	3	2	2		
62	KME	45	Female	3	3	3	3		
63	MRG	51	Female						
68	SAM	53	Female	3	2	2	2		
69	GHD	55	Female	3	2	2	2		
70	CAC	62	Female	4	2	2	3		
71	JAR	40	Female	3	2	2	2		
72	NRC	56	Female	3	3	2	2		
73	NLW	47	Female						
	Discontinu	ied	Mean	2.61	2.30	2.07	2.10		
			SD	0.72	0.53	0.45	0.61		
			Median	3.00	2.00	2.00	2.00		
			N	31	30	30	30		
1 = Much	Improved								

ı	=	Much Improved	
٠	_	Commenced Incomment	

<sup>2 =</sup> Somewhat Improve 3 = No Change 4 = Somewhat Worse 5 = Much Worse

				Subject's Self Asse	ssment of Fine Wrinkles In	tra-Subject Change
Subject No.	Subject Initials	Age	Sex	Week 4 Minus Week 2	Week 8 Minus Week 2	Week 12 Minus Week 2
4	SKH	46	Female	0	0	1
5	LMP	45	Female	-1	-1	-1
6	PJW	43	Female			
10	JCL	41	Female	0	0	-1
11	TLM	50	Female	0	0	0
13	DKS	38	Female	-2	-2	-3
14	LKB	56	Female	0	-1	-1
15	NHK	56	Female			
16	VLH	57	Female	-1	-1	-1
22	JKP	48	Female			
23	RMS	51	Female	0	0	0
25	TJJ	40	Female	-2	-1	-2
29	DSE	59	Female	0	-1	0
30	MMC	64	Female	1	0	1
33	J-G	47	Female			
34	LLL	31	Female			
35	DLM	52	Female	0	0	0
36	MAE	51	Female	0	-1	-1
37	GLJ	54	Female	-1	-1	-1
38	KAS	42	Female	_		
41	E-N	61	Female	0	-1 0	-1
42	KAM	52	Female	0		0
43	CGC	48	Female	0	0	0
45	TDC	48	Female	0 -1	-1 0	0
48 50	JLL DKH	47 49	Female Female	-1 0	0	0 1
50 52	CJL	53	Female	0	0	0
53	DSB	54	Female	2	1	0
55 55	SKR	57	Female	-1	-1	-2
56	DAH	45	Female	-1	-1	-2
58	CZR	49	Female	1	0	0
62	KME	45	Female	0	0	0
63	MRG	51	Female	,	,	· ·
68	SAM	53	Female	-1	-1	-1
69	GHD	55	Female	-1	-1	-1
70	CAC	62	Female	-2	-2	-1
71	JAR	40	Female	-1	-1	-1
72	NRC	56	Female	0	-1	-1
73	NLW	47	Female	,	·	
			Mean	-0.33	-0.57	-0.53
			SD	0.88	0.68	0.90
			Median	0.00	-1.00	-0.50
			N	30	30	30

### Subject's Self Assessment of Overall Improvement

		t of Overall I	mprovement				
Subject No.	Subject Initials	Age	Sex	Week 2	Week 4	Week 8	Week 12
4	SKH	46	Female	2	2	2	2
5	LMP	45	Female	2	2	2	2
6	PJW	43	Female				
10	JCL	41	Female	3	3	2	2
11	TLM	50	Female	3	3	3	2
13	DKS	38	Female	3	2	1	1
14	LKB	56	Female	3	3	2	2
15	NHK	56 57	Female	4	2	2	1
16 22	VLH JKP	48	Female	3	2	2	- 1
23	RMS	51	Female Female	2	2	2	2
25	TJJ	40	Female	4	2	2	2
29	DSE	59	Female	2	2	1	2
30	MMC	64	Female	2	3	2	3
33	J-G	47	Female				
34	LLL	31	Female				
35	DLM	52	Female	2	2	2	2
36	MAE	51	Female	2	2	1	1
37	GLJ	54	Female	4	2	2	2
38	KAS	42	Female				
41	E-N	61	Female	3	2	2	2
42	KAM	52	Female	2	2	2	2
43	CGC	48	Female	3	2	2	2
45	TDC	48	Female	2	3	2	2
48	JLL	47	Female	2	2	3	2
50	DKH	49	Female	3	2	2	2
52	CJL	53	Female	2	2	2	2
53	DSB	54	Female	1	2	2	1
55	SKR	57	Female	3	2	2	1
56	DAH	45	Female				
58	CZR	49	Female	2	3	2	2
62	KME	45	Female	3	3	3	2
63 68	MRG SAM	51 53	Female Female	3	2	2	2
69	GHD	55	Female	3	2	2	2
70	CAC	62	Female	2	2	2	3
71	JAR	40	Female	2	2	2	1
72	NRC	56	Female	3	2	2	2
73	NLW	47	Female	J			
	Discontinu		Mean	2.58	2.23	2.00	1.87
	SD SD				0.43	0.45	0.51
			Median	0.72 3.00	2.00	2.00	2.00
			N	31	30	30	30
1 = Much	Improved						

1	=	Much Improved
2	=	Somewhat Improved

<sup>3 =</sup> No Change 4 = Somewhat Worse 5 = Much Worse

				Subject's Self Assessment of Overall Improvement Intra-Subject Change				
Subject No.	Subject Initials	Age	Sex	Week 4 Minus Week 2	Week 8 Minus Week 2	Week 12 Minus Week 2		
4	SKH	46	Female	0	0	0		
5	LMP	45	Female	0	0	0		
6	PJW	43	Female					
10	JCL	41	Female	0	-1	-1		
11	TLM	50	Female	0	0	-1		
13	DKS	38	Female	-1	-2	-2		
14	LKB	56	Female	0	-1	-1		
15	NHK	56	Female					
16	VLH	57	Female	-1	-1	-2		
22	JKP	48	Female					
23	RMS	51	Female	0	0	0		
25	TJJ	40	Female	-2	-2	-2		
29	DSE	59	Female	0	-1	0		
30	MMC	64	Female	1	0	1		
33	J-G	47	Female					
34	LLL	31	Female					
35	DLM	52	Female	0	0	0		
36	MAE	51	Female	0	-1	-1		
37	GLJ	54	Female	-2	-2	-2		
38	KAS	42	Female	-2	-2	-2		
41	E-N	61	Female	-1	-1	-1		
42	KAM	52	Female	0	0	0		
43	CGC	48	Female	-1	-1	-1		
45	TDC	48	Female	1	0	0		
48	JLL	47	Female	0	1	0		
50	DKH	49	Female	-1	-1	-1		
52	CJL	53	Female	0	0	0		
52	DSB	53 54	Female	1	1	0		
55	SKR	54 57	Female	-1	-1	-2		
56	DAH	45	Female	-1	-1	-2		
58	CZR	45	Female	1	0	0		
62	KME	49	Female	0	0	-1		
63	MRG	45 51	Female	U	U	-1		
68	SAM	53	Female	-1	-1	-1		
69	GHD	53 55	Female	-1 -1	-1 -1	-1 -1		
	CAC	62	Female	-1 0	-1 0	-1 1		
70								
71	JAR	40	Female	0	0	-1		
72	NRC	56	Female	-1	-1	-1		
73	NLW	47	Female	0.00	0.50	0.07		
			Mean	-0.30	-0.53	-0.67		
			SD	0.79	0.78	0.84		
			Median	0.00	-0.50	-1.00		
			N	30	30	30		

#### Expert Assessment of Fine Wrinkles

					Expert /	Assessment of Fin	e Wrinkles	
Subject No.	Subject Initials	Age	Sex	Baseline	Week 2	Week 4	Week 8	Week 12
1	SDC	40	Female	2				
2	MLE	50	Female	3	2	1	1	1
3	SKH	47	Female	2	2	2	2	2
7	DBK	52	Female	4	4	4	3	3
8	JCF	54	Female	2	2	1	1	1
9	JRB	53	Female	2				
12	EFK	57	Female	3	3	3	2	2
17	BFH	59	Female	4	4	4	4	4
18	LJR	58	Female	3	3	3	3	3
19	D-M	58	Female	3	3	3	2	2
20	RLA	45	Female					
21	LGD	57	Female	2	2	2	2	2
24	VIP	52	Female	3	2	2	1	1
26	PKM	46	Female	1	1	1	1	
27	SMM	59	Female	3	3	3	3	3
28	EJD	56	Female	3				
31	JAC	56	Female	3	3	3	2	2
32	TML	38	Female	2	2	1	1	1
39	DKD	50	Female	2	1	1	1	1
40	CLM	43	Female	2	2	1	1	1
44	GSR	52	Female	3	3	3	2	1
46	LAA	55	Female	3	3	3	3	3
47	CMP	47	Female	2	2	2	1	1
49	L-R	58	Female	3	3	3	3	3
51	PCB	59	Female	3	3	3	3	3
54	TWS	55	Female	3	3			
57	MDS	52	Female	4	4	3	3	3
59	GFM	64	Female	3	3	3	3	3
60	JLF	32	Female	1	1	1	1	1
61	GEP	53	Female	3				
64	KKF	36	Female	3	3	2	2	2
65	EMM	39	Female	1	1	1	1	1
66	CYR	39	Female	2	2	2	2	1
67	AMM	37	Female	1	1	1	1	1
	Discontinu	ued	Mean	2.55	2.45	2.21	1.96	1.93
			SD	0.87	0.91	0.99	0.92	0.96
			Median	3.00	3.00	2.00	2.00	2.00

				Expert Assessment of Fine Wrinkles Intra-Subject Change					
Subject No.	Subject Initials	Age	Sex	Week 2 Minus Baseline	Week 4 Minus Baseline	Week 8 Minus Baseline	Week 12 Minus Baseline		
1	SDC	40	Female						
2	MLE	50	Female	-1	-2	-2	-2		
3	SKH	47	Female	0	0	0	0		
7	DBK	52	Female	0	0	-1	-1		
8	JCF	54	Female	0	-1	-1	-1		
9	JRB	53	Female						
12	EFK	57	Female	0	0	-1	-1		
17	BFH	59	Female	0	0	0	0		
18	LJR	58	Female	0	0	0	0		
19	D-M	58	Female	0	0	-1	-1		
20	RLA	45	Female						
21	LGD	57	Female	0	0	0	0		
24	VIP	52	Female	-1	-1	-2	-2		
26	PKM	46	Female	0	0	0			
27	SMM	59	Female	0	0	0	0		
28	EJD	56	Female						
31	JAC	56	Female	0	0	-1	-1		
32	TML	38	Female	0	-1	-1	-1		
39	DKD	50	Female	-1	-1	-1	-1		
40	CLM	43	Female	0	-1	-1	-1		
44	GSR	52	Female	0	0	-1	-2		
46	LAA	55	Female	0	0	0	0		
47	CMP	47	Female	0	0	-1	-1		
49	L-R	58	Female	0	0	0	0		
51	PCB	59	Female	0	0	0	0		
54	TWS	55	Female	0					
57	MDS	52	Female	0	-1	-1	-1		
59	GFM	64	Female	0	0	0	0		
60	JLF	32	Female	0	0	0	0		
61	GEP	53	Female						
64	KKF	36	Female	0	-1	-1	-1		
65	EMM	39	Female	0	0	0	0		
66	CYR	39	Female	0	0	0	-1		
67	AMM	37	Female	0	0	0	0		
			Mean	-0.10	-0.32	-0.57	-0.67		
			SD	0.31	0.55	0.63	0.68		
			Median	0.00	0.00	-0.50	-1.00		
			N	29	28	28	27		

<sup>0 =</sup> None 1 = Minimal 2 = Mild 3 = Moderate 4 = Severe

#### Expert Assessment of Coarse Wrinkles

					Expert Ass	essment of Coar	se Wrinkles	
Subject No.	Subject Initials	Age	Sex	Baseline	Week 2	Week 4	Week 8	Week 12
1	SDC	40	Female	1				
2	MLE	50	Female	1	1	1	1	1
3	SKH	47	Female	3	3	3	3	3
7	DBK	52	Female	3	3	3	3	3
8	JCF	54	Female	1	1	1	0	0
9	JRB	53	Female	1			-	_
12	EFK	57	Female	3	3	3	3	3
17	BFH	59	Female	3	3	3	3	3
18	LJR	58	Female	4	4	4	4	4
19	D-M	58	Female	3	3	3	3	3
20	RLA	45	Female					
21	LGD	57	Female	1	1	1	1	1
24	VIP	52	Female	1	0	0	0	0
26	PKM	46	Female	0	0	0	0	
27	SMM	59	Female	4	4	4	4	4
28	EJD	56	Female	3				
31	JAC	56	Female	4	4	4	4	4
32	TML	38	Female	1	1	1	0	0
39	DKD	50	Female	1	1	0	1	1
40	CLM	43	Female	0	0	0	0	0
44	GSR	52	Female	2	2	2	2	2
46	LAA	55	Female	4	4	4	4	3
47	CMP	47	Female	1	1	1	1	1
49	L-R	58	Female	1	1	1	1	1
51	PCB	59	Female	2	2	2	2	2
54	TWS	55	Female	1	1			
57	MDS	52	Female	3	2	2	2	2
59	GFM	64	Female	4	4	4	4	4
60	JLF	32	Female	0	0	0	0	0
61	GEP	53	Female	1				
64	KKF	36	Female	1	1	0	0	0
65	EMM	39	Female	0	0	0	0	0
66	CYR	39	Female	1	1	1	1	1
67	AMM	37	Female	0	0	0	0	0
	Discontinu	led	Mean	1.83	1.76	1.71	1.68	1.70
			SD	1.42	1.43	1.51	1.54	1.49
			Median	1.00	1.00	1.00	1.00	1.00
0 - Nana			N	29	29	28	28	27

Subject	Subject	Age	Sex	Week 2 Minus	Week 4 Minus	Week 8 Minus	Week 12 Minus	
No.	Initials	٠		Baseline	Baseline	Baseline	Baseline	
1	SDC	40	Female					
2	MLE	50	Female	0	0	0	0	
3	SKH	47	Female	0	0	0	0	
7	DBK	52	Female	0	0	0	0	
8	JCF	54	Female	0	0	-1	-1	
9	JRB	53	Female					
12	EFK	57	Female	0	0	0	0	
17	BFH	59	Female	0	0	0	0	
18	LJR	58	Female	0	0	0	0	
19	D-M	58	Female	0	0	0	0	
20	RLA	45	Female					
21	LGD	57	Female	0	0	0	0	
24	VIP	52	Female	-1	-1	-1	-1	
26	PKM	46	Female	0	0	0		
27	SMM	59	Female	0	0	0	0	
28	EJD	56	Female					
31	JAC	56	Female	0	0	0	0	
32	TML	38	Female	0	0	-1	-1	
39	DKD	50	Female	0	-1	0	0	
40	CLM	43	Female	0	0	0	0	
44	GSR	52	Female	0	0	0	0	
46	LAA	55	Female	0	0	0	-1	
47	CMP	47	Female	0	0	0	0	
49	L-R	58	Female	0	0	0	0	
51	PCB	59	Female	0	0	0	0	
54	TWS	55	Female	0				
57	MDS	52	Female	-1	-1	-1	-1	
59	GFM	64	Female	0	0	0	0	
60	JLF	32	Female	0	0	0	0	
61	GEP	53	Female					
64	KKF	36	Female	0	-1	-1	-1	
65	EMM	39	Female	0	0	0	0	
66	CYR	39	Female	0	0	0	0	
67	AMM	37	Female	0	0	0	0	
			Mean	-0.07	-0.14	-0.18	-0.22	
			SD	0.26	0.36	0.39	0.42	
			Median	0.00	0.00	0.00	0.00	
			N	29	28	28	27	

Expert Assessment of Coarse Wrinkles Intra-Subject Change

<sup>0 =</sup> None 1 = Minimal 2 = Mild 3 = Moderate 4 = Severe

### Expert Assessment of Roughness

				Expert Assessment of Roughnness						
Subject No.	Subject Initials	Age	Sex	Baseline	Week 2	Week 4	Week 8	Week 12		
1	SDC	40	Female	2						
2	MLE	50	Female	3	3	2	1	1		
3	SKH	47	Female	1	2	0	1	0		
7	DBK	52	Female	3	3	2	2	1		
8	JCF	54	Female	3	2	1	1	1		
9	JRB	53	Female	3						
12	EFK	57	Female	2	3	1	0	0		
17	BFH	59	Female	2	1	1	1	0		
18	LJR	58	Female	1	1	0	0	0		
19	D-M	58	Female	2	1	0	0	0		
20	RLA	45	Female							
21	LGD	57	Female	3	3	2	2	1		
24	VIP	52	Female	3	2	1	1	0		
26	PKM	46	Female	3	2	2	1			
27	SMM	59	Female	3	2	2	1	2		
28	EJD	56	Female	2						
31	JAC	56	Female	3	3	1	0	0		
32	TML	38	Female	2	1	1	0	0		
39	DKD	50	Female	3	0	1	1	1		
40	CLM	43	Female	3	1	1	1	1		
44	GSR	52	Female	2	1	0	0	0		
46	LAA	55	Female	2	1	1	1	1		
47	CMP	47	Female	3	2	1	0	0		
49	L-R	58	Female	2	1	1	2	0		
51	PCB	59	Female	2	2	1	0	0		
54	TWS	55	Female	1	0					
57	MDS	52	Female	2	2	2	2	0		
59	GFM	64	Female	2	1	1	1	0		
60	JLF	32	Female	3	2	2	2	2		
61	GEP	53	Female	3						
64	KKF	36	Female	3	1	1	0	0		
65	EMM	39	Female	3	2	2	2	1		
66	CYR	39	Female	2	1	0	0	0		
67	AMM	37	Female	3	0	0	0	0		
	Discontinu	ıed	Mean	2.41	1.59	1.07	0.82	0.44		
	SD			0.68	0.91	0.72	0.77	0.64		
			Median	3.00	2.00	1.00	1.00	0.00		
			N	29	29	28	28	27		
0 = None										

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0	=	None
1	=	Minima

<sup>1 =</sup> Minimal 2 = Mild 3 = Moderate 4 = Severe

				Expert Assessment of Roughness Intra-Subject Change					
Subject No.	Subject Initials	Age	Sex	Week 2 Minus Baseline	Week 4 Minus Baseline	Week 8 Minus Baseline	Week 12 Minus Baseline		
1	SDC	40	Female						
2	MLE	50	Female	0	-1	-2	-2		
3	SKH	47	Female	1	-1	0	-1		
7	DBK	52	Female	0	-1	-1	-2		
8	JCF	54	Female	-1	-2	-2	-2		
9	JRB	53	Female						
12	EFK	57	Female	1	-1	-2	-2		
17	BFH	59	Female	-1	-1	-1	-2		
18	LJR	58	Female	0	-1	-1	-1		
19	D-M	58	Female	-1	-2	-2	-2		
20	RLA	45	Female						
21	LGD	57	Female	0	-1	-1	-2		
24	VIP	52	Female	-1	-2	-2	-3		
26	PKM	46	Female	-1	-1	-2			
27	SMM	59	Female	-1	-1	-2	-1		
28	EJD	56	Female						
31	JAC	56	Female	0	-2	-3	-3		
32	TML	38	Female	-1	-1	-2	-2		
39	DKD	50	Female	-3	-2	-2	-2		
40	CLM	43	Female	-2	-2	-2	-2		
44	GSR	52	Female	-1	-2	-2	-2		
46	LAA	55	Female	-1	-1	-1	-1		
47	CMP	47	Female	-1	-2	-3	-3		
49	L-R	58	Female	-1	-1	0	-2		
51	PCB	59	Female	0	-1	-2	-2		
54	TWS	55	Female	-1					
57	MDS	52	Female	0	0	0	-2		
59	GFM	64	Female	-1	-1	-1	-2		
60	JLF	32	Female	-1	-1	-1	-1		
61	GEP	53	Female						
64	KKF	36	Female	-2	-2	-3	-3		
65	EMM	39	Female	-1	-1	-1	-2		
66	CYR	39	Female	-1	-2	-2	-2		
67	AMM	37	Female	-3	-3	-3	-3		
			Mean	-0.83	-1.39	-1.64	-2.00		
			SD	0.93	0.63	0.87	0.62		
			Median	-1.00	-1.00	-2.00	-2.00		
			N	29	28	28	27		

### Expert Assessment of Mottled Hyperpigmentation

				Expert Assessment of Mottled Hyperpigmentation							
Subject	Subject	Age	Sex	Baseline	Week 2	Week 4	Week 8	Week 12			
No.	Initials				WEEK 2	WEEK 4	Week 0	WEEK 12			
1	SDC	40	Female	1							
2	MLE	50	Female	1	1	1	1	1			
3	SKH	47	Female	3	3	2	3	3			
7	DBK	52	Female	2	1	1	1	1			
8	JCF	54	Female	2	3	2	2	2			
9	JRB	53	Female	1							
12	EFK	57	Female	1	1	1	1	1			
17	BFH	59	Female	2	2	1	1	1			
18	LJR	58	Female	3	3	3	3	3			
19	D-M	58	Female	3	3	2	1	1			
20	RLA	45	Female								
21	LGD	57	Female	4	4	3	3	2			
24	VIP	52	Female	0	0	0	0	0			
26	PKM	46	Female	1	1	1	1				
27	SMM	59	Female	2	1	1	1	1			
28	EJD	56	Female	2							
31	JAC	56	Female	2	1	1	1	1			
32	TML	38	Female	1	1	1	1	1			
39	DKD	50	Female	2	1	1	1	1			
40	CLM	43	Female	2	2	2	2	2			
44	GSR	52	Female	2	1	1	1	1			
46	LAA	55	Female	1	1	1	1	1			
47	CMP	47	Female	1	1	1	1	1			
49	L-R	58	Female	3	3	2	2	1			
51	PCB	59	Female	1	1	1	1	1			
54	TWS	55	Female	3	3						
57	MDS	52	Female	0	0	0	0	1			
59	GFM	64	Female	2	2	1	1	1			
60	JLF	32	Female	2	1	1	1	1			
61	GEP	53	Female	2							
64	KKF	36	Female	2	1	1	1	1			
65	EMM	39	Female	2	2	1	0	0			
66	CYR	39	Female	2	2	1	2	2			
67	AMM	37	Female	2	1	1	2	2			
	Discontinu	ıed	Mean	1.86	1.62	1.25	1.29	1.26			
			SD	0.92	1.01	0.70	0.81	0.71			
			Median	2.00	1.00	1.00	1.00	1.00			
			N	29	29	28	28	27			

							,
Subject	Subject	Age	Sex	Week 2 Minus	Week 4 Minus	Week 8 Minus	Week 12 Minus
No.	Initials			Baseline	Baseline	Baseline	Baseline
1	SDC	40	Female				
2	MLE	50	Female	0	0	0	0
3	SKH	47	Female	0	-1	0	0
7	DBK	52	Female	-1	-1	-1	-1
8	JCF	54	Female	1	0	0	0
9	JRB	53	Female				
12	EFK	57	Female	0	0	0	0
17	BFH	59	Female	0	-1	-1	-1
18	LJR	58	Female	0	0	0	0
19	D-M	58	Female	0	-1	-2	-2
20	RLA	45	Female				
21	LGD	57	Female	0	-1	-1	-2
24	VIP	52	Female	0	0	0	0
26	PKM	46	Female	0	0	0	
27	SMM	59	Female	-1	-1	-1	-1
28	EJD	56	Female				
31	JAC	56	Female	-1	-1	-1	-1
32	TML	38	Female	0	0	0	0
39	DKD	50	Female	-1	-1	-1	-1
40	CLM	43	Female	0	0	0	0
44	GSR	52	Female	-1	-1	-1	-1
46	LAA	55	Female	0	0	0	0
47	CMP	47	Female	0	0	0	0
49	L-R	58	Female	0	-1	-1	-2
51	PCB	59	Female	0	0	0	0
54	TWS	55	Female	0			
57	MDS	52	Female	0	0	0	1
59	GFM	64	Female	0	-1	-1	-1
60	JLF	32	Female	-1	-1	-1	-1
61	GEP	53	Female				
64	KKF	36	Female	-1	-1	-1	-1
65	EMM	39	Female	0	-1	-2	-2
66	CYR	39	Female	0	-1	0	0
67	AMM	37	Female	-1	-1	0	0
			Mean	-0.24	-0.57	-0.54	-0.59
			SD	0.51	0.50	0.64	0.80
			Median	0.00	-1.00	0.00	0.00
			N	29	28	28	27

Expert Assessment of Mottled Hyperpigmentation Intra-Subject Change

<sup>0 =</sup> None 1 = Minimal 2 = Mild 3 = Moderate 4 = Severe

### Expert Assessment of Overall Severity (Skin Aging)

				Expert Assessment of Overall Severity (Skin Aging)						
Subject No.	Subject Initials	Age	Sex	Baseline	Week 2	Week 4	Week 8	Week 12		
1	SDC	40	Female	4						
2	MLE	50	Female	3	2	2	1	1		
3	SKH	47	Female	5	5	4	5	5		
7	DBK	52	Female	5	5	4	4	4		
8	JCF	54	Female	3	2	2	2	2		
9	JRB	53	Female	2						
12	EFK	57	Female	5	5	3	3	3		
17	BFH	59	Female	5	5	4	4	4		
18	LJR	58	Female	6	6	5	5	5		
19	D-M	58	Female	5	5	4	3	3		
20	RLA	45	Female							
21	LGD	57	Female	4	4	4	4	3		
24	VIP	52	Female	2	1	1	1	1		
26	PKM	46	Female	1	1	1	1			
27	SMM	59	Female	6	5	5	5	5		
28	EJD	56	Female	4						
31	JAC	56	Female	6	6	5	5	5		
32	TML	38	Female	3	2	1	1	1		
39	DKD	50	Female	4	2	2	1	1		
40	CLM	43	Female	3	2	2	2	2		
44	GSR	52	Female	4	4	4	3	2		
46	LAA	55	Female	6	5	5	5	5		
47	CMP	47	Female	3	2	2	1	2		
49	L-R	58	Female	5	4	4	4	4		
51	PCB	59	Female	3	3	2	3	3		
54	TWS	55	Female	5	4					
57	MDS	52	Female	5	5	5	4	4		
59	GFM	64	Female	6	6	5	5	5		
60	JLF	32	Female	2	1	1	1	1		
61	GEP	53	Female	4						
64	KKF	36	Female	4	3	2	1	1		
65	EMM	39	Female	3	2	2	2	1		
66	CYR	39	Female	3	2	2	3	2		
67	AMM	37	Female	2	1	1	1	1		
			Mean	4.03	3.45	3.00	2.86	2.81		
			SD	1.43	1.70	1.49	1.58	1.57		
			Median	4.00	4.00	2.50	3.00	3.00		
			N	29	29	28	28	27		
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Subject	Subject	Age	Sex	Week 2 Minus	Week 4 Minus	Week 8 Minus	Week 12 Minus
No.	Initials	Age	sex	Baseline	Baseline	Baseline	Baseline
1	SDC	40	Female				
2	MLE	50	Female	-1	-1	-2	-2
3	SKH	47	Female	0	-1	0	0
7	DBK	52	Female	0	-1	-1	-1
8	JCF	54	Female	-1	-1	-1	-1
9	JRB	53	Female				
12	EFK	57	Female	0	-2	-2	-2
17	BFH	59	Female	0	-1	-1	-1
18	LJR	58	Female	0	-1	-1	-1
19	D-M	58	Female	0	-1	-2	-2
20	RLA	45	Female				
21	LGD	57	Female	0	0	0	-1
24	VIP	52	Female	-1	-1	-1	-1
26	PKM	46	Female	0	0	0	
27	SMM	59	Female	-1	-1	-1	-1
28	EJD	56	Female				
31	JAC	56	Female	0	-1	-1	-1
32	TML	38	Female	-1	-2	-2	-2
39	DKD	50	Female	-2	-2	-3	-3
40	CLM	43	Female	-1	-1	-1	-1
44	GSR	52	Female	0	0	-1	-2
46	LAA	55	Female	-1	-1	-1	-1
47	CMP	47	Female	-1	-1	-2	-1
49	L-R	58	Female	-1	-1	-1	-1
51	PCB	59	Female	0	-1	0	0
54	TWS	55	Female	-1			
57	MDS	52	Female	0	0	-1	-1
59	GFM	64	Female	0	-1	-1	-1
60	JLF	32	Female	-1	-1	-1	-1
61	GEP	53	Female				
64	KKF	36	Female	-1	-2	-3	-3
65	EMM	39	Female	-1	-1	-1	-2
66	CYR	39	Female	-1	-1	0	-1
67	AMM	37	Female	-1	-1	-1	-1
			Mean	-0.59	-1.00	-1.14	-1.30
			SD	0.57	0.54	0.80	0.72
			Median	-1.00	-1.00	-1.00	-1.00
			N	29	28	28	27

Expert Assessment of Overall Severity (Skin Aging) Intra-Subject Change

<sup>0 =</sup> None 1-3 = Mild 4-6 = Moderate 7-9 = Severe

### Expert Assessment of Overall Severity (Skin Aging)

					Expert Assessn	nent of Improven	nent (Skin Aging)	
Subject No.	Subject Initials	Age	Sex	Baseline	Week 2	Week 4	Week 8	Week 12
1	SDC	40	Female	N/A				
2	MLE	50	Female	N/A	4	4	4	4
3	SKH	47	Female	N/A	5	5	5	5
7	DBK	52	Female	N/A	5	5	4	4
8	JCF	54	Female	N/A	5	4	4	4
9	JRB	53	Female	N/A				
12	EFK	57	Female	N/A	5	4	4	4
17	BFH	59	Female	N/A	5	5	5	5
18	LJR	58	Female	N/A	5	5	5	5
19	D-M	58	Female	N/A	5	4	4	4
20	RLA	45	Female	N/A				
21	LGD	57	Female	N/A	5	4	4	4
24	VIP	52	Female	N/A	4	4	4	4
26	PKM	46	Female	N/A	5	5	4	
27	SMM	59	Female	N/A	4	5	5	5
28	EJD	56	Female	N/A				
31	JAC	56	Female	N/A	5	5	5	5
32	TML	38	Female	N/A	4	4	4	4
39	DKD	50	Female	N/A	4	4	4	4
40	CLM	43	Female	N/A	5	4	4	4
44	GSR	52	Female	N/A	5	4	4	4
46	LAA	55	Female	N/A	4	5	5	5
47	CMP	47	Female	N/A	4	4	4	4
49	L-R	58	Female	N/A	5	5	5	4
51	PCB	59	Female	N/A	5	5	5	5
54	TWS	55	Female	N/A	5			
57	MDS	52	Female	N/A	5	4	4	4
59	GFM	64	Female	N/A	5	4	4	4
60	JLF	32	Female	N/A	4	4	4	4
61	GEP	53	Female	N/A				
64	KKF	36	Female	N/A	4	4	4	4
65	EMM	39	Female	N/A	5	5	5	4
66	CYR	39	Female	N/A	5	4	4	4
67	AMM	37	Female	N/A	4	4	4	4
	Discontinu	ued		Mean	4.66	4.39	4.32	4.26
				SD	0.48	0.50	0.48	0.45
				Median	5.00	4.00	4.00	4.00
				N	29	28	28	27
1 = Evcel	lent Impro	amont	(~100%)					

				·	nt of Improvement ( Subject Change	
Subject No.	Subject Initials	Age	Sex	Week 4 Minus Week 2	Week 8 Minus Week 2	Week 12 Minus Week 2
1	SDC	40	Female			
2	MLE	50	Female	0	0	0
3	SKH	47	Female	0	0	0
7	DBK	52	Female	0	-1	-1
8	JCF	54	Female	-1	-1	-1
9	JRB	53	Female			
12	EFK	57	Female	-1	-1	-1
17	BFH	59	Female	0	0	0
18	LJR	58	Female	0	0	0
19	D-M	58	Female	-1	-1	-1
20	RLA	45	Female			
21	LGD	57	Female	-1	-1	-1
24	VIP	52	Female	0	0	0
26	PKM	46	Female	0	-1	
27	SMM	59	Female	1	1	1
28	EJD	56	Female			
31	JAC	56	Female	0	0	0
32	TML	38	Female	0	0	0
39	DKD	50	Female	0	0	0
40	CLM	43	Female	-1	-1	-1
44	GSR	52	Female	-1	-1	-1
46	LAA	55	Female	1	1	1
47	CMP	47	Female	0	0	0
49	L-R	58	Female	0	0	-1
51	PCB	59	Female	0	0	0
54*	TWS	55	Female			
57	MDS	52	Female	-1	-1	-1
59	GFM	64	Female	-1	-1	-1
60	JLF	32	Female	0	0	0
61	GEP	53	Female			
64	KKF	36	Female	0	0	0
65	EMM	39	Female	0	0	-1
66	CYR	39	Female	-1	-1	-1
67	AMM	37	Female	0	0	0
			Mean	-0.25	-0.32	-0.37
			SD	0.59	0.61	0.63
			Median	0.00	0.00	0.00
			N	28	28	27

<sup>1 =</sup> Excellent Improvement (~100%) 2 = Marked Improvement (~75%) 3 = Moderate Improvement (~50%) 4 = Slight Improvement (~25%) 5 = No Improvement (0%) 6 = Worse

#### Expert Assessment of Skin Irritation

					Expert As	ssessment of Ski	n Irritation	
Subject No.	Subject Initials	Age	Sex	Baseline	Week 2	Week 4	Week 8	Week 12
1	SDC	40	Female	1				
2	MLE	50	Female	1	1	1	1	0
3	SKH	47	Female	0	0	0	0	0
7	DBK	52	Female	1	1	1	0	0
8	JCF	54	Female	1	0	0	0	0
9	JRB	53	Female	1				
12	EFK	57	Female	1	1	1	0	0
17	BFH	59	Female	1	1	1	1	0
18	LJR	58	Female	0	1	0	0	0
19	D-M	58	Female	1	0	0	0	0
20	RLA	45	Female					
21	LGD	57	Female	1	1	1	0	0
24	VIP	52	Female	1	1	0	0	0
26	PKM	46	Female	2	2	2	2	
27	SMM	59	Female	0	0	0	0	0
28	EJD	56	Female	1				
31	JAC	56	Female	1	0	0	0	0
32	TML	38	Female	1	0	0	0	0
39	DKD	50	Female	2	1	1	1	1
40	CLM	43	Female	1	1	1	1	1
44	GSR	52	Female	1	1	0	0	0
46	LAA	55	Female	1	1	0	0	0
47	CMP	47	Female	1	1	1	1	0
49	L-R	58	Female	1	1	0	0	0
51	PCB	59	Female	1	0	0	0	0
54	TWS	55	Female	1	1			
57	MDS	52	Female	1	1	1	0	0
59	GFM	64	Female	1	1	0	0	0
60	JLF	32	Female	1	0	0	0	1
61	GEP	53	Female	1				
64	KKF	36	Female	1	1	0	1	0
65	EMM	39	Female	1	0	0	0	0
66	CYR	39	Female	1	0	0	0	0
67	AMM	37	Female	1	1	1	1	1
	Discontinu	ıed	Mean	0.97	0.69	0.43	0.32	0.15
			SD	0.42	0.54	0.57	0.55	0.36
			Median	1.00	1.00	0.00	0.00	0.00
0 - None			N	29	29	28	28	27

				Expert Assessment of Skin Irritation Intra-Subject Change					
Subject	Subject	۸۰۰	Sex	Week 2 Minus	Week 4 Minus	Week 8 Minus	Week 12 Minus		
No.	Initials	Age	Sex	Baseline	Baseline	Baseline	Baseline		
1	SDC	40	Female						
2	MLE	50	Female	0	0	0	-1		
3	SKH	47	Female	0	0	0	0		
7	DBK	52	Female	0	0	-1	-1		
8	JCF	54	Female	-1	-1	-1	-1		
9	JRB	53	Female						
12	EFK	57	Female	0	0	-1	-1		
17	BFH	59	Female	0	0	0	-1		
18	LJR	58	Female	1	0	0	0		
19	D-M	58	Female	-1	-1	-1	-1		
20	RLA	45	Female						
21	LGD	57	Female	0	0	-1	-1		
24	VIP	52	Female	0	-1	-1	-1		
26	PKM	46	Female	0	0	0			
27	SMM	59	Female	0	0	0	0		
28	EJD	56	Female						
31	JAC	56	Female	-1	-1	-1	-1		
32	TML	38	Female	-1	-1	-1	-1		
39	DKD	50	Female	-1	-1	-1	-1		
40	CLM	43	Female	0	0	0	0		
44	GSR	52	Female	0	-1	-1	-1		
46	LAA	55	Female	0	-1	-1	-1		
47	CMP	47	Female	0	0	0	-1		
49	L-R	58	Female	0	-1	-1	-1		
51	PCB	59	Female	-1	-1	-1	-1		
54	TWS	55	Female	0					
57	MDS	52	Female	0	0	-1	-1		
59	GFM	64	Female	0	-1	-1	-1		
60	JLF	32	Female	-1	-1	-1	0		
61	GEP	53	Female						
64	KKF	36	Female	0	-1	0	-1		
65	EMM	39	Female	-1	-1	-1	-1		
66	CYR	39	Female	-1	-1	-1	-1		
67	AMM	37	Female	0	0	0	0		
			Mean	-0.28	-0.54	-0.64	-0.78		
			SD	0.53	0.51	0.49	0.42		
			Median	0.00	-1.00	-1.00	-1.00		

<sup>0 =</sup> None 1 = Mild 2 = Moderate 3 = Severe

#### Expert Assessment of Overall Severity (Acne)

Subject No.	Subject	Age	Sex	Baseline	Week 2	Week 4	Week 8	Week 12
1	SDC	40	Female	1				
2	MLE	50	Female	1	1	0	1	0
3	SKH	47	Female	0	0	0	0	0
7	DBK	52	Female	1	0	0	1	0
8	JCF	54	Female	0	1	0	1	0
9	JRB	53	Female	1				
12	EFK	57	Female	0	0	0	1	1
17	BFH	59	Female	1	1	1	0	1
18	LJR	58	Female	1	1	0	0	0
19	D-M	58	Female	1	1	0	0	1
20	RLA	45	Female					
21	LGD	57	Female	1	1	1	1	1
24	VIP	52	Female	0	1	1	0	1
26	PKM	46	Female	1	0	1	0	
27	SMM	59	Female	0	1	0	0	0
28	EJD	56	Female	1				
31	JAC	56	Female	0	1	0	0	1
32	TML	38	Female	0	1	1	1	1
39	DKD	50	Female	1	0	1	1	1
40	CLM	43	Female	1	1	1	1	1
44	GSR	52	Female	1	1	1	1	1
46	LAA	55	Female	0	0	0	0	1
47	CMP	47	Female	1	0	1	0	0
49	L-R	58	Female	0	0	0	0	0
51	PCB	59	Female	0	1	0	0	0
54	TWS	55	Female	1	0			
57	MDS	52	Female	1	0	0	1	0
59	GFM	64	Female	1	1	1	1	0
60	JLF	32	Female	1	1	1	1	1
61	GEP	53	Female	1				
64	KKF	36	Female	1	1	2	1	1
65	EMM	39	Female	1	1	1	1	0
66	CYR	39	Female	1	1	1	1	1
67	AMM	37	Female	1	1	1	1	1
	Discontinu	ied	Mean	0.66	0.66	0.57	0.57	0.56
			SD	0.48	0.48	0.57	0.50	0.51
			Median	1.00	1.00	1.00	1.00	1.00
			N	29	29	28	28	27
= None = Mild								

				Expert	Assessment of Overall Se	everity (Acne) Intra-Subject	Change
Subject No.	Subject Initials	Age	Sex	Week 2 Minus Baseline	Week 4 Minus Baseline	Week 8 Minus Baseline	Week 12 Minus Baseline
1	SDC	40	Female				
2	MLE	50	Female	0	-1	0	-1
3	SKH	47	Female	0	0	0	0
7	DBK	52	Female	-1	-1	0	-1
8	JCF	54	Female	1	0	1	0
9	JRB	53	Female				
12	EFK	57	Female	0	0	1	1
17	BFH	59	Female	0	0	-1	0
18	LJR	58	Female	0	-1	-1	-1
19	D-M	58	Female	0	-1	-1	0
20	RLA	45	Female				
21	LGD	57	Female	0	0	0	0
24	VIP	52	Female	1	1	0	1
26	PKM	46	Female	-1	0	-1	
27	SMM	59	Female	1	0	0	0
28	EJD	56	Female				
31	JAC	56	Female	1	0	0	1
32	TML	38	Female	1	1	1	1
39	DKD	50	Female	-1	0	0	0
40	CLM	43	Female	0	0	0	0
44	GSR	52	Female	0	0	0	0
46	LAA	55	Female	0	0	0	1
47	CMP	47	Female	-1	0	-1	-1
49	L-R	58	Female	0	0	0	0
51	PCB	59	Female	1	0	0	0
54	TWS	55	Female	-1			
57	MDS	52	Female	-1	-1	0	-1
59	GFM	64	Female	0	0	0	-1
60	JLF	32	Female	0	0	0	0
61	GEP	53	Female				
64	KKF	36	Female	0	1	0	0
65	EMM	39	Female	0	0	0	-1
66	CYR	39	Female	0	0	0	0
67	AMM	37	Female	0	0	0	0
			Mean	0.00	-0.07	-0.07	-0.07
			SD	0.65	0.54	0.54	0.68
			Madian	0.00			

#### Inflammatory Lesion Count

					Inflammato	ory Lesion Count	(Forehead)	
Subject No.	Subject Initials	Age	Sex	Baseline	Week 2	Week 4	Week 8	Week 12
1	SDC	40	Female	0				
2	MLE	50	Female	0	1	0	1	0
3	SKH	47	Female	0	0	0	0	0
7	DBK	52	Female	0	0	0	0	0
8	JCF	54	Female	0	1	0	1	0
9	JRB	53	Female	1				
12	EFK	57	Female	0	0	0	1	0
17	BFH	59	Female	0	0	0	0	0
18	LJR	58	Female	0	0	0	0	0
19	D-M	58	Female	0	0	0	0	1
20	RLA	45	Female					
21	LGD	57	Female	0	0	6	0	0
24	VIP	52	Female	0	0	0	0	0
26	PKM	46	Female	1	0	2	0	
27	SMM	59	Female	0	0	0	0	0
28	EJD	56	Female	0				
31	JAC	56	Female	0	2	0	0	0
32	TML	38	Female	0	2	0	1	0
39	DKD	50	Female	0	0	2	0	1
40	CLM	43	Female	0	2	1	1	0
44	GSR	52	Female	0	0	0	0	0
46	LAA	55	Female	0	0	0	0	0
47	CMP	47	Female	1	0	0	0	0
49	L-R	58	Female	0	0	0	0	0
51	PCB	59	Female	0	0	0	0	0
54	TWS	55	Female	2	0			
57	MDS	52	Female	1	0	0	0	0
59	GFM	64	Female	0	0	0	0	0
60	JLF	32	Female	0	0	2	4	0
61	GEP	53	Female	2				
64	KKF	36	Female	0	0	1	2	1
65	EMM	39	Female	4	1	1	0	0
66	CYR	39	Female	1	2	0	0	0
67	AMM	37	Female	0	0	0	0	0
	Discontinu	Jed	Mean	0.34	0.38	0.54	0.39	0.11
			SD	0.86	0.73	1.26	0.88	0.32
			Median	0.00	0.00	0.00	0.00	0.00
			N	29	29	28	28	27

				Infl	ammatory Lesion Count (F	Forehead) Intra-Subject C	hange		
Subject No.	Subject Initials	Age	Sex	Week 2 Minus Baseline	Week 4 Minus Baseline	Week 8 Minus Baseline	Week 12 Minus Baseline		
1	SDC	40	Female						
2	MLE	50	Female	1	0	1	0		
3	SKH	47	Female	0	0	0	0		
7	DBK	52	Female	0	0	0	0		
8	JCF	54	Female	1	0	1	0		
9	JRB	53	Female						
12	EFK	57	Female	0	0	1	0		
17	BFH	59	Female	0	0	0	0		
18	LJR	58	Female	0	0	0	0		
19	D-M	58	Female	0	0	0	1		
20	RLA	45	Female						
21	LGD	57	Female	0	6	0	0		
24	VIP	52	Female	0	0	0	0		
26	PKM	46	Female	-1	1	-1			
27	SMM	59	Female	0	0	0	0		
28	EJD	56	Female						
31	JAC	56	Female	2	0	0	0		
32	TML	38	Female	2	0	1	0		
39	DKD	50	Female	0	2	0	1		
40	CLM	43	Female	2	1	1	0		
44	GSR	52	Female	0	0	0	0		
46	LAA	55	Female	0	0	0	0		
47	CMP	47	Female	-1	-1	-1	-1		
49	L-R	58	Female	0	0	0	0		
51	PCB	59	Female	0	0	0	0		
54	TWS	55	Female	-2					
57	MDS	52	Female	-1	-1	-1	-1		
59	GFM	64	Female	0	0	0	0		
60	JLF	32	Female	0	2	4	0		
61	GEP	53	Female						
64	KKF	36	Female	0	1	2	1		
65	EMM	39	Female	-3	-3	-4	-4		
66	CYR	39	Female	1	-1	-1	-1		
67	AMM	37	Female	0	0	0	0		
		•	Mean	0.03	0.25	0.11	-0.15		
			SD	1.05	1.46	1.29	0.91		
			Median	0.00	0.00	0.00	0.00		
			N	29	28	28	27		

#### Inflammatory Lesion Count

				Inflammatory Lesion Count (Left Cheek)							
Subject No.	Subject Initials	Age	Sex	Baseline	Week 2	Week 4	Week 8	Week 12			
1	SDC	40	Female	0							
2	MLE	50	Female	2	1	0	0	0			
3	SKH	47	Female	0	0	0	0	0			
7	DBK	52	Female	0	0	0	0	0			
8	JCF	54	Female	0	0	0	0	0			
9	JRB	53	Female	0							
12	EFK	57	Female	0	0	0	0	1			
17	BFH	59	Female	0	0	0	0	0			
18	LJR	58	Female	0	2	0	0	0			
19	D-M	58	Female	0	0	0	0	0			
20	RLA	45	Female								
21	LGD	57	Female	1	0	1	1	0			
24	VIP	52	Female	0	0	0	0	1			
26	PKM	46	Female	0	0	0	0				
27	SMM	59	Female	0	0	0	0	0			
28	EJD	56	Female	0							
31	JAC	56	Female	0	0	0	0	0			
32	TML	38	Female	0	0	0	0	0			
39	DKD	50	Female	0	0	0	0	1			
40	CLM	43	Female	0	0	2	0	0			
44	GSR	52	Female	0	0	1	0	0			
46	LAA	55	Female	0	0	0	0	1			
47	CMP	47	Female	1	0	0	0	0			
49	L-R	58	Female	0	0	0	0	0			
51	PCB	59	Female	0	0	0	0	0			
54	TWS	55	Female	0	0						
57	MDS	52	Female	0	0	0	0	0			
59	GFM	64	Female	0	0	0	0	0			
60	JLF	32	Female	2	5	0	4	4			
61	GEP	53	Female	0							
64	KKF	36	Female	0	0	2	0	0			
65	EMM	39	Female	1	1	0	0	0			
66	CYR	39	Female	1	0	0	0	1			
67	AMM	37	Female	0	2	2	1	0			
			Mean	0.28	0.38	0.29	0.21	0.33			
			SD	0.59	1.05	0.66	0.79	0.83			
			Median	0.00	0.00	0.00	0.00	0.00			
			N	29	29	28	28	27			

				1-8-	ammatory Lesion Count (L	-#-ObII) I-t Oubla-+ O	h		
				Inna	immatory Lesion Count (L	en Cheek) intra-Subject C	nange		
Subject	Subject	Age	Sex	Week 2 Minus Baseline	Week 4 Minus Baseline	Week 8 Minus Baseline	Week 12 Minus Baseline		
No.	Initials	-		Week 2 Millios Dascille	Week 4 Millios Dascillie	Week o Milios Dascille	Week 12 Willias Daseille		
1	SDC	40	Female						
2	MLE	50	Female	-1	-2	-2	-2		
3	SKH	47	Female	0	0	0	0		
7	DBK	52	Female	0	0	0	0		
8	JCF	54	Female	0	0	0	0		
9	JRB	53	Female						
12	EFK	57	Female	0	0	0	1		
17	BFH	59	Female	0	0	0	0		
18	LJR	58	Female	2	0	0	0		
19	D-M	58	Female	0	0	0	0		
20	RLA	45	Female						
21			Female	-1	0	0	-1		
24			Female	0	0	0	1		
26						0	0	0	
27	SMM	59	Female	0	0	0	0		
28	EJD	56	Female						
31	JAC	56	Female	0	0	0	0		
32	TML	38	Female	0	0	0	0		
39	DKD	50	Female	0	0	0	1		
40	CLM	43	Female	0	2	0	0		
44	GSR	52	Female	0	1	0	0		
46	LAA	55	Female	0	0	0	1		
47	CMP	47	Female	-1	-1	-1	-1		
49	L-R	58	Female	0	0	0	0		
51	PCB	59	Female	0	0	0	0		
54	TWS	55	Female	0					
57	MDS	52	Female	0	0	0	0		
59	GFM	64	Female	0	0	0	0		
60	JLF	32	Female	3	-2	2	2		
61	GEP	53	Female						
64	KKF	36	Female	0	2	0	0		
65	EMM	39	Female	0	-1	-1	-1		
66	CYR	39	Female	-1	-1	-1	0		
67	AMM	37	Female	2	2	1	0		
			Mean	0.10	0.00	-0.07	0.04		
			SD	0.86	0.94	0.66	0.76		
			Median	0.00	0.00	0.00	0.00		
			N	29	28	28	27		

				Inflammatory Lesion Count (Right Cheek)						
Subject No.	Subject Initials	Age	Sex	Baseline	Week 2	Week 4	Week 8	Week 12		
1	SDC	40	Female	0						
2	MLE	50	Female	2	1	0	2	0		
3	SKH	47	Female	0	0	0	0	0		
7	DBK	52	Female	0	0	0	0	0		
8	JCF	54	Female	0	2	0	0	0		
9	JRB	53	Female	0						
12	EFK	57	Female	0	0	0	1	0		
17	BFH	59	Female	0	0	1	0	0		
18	LJR	58	Female	0	2	0	0	0		
19	D-M	58	Female	0	0	0	0	0		
20	RLA	45	Female							
21	LGD	57	Female	1	0	1	0	0		
24	VIP	52	Female	0	1	1	0	2		
26	PKM	46	Female	0	0	1	0			
27	SMM	59	Female	0	0	0	0	0		
28	EJD	56	Female	0						
31	JAC	56	Female	0	0	0	0	1		
32	TML	38	Female	0	0	0	1	0		
39	DKD	50	Female	0	0	0	0	0		
40	CLM	43	Female	0	0	3	0	0		
44	GSR	52	Female	0	0	0	0	1		
46	LAA	55	Female	0	0	0	0	0		
47	CMP	47	Female	0	0	ō	ō	ō		
49	L-R	58	Female	Ó	0	0	0	0		
51	PCB	59	Female	0	0	0	0	0		
54	TWS	55	Female	1	0					
57	MDS	52	Female	0	0	0	0	0		
59	GFM	64	Female	0	0	0	0	ō		
60	JLF	32	Female	1	3	2	8	6		
61	GEP	53	Female	0		_	_	_		
64	KKF	36	Female	1	0	1	1	0		
65	EMM	39	Female	0	0	0	Ó	ō		
66	CYR	39	Female	ō	1	1	1	1 1		
67	AMM	37	Female	ō	1	1	0	1		
			Mean	0.21	0.38	0.43	0.50	0.44		
			SD	0.49	0.78	0.74	1.55	1.22		
			Median	0.00	0.00	0.00	0.00	0.00		
			N	29	29	28	28	27		

Subject   Subject   No.   Initial   Age   Sex   Week 2 Minus Baseline   Week 4 Minus Baseline   Week 12 Minus Baseline   1	
2	aseline
3	
T	
B   JCF   54   Female   2   0   0   0   0     9   JRB   53   Female       12   EFK   57   Female   0   0   1   0   0     17   BFH   59   Female   0   0   0   0   0     18   LJR   58   Female   2   0   0   0   0     19   D-M   58   Female   2   0   0   0   0     20   RLA   45   Female       21   LGD   57   Female   -1   0   -1   -1   -1     24   VIP   52   Female   0   0   0   0     26   FKM   46   Female   0   0   0   0     27   SMM   59   Female   0   0   0   0     28   EJD   56   Female   0   0   0     31   JAC   56   Female   0   0   0   1     32   TML   38   Female   0   0   0   1     39   DKD   50   Female   0   0   0   0     40   CLM   43   Female   0   0   0   0     41   GSR   52   Female   0   0   0   0     42   CLM   43   Female   0   0   0   0     43   Female   0   0   0   0     44   CLM   43   Female   0   0   0   0     45   CLM   47   Female   0   0   0   0     47   CMP   47   Female   0   0   0   0     51   PCB   59   Female   0   0   0   0     51   TWS   55   Female   0   0   0   0     55   GFM   64   Female   0   0   0   0     56   GFM   64   Female   0   0   0   0     57   MDS   52   Female   0   0   0   0     58   GFM   64   Female   0   0   0   0     59   GFM   64   Female   0   0   0   0     50   GFM   64   Female   0   0   0   0	
9	
12	
17	
18	
19	
20	
21	
24	
26	
27   SMM   59   Female   0   0   0   0   0   0   0   0   0	
28	
31	
32	
39	
40	
44         GSR         52         Female         0         0         1           46         LAA         55         Female         0         0         0         0           47         CMP         47         Female         0         0         0         0         0           51         PCB         59         Female         0         0         0         0         0           54         TWS         55         Female         -1 <td< td=""><td></td></td<>	
46         LAA         55         Female         0	
47         CMP         47         Female         0	
49         L-R         58         Female         0         0         0         0           51         PCB         59         Female         0         0         0         0         0           54         TWS         55         Female         -1         -1	
51         PCB         59         Female         0         0         0         0           54         TWS         55         Female         -1 <t< td=""><td></td></t<>	
54         TWS         55         Female         -1           57         MDS         52         Female         0         0         0           59         GFM         64         Female         0         0         0         0	
57         MDS         52         Female         0         0         0         0           59         GFM         64         Female         0         0         0         0	
59 GFM 64 Female 0 0 0 0	
60 JLF 32 Female 2 1 7 5	
61 GEP 53 Female	
64 KKF 36 Female -1 0 0 -1	
65 EMM 39 Female 0 0 0 0	
66 CYR 39 Female 1 1 1 1	
67 AMM 37 Female 1 1 0 1	
Mean 0.17 0.25 0.32 0.26	
SD 0.80 0.80 1.36 1.20	
Median 0.00 0.00 0.00 0.00	
N 29 28 28 27	

				Inflammatory Lesion Count (Chin)							
Subject No.	Subject Initials	Age	Sex	Baseline	Week 2	Week 4	Week 8	Week 12			
1	SDC	40	Female	3							
2	MLE	50	Female	0	0	0	0	0			
3	SKH	47	Female	0	0	0	0	0			
7	DBK	52	Female	0	0	0	0	0			
8	JCF	54	Female	0	0	0	0	0			
9	JRB	53	Female	0							
12	EFK	57	Female	0	0	0	0	0			
17	BFH	59	Female	1	1	0	0	0			
18	LJR	58	Female	0	0	0	0	0			
19	D-M	58	Female	2	0	0	0	0			
20	RLA	45	Female								
21	LGD	57	Female	0	0	1	0	1			
24	VIP	52	Female	0	0	1	0	0			
26	PKM	46	Female	0	0	0	0				
27	SMM	59	Female	0	1	0	0	0			
28	EJD	56	Female	2							
31	JAC	56	Female	0	0	0	0	1			
32	TML	38	Female	0	2	0	0	2			
39	DKD	50	Female	1	0	0	0	0			
40	CLM	43	Female	0	2	2	1	0			
44	GSR	52	Female	0	0	0	0	0			
46	LAA	55	Female	0	0	0	0	0			
47	CMP	47	Female	0	0	0	0	0			
49	L-R	58	Female	0	0	0	0	0			
51	PCB	59	Female	0	2	0	0	0			
54	TWS	55	Female	1	0						
57	MDS	52	Female	0	0	0	0	0			
59	GFM	64	Female	0	0	0	0	0			
60	JLF	32	Female	1	4	2	3	5			
61	GEP	53	Female	0							
64	KKF	36	Female	0	2	1	1	0			
65	EMM	39	Female	0	0	0	0	0			
66	CYR	39	Female	2	1	2	1	0			
67	AMM	37	Female	3	0	0	1	1			
			Mean	0.38	0.52	0.32	0.25	0.37			
			SD	0.78	0.99	0.67	0.65	1.04			
			8.4 II	0.00	0.00	0.00	0.00	0.00			

				1	nflammatory Lesion Count	t (Chin) Intra-Subject Char	nge				
Subject	Subject	Age	Sex	Week 2 Minus Baseline	Week 4 Minus Baseline	Week 8 Minus Baseline	Week 12 Minus Baseline				
No.	Initials	-									
1	SDC	40	Female								
2	MLE	50	Female	0	0	0	0				
3	SKH	47	Female	0	0	0	0				
7	DBK	52	Female			0	0				
8	JCF	54	Female	0	0	0	0				
9	JRB	53	Female								
12	EFK	57	Female	0	0	0	0				
17	BFH	59	Female	0	-1	-1	-1				
18	LJR	58	Female	0	0	0	0				
19	D-M	58	Female	-2	-2	-2	-2				
20	RLA	45	Female								
21	LGD	57	Female	0	1	0	1				
24			Female	0	1	0	0				
26	PKM	46 Female		0	0	0					
27	SMM	59	Female	1	0	0	0				
28	EJD	56	Female								
31	JAC	56	Female	0	0	0	1				
32	TML	38	Female	2	0	0	2				
39	DKD	50	Female	-1	-1	-1	-1				
40	CLM	43	Female	2	2	1	0				
44	GSR	52	Female	0	0	0	0				
46	LAA	55	Female	0	0	0	0				
47	CMP	47	Female	0	0	0	0				
49	L-R	58	Female	0	0	0	0				
51	PCB	59	Female	2	0	0	0				
54	TWS	55	Female	-1							
57	MDS	52	Female	0	0	0	0				
59	GFM	64	Female	0	0	0	0				
60	JLF	32	Female	3	1	2	4				
61	GEP	53	Female								
64	KKF	36	Female	2	1	1	0				
65	EMM	39	Female	0	0	0	0				
66	CYR	39	Female	-1	0	-1	-2				
67	AMM	37	Female	-3	-3	-2	-2				
			Mean	0.14	-0.04	-0.11	0.00				
			SD	1.22	0.92	0.79	1.18				
			Median	0.00	0.00	0.00	0.00				
			N	29	28	28	27				

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				N	on-Inflammat	ory Lesion Co	ount (Forehea	d)
Subject No.	Subject Initials	Age	Sex	Baseline	Week 2	Week 4	Week 8	Week 12
- 1	SDC	40	Female	6				
2	MLE	50	Female	0	0	0	0	0
3	SKH	47	Female	0	0	0	0	0
7	DBK	52	Female	0	0	0	1	1
8	JCF	54	Female	0	1	0	0	0
9	JRB	53	Female	3				
12	EFK	57	Female	0	0	0	0	0
17	BFH	59	Female	0	0	0	0	2
18	LJR	58	Female	0	0	0	0	0
19	D-M	58	Female	0	0	0	0	0
20	RLA	45	Female					
21	LGD	57	Female	2	1	6	0	3
24	VIP	52	Female	0	3	2	0	0
26	PKM	46	Female	0	0	0	0	
27	SMM	59	Female	0	0	0	0	0
28	EJD	56	Female	4				
31	JAC	56	Female	0	0	0	0	0
32	TML	38	Female	0	0	3	0	2
39	DKD	50	Female	3	0	0	4	2
40	CLM	43	Female	7	0	1	5	3
44	GSR	52	Female	0	0	o o	ō	ō
46	LAA	55	Female	0	0	ō	ō	ō
47	CMP	47	Female	1	0	0	0	0
49	L-R	58	Female	0	0	0	0	0
51	PCB	59	Female	0	Ō	ō	ō	0
54	TWS	55	Female	0	0			
57	MDS	52	Female	0	0	0	0	0
59	GFM	64	Female	0	ō	ō	ō	0
60	JLF	32	Female	3	ō	ō	ō	0
61	GEP	53	Female	0	-	_	-	-
64	KKF	36	Female	0	0	7	0	0
65	EMM	39	Female	7	ō	2	ő	ő
66	CYR	39	Female	0	ō	0	ō	0
67	AMM	37	Female	2	ő	0	0	0
	Discontinu		Mean	0.86	0.17	0.75	0.36	0.48
			SD	1.92	0.60	1.80	1.19	0.98
			Median	0.00	0.00	0.00	0.00	0.00

				Non-	-Inflammatory Lesion Count	(Forehead) Intra-Subject Ch	hange
Subject No.	Subject Initials	Age	Sex	Week 2 Minus Baseline	Week 4 Minus Baseline	Week 8 Minus Baseline	Week 12 Minus Baseline
1	SDC	40	Female				
2	MLE	50	Female	0	0	0	0
3	SKH	47	Female	0	0	0	0
7	DBK	52	Female	0	0	1	1
8	JCF	54	Female	1	0	0	0
9	JRB	53	Female				
12	EFK	57	Female	0	0	0	0
17	BFH	59	Female	0	0	0	2
18	LJR	58	Female	0	0	0	0
19	D-M	58	Female	0	0	0	0
20	RLA	45	Female				
21	LGD	57	Female	-1	4	-2	1
24	VIP	52	Female	3	2	0	0
26	PKM	46	Female	0	0	0	
27	SMM	59	Female	0	0	0	0
28	EJD	56	Female				
31	JAC	56	Female	0	0	0	0
32	TML	38	Female	0	3	0	2
39	DKD	50	Female	-3	-3	1	-1
40	CLM	43	Female	-7	-6	-2	-4
44	GSR	52	Female	0	0	0	0
46	LAA	55	Female	0	0	0	0
47	CMP	47	Female	-1	-1	-1	-1
49	L-R	58	Female	0	0	0	0
51	PCB	59	Female	0	0	0	0
54	TWS	55	Female	0			
57	MDS	52	Female	0	0	0	0
59	GFM	64	Female	0	0	0	0
60	JLF	32	Female	-3	-3	-3	-3
61	GEP	53	Female				
64	KKF	36	Female	0	7	0	0
65	EMM	39	Female	-7	-5	-7	-7
66	CYR	39	Female	0	0	0	0
67	AMM	37	Female	-2	-2	-2	-2
			Mean	-0.69	-0.14	-0.54	-0.44
			SD	2.05	2.45	1.55	1.80
			Median	0.00	0.00	0.00	0.00
			N	20	20	20	27

				No	on-Inflammate	ory Lesion Co	unt (Left Che	ek)
Subject No.	Subject Initials	Age	Sex	Baseline	Week 2	Week 4	Week 8	Week 12
1	SDC	40	Female	8				
2	MLE	50	Female	0	1	0	0	0
3	SKH	47	Female	0	0	0	0	0
7	DBK	52	Female	2	0	0	0	1
8	JCF	54	Female	0	0	0	0	0
9	JRB	53	Female	0				
12	EFK	57	Female	0	0	0	0	0
17	BFH	59	Female	0	0	0	0	1
18	LJR	58	Female	0	0	0	0	0
19	D-M	58	Female	1	1	0	0	2
20	RLA	45	Female					
21	LGD	57	Female	0	1	3	0	0
24	VIP	52	Female	0	0	0	0	0
26	PKM	46	Female	0	0	0	0	
27	SMM	59	Female	0	0	0	0	0
28	EJD	56	Female	2				
31	JAC	56	Female	0	0	0	0	0
32	TML	38	Female	0	0	0	0	0
39	DKD	50	Female	1	0	0	3	0
40	CLM	43	Female	0	2	0	0	0
44	GSR	52	Female	0	0	0	1	0
46	LAA	55	Female	0	0	0	0	0
47	CMP	47	Female	0	0	1	0	0
49	L-R	58	Female	0	0	0	0	0
51	PCB	59	Female	0	0	0	0	0
54	TWS	55	Female	0	0			
57	MDS	52	Female	0	0	0	2	2
59	GFM	64	Female	2	1	1	1	0
60	JLF	32	Female	3	0	1	0	0
61	GEP	53	Female	0				
64	KKF	36	Female	3	2	8	4	0
65	EMM	39	Female	6	0	1	3	0
66	CYR	39	Female	1	0	1	0	0
67	AMM	37	Female	2	4	4	0	3
			Mean	0.72	0.41	0.71	0.50	0.33
			SD	1.39	0.91	1.72	1.11	0.78
			Median	0.00	0.00	0.00	0.00	0.00
			N	29	29	28	28	27
	Discontinu	ued						

				Non-	Inflammatory Lesion Count (	(Left Cheek) Intra-Subject C	hange
Subject No.	Subject Initials	Age	Sex	Week 2 Minus Baseline	Week 4 Minus Baseline	Week 8 Minus Baseline	Week 12 Minus Baseline
1	SDC	40	Female				
2	MLE	50	Female	1	0	0	0
3	SKH	47	Female	0	0	0	0
7	DBK	52	Female	-2	-2	-2	-1
8	JCF	54	Female	0	0	0	0
9	JRB	53	Female				
12	EFK	57	Female	0	0	0	0
17	BFH	59	Female	0	0	0	1
18	LJR	58	Female	0	0	0	0
19	D-M	58	Female	0	-1	-1	1
20	RLA	45	Female				
21	LGD	57	Female	1	3	0	0
24	VIP	52	Female	0	0	0	0
26	PKM	46	Female	0	0	0	
27	SMM	59	Female	0	0	0	0
28	EJD	56	Female				
31	JAC	56	Female	0	0	0	0
32	TML	38	Female	0	0	0	0
39	DKD	50	Female	-1	-1	2	-1
40	CLM	43	Female	2	0	0	0
44	GSR	52	Female	0	O	1	0
46	LAA	55	Female	0	0	0	0
47	CMP	47	Female	0	1	0	0
49	L-R	58	Female	0	0	0	0
51	PCB	59	Female	0	0	0	0
54	TWS	55	Female	Ō			-
57	MDS	52	Female	0	0	2	2
59	GFM	64	Female	-1	-1	-1	-2
60	JLF	32	Female	-3	-2	-3	-3
61	GEP	53	Female				
64	KKF	36	Female	-1	5	1	-3
65	EMM	39	Female	-6	-5	-3	-6
66	CYR	39	Female	-1	0	-1	-1
67	AMM	37	Female	2	2	-2	1
			Mean	-0.31	-0.04	-0.25	-0.44
			SD	1.47	1.67	1.17	1.55
			Modion	0.00	0.00	0.00	0.00

				Non-Inflammatory Lesion Count (Right Cheek)						
Subject No.	Subject Initials	Age	Sex	Baseline	Week 2	Week 4	Week 8	Week 12		
1	SDC	40	Female	8						
2	MLE	50	Female	0	2	0	0	0		
3	SKH	47	Female	0	0	0	0	0		
7	DBK	52	Female	1	0	0	0	0		
8	JCF	54	Female	0	0	0	0	0		
9	JRB	53	Female	0						
12	EFK	57	Female	0	0	0	0	0		
17	BFH	59	Female	0	2	0	0	0		
18	LJR	58	Female	2	0	0	0	0		
19	D-M	58	Female	2	4	0	0	0		
20	RLA	45	Female							
21	LGD	57	Female	0	0	2	0	2		
24	VIP	52	Female	0	0	1	0	1		
26	PKM	46	Female	2	0	0	0			
27	SMM	59	Female	0	1	0	0	0		
28	EJD	56	Female	3						
31	JAC	56	Female	0	0	0	0	0		
32	TML	38	Female	0	0	0	0	0		
39	DKD	50	Female	0	0	0	1	0		
40	CLM	43	Female	0	1	2	3	2		
44	GSR	52	Female	4	1	1	1	1		
46	LAA	55	Female	0	0	0	0	2		
47	CMP	47	Female	0	0	1	0	0		
49	L-R	58	Female	0	0	0	0	0		
51	PCB	59	Female	0	0	0	0	0		
54	TWS	55	Female	1	0					
57	MDS	52	Female	1	0	0	2	1		
59	GFM	64	Female	1	2	0	1	0		
60	JLF	32	Female	7	0	1	2	0		
61	GEP	53	Female	0						
64	KKF	36	Female	0	3	14	2	0		
65	EMM	39	Female	9	4	2	8	0		
66	CYR	39	Female	2	0	2	0	0		
67	AMM	37	Female	0	0	0	0	4		
			Mean	1.10	0.69	0.93	0.71	0.48		
			SD	2.16	1.23	2.67	1.65	0.98		
			Median	0.00	0.00	0.00	0.00	0.00		
			N	29	29	28	28	27		

				Non-Ir	nflammatory Lesion Count (I	Right Cheek) Intra-Subject (	Change
Subject No.	Subject Initials	Age	Sex	Week 2 Minus Baseline	Week 4 Minus Baseline	Week 8 Minus Baseline	Week 12 Minus Baseline
1	SDC	40	Female				
2	MLE	50	Female	2	0	0	0
3	SKH	47	Female	0	0	0	0
7	DBK	52	Female	-1	-1	-1	-1
8	JCF	54	Female	0	0	0	0
9	JRB	53	Female				
12	EFK	57	Female	0	0	0	0
17	BFH	59	Female	2	0	0	0
18	LJR	58	Female	-2	-2	-2	-2
19	D-M	58	Female	2	-2	-2	-2
20	RLA	45	Female				
21	LGD	57	Female	0	2	0	2
24	VIP	52	Female	0	1	0	1
26	PKM	46	Female	-2	-2	-2	
27	SMM	59	Female	1	0	0	0
28	EJD	56	Female				
31	JAC	56	Female	0	0	0	0
32	TML	38	Female	0	0	0	0
39	DKD	50	Female	0	0	1	0
40	CLM	43	Female	1	2	3	2
44	GSR	52	Female	-3	-3	-3	-3
46	LAA	55	Female	0	0	0	2
47	CMP	47	Female	0	1	0	0
49	L-R	58	Female	0	0	0	0
51	PCB	59	Female	0	0	0	0
54	TWS	55	Female	-1			
57	MDS	52	Female	-1	-1	1	0
59	GFM	64	Female	1	-1	0	-1
60	JLF	32	Female	-7	-6	-5	-7
61	GEP	53	Female				
64	KKF	36	Female	3	14	2	0
65	EMM	39	Female	-5	-7	-1	-9
66	CYR	39	Female	-2	0	-2	-2
67	AMM	37	Female	0	0	0	4
			Mean	-0.41	-0.18	-0.39	-0.59
			SD	2.04	3.41	1.52	2.58
			Median	0.00	0.00	0.00	0.00
			N	29	28	28	27

					Non-Inflamm	natory Lesion	Count (Chin)	
Subject No.	Subject Initials	Age	Sex	Baseline	Week 2	Week 4	Week 8	Week 12
1	SDC	40	Female	2				
2	MLE	50	Female	0	0	0	1	0
3	SKH	47	Female	0	0	0	0	0
7	DBK	52	Female	0	0	0	0	0
8	JCF	54	Female	0	0	0	0	0
9	JRB	53	Female	0				
12	EFK	57	Female	0	0	0	0	0
17	BFH	59	Female	0	0	0	0	1
18	LJR	58	Female	0	0	0	0	0
19	D-M	58	Female	0	0	0	0	0
20	RLA	45	Female					
21	LGD	57	Female	1	0	3	1	0
24	VIP	52	Female	0	1	0	0	0
26	PKM	46	Female	0	0	0	0	
27	SMM	59	Female	0	0	0	0	0
28	EJD	56	Female	0				
31	JAC	56	Female	0	0	0	0	0
32	TML	38	Female	0	0	0	0	0
39	DKD	50	Female	0	0	0	0	0
40	CLM	43	Female	0	2	0	1	0
44	GSR	52	Female	1	3	1	2	1
46	LAA	55	Female	0	0	0	0	2
47	CMP	47	Female	0	0	0	0	0
49	L-R	58	Female	0	0	0	0	0
51	PCB	59	Female	0	0	0	0	0
54	TWS	55	Female	3	0			
57	MDS	52	Female	0	0	0	0	0
59	GFM	64	Female	1	0	0	0	0
60	JLF	32	Female	0	0	0	1	0
61	GEP	53	Female	0				
64	KKF	36	Female	0	2	4	5	2
65	EMM	39	Female	0	0	0	2	0
66	CYR	39	Female	1	0	0	1	0
67	AMM	37	Female	2	0	0	0	0
			Mean	0.31	0.28	0.29	0.50	0.22
			SD	0.71	0.75	0.94	1.07	0.58
			Median	0.00	0.00	0.00	0.00	0.00
			N	29	29	28	28	27
	Discontinu	ıed						

				Ne	on-Inflammatory Lesion Cou	int (Chin) Intra-Subject Char	nge
Subject No.	Subject Initials	Age	Sex	Week 2 Minus Baseline	Week 4 Minus Baseline	Week 8 Minus Baseline	Week 12 Minus Baseline
1	SDC	40	Female				
2	MLE	50	Female	0	0	1	0
3	SKH	47	Female	0	0	0	0
7	DBK	52	Female	0	0	0	0
8	JCF	54	Female	0	0	0	0
9	JRB	53	Female				
12	EFK	57	Female	0	0	0	0
17	BFH	59	Female	0	0	0	1
18	LJR	58	Female	0	0	0	0
19	D-M	58	Female	0	0	0	0
20	RLA	45	Female				
21	LGD	57	Female	-1	2	0	-1
24	VIP	52	Female	1	0	0	0
26	PKM	46	Female	0	0	0	
27	SMM	59	Female	0	0	0	0
28	EJD	56	Female				
31	JAC	56	Female	0	0	0	0
32	TML	38	Female	0	0	0	0
39	DKD	50	Female	0	0	0	0
40	CLM	43	Female	2	0	1	0
44	GSR	52	Female	2	0	1	0
46	LAA	55	Female	0	0	0	2
47	CMP	47	Female	0	0	0	0
49	L-R	58	Female	0	0	0	0
51	PCB	59	Female	0	0	0	0
54	TWS	55	Female	-3			
57	MDS	52	Female	0	0	0	0
59	GFM	64	Female	-1	-1	-1	-1
60	JLF	32	Female	0	0	1	0
61	GEP	53	Female				
64	KKF	36	Female	2	4	5	2
65	EMM	39	Female	0	0	2	0
66	CYR	39	Female	-1	-1	0	-1
67	AMM	37	Female	-2	-2	-2	-2
	•		Mean	-0.03	0.07	0.29	0.00
			SD	1.02	0.98	1.15	0.78
			Modion	0.00	0.00	0.00	0.00

### Total Inflammatory Lesion Count

Subject					ı otal In	flammatory I	esions	
No.	Subject Initials	Age	Sex	Baseline	Week 2	Week 4	Week 8	Week 12
1	SDC	40	Female	3				
2	MLE	50	Female	4	3	0	3	0
3	SKH	47	Female	0	0	0	0	0
7	DBK	52	Female	0	0	0	0	0
8	JCF	54	Female	0	3	0	1	0
9	JRB	53	Female	1				
12	EFK	57	Female	0	0	0	2	1
17	BFH	59	Female	1	1	1	0	0
18	LJR	58	Female	0	4	0	0	0
19	D-M	58	Female	2	0	0	0	1
20	RLA	45	Female					
21	LGD	57	Female	2	0	9	1	1
24	VIP	52	Female	0	1	2	0	3
26	PKM	46	Female	1	0	3	0	
27	SMM	59	Female	0	1	0	0	0
28	EJD	56	Female	2				
31	JAC	56	Female	0	2	0	0	2
32	TML	38	Female	0	4	0	2	2
39	DKD	50	Female	1	0	2	0	2
40	CLM	43	Female	0	4	8	2	0
44	GSR	52	Female	0	0	1	0	1
46	LAA	55	Female	0	0	0	0	1
47	CMP	47	Female	2	0	0	0	0
49	L-R	58	Female	0	0	0	0	0
51	PCB	59	Female	0	2	0	0	0
54	TWS	55	Female	4	0			
57	MDS	52	Female	1	0	0	0	0
59	GFM	64	Female	0	0	0	0	0
60	JLF	32	Female	4	12	6	19	15
61	GEP	53	Female	2				
64	KKF	36	Female	1	2	5	4	1
65	EMM	39	Female	5	2	1	0	0
66	CYR	39	Female	4	4	3	2	2
67	AMM	37	Female	3	3	3	2	2
	Discontinu	ıed	Mean	1.21	1.66	1.57	1.36	1.26
			SD	1.61	2.50	2.54	3.63	2.89
			Median	0.00	1.00	0.00	0.00	0.00
			N	29	29	28	28	27

				Total Ir		ns Intra-Subject (	Change
Subject	Subject	Age	Sex	Week 2 Minus	Week 4 Minus	Week 8 Minus	Week 12 Minus
No.	Initials	Age	Sex	Baseline	Baseline	Baseline	Baseline
1	SDC	40	Female				
2	MLE	50	Female	-1	-4	-1	-4
3	SKH	47	Female	0	0	0	0
7	DBK	52	Female	0	0	0	0
8	JCF	54	Female	3	0	1	0
9	JRB	53	Female				
12	EFK	57	Female	0	0	2	1
17	BFH	59	Female	0	0	-1	-1
18	LJR	58	Female	4	0	0	0
19	D-M	58	Female	-2	-2	-2	-1
20	RLA	45	Female				
21	LGD	57	Female	-2	7	-1	-1
24	VIP	52	Female	1	2	0	3
26	PKM	46	Female	-1	2	-1	
27	SMM	59	Female	1	0	0	0
28	EJD	56	Female				
31	JAC	56	Female	2	0	0	2
32	TML	38	Female	4	0	2	2
39	DKD	50	Female	-1	1	-1	1
40	CLM	43	Female	4	8	2	0
44	GSR	52	Female	0	1	0	1
46	LAA	55	Female	0	0	0	1
47	CMP	47	Female	-2	-2	-2	-2
49	L-R	58	Female	0	0	0	0
51	PCB	59	Female	2	Ö	ō	ō
54	TWS	55	Female	-4		-	_
57	MDS	52	Female	-1	-1	-1	-1
59	GFM	64	Female	0	0	0	0
60	JLF	32	Female	8	2	15	11
61	GEP	53	Female		_	-	
64	KKF	36	Female	1	4	3	0
65	EMM	39	Female	-3	-4	-5	-5
66	CYR	39	Female	0	-1	-2	-2
67	AMM	37	Female	ő	o o	-1	-1
			Mean	0.45	0.46	0.25	0.15
			SD	2.44	2.57	3.27	2.74
			Median	0.00	0.00	0.00	0.00
			N	29	28	28	27

### Total Non-Inflammatory Lesion Count

				Total Non-Inflammatory Lesion Count							
Subject No.	Subject Initials	Age	Sex	Baseline	Week 2	Week 4	Week 8	Week 12			
1	SDC	40	Female	24	0						
2	MLE	50	Female	0	3	0	1	0			
3	SKH	47	Female	0	0	0	0	0			
7	DBK	52	Female	3	0	0	1	2			
8	JCF	54	Female	0	1	0	0	0			
9	JRB	53	Female	3							
12	EFK	57	Female	0	0	0	0	0			
17	BFH	59	Female	0	2	0	0	4			
18	LJR	58	Female	2	0	0	0	0			
19	D-M	58	Female	3	5	0	0	2			
20	RLA	45	Female								
21	LGD	57	Female	3	2	14	1	5			
24	VIP	52	Female	0	4	3	0	1			
26	PKM	46	Female	2	0	0	0				
27	SMM	59	Female	0	1	0	0	0			
28	EJD	56	Female	9	0						
31	JAC	56	Female	0	0	0	0	0			
32	TML	38	Female	0	0	3	0	2			
39	DKD	50	Female	4	0	0	8	2			
40	CLM	43	Female	7	5	3	9	2 5 2			
44	GSR	52	Female	5	4	2	4	2			
46	LAA	55	Female	0	0	0	0	4			
47	CMP	47	Female	1	0	2	0	0			
49	L-R	58	Female	0	0	0	0	0			
51	PCB	59	Female	0	0	0	0	0			
54	TWS	55	Female	4	0						
57	MDS	52	Female	1	0	0	4	3			
59	GFM	64	Female	4	3	1	2	0			
60	JLF	32	Female	13	0	2	3	0			
61	GEP	53	Female	0	0						
64	KKF	36	Female	3	7	33	11	2			
65	EMM	39	Female	22	4	5	13	0			
66	CYR	39	Female	4	0	3	1	0 7			
67	AMM	37	Female				0				
	Discontinu	ied	Mean SD	3.00 4.68	1.55 2.08	2.68 6.59	2.07 3.67	1.52 1.99			
			Median	2.00	0.00	0.00	0.00	0.00			
			N	29	29	28	28	27			

				Total Non-l	nflammatory Lesio	on Count Intra-Sub	ject Change
Subject	Subject		Sex	Week 2 Minus	Week 4 Minus	Week 8 Minus	Week 12 Minus
No.	Initials	Age		Baseline	Baseline	Baseline	Baseline
1	SDC	40	Female				
2	MLE	50	Female	3	0	1	0
3	SKH	47	Female	0	0	0	0
7	DBK	52	Female	-3	-3	-2	-1
8	JCF	54	Female	1	0	0	0
9	JRB	53	Female				
12	EFK	57	Female	0	0	0	0
17	BFH	59	Female	2	0	0	4
18	LJR	58	Female	-2	-2	-2	-2
19	D-M	58	Female	2	-3	-3	-1
20	RLA	45	Female				
21	LGD	57	Female	-1	11	-2	2
24	VIP	52	Female	4	3	0	1
26	PKM	46	Female	-2	-2	-2	
27	SMM	59	Female	1	0	0	0
28	EJD	56	Female				
31	JAC	56	Female	0	0	0	0
32	TML	38	Female	0	3	0	2
39	DKD	50	Female	-4	-4	4	-2
40	CLM	43	Female	-2	-4	2	-2
44	GSR	52	Female	-1	-3	-1	-3
46	LAA	55	Female	0	0	0	4
47	CMP	47	Female	-1	1	-1	-1
49	L-R	58	Female	0	0	0	0
51	PCB	59	Female	0	0	0	0
54	TWS	55	Female	-4			
57	MDS	52	Female	-1	-1	3	2
59	GFM	64	Female	-1	-3	-2	-4
60	JLF	32	Female	-13	-11	-10	-13
61	GEP	53	Female				
64	KKF	36	Female	4	30	8	-1
65	EMM	39	Female	-18	-17	-9	-22
66	CYR	39	Female	-4	-1	-3	-4
67	AMM	37	Female	-2	-2	-6	1
			Mean	-1.45	-0.29	-0.89	-1.48
			SD	4.48	7.53	3.49	5.18
			Median	-1.00	0.00	0.00	0.00
			N	29	28	28	27

### Total Inflammatory and Non-Inflammatory Lesion Count

					Total Lesion Count (Inflammatory and Non-Inflammatory)						
Subject No.	Subject Initials	Age	Sex	Baseline	Week 2	Week 4	Week 8	Week 12			
1	SDC	40	Female	27							
2	MLE	50	Female	4	6	0	4	0			
3	SKH	47	Female	0	0	0	0	0			
7	DBK	52	Female	3	0	0	1	2			
8	JCF	54	Female	0	4	0	1	0			
9	JRB	53	Female	4							
12	EFK	57	Female	0	0	0	2	1			
17	BFH	59	Female	1	3	1	0	4			
18	LJR	58	Female	2	4	0	0	0			
19	D-M	58	Female	5	5	0	0	3			
20	RLA	45	Female								
21	LGD	57	Female	5	2	23	2	6			
24	VIP	52	Female	0	5	5	0	4			
26	PKM	46	Female	3	0	3	0				
27	SMM	59	Female	0	2	0	0	0			
28	EJD	56	Female	11							
31	JAC	56	Female	0	2	0	0	2			
32	TML	38	Female	0	4	3	2	4			
39	DKD	50	Female	5	0	2	8	4			
40	CLM	43	Female	7	9	11	11	0			
44	GSR	52	Female	5	4	3	4	3			
46	LAA	55	Female	0	0	0	0	5			
47	CMP	47	Female	3	0	2	0	0			
49	L-R	58	Female	0	0	0	0	0			
51	PCB	59	Female	0	2	0	0	0			
54	TWS	55	Female	8	0						
57	MDS	52	Female	2	0	0	4	3			
59	GFM	64	Female	4	3	1	2	0			
60	JLF	32	Female	17	12	8	22	15			
61	GEP	53	Female	2							
64	KKF	36	Female	4	9	38	15	3			
65	EMM	39	Female	27	6	6	13	0			
66	CYR	39	Female	8	4	6	3	2			
67	AMM	37	Female	9	7	7	2	9			
	Discontinu	led	Mean	4.21	3.21	4.25	3.43	2.59			
			SD	5.81	3.23	8.24	5.49	3.39			
			Median	3.00	3.00	1.00	1.50	2.00			
			N	29	29	28	28	27			

				Total Lesion Count (Inflammatory and Non-Inflammatory) Intra- Subject Change					
Subject	Subject	Age	Sex	Week 2 Minus	Week 4 Minus	Week 8 Minus	Week 12 Minus		
No.	Initials	,		Baseline	Baseline	Baseline	Baseline		
1	SDC	40	Female						
2	MLE	50	Female	2	-4	0	-4		
3	SKH	47	Female	0	0	0	0		
7	DBK	52	Female	-3	-3	-2	-1		
8	JCF	54	Female	4	0	1	0		
9	JRB	53	Female						
12	EFK	57	Female	0	0	2	1		
17	BFH	59	Female	2	0	-1	3		
18	LJR	58	Female	2	-2	-2	-2		
19	D-M	58	Female	0	-5	-5	-2		
20	RLA	45	Female						
21	LGD	57	Female	-3	18	-3	1		
24	VIP	52	Female	5	5	0	4		
26	PKM	46	Female	-3	0	-3			
27	SMM	59	Female	2	0	0	0		
28	EJD	56	Female						
31	JAC	56	Female	2	0	0	2		
32	TML	38	Female	4	3	2	4		
39	DKD	50	Female	-5	-3	3	-1		
40	CLM	43	Female	2	4	4	-7		
44	GSR	52	Female	-1	-2	-1	-2		
46	LAA	55	Female	0	0	0	5		
47	CMP	47	Female	-3	-1	-3	-3		
49	L-R	58	Female	0	0	0	0		
51	PCB	59	Female	2	0	0	0		
54	TWS	55	Female	-8					
57	MDS	52	Female	-2	-2	2	1		
59	GFM	64	Female	-1	-3	-2	-4		
60	JLF	32	Female	-5	-9	5	-2		
61	GEP	53	Female						
64	KKF	36	Female	5	34	11	-1		
65	EMM	39	Female	-21	-21	-14	-27		
66	CYR	39	Female	-4	-2	-5	-6		
67	AMM	37	Female	-2	-2	-7	0		
			Mean	-1.00	0.18	-0.64	-1.52		
			SD	4.99	8.90	4.34	5.83		
			Median	0.00	0.00	0.00	0.00		
			N	29	28	28	27		

#### Subject's Self Assessment of Skin Texture

				Sub	ject's Self Assessr	nent of Skin Textu	re
Subject	Subject	Age	Sex	Week 2	Week 4	Week 8	Week 12
No.	Initials			WOOK Z	WCCK 4	WCCKO	WCCK 12
1	SDC	40	Female				
2	MLE	50	Female	3	3	2	2
3	SKH	47	Female	2	3	2	3
7	DBK	52	Female	2 2	4 2	2 2	2
8	JCF	54 53	Female Female	2	2	2	1
12	JRB EFK	53		2	2	2	2
17	BFH	57 59	Female	1	2	2	1
17	LJR	59 58	Female Female	2	2	2	2
19	D-M	58	Female	2	2	1	1
20	RLA	45	Female			'	1
21	LGD	57	Female	2	1	2	1
24	VIP	52	Female	3	2	2	2
26	PKM	46	Female	2	2	1	
27	SMM	59	Female	3	2	2	2
28	EJD	56	Female				_
31	JAC	56	Female	3	2	2	2
32	TML	38	Female	2	1	1	1
39	DKD	50	Female	3	3	2	2
40	CLM	43	Female	2	3	2	2
44	GSR	52	Female	1	2	2	1
46	LAA	55	Female	2	2	2	2
47	CMP	47	Female	2	2	1	2
49	L-R	58	Female	3	2	2	2
51	PCB	59	Female	3	3	3	3
54	TWS	55	Female	3			
57	MDS	52	Female	3	3	2	3
59	GFM	64	Female	3	3	2	2
60	JLF	32	Female	2	2	2	2
61	GEP	53	Female				
64	KKF	36	Female	1	2	1	1
65	EMM	39	Female	2	2	1	1
66	CYR	39	Female	2 2	2 2	2 1	2
67	AMM	37	Female				1
	Discontin	ned	Mean SD	2.24 0.64	2.25 0.65	1.79 0.50	1.78 0.64
			Median	2.00	2.00	2.00	2.00
			Median N	2.00	2.00	2.00	2.00
			IN	29	20	20	21

1	=	Much	Improved

<sup>1 =</sup> Much Improved 2 = Somewhat Improved 3 = No Change 4 = Somewhat Worse 5 = Much Worse

				Subject's Self Assessment of Skin Texture In Subject Change			
Subject	Subject	۸	Sex	Week 4 Minus	Week 8 Minus	Week 12 Minus	
No.	Initials	Age		Week 2	Week 2	Week 2	
1	SDC	40	Female				
2	MLE	50	Female	0	-1	-1	
3	SKH	47	Female	1	0	1	
7	DBK	52	Female	2	0	0	
8	JCF	54	Female	0	0	-1	
9	JRB	53	Female				
12	EFK	57	Female	0	0	0	
17	BFH	59	Female	1	1	0	
18	LJR	58	Female	0	0	0	
19	D-M	58	Female	0	-1	-1	
20	RLA	45	Female				
21	LGD	57	Female	-1	0	-1	
24	VIP	52	Female	-1	-1	-1	
26	PKM	46	Female	0	-1		
27	SMM	59	Female	-1	-1	-1	
28	EJD	56	Female				
31	JAC	56	Female	-1	-1	-1	
32	TML	38	Female	-1	-1	-1	
39	DKD	50	Female	0	-1	-1	
40	CLM	43	Female	1	0	0	
44	GSR	52	Female	1	1	0	
46	LAA	55	Female	0	0	0	
47	CMP	47	Female	0	-1	0	
49	L-R	58	Female	-1	-1	-1	
51	PCB	59	Female	0	0	0	
54	TWS	55	Female				
57	MDS	52	Female	0	-1	0	
59	GFM	64	Female	0	-1	-1	
60	JLF	32	Female	0	0	0	
61	GEP	53	Female				
64	KKF	36	Female	1	0	0	
65	EMM	39	Female	0	-1	-1	
66	CYR	39	Female	0	0	0	
67	AMM	37	Female	0	-1	-1	
			Mean	0.04	-0.43	-0.44	
			SD	0.74	0.63	0.58	
			Median	0.00	-0.50	0.00	
			N	28	28	27	

Subject's Self Assessment of Skin Color Intra-Subject Change

# Data Listing 2 Panel 1837 A CLINICAL STUDY OF TOPICAL ZEATIN FOR IMPROVING THE APPEARANCE OF PHOTODAMAGED SKIN

#### Subject's Self Assessment of Skin Color

				Subject's Self Assessment of Skin Color			
Subject No.	Subject Initials	Age	Sex	Week 2	Week 4	Week 8	Week 12
1	SDC	40	Female				
2	MLE	50	Female	3	2	3	3
3	SKH	47	Female	3	3	2	3
7	DBK	52	Female	3	3	2	1
8	JCF	54	Female	2	2	2	2
9	JRB	53	Female				
12	EFK	57	Female	2	2	2	2
17	BFH	59	Female	2	3	2	1
18	LJR	58	Female	3	2	2	3
19	D-M	58	Female	2	2	1	1
20	RLA	45	Female				
21	LGD	57	Female	3	2	2	2
24	VIP	52	Female	3	3	2	3
26	PKM	46	Female	3	2	1	
27	SMM	59	Female	3	3	3	3
28	EJD	56	Female				
31	JAC	56	Female	3	3	3	3
32	TML	38	Female	3	3	2	2
39	DKD	50	Female	3	2	2 2	2
40	CLM	43	Female	3	3	2	2
44	GSR	52	Female	2	2	2 2	1
46	LAA	55	Female	2	2	2	2
47	CMP	47	Female	3	2	2	3
49	L-R	58	Female	3	3	2	3
51	PCB	59	Female	3	3	3	3
54	TWS	55	Female	3			
57	MDS	52	Female	4	3	2	3
59	GFM	64	Female	2	3	3	2
60	JLF	32	Female	3	2	2	2
61	GEP	53	Female				
64	KKF	36	Female	2	1	2	2
65	EMM	39	Female	3	2	1	1
66	CYR	39	Female	3	2	2	2
67	AMM	37	Female	2	2	2	2
	Discontinu	ued	Mean	2.72	2.39	2.07	2.19
SD				0.53	0.57	0.54	0.74
			Median	3.00	2.00	2.00	2.00
			N	29	28	28	27

No.	Initials	Age	Sex	Week 4 Minus Week 2	Week 8 Minus Week 2	Week 12 Minus Week 2
1	SDC	40	Female			
2	MLE	50	Female	-1	0	0
3	SKH	47	Female	0	-1	0
7	DBK	52	Female	0	-1	-2
8	JCF	54	Female	0	0	0
9	JRB	53	Female			
12	EFK	57	Female	0	0	0
17	BFH	59	Female	1	0	-1
18	LJR	58	Female	-1	-1	0
19	D-M	58	Female	0	-1	-1
20	RLA	45	Female			
21	LGD	57	Female	-1	-1	-1
24	VIP	52	Female	0	-1	0
26	PKM	46	Female	-1	-2	
27	SMM	59	Female	0	0	0
28	EJD	56	Female			
31	JAC	56	Female	0	0	0
32	TML	38	Female	0	-1	-1
39	DKD	50	Female	-1	-1	-1
40	CLM	43	Female	0	-1	-1
44	GSR	52	Female	0	0	-1
46	LAA	55	Female	0	0	0
47	CMP	47	Female	-1	-1	0
49	L-R	58	Female	0	-1	0
51	PCB	59	Female	0	0	0
54	TWS	55	Female			
57	MDS	52	Female	-1	-2	-1
59	GFM	64	Female	1	1	0
60	JLF	32	Female	-1	-1	-1
61	GEP	53	Female			
64	KKF	36	Female	-1	0	0
65	EMM	39	Female	-1	-2	-2
66	CYR	39	Female	-1	-1	-1
67	AMM	37	Female	0	0	0
			Mean	-0.32	-0.64	-0.52
			SD	0.61	0.73	0.64
			Median	0.00	-1.00	0.00
			N	28	28	27

<sup>1 =</sup> Much Improved 2 = Somewhat Improved 3 = No Change 4 = Somewhat Worse 5 = Much Worse

### Subject's Self Assessment of Skin Blotchiness

Subject   Subject   No.   Subject   No.   Subject   Initialis   Age   Sex   Week 2   Week 4   Week 8   Week 12					Subject's	Self Assessment of Sk	in Blotchiness - Brown	Spots
2		Initials			Week 2	Week 4	Week 8	Week 12
SKH   47   Female   3   3   2   3								
Total Continuer								
8         JCF         54         Female         3         3         3         3         3         3           12         EFK         57         Female         3         2         2         2         2         1								
9								
12					3	3	3	3
17								
18         LJR         58         Female         3         3         2         2         2           20         RLA         45         Female         2         3         1         2           21         LGD         57         Female         3         2         1         1         1           24         VIP         52         Female         3								
19								
20								
21	19	D-M	58	Female	2	3	1	2
24         VIP         52         Female         3         3         3         3         3           26         PKM         46         Female         3         3         1         3           27         SMM         59         Female         3         3         3         3           28         EJD         56         Female	20	RLA						
26         PKM         46         Female         3         3         1           27         SMM         59         Female         3         3         3         3           28         EJD         56         Female         3         3         3           31         JAC         56         Female         3         3         3         2           32         TML         38         Female         4         3         3         3         2           49         DKD         50         Female         3				Female				
27	24	VIP	52	Female	3	3	3	3
28	26	PKM	46	Female	3	3	1	
31	27	SMM	59	Female	3	3	3	3
32 TML 38 Female 4 3 3 3 2 39 DKD 50 Female 3 3 3 3 3 40 CLM 43 Female 2 2 2 2 1 44 GSR 52 Female 2 2 2 2 1 47 CMP 47 Female 3 2 2 2 2 47 CMP 47 Female 3 3 3 3 3 51 PCB 59 Female 3 3 3 3 3 51 PCB 59 Female 2 3 3 3 3 3 51 PCB 59 Female 3 3 3 3 3 3 51 PCB 59 Female 3 3 3 3 3 3 51 PCB 59 Female 2 5 57 MDS 52 Female 2 5 58 GFM 64 Female 3 2 3 3 3 3 3 59 GFM 64 Female 3 2 2 2 2 60 GFM 64 Female 3 2 2 2 2 61 GEP 53 Female 5 3 3 2 2 2 61 GEP 53 Female 5 3 3 3 3 3 3 3 66 UJF 32 Female 6 3 3 2 2 2 67 GFM 39 Female 3 3 3 3 1 1 1 68 CVR 39 Female 3 3 2 2 2 2 69 Discontinued Mean 2.86 2.79 2.32 2.26 60 JDS OLAH 0.50 0.77 0.76	28	EJD	56	Female				
39	31	JAC	56	Female	3		3	3
40	32	TML	38	Female	4	3	3	2
44         GSR         52         Female         2         2         2         1           46         LAA         55         Female         3         2         2         2         2           47         CMP         47         Female         3         2         2         2         2         2         2         2         2         2         2         2         2         2         2	39	DKD	50	Female	3	3	3	3
46 LAA 55 Female 3 2 2 2 2 47 CMP 47 Female 3 3 3 3 3 3 3 3 4 9 L-R 58 Female 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3	40	CLM	43	Female	3		3	3
46 LAA 55 Female 3 2 2 2 2 47 CMP 47 Female 3 3 3 3 3 3 3 3 4 9 L-R 58 Female 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3	44	GSR	52	Female	2	2	2	
49         L-R         58         Female         3         2         2         3         2         2         3         2         2         2         6         1         3         2	46	LAA	55	Female	3	2	2	2
51         PCB         59         Female         3         3         3         3           54         TWS         55         Female         2         3         3         3         3         3         3         3         3         3         3         3         3         3         3         3         3         3         3         3         2         2         2         6         6         Female         3         2 <td>47</td> <td>CMP</td> <td>47</td> <td>Female</td> <td>3</td> <td>3</td> <td>3</td> <td>3</td>	47	CMP	47	Female	3	3	3	3
54         TWS         55         Female         2           57         MDS         52         Female         3         3         3         3         3         2         2           59         GFM         64         Female         3         2         2         3         2         2         2           60         JLF         32         Female         3         3         2         3         3         1         1	49	L-R	58	Female	3	3	3	3
57         MDS         52         Female         3         3         3         3         3           59         GFM         64         Female         3         2         3         2         2           60         JLF         32         Female         3         3         2         2           61         GEP         53         Female         8         8         2         2         2         2         2         2         6         2         3         3	51	PCB	59	Female	3	3	3	3
59         GFM         64         Female         3         2         3         2         2           61         GEP         53         Female         3         3         2         2           64         KKF         36         Female         2         2         2         2           65         EMM         39         Female         3         3         1         1         1           66         CVR         39         Female         3         2         2         2         2         2           67         AMM         37         Female         3         3         1         1         1           Discontinued         Mean         2.86         2.79         2.32         2.26           SD         0.44         0.50         0.77         0.76           Median         3.00         3.00         2.50         2.00	54	TWS	55	Female	2			
60         JLF         32         Female         3         3         2         2           61         GEP         55         Female         -	57	MDS	52	Female	3	3	3	3
61         GEP         53         Female         2         2         2         2         2           64         KKF         36         Female         2         2         2         2         2         2         2         6         1         2         2         2         2         2         2         2	59	GFM	64	Female	3	2		
64 KKF 36 Female 2 2 2 2 2 6 6	60	JLF	32	Female	3	3	2	2
65         EMM         39         Female         3         3         1         1           66         CVR         39         Female         3         2         2         2           67         AMM         37         Female         3         2         2         2           Discontinued         Mean         2.86         2.79         2.32         2.26           SD         0.44         0.50         0.77         0.76           Median         3.00         3.00         2.50         2.00	61	GEP	53	Female				
66         CYR         39         Female         3         2         2         2         1           67         AMM         37         Female         3         3         1         1           Discontinued         Mean         2.86         2.79         2.32         2.26           SD         0.44         0.50         0.77         0.76           Median         3.00         3.00         2.50         2.00	64	KKF	36	Female	2	2	2	2
67         AMM         37         Female         3         3         1         1           Discontinued         Mean         2.86         2.79         2.32         2.26           SD         0.44         0.50         0.77         0.76           Median         3.00         3.00         2.50         2.00	65	EMM	39	Female	3	3	1	1
67         AMM         37         Female         3         3         1         1           Discontinued         Mean         2.86         2.79         2.32         2.26           SD         0.44         0.50         0.77         0.76           Median         3.00         3.00         2.50         2.00		CYR	39	Female	3	2	2	2
SD 0.44 0.50 0.77 0.76 Median 3.00 3.00 2.50 2.00	67			Female	3	3	1	1
SD 0.44 0.50 0.77 0.76 Median 3.00 3.00 2.50 2.00		Discontinu	ied	Mean	2.86	2.79	2.32	2.26
				SD	0.44	0.50	0.77	0.76
N 29 28 28 27				Median	3.00	3.00	2.50	2.00
1 = Much Improved				N	29	28	28	27

				Subject's Self Assessment of Skin Blotchiness - Brown Spots Intra-Subject Change			
Subject No.	Subject Initials	Age	Sex	Week 4 Minus Week 2	Week 8 Minus Week 2	Week 12 Minus Week 2	
1	SDC	40	Female				
2	MLE	50	Female	1	1	1	
3	SKH	47	Female	0	-1	0	
7	DBK	52	Female	1	0	-1	
8	JCF	54	Female	0	0	0	
9	JRB	53	Female				
12	EFK	57	Female	-1	-1	-1	
17	BFH	59	Female	0	-1	-2	
18	LJR	58	Female	0	-1	-1	
19	D-M	58	Female	1	-1	0	
20	RLA	45	Female				
21	LGD	57	Female	-1	-2	-2	
24	VIP	52	Female	0	0	0	
26	PKM	46	Female	0	-2		
27	SMM	59	Female	0	0	0	
28	EJD	56	Female				
31	JAC	56	Female	0	0	0	
32	TML	38	Female	-1	-1	-2	
39	DKD	50	Female	0	0	0	
40	CLM	43	Female	0	0	0	
44	GSR	52	Female	0	0	-1	
46	LAA	55	Female	-1	-1	-1	
47	CMP	47	Female	0	0	0	
49	L-R	58	Female	0	0	0	
51	PCB	59	Female	0	0	0	
54	TWS	55	Female				
57	MDS	52	Female	0	0	0	
59	GFM	64	Female	-1	0	-1	
60	JLF	32	Female	0	-1	-1	
61	GEP	53	Female				
64	KKF	36	Female	0	0	0	
65	EMM	39	Female	0	-2	-2	
66	CYR	39	Female	-1	-1	-1	
67	AMM	37	Female	0	-2	-2	
			Mean	-0.11	-0.57	-0.63	
			SD	0.57	0.79	0.84	
			Median	0.00	0.00	0.00	
			N	28	28	27	

<sup>1 =</sup> Much Improved 2 = Somewhat Improved 3 = No Change 4 = Somewhat Worse 5 = Much Worse

#### Subject's Self Assessment of Fine Wrinkles

				Subject's Self Assessment of Fine Wrinkles			
Subject	Subject	Age	Sex	Week 2	Week 4	Week 8	Week 12
No.	Initials	,					
1	SDC	40	Female	_	_		
2	MLE	50	Female	2	2	1	2
3 7	SKH	47	Female	2	2	2	3
	DBK	52	Female	3	4	2	2
8	JCF	54	Female	3	3	3	2
9	JRB	53	Female				
12	EFK	57	Female	2	2	2	2
17	BFH	59	Female	2	3	2	1
18	LJR	58	Female	3	3	2	2
19	D-M	58	Female	3	2	2	2
20	RLA	45	Female	_	_		
21	LGD	57	Female	2	2	1	1
24	VIP	52	Female	2	2	2	1
26	PKM	46	Female	3	3	2	
27	SMM	59	Female	3	2	2	2
28	EJD	56	Female				
31	JAC	56	Female	2	2	2	2
32	TML	38	Female	3	2	2	1
39	DKD	50	Female	3	3	3	3
40	CLM	43	Female	2	2	3	2
44	GSR	52	Female	2	2 2	2 2	1
46	LAA	55	Female	2	2	2	2
47	CMP	47	Female	2	2	2	3
49	L-R	58	Female	2	2	2	2
51	PCB	59	Female	3	3	3	3
54	TWS	55	Female	2			
57	MDS	52	Female	3	3	2	4
59	GFM	64	Female	2	2	2	2
60	JLF	32	Female	2	2	2	1
61	GEP	53	Female				
64	KKF	36	Female	3	1	2	1
65	EMM	39	Female	2	2	2	1
66	CYR	39	Female	3	2	2	2
67	AMM	37	Female	2	2	2	2
	Discontinu	led	Mean	2.41	2.29	2.07	1.93
			SD	0.50	0.60	0.47	0.78
			Median	2.00	2.00	2.00	2.00
	Improved		N	29	28	28	27

1	=	Much	Improved

				Subject's Self Assessment of Fine Wrinkles Intra Subject Change			
Subject	Subject	٨٥٥	Sex	Week 4 Minus	Week 8 Minus	Week 12 Minus	
No.	Initials	Age		Week 2	Week 2	Week 2	
1	SDC	40	Female				
2	MLE	50	Female	0	-1	0	
3	SKH	47	Female	0	0	1	
7	DBK	52	Female	1	-1	-1	
8	JCF	54	Female	0	0	-1	
9	JRB	53	Female				
12	EFK	57	Female	0	0	0	
17	BFH	59	Female	1	0	-1	
18	LJR	58	Female	0	-1	-1	
19	D-M	58	Female	-1	-1	-1	
20	RLA	45	Female				
21	LGD	57	Female	0	-1	-1	
24	VIP	52	Female	0	0	-1	
26	PKM	46	Female	0	-1		
27	SMM	59	Female	-1	-1	-1	
28	EJD	56	Female				
31	JAC	56	Female	0	0	0	
32	TML	38	Female	-1	-1	-2	
39	DKD	50	Female	0	0	0	
40	CLM	43	Female	0	1	0	
44	GSR	52	Female	0	0	-1	
46	LAA	55	Female	0	0	0	
47	CMP	47	Female	0	0	1	
49	L-R	58	Female	0	0	0	
51	PCB	59	Female	0	0	0	
54	TWS	55	Female				
57	MDS	52	Female	0	-1	1	
59	GFM	64	Female	0	0	0	
60	JLF	32	Female	0	0	-1	
61	GEP	53	Female				
64	KKF	36	Female	-2	-1	-2	
65	EMM	39	Female	0	0	-1	
66	CYR	39	Female	-1	-1	-1	
67	AMM	37	Female	0	0	0	
P.	•	•	Mean	-0.14	-0.36	-0.48	
			SD	0.59	0.56	0.80	
			Median	0.00	0.00	-1.00	
			N	28	28	27	

<sup>1 =</sup> Much Improved 2 = Somewhat Improved 3 = No Change 4 = Somewhat Worse 5 = Much Worse

# Data Listing 2 Panel 1837 A CLINICAL STUDY OF TOPICAL ZEATIN FOR IMPROVING THE APPEARANCE OF PHOTODAMAGED SKIN

#### Subject's Self Assessment of Overall Improvement

				Subjec	t's Self Assessment	of Overall Improven	nent
Subject	Subject	Age	Sex	Week 2	Week 4	Week 8	Week 12
No.	Initials	-		WEER 2	WEEK 4	Week o	WEEK 12
1	SDC	40	Female				
2	MLE	50	Female	2	2	2	2
3	SKH	47	Female	2	3	2	3
7	DBK	52	Female	2	3	3	2
8	JCF	54	Female	2	2	2	2
9	JRB	53	Female				
12	EFK	57	Female	2	2	2	2
17	BFH	59	Female	2	2	2	1
18	LJR	58	Female	3	2	2	2
19	D-M	58	Female	2	2	1	2
20	RLA	45	Female				
21	LGD	57	Female	2	2	2	1
24	VIP	52	Female	2	2	2	1
26	PKM	46	Female	3	2	1	
27	SMM	59	Female	3	2	2	2
28	EJD	56	Female				
31	JAC	56	Female	2	2	2	2
32	TML	38	Female	3	2	2	2
39	DKD	50	Female	3	2 3	2	2
40	CLM	43	Female	3		3	2
44	GSR	52	Female	2	1	2	1
46	LAA	55	Female	2	2 2	2	2
47	CMP	47	Female	2	2	2	2
49	L-R	58	Female	3	2	2	2
51	PCB	59	Female	3	3	3	3
54	TWS	55	Female	2			
57	MDS	52	Female	3	4	2	3
59	GFM	64	Female	2	2	2	2
60	JLF	32	Female	2	2	2	2
61	GEP	53	Female			_	
64	KKF	36	Female	2	2	2	2
65	EMM	39	Female	3	2	2	1
66	CYR	39	Female	2 2	2 2	2 1	2 1
67	AMM	37	Female				
	Discontinu	nea	Mean	2.34	2.18	2.00	1.89
			SD	0.48	0.55	0.47	0.58
			Median N	2.00	2.00	2.00	2.00
4 14			N	29	28	28	27

1	= Much Improved	

<sup>1 =</sup> Much Improved 2 = Somewhat Improved 3 = No Change 4 = Somewhat Worse 5 = Much Worse

					ssessment of Over ntra-Subject Chang	
Subject No.	Subject Initials	Age	Sex	Week 4 Minus Week 2	Week 8 Minus Week 2	Week 12 Minus Week 2
1	SDC	40	Female			
2	MLE	50	Female	0	0	0
3	SKH	47	Female	1	0	1
7	DBK	52	Female	1	1	0
8	JCF	54	Female	0	0	0
9	JRB	53	Female			
12	EFK	57	Female	0	0	0
17	BFH	59	Female	0	0	-1
18	LJR	58	Female	-1	-1	-1
19	D-M	58	Female	0	-1	0
20	RLA	45	Female			
21	LGD	57	Female	0	0	-1
24	VIP	52	Female	0	0	-1
26	PKM	46	Female	-1	-2	
27	SMM	59	Female	-1	-1	-1
28	EJD	56	Female			
31	JAC	56	Female	0	0	0
32	TML	38	Female	-1	-1	-1
39	DKD	50	Female	-1	-1	-1
40	CLM	43	Female	0	0	-1
44	GSR	52	Female	-1	0	-1
46	LAA	55	Female	0	0	0
47	CMP	47	Female	0	0	0
49	L-R	58	Female	-1	-1	-1
51	PCB	59	Female	0	0	0
54	TWS	55	Female			
57	MDS	52	Female	1	-1	0
59	GFM	64	Female	0	0	0
60	JLF	32	Female	0	0	0
61	GEP	53	Female			
64	KKF	36	Female	0	0	0
65	EMM	39	Female	-1	-1	-2
66	CYR	39	Female	0	0	0
67	AMM	37	Female	0	-1	-1
			Mean	-0.18	-0.36	-0.44
			SD	0.61	0.62	0.64
			Median	0.00	0.00	0.00
			N	28	28	27

TEWL Values (g/m2/hr) of Both Cheeks (Average of Right and Left)

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			0.32	9 6	0.53	0.35	0.04	035	0.49	1.17		0.28	0.49	0.49	0.00	2 2	0.04	2 0	9 5	9 9	0 14		0.32	0.67	0.74			0.35	0.18	0.85	0.81		0 1	2 5			0.42		0.46	0.04	ć	3		
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5		2						_			000000000000000000000000000000000000000		_		_			_	_		_										_						_	000000000000000000000000000000000000000			+		4	
30.49	4.08	11.61		23.35	13.95	: i	1 2	6.88	- -		3	į	9 6	7 5	De	10.30	10.58	9.58	8.88	8.70	7.88		5.45 5	13.20	0.48			ž	0.23	15.40	8.50		9.70		9.78	12 10	14.05	13.98	9	5 5	2	Mean		
				1.06	0.57	0.43	6	0.25	į	2 -	5		3 .	2	0.49	0.85	0.53	0.53	0.04	0.57	0.18		24	9		3		8	62.2	20.0	2 2		0.14		.03	0.35	=	0.92		0 78	1	S	L	
				26.7	12.4	10.9	= =	7.0		4 6	16.4			ъ.	8.7	10.1	13.4	12.4	11.4	8.4	8.9		11.7		2.5			9.7	12.4		9,4		9.2		9.7	9.8	15.2	12.0		1 5	130	Measurement 1		
				_				-			000000000000000000000000000000000000000		_		_		_		_																_			_			+			
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30	5 5	4 -	:	27.	ri Fi	<b>5</b>	=	6.98		7 ;	6		J.	9.6	7.5	9.95	ŗ.	12	=	80			ē	5 5 5		5		9		3 3	14.76		8./		6	9.93	15.2	12.6		1 63	1	2 Mean		
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	٤,	, i		2	_	7	_	9		-	=		7	60	=		=	_		. "						4			-	7	<del>-</del> -				72	<u> </u>	- 5			5	5	Measurement 2	5	
z	di d	e i	an .	8.9	1.2	7.8	2.9	7		3	33		0	œ	9.0		-	3.61	0.0	ن	- 6	0		7	50 1	179			7	on :	16.4	•	0.0	200000000000000000000000000000000000000	-	6	8	9		15.8	5	ement 2	Veek 12	
30	10.65	4 5	11.84	28.78	11.10	7.90	12.60	9.55		11.55	18.30		7.38	8.50	10.18	12.18	9.95	10.28	13.73	100	3 6	9 18		10.03	040	13 25			11 40	7.25	5 88	ŝ	è	3	: 88	14.68	15.70	10.90		15.45	10.05	Mean		
				011	0.07	0.21	0.35	0.14		0.35	0.07		0.53	0.42	0.25	1.17	0.21	0.39	3 :		0.50	0 53		0.46	0.57	049			0.35	0.49	0.74	25.0		:	0.25	0.18	0.07	0.00		0.49	0.57	SD		
			-	-	_		_	_	_	_	-	_	_	_	_	_	_	_	_		_	_	_	_	_	_	_	_	_	_	_	_	_	_	_			_		_	_			

Intra-Subject Change in TEWL Values (g/m2/hr) of Both Cheeks (Average of Right and Left)

	73	7:	71 7	70	68	2	3 8	58	56	55	53	52	50	48	45	43	42	41	38	37	36	35	34	33	30	29	25	23	23	16	15	74	<del>1</del> 3	=	10	თ	5	4	Number	Subject
Discontinu	NLW	NR.	i S	2 6	SAM	MKG	ZME	CZR	DAH	SKR	DSB	5	PKH	Ë	TDC	cec	KAM	m	XAS	eE.	MAE	DLM	F	<u>ب</u>	MMC	DSE	Ţ	RMS	Š	Ę	NHK	돖	DKS	Į.	ζĊ	PJW	EMP	SKH	Initials	Subject's
red	47	56	3 6	3 5	3 23		1 8	49	45	57	54	53	49	47	48	48	52	61	<del>2</del>	5	51	52	31	47	2	59	40	51	48	57	56	56	38	50	41	<del>ವಿ</del>	45	46	Initials Age	Subject's
-	Female	Female	Female	Formale	Female	Petitian	remale	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Geine	
	25.0	1 1 8	2 6	6.7	2.7		0.3	. ω		-1.0	1.4	0.4	9.3	1.7	.2.9	1.3	2.0	1.8		1.9	4.5	2.0			3.8	0.3	-0.6	-2.6		-0.4	9.6	-0.4	4.0	4.7	-7.8		-6.3	9.5	Measurement 1	Week 2 vs. Baseline
Mean SD Median N	29.8	<u>.</u>	27	7.5			Ξ	2.3		-0.8	1.4	1.6	=======================================	2.0	3.9	0.7	1.5	2.2		3.6	4.3	2.1			3.9	0.4	0.0	-2.8		-0.6	8.8	-6.1	3,9	3.9	-6.3		÷.5	10.8	Measurement 2	. Baseline
2.00 3.82 1.85 31	27.40	0.25	2.73	705	3.08		0.00	2.65		-0.88	1.40	0.98	10.18	1.85	3.38	0.98	1.73	1.95		2.73	4.38	2.03			3.83	0.33	-0.30	-2.70		-0.48	9.18	-0.20	3.93	4.30	-7.05		-5.88	10.13	1100011	Mean
	3.39	2.12	0.04	0.42	0.00		0.00	0.57		0.18	0.00	0.81	1.31	0.21	0.67	0.46	0.32	0.28		1.24	0.11	0.11			0.11	0.11	0.42	0.14		0.18	0.53	0.21	0.04	0.57	1.06		0.60	0.95	1	S
		4	22	A	1.3	ò	3.0	3.4		6.0	0.2	0.5	-1.0	3.8	3.1	-0.9	0.4	-0.9		-0.9	5.2	2.7			3,3	1.8	-2.5	0.0		-1.4		0.5	2.2	2.9	-3.8		-1.9		Measurement 1	Week 4 vs. Baseline
Mean SD Median N		4	2.4	A 0	2 .5		6.7-	ى د د		J.0	0.4	0.5	0.2	4.7	3.9	-1.9	-0.2	-0.4		-0.2	5.4	2.2			4.3	1.9	-2.9	-0.1		-1.3		1.7	2.6	4.8	-1.9		-1.5	4.1	Measurement 2	Baseline
0.79 2.48 0.31 30		-3.70	2.28	A 6	3.5	,	.e.2-	3.33		0.93	-0.13	0.50	-0.40	4.20	3.50	-1.35	0.13	-0.67		-0.52	5.28	2.40			3.80	1.80	-2.70	-0.07		-1.33		1.10	2.38	3.83	-2.80		-1.68	3.05		Mean
		0.92	0.18	011	0.24	8	ç.	0.07	ì	0.11	0.46	0.00	0.85	0.64	0.57	0.71	0.39	0.32		0.46	0.18	0.35			0.71	0.07	0.28	0.04		0.04		0.85	0.25	1.31	1.34		0.32	1.41		SD
		=	0.9	A 4	3 ±			7.5		0.8	2.5	0.9	-0.6	6.9	6.3	1.6	0.5	0.3		-0.1	2.1	3.4			3.3	6.1	-3.2	1.4		-1.8		1.1	0.2	5.1	5.1		-5.5		Measurement 1	Week 8 vs. Baseline
Mean SD Median N		-0.6	0.2	2 1	<u>ا</u> د	,	Š	4.0		1.1	2.1	Ė	-0.9	6.6	7.2	=	-0.6	0.8		-0.8	1.7	2.0			2.2	5.3	-3.6	0.0		-2.9		1.9	0.3	5.0	-3.0		-5.9	2.5	Measurement 2	Baseline
0.49 3.37 0.54 30		0.23	0.55	بر در در در	3 6	2		7 80	3	0.93	2.30	-0.07	-0.75	6.73	6./3	1.33	-0.07	0.53		-0.45	1.88	2.68			2.70	5.68	-3.35	0.68		-2.33		1.48	0.20	5.03	4.03		-5.65	2.45	1	Mean
		1.17	0.57	100	9.0	8	9.4.	3 6	3	0.25	0.28	1.45	0.21	0.25	0.60	0.39	0.74	0.39		0.42	0.32	0.95			0.78	0.53	0.28	0.95		0.74		0.53	0.07	0.04	1.45		0.28	0.00		SD
		3.1	0.4	i	2	,	.2.0	ာ <u>ငံ</u>	2	2.5	7.2	1.7	2.3	3.4	3.9	3.9	0.5	0.9		-0.9	2.6	6.1			4.7	0.6	-2.2	1.4		-2.2		3.2	5.2	5.5	-6.1		-1.9	-1.8	Measurement 1 Measurement 2	Week 12 vs. Baseline
Mean SD Median N		0.4	-0.8	0.4	0.7		4.0	2.2	;	2.2	3 = 1	. 0	0.7	 	4.0		0.0	0.4		-1.1	2.4	4.3			4.7	11	-2.3	0.7		-2.5		3.3	4.8	5.5	5.5		-1.8	-1.1	Measurement 2	3. Baseline
1.03 2.74 1.11 30		1.73	-0.57	0 93	75	3	6.50	3.50	3	2.30	1.15	213	1.48	3.58	4.20	3.50	0.25	0.63		-0.95	2.48	5.18			4.70	0.83	-2.23	1.08		-2.33		3.20	4.95	5.48	-5.80		-1.83	-1.43		Mean
		1.87	0.32	0.74	9 5	à	9.50	0.85	2	67.0	0.07	0.74	1.17	0.32	0.42	0.57	0.35	0.39		0.14	0.11	1.24			0.00	0.32	0.11	0.46		0.25		0.07	0.28	0.04	0.42		0.04	0.53		SD

	C	72	۷.	7		<b>D</b>		<u>.</u>	(JT	cn.	cn	ch	ر د	on .	4	4	4	4	4	، د	ى د	ه د	. د	a w	ω	2	2	2	N -		_	-:		± c	h ()	4.6	Numbe	9
C	L					20000			-										demos				3					-					_ _	٠,	<b>.</b>	- 0	17.	1
continued						3			-										- 3				0000											- 3			Initials	
	47	8	4	8	87	<u>ස</u> :	57	8	49	45	57	2	53	49	47	48	48	5	9	5	2 5	2 5	ર :	4	2	59	40	<u>გ</u>	48	1 8	8	38	5	4 8	3 8	6 fi	Age	
	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Famala	Female	Female	remale	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	T dilaid	Female	Gender	
	17.4	24.2	11.8	6.6	12.9	61	10.0	14.0	18.3		4.6	4.3	7.4	10.8	6.9	6.1	6.7	7.5	8.7		11.9	8 9	6.5		6.0	5.7	16.8	9.2	9.0	2.8	9.8	9.4	10.9	17.6	7.0.2	12.3	Measurem	
						HOUNDSTONE													200000000000000000000000000000000000000																		nt 1 Me	Raseline
SD Median	15.9	24.7	12.0	7.9	12.6	7.1	10.6	15.3	20.6		4.6	5.2	8.2	10.6	6 51	6.3	8.3	9.5	8.8		10.3	9 2	74		5.3	6.1	17.0	10.0	0.0	9 N	10.1	9.1	11.3	16.7		10.7	Measurement	
4.76 9.10	10.65	24.45	11.90	7.25	12.75	6.60	10.30	14.65	19.45		4.60	4.75	7.80	10.70	6.70	6.20	7.50	8.50	8.75		11.10	8 70	6 95		G	5.90	16.90	9.60	9.0	9 .	9.95	9.25	11.10	17.15		12.35	2 Mean	-
		0.35							-							0.14					1 3	0.71	0.64		0.07	0.28	0.14	0.57	0.40	0.42	0.21	0.21	0.28	0.64		3 00	S.	3
	F							_						_	_	_							- Marian Control														z	-
	35.5	30.3	14.8	15.2	12.5	12.0		<u>16.1</u>	20.2		4.3	7.8	6.1	21.9	8.3	9.5	10.1	9.6	10.6		12.8	123	10.2		10.4	6.2	19.5	5.0		5 6	8.0	13.3	12.9	8.8		20.8	easurement 1	Ve
M		2 12	<b>7</b> 2		<del>,</del>	1		=	21.1		4	æ	7	23	00	=	1	=	1		<b>.</b>	=	<u>.</u>		1	. 7	21.4	0		10.0	, c		1.	9		140	Measurement	ěK Z
SD Median		7.3	91	7.3	3.7	2.6		3	=		ω	_	9	<u> </u>	.7	<u>~</u>	.7	.8	=		13.6	œ	80		c	, 0	4	6		5 0		5	6	7		هٔ د	ement 2	
5.50	130.73	28.80	14.95	16.25	13,10	12.30		17.70	20.65		4.30	7.95	7.00	22.50	8.50	9.75	10.40	10.20	10.35		13.20	12.55	11.00		; 2	5 5	20.45	5.80		10.95	9 9	13.40	12.75	9.25		12 80	Medit	
	1.//	2.12	0.21	1.48	0.85	0.42		2.26	0.64		0.00	0.21	1.27	0.85	0.28	0.35	0.42	0.85	0.35		0.57	0.35	1.13		Ç.#.	26.0	1.34	1.13		0.25	0.35	0.14	0.21	0.64		1 70	2	9
		24.	15.8	<u>;</u> :1	13.	7.7		12	25.0		5.5	6.6	7.8	9.1	10.	9.3	3.8	3.8	8.1		10.6	14			9.0	2.5	1 5	7.9		9.0	9.0	13	13	14.		17.5	Measurement 1	
		4	8	2	G	_		_	0				<u>.</u>		2						0	2	on					, -				. 4.		0		D1 C	-	A VOOL H
SD Mediar	Moon	26.7	16.6	11.5	13.7	8.0		13.0	27.0		<u>5</u>	6.51	60	11.2	11.1	9.6	9.0	9.0	8.7		10.9	15.3	10.9			1	15.6	99		93	Ξ	14.1	15.8	16.5		18.3	eas	#
J.		2	_	_	_			_	N									~	~				_					. ~		·0			_	_1		<u>.</u>	$\top$	_
4.85	203		16.20						26.00							9.45					10.75						15.30			9 15 5		13.75				17.90		Mean
		1.63	0.57	0.21	0.14	0.64		0.64	1.41		0.28	0.07	0.49	1.48	0.64	0.21	0.35	0.28	0.42		0.21	0.78	0.28		2	2 2	2.4.	0.85		0.21	-	0.49	1.98	1.77		0.57	╄	3
		25.4	14.0	10.4	10.7	7.4		6.4	19.0		5.9	8.0	9.	9.4	13.5	9.9	12.3	7.9	7.6		10.0	9.2	10,4		ē	10.0	14.0	. 8		7.6	Ç.	10.1	14.3	11.7		12.3	Measurement 1 Measurement 2	
																																					nt 1 Mea	ALCOUR
SD	Mean	26.4	14.0	10.9	11.9	8.7		6.4	17.7		6.2	0.00	7.2	9.3	11.6	10.0	12.9	8.4	8.8		10.2	9.6	10.5		70.6	3 0	4 6	9.		6 6	:	19.7	14.2	11.9		12.2	surement	
3.95	11 25	25.90	14.00	10.65	11.30	8.05		6.40	18.35		6.05	8.15	8.15	9.35	12.55	999	12.60	8.15	8.20		10.10	9,40	10.45			10.00	1 4 9	9.25		7.10	11.00	9.90	14.25	11.80		12.25	1	Mean
			0.00					0.00	0.92		0.21	0.21	1.34	0.07	1.34	0.07	0.42	0.35	0.85		0.14	0.28	0.07		0.76	0 0	0.00	0.04		0.71	0.07	0.28	0.07	0.14		0.07		S
													_			_									i	<u> </u>											Measu	-
		30.2	11.2	7.4	2.7	9.5		9.7	18.1		5.7	1 6	9 9	2.8	9 8	0.6	2/	6.00	B 51		9.0	9.4	33		0.0	5 6	n Z	ο `		8.3	1	3	9 0	1.9		14.1	rement 1	
SD Mediar	Mea	30.	10.8	6.9	12.1	9.5		9.4	17.8		o o	1 0	1 (0	2 = =	10.	1	12.		8.0		8.7	9.7	12.		į	10 5	71.0	1 K	,	8.3	į	1 4 5 0	ō	10.1		14.6	Measurement 1 Measurement 2	
-																						_	_														+	
4.61 10.65	11 32	30.25	11.00	7.15	12.80	9.50			17.95	200000	9.00	0.00	9 2	12.25	0.00	3.5	12.50	7.40	8.25		8.85	9.55	13.00			11 70	630	9.20	3	8.30	į	10.90	2 2	11.20		14.35	10 30	MEGN
		0.07	0.28	0.35	0.14	0.00		12.0	0.21		Ç.	2.2	2.0	0.78	02.0	9 9	0.20	2 2	0.35		0.21	0.21	0.42			3 7	3 .	1 C	2	0.00		0.92	2 4 2	0.99		0.35	0 71	č

# Data Listing 3 a CLINICAL STUDY OF TOPICAL ZEATIN FOR IMPROVING THE APPEARANCE OF PHOTODAMAGED SKIN

Intra-Subject Change in TEWL Values (g/m²/hr) of the Right Cheek

National Salpolita   Salpoli																		_														_								Z S	1
Subject   Carde	Di	_					_		_													_															5 <b>σ</b>		4		
Application	scontinue	NLW	NRC	JAR	CAC	용	SAM	MRG	XME	CZR	DA H	SKR	DSB	<u>ي</u>	옷	F	TDC	6 6 -	XAM	m Ż	\$	ମ	MAE	DLM	F	<u>-</u> 6	MMC	DSE	Ţ	RMS	듀	¥	Y .	£ 6	האם האם	7 C	7 <b>7</b>	MP	SKH	ubject's nitials	
Monte   Procedure   Escalina   Monte   SD	ğ	47	56	40	62	55	53	5	<b>5</b>	49	45	57	54	53	49	47	48	48	52	61	đ	54	51	52	34	47	2	59	40	51	48	57	56	56	2 6	50 :	2 £	8	46	Subject's Age	
No. Biasulime         No. Wicek 4 vs. Biasulime         Mass         5D         Wicek 4 vs. Biasulime         Mass         5D         Wicek 4 vs. Biasulime         Mass         5D         Massilime         Mass         5D         Massilime         Mass         5D         Massilime         Massilime <th></th> <th>Female</th> <th>Gender</th> <th></th>		Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Gender								
Main   SD   Work   A Baseline   A Base		18.1	6.1	3.0	8.6	-0.4	5.9		2.1	1.9		-0.3	3.5	-1.3	11.1	1.4	3.4	.3 .4	2.1	1.9		0.9	4.1	3.7			4.4	0.5	2.7	4.2		1.2	10.3	-1.3	ا د	2.0	188	-6.6	8.5	VS.	
No	Mean SD Median N	22.1	2.6	3.1	9.4	1.1	5.5		4.0	0.5		-0.3	2.9	-0.3	12.5	2.2	3.7	2.4	1.3	1.3		3.3	3.6	4.4			4.9	1.4	4.4	-3.4		=	10.6	<u>-</u>	4 4	<u>.</u>	<i>-7</i> 0	-5.7	8.9	Baseline Measurement 2	
Work Av. St. Beschine Log         Av. St. St. St. St. St. St. St. St. St. St	2.53 4.19 2.90 31	20.10	4.35	3.05	9.00	0.35	5.70		3.05	1.20		-0.30	3.20	-0.80	11.80	1.80	3.55	2.90	1.70	1.60		2.10	3.85	4.05			4.65	0.95	3.55	-3.80		1.15	10.45	-1.20	4 15	<u>.</u>	-7 90	-6.15	8.70	Mean	
Measurement 2		2.83	2.47	0.07	0.57	1.06	0.28		1.34	0.99		0.00	0.42	0.71	0.99	0.57	0.21	0.71	0.57	0.42		1.70	0.35	0.49			0.35	0.64	1.20	0.57		0.07	0.21	0.14	0.35	0.49	1 27	0.64	0.28	SD	
Mean   SD			0.2	4.0	4.6	0.6	1.0		-1.9	6.7		0.9	2.3	0.4	-1.7	3.3	3.2	1.8	=	-0.6		-1.3	6.0	4.0			3.0	1.9	-1.8	-1.3		-0.3		-0.3	40	2.1	-36	-0.7	0.2	Week 4 vs. Measurement 1	
SD         Week 8 vs. Baseline         Mean         SD         Week 12 vs. Baseline         Mean         SD         Week 12 vs. Baseline         Mean           1,34         2.99         2.7.5         2.80         0.14         -2.25         -1.6         -2.05           2,40         -5.9         -7.5         -6.70         1.13         -4.1         -5.1         -4.0           1,70         -3.9         -7.5         -6.70         1.13         -2.1         -6.2         -2.05           2,40         -5.9         -7.5         -6.80         0.07         -5.7         -6.2         -5.9           0,71         0.7         0.6         0.85         0.07         -5.7         -6.2         -2.95           0,71         0.7         0.6         0.85         0.07         -0.5         -0.3         -0.4           0,22         1.1         1.6         1.33         0.35         2.5         2.4         2.45           0,02         1.1         1.6         1.33         0.35         0.07         -0.5         -0.3         -0.40           0,49         7.5         7.7         0.28         -1.4         -2.1         -0.40         -0.40	Mean SD Median N		2.0	4.6	3.6	:1	0.9		-2.3	6.4		0.5	1.3	0.3	0.6	4.6	3.3	0.7	-0.5	-0.1		0.6	6.1	3.5			5.2	1.2	-1.4	-0.9		0.4		1.0	5.0	4.5	-02	-1.4	2.1	Measurement 2	-
Week 8 vs. Baseline         Mean         SD         Week 12 vs. Baseline         Mean         Mean           2.9         -2.9         -2.80         0.14         -2.5         -2.05         -2.05           5.9         -7.5         -8.70         1.13         -4.1         -5.1         -4.60           -5.9         -4.8         -5.35         0.78         -5.7         -6.2         -5.96           3.4         2.9         3.15         0.35         0.35         3.6         3.9         3.75           1.1         1.6         1.35         0.03         2.5         2.4         2.45           -0.4         -0.3         -0.35         0.07         -0.5         -1.0         -0.6         -0.80           -0.4         -0.3         -0.35         0.07         -2.8         -1.0         -0.6         -0.80           -0.4         -0.3         -0.35         0.07         -2.8         -1.0         -0.40         -2.45           -0.4         -0.3         0.07         -0.5         -0.5         -0.40         -0.20         -0.40           -0.2         -0.2         -0.2         -0.5         -0.5         -0.5         -0.6         6.7	1.51 2.35 1.03 30		1.10	4.30	4.10	0.85	0.95		-2.10	6.55		0.70	1.80	0.35	-0.55	3.95	3.25	1.25	0.30	-0.35		-0.35	6.05	3.75			4.10	1.55	-1.60	-1.10		0.05		0.35	4.50	3.30	-1.90	-1.05	1.15	Mean	
vs. Baseline         Mean         SD         Week 12 vs. Baseline         Mean         Mean           1 Measurement 12         280         0.14         —2.5         —2.05         —2.05           27         280         0.14         —2.5         —2.05         —2.05           4.8         —5.35         0.78         —5.7         —6.2         —5.95           0.6         0.65         0.07         3.9         5.5         2.4         2.45           2.9         3.15         0.35         3.6         3.9         3.75         4.60         —4.60           2.9         3.15         0.35         3.5         2.5         2.4         2.45         2.45           1.6         1.35         0.35         0.35         2.5         2.4         2.45           2.3         —2.05         0.04         —1.0         —0.6         —0.80           2.4         —2.35         0.07         —2.8         —1.4         —2.10           2.4         —2.35         0.07         —2.8         —1.4         —2.10           2.4         —2.25         0.02         —2.8         —1.0         —2.4           3.1         0.70         0.42			1.27	0.42	0.71	0.35	0.07		0.28	0.21		0.28	0.71	0.07	1.63	0.92	0.07	0.78	1.13	0.35		1.34	0.07	0.35			1.56	0.49	0.28	0.28		0.49		0.92	0.71	1.70	2.40	0.49	1.34	SD	
ment 2         Mean Property (Color of the color of			1.2	2.2	3.8	-2.2	1.3		-7.6	0.7		1.3	3.7	1.7	-1.4	6.6	3.8	5.6	0.4	÷		-1.9	1.0	3.9			4.8	7.9	-2.3	-0.4		-1.7		=======================================	0.7	3.4	-5.9	-5.9	2.9	_ ×	
SD         Week 12 vs. Baseline         Measurement 2         Mean           0.14         -2.5         -2.05         -2.05           1.13         -4.1         -5.1         -4.60           0.378         -5.7         -6.2         -5.95           0.35         3.6         3.9         3.75           0.07         3.9         5.5         2.4         2.45           0.07         -0.5         -0.3         -0.40         -0.80           0.07         -2.8         -1.4         -2.10         -0.40           0.07         -2.8         -1.4         -2.10         -0.40           0.07         -2.8         -1.4         -2.10         -0.40           0.07         -2.8         -1.4         -2.10         -0.40           0.49         4.6         6.7         5.65         -0.2         -0.80           0.42         1.2         -0.2         -0.8         -0.40         -0.40         -0.40         -0.40         -0.40         -0.40         -0.40         -0.40         -0.40         -0.40         -0.40         -0.40         -0.40         -0.40         -0.40         -0.40         -0.40         -0.50         -0.50         -0.50 </th <th>Mean SD Median N</th> <th></th> <th>1.7</th> <th>2.0</th> <th>3.0</th> <th>-0.7</th> <th>1.6</th> <th></th> <th>-8.9</th> <th>-2.9</th> <th></th> <th>1.6</th> <th><u>ω</u></th> <th>-1.0</th> <th>-1.3</th> <th>5.1</th> <th>3.7</th> <th>4.6</th> <th><u>-</u></th> <th>0.0</th> <th></th> <th>-0.1</th> <th>0.4</th> <th>3.1</th> <th></th> <th></th> <th>4.1</th> <th>7.5</th> <th>-2.4</th> <th>-0.3</th> <th></th> <th>-2.3</th> <th></th> <th>1.6</th> <th>0.6</th> <th>2.9</th> <th>-4.8</th> <th>-7.5</th> <th>2.7</th> <th>leasurement 2</th> <th></th>	Mean SD Median N		1.7	2.0	3.0	-0.7	1.6		-8.9	-2.9		1.6	<u>ω</u>	-1.0	-1.3	5.1	3.7	4.6	<u>-</u>	0.0		-0.1	0.4	3.1			4.1	7.5	-2.4	-0.3		-2.3		1.6	0.6	2.9	-4.8	-7.5	2.7	leasurement 2	
Week 12 vs. Baseline         Mean           Measurement 1         -2.05           -2.1         -5.1         -2.05           -4.1         -5.1         -4.60           -5.7         -6.2         -5.95           3.6         3.9         3.75           3.9         5.5         2.4           2.5         2.4         2.45           -0.2         -0.0         -0.00           -0.2         -1.0         -0.40           -0.2         -1.0         -0.0           -0.2         -0.5         -0.40           -0.2         -0.5         -0.40           -0.2         -0.5         -0.40           -0.2         -0.5         -0.50           -0.7         -1.6         -2.25           -0.9         -1.6         -2.25           -0.7         -1.5         -1.10           -0.8         -0.50         -0.50           -0.7         -1.5         -1.10           -0.8         -1.1         1.25           -0.3         1.1         1.70           1.1         0.9         1.00           -0.8         -1.0         0.05	0.73 3.53 1.03 30		1.45	2.10	3.40	-1,45	1.45		-8.25	-1.10		1.45	3.40	0.35	-1.35	5.85	3.75	5.10	-0.35	-0.55		-1.00	0.70	3.50			4.45	7.70	-2.35	-0.35		-2.00		1.35	0.65	3.15	535	-6.70	2.80	Mean	
Mean  -2.05  -4.65  -4.65  -4.75  -2.16  -0.40  -0.40  -0.40  -0.40  -0.40  -0.55  -0.			0.35	0.14	0.57	1.06	0.21		0.92	2.55		0.21	0.42	1.91	0.07	1.06	0.07	0.71	1.06	0.78		1.27	0.42	0.57			0.49	0.28	0.07	0.07		0.42		0.35	0.07	0.35	0.78	1.13	0.14	SD	
Mean  -2.05  -4.65  -4.65  -4.75  -2.16  -0.40  -0.40  -0.40  -0.40  -0.40  -0.55  -0.			6.0	-0.6	0.8	-0.2	3.4		4.3	-0.2		≐	1.9	2.3	2.0	2.9	4.5	6.0	-0.7	-0.2		-2.9	1.2	6.8			4.6	-0.2	-2.8	-0.5		-1.0		2.5	3.9	3.6	-5.7	4.7	-2.5	Measurement 1 M	1 31 (47 10-141
	Mean SD Median N		5.6	-1.2	-1.0	0.3	2.4		-5.9	-2.8		0.9	0.7	1	1.1	3.7	5.2	4.0	-1.5	-0.8		-1.6	0.5	5.3			6.7	1.0	-1.4	-0.3		-0.6		2.4	5.5	3.9	-6.2	-5.1	1.6	leasurement 2	7
90 90 90 90 90 90 90 90 90 90 90 90 90 9	0.80 3.23 0.63 30		5.80	-0.90	-0.10	0.05	2.90		-5.10	-1.50		1.00	1.30	1.70	1.55	3.30	4.85	5.00	-1.10	-0.50		-2.25	0.85	6.05			5.65	0.40	-2.10	-0.40		-0.80		2.45	4.70	3.75	-5.95	4.00	205	Mean	
0 22 8207 8 4688 868 872672884 20 28788			0.28	0.42	1.27	0.35	0.71		1.13	1.84		0.14	0.85	0.85	0.64	0.57	0.49	1.41	0.57	0.42		0.92	0.49	1.06			1.48	0.85	0.99	0.14		0.28		0.07	1.13	0.21	0.35		0.54	SB	

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4.98 11.05 31	12.46	25.80	13.85	11.80	13.20	9.70		13.45	24.00		<u></u>		20.00	1 2 2	19 25	7.95	9.15	12.00	10.40	0.00	1000	7.20	14 20	300	920			10.35	n :	in 6	n S	5	100	a 20	3 2	3 0	3 0	5 R	0.00	3 6		Mean
	2 00	1.84	0.49	0.71	0.71	0.57		0.07	0.57		0.21	200	0.78	1 34	1.77	0.07	0.92	0.00	0.42	9 9	000	į	1 27	0.78	0.57			0.49	25.0	20	0 21		0 0	24.0	2 5	3 2	2 4	0 84	0.16	0.43	63	SD
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		0.49	0.57	0.64	2.05	0.14		2+.0	3 6	2 70		007	0.14	0.49	0.21	0.42	0.85	1	3 6	0 85	0 07		0.07	0.92	0.49			0.49	0.71	0.71	0.71		0.07		0.92	0.21	0.85	0.07		0.99	4	SD
		28.0	10.7	11.4	11.3	0	,	:	77	Š		60	11.0	8.2	10.8	13.2	14.9		10.1	20	102		12.1	9,9	11.4			8.6	11.1	14.2	9.9		10.7		8.4	9.5	16,1	12.2		10.7	126	Week 8
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Median	Mean	29.3	10.2	9.3	11.		3	;	70.0	15.2		56	11.3	7.4	10.3	14.1	0	100	10.6	8.9	9.7		9.8	10.5	10.7			8.0	10.1	15.7	8.6		9.9		9.6	10.4	16.4	14.9		11.3	12.8	surement
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Median N	Mear SD		27.4	1 0	2 2	100	8 0		13.2	18.7		<u>0</u> .5	11.7	10.7			10 1	9.6	15.3	10.5	9.6		10.7	11.9		3			0	17.2	10.1		8.9		11.6	14.5	16.3	11.3		17.0	10.1	Week 12 Measurement 1 Measurement 2
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			014	242	207	3 57	0.28		0.49	0.07		28.0	8 8	2 2 2	2 6	5	14	214	0.49	0.35	2.7		2	28.0	3 9	2		٤	1	2 2	2	8	0.28	3	3	2/2/	1 6	99.0	3	2	0.42	SD

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ued	47	n e	8	셠	ដ	51	451	49	45	57	2	8	40 :	47	4 6	4 1	57	61 <b>4</b>	3 5	2 :	5 1	52 :	4 E	2	59	4	언	48	57	56	87 1	38	g	41	3 (	h 6	Γ	Ś	
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	319	2.0	4.7	-0.6	-0.5		-1.6	4.2		-1.7	-0.7	2.1	7.4	20	2.4	-0.8		1.6		28	4.8	0.2		3.1	0.0	-3.9	-1.0		-1.9	8.8	0.6	40	7.4	-6.8		å ö	Measurement 1	Week 2 vs. Baseline	
Mean SD Median N	37.5	5 10	3 5	-0.9	14		-1.8	4.0		-1.2	-0.1	34	9.7	1.8	4.0	<u>:</u>	1.7	3.0		39	5.0	-0.2		5.7	-0.6	4	-22		-2.3	7.0	1.0	3,4	6.5	ύn On		52	Measurement 2	Baseline	
1.47 4.09 1.75 31	34 70	ا دا 19 خ	2 5	0.75	0.45		-1.70	4.10		-1.45	0.40	2.75	8.55	1.90	3.20	-0.95	1.75	2.30		3.35	4.90	0.00		3.00	0.30	4.	.9		-2.10	7.90	0.80	3.70	6.95	-6.20		6 E		Mean	
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TEWL Values (g/m<sup>2</sup>/hr) of Both Cheeks (Average of Right and Left)

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Control   Cont			S Comments	Discontinu	AMM M	CYR	EMM	죾	GEP	片	GFM	MDS	SWI	PCB	Æ	CMP	ξ	GSR	CLM	DKO	TME	JAC	Ę	SMM	PKM	 Yp	LGD	R S	P K	5	BFH	Ę	JRB	င်ရ	DAK	SKH	M &	2	Subjects	
Control   Cont			ž	i.	37	3	ಜ	အ	8	32	2	52	55	8	8	47	55	బ	đ	8	s a	SS	56	59	6	22	গ্ৰ	Ġ	58	58	59	গ্ৰ	53	2	57	47	8	5	Subject's Age	
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Marie   S.D   Massurement				Ì	_						_	-			_									_			-			_	_	9	<u> </u>		-	_	***			
Marie   S.D   Massurement					-	3.6	8.7	2.2	3	4	.6	0.7	9	5	57	1.8	8.5	6.9	0.2	0.3	8.0	65		0.5	2.	0.5	4		¥ 	4	3.1	7	07		ω 	=	6	8	ement 1	
Marie   S.D   Massurement	N N	Herie	s	Mear	8.3	13.8	21.1	12.6	10.2	13.1	5.6	12.0	4.2	9.5	7.0	12.4	19.4	17.6	11.9	10.8	17.8	16.9		11.7	12.6	11.0	7.1		10.2	10.5	14.1	10.0	10.1	6.8	4.	11.2	14.4	100	Measurem	Bas
SD	•	•				_								_			_							_			_													eline
Measurement1   Measurement2   Man   SD   Measurement2   Measurement2   Man   SD   Measurement2   Measurement2   Man   SD   Measurement2   Meas	8	1 1	4 14	11.30	8.18	13.68	19.88	12.35	970	12.20	5.58	133	4.05	8.98	6.83	12.08	18.93	17,25	11.03	10.55	17.85	16,68		1.10	12.35	10.75	6.73		9.78	0.43	13,55	9.83	0.38	6.38	4.35	1.13	3.98	0 84	dean	
Water   Wate					0.18	0.18	1.73	0.28	0.64	1.20	0.04	0.88	0.21	0.74	0.25	0.39	0.67	0.49	1.17	0.35	0.14	0.25		0.85	0.35	0.35	0.53		0.53	0.1	0.71	0.18	0.39	0.60	0.14	0.11	0.60	2	SO	L
Water   Wate					11.2	21.5	18.4	11.8		18.6	, (5)	23.9	8.7	11.6	5.3	10.9	14.7	23.9	12.8	8.3	10.1	20.2		10.2	11.9	8.4	6.2		6.1	14.1	14.4	12.8		8.0	4.51	10.7	13.4		Measurem	
Mart   SD					_					L						_								_		_									_		-			
Maan   SD   Maanumment   Maan	z	Median	8	Mean	11.2	21.4	18.2	13.0		18.1	6.8	25.4	8.9	12.8	5.6	12.1	15.6	26.5	13.6	8.5	11.7	21.2		10.9	12.1	9	6.0		10.3	14.3	15.3	13.1		7.9	4.7	10.7	13.9		sasuremen	Week 2
SD	2	12	on ;	12	=======================================	21	18	12		18		- 1		12	on.	=	55	25	ü		10	23		10	12	.8	6		ő	7	<u> </u>	12.		7.5	4	10	13		-	2
Measurement	6	8	37		_	_	_		8									_	_					-				*	-	-	_			_	_				_	
Measurement   Mean   SD   Measurement   Me					24	=	68	85		3	8	2	4	=	- 2	85	2	87	57	4	13	-		6	4	tô	4		-	4	2	21		2	4	2	38		_	-
Measurement   Mean   SD   Measurement   Me					10.1	13.5	14.7	1.5		11.3	6.6	12.7		13.8	7.1	13.3	10.8	17.9	11.0	8.2	11.1	17.5		12.0	9.4	8.5	7.2		11.7	12.0	13.8	11.9		6.6	5.0	12.0	11.7		asurement	
Mean         SD         Measurement I         <					_																_				_	-											1000			
Mean         SD         Measurement I         <	z	dedian	SD	Mean	10.8	14.5	16.9	12.2		11.4	7.0	Ī		15.0	7.8	4.4	11.1	19.8	11.7	8.4	13.2	17.1		12.5	9.6	8.7	7.0		12.1	13.3	14.5	13.7		6.9	4.5	13.0	11.2		urement 2	Week 4
Measurement	28	11.85	3.29	11.50	10.45	13.98	15.78	17.63		1.30	6.80	10.40	3	14.38	7.40	13.80	10.90	18.83	11.35	8.28	12.10	17.28		12.25	9.45	8.58	7.08		11.88	12.63	14.15	12.78		6.75	4.73	12.48	11.46		-	
Massurement 2   Mann   SD   Massurement 1   Massurement 2   Mann   Massurement 1   Massurement 2   Mann   Massurement 2   Mass					0.49	0.67	1.59	0.46		0.07	0.20	2 5		0.88	0.49	0.78	0.21	<u>.</u>	0.49	0.1	1.48	0.32		0.35	0.14	0.18	0.11		0.25	0.95	0.49	1.24		0.21	0.32	0.67	0.35		so	
Massurement 2   Mann   SD   Massurement 1   Massurement 2   Mann   Massurement 1   Massurement 2   Mann   Massurement 2   Mass					L	_	_	_			_	_					_	_	_	_	_			-		_	_		-		_	_				_	_		Measu	
Mean   SD   Measurement   Me					7.9	4	:3	0.8			; :	-	7	3.4		1.7	2	- 4	Ü	1.2	-	.00		-	.4	5			8	4.3	1.5	-		3.6		2.8	:3		-	
Mean   SD   Measurement   Me	z	Media	S	Mear	7.9	12.3	11.5	17.4		<u>.</u>		10.0		14.2	8.4	11.8	15.6	15.9	11.5	8.4	14.4	16.3		7.11	8.5	9.0	6.2		9.0	14.0	11.3	10.4		8.6	3.9	13.6	10.0		Measurem	We
SD   Measurement   Measureme		_			L													_			_											_					_		2	e a
Measurement I Measurement Z Mean  Measurement I Measurement Z Mean  1507 113.5 15.00  160.6 9.1 8.50  161.6 16.4 8.50  163.6 16.2 16.25  1	28	10.90	3.08	10.55	7.88	11.85	11.35	17.05		200	2 2	100	3	13.75	220	11.75	15.33	5.33	48	8.25	14.25	16.03		135	7.95	8.73	6.20		8.88	14.05	1.38	10.75		8.58	3.98	13.20	10.60		Mean	
Mean 15.00 5.90 5.90 5.90 10.03 11.00 8.93 1					0.04	0.64	14	0.42		- -	5	2 9	•	0.57	1 2	0.07	28.0	0.74	0.04	0.14	0.21	0.32		0.42	0.78	95.0	0.07		0.18	0.07	0.18	0.49		004	0.18	0.57	0.92		_	
Mean 15.00 5.90 5.90 5.90 10.00 11.25 11.2					9.1	15.8	15.5	14.0		27.2	, ,	3	:	13.6	1 1 1	12.1	ő	13.4	127	. ~	19.4	13.6		11.0		11.0	0.4		14.5	10.3	ă.	10.4		88	6.0	12.7	15.6		Aeasureme	
Mean 15.00 5.90 5.90 5.90 10.00 11.25 11.2					L		-		200000000000000000000000000000000000000									_												_	_				_				nt 1 Mea:	
Mean 15.00 5.90 5.90 5.90 10.00 11.25 11.2	z	Median	SD	Mean	9.6	14.4	15.0	13.6		19.0	0.0	0 6	6	14.1	10.	11.9	10.0	14.4	8.71	2.2	0.27	13.4		10.0		7	0.0		15.2	0.0	4	11.2		9.1	5.8	13.2	14.5		surement 2	71 VDDAA
	27	12.00	3.72	12.23	9.35	15.05	15.25	10.00		è	3 .	7 7 7	: :	582	3 6	12.00	10.03	13.90	12.75	8	20.99	13.48		200		-			14.83	10.10	0.23	10.75		8.93	9.90	12.93	15.00		1	-
					ŀ				8			-	- 8	26.0	0.70	0.14	0.07	2 2	0.07	0.5	-	9 5			3	-			0.46	0.23	0.10			-					S	

Intra-Subject Change in TEWL Values ( $g/m^2\hbar r$ ) of Both Cheeks (Average of Right and Left)

	67	66	65	2	61	8	59	57	2	51	49	47	46	4	40	39	32	2	28	27	26	24	21	20	<del>1</del> 9	18	17	12	<b>6</b> 00		7 (	، د	٠.	1	Subject
Discontinued	AMM	CYR	EMM	죾	GEP	ĴΈ	GFM	MDS	SWI	PCB	Ę	CMP	§	GSR	CLM	DKO	¥	JAC	E	SMM	PKM	≤g	မြ	æ	Š	Ę	BFH	Ę	בי מלי	1 9	DB S	S I	<u>Σ</u> (	SDC	Subject's
8.	37	39	u	36	53	32	2	52	8	59	55	47	55	52	å	প্ত	38	କ୍ଷ	8	59	46	స	গ্ৰ	\$	58	8	59	57	සු ¥	2 1	52 :	47	8	4	Subject's
	Female	Fernale	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female		Female	Female	Female	Female	Gender							
	3.2	8.0	-0.3	-0.4		7.2	1.2	13.2	4.8	3.2	-1.4	-1.0	-3.G	7.0	2.6	-2.1	-7.9	3.7		-0.3	-0.2	-2.2	-0.2		0.7	3.7	1.4	3.1	7.0	3 :	0.2	5	-0.2		Week 2 vs. Baseline Measurement 1 Measure
Mean SD Median N	2.9	7.6	-3.0	0.4		5.0	1.3	13.4	4.7	3.3	-1.5	-0.3	ن 8.	8.9	1.8	-2.4	<u>6.1</u>	4.4		-0.8	0.51	-2.0	÷		0.1	3.co	1.3	3.2	Ξ	- 1	0.2	-D :	ь 6		s. Baseline Measurement 2
1.48 3.98 0.38 29	3.00	7.75	-1.60	0.05		6.10	1.23	13.30	4.75	3.20	-1.43	-0.63	-3.78	7.93	2.18	-2.20	-6.95	4.03		-0.57	-0.35	-2.05	-0.63		0.38	3.73	1.30	3.13	Ę	'n	0.20	0 45	-0.35		Mean
	0.21	0.28	1.91	0.57		1.56	0.04	0.14	0.07	0.07	0.04	0.46	0.04	1.38	0.60	0.21	1.27	0.46		0.39	0.21	0,14	0.67		0.39	0.04	0.07	0.04	Ş	2	0.00	0.07	0.21		SD
	2.1	-0.1	4.0	-0.7		6.1	1.0	2.0		5.3	0,4	1.5	-7.7	:0	0.8	21	-6.9	1.0		1.5	-2.8	-21	0.8		2.3	1.6	0.8	22	6.6	2 2	0.7	0.9	-1.9		Week 4 vs. Baseline Measurement 1 Measur
Mean SD Median N	2.5	0.6	4.2	-0,4		-1.7	1.5	2.2		5.5	0.8	2.0	-8.4	2.2	-0.2	-2.5	4.6	0.2		8.0	<u>.</u>	-2.3	-0.1		1.9	2.8	0.4	3.7	٠.	2	0.0		-33		Baseline Measurement 2
-0.06 2.78 0.48 28	2.28	0.30	4.10	-0.53		-0.90	1.23	2.08		5.40	0.58	1.73	-8.03	1.58	0.33	-2.28	-5.75	0.60		1.15	-2.90	-218	0.35		2.10	2.20	0.60	2.95		38	0.38	1.35	-2.58		Mean
	0.32	0.49	0.14	0.18		1.13	0.32	0.18		0.14	0.25	0.39	0.46	0.81	0.67	0.25	63	0.57		0.49	0.21	0.18	0.64		0.28	0.85	0.21	1.06		39	0.46	0.57	0.95		SD
	-0.2	-2.2	-7.4	-1.4		-0.7	-0.9	<u>4</u> 3.1		4.9	1.5	-0.1	3.4	-21	1.3	-2.2	-3.9	-0.7		0.6	4.7	-2.1	-0.1		-0.7	3.8	-1.6	1.4		26	-0.2	1.8	-23		Week 8 vs. Baseline Measurement 1 Measurer
Mean SD Median N	-0.4	-1	-9.7	-1.2		4.0	0.1	-3.2		4.7	1.4	-0.5	-3.9	-1.	0.4	-2.5	-3.4	-0.6		0.0	4	-20	-0.9		-1.2	3.5	-2.8	0.5		<del>-</del>	-0,6	2.4	4. ro:		s. Baseline Measurement 2
-1.01 2.65 -0.78 28	-0.30	1.83	6.53	-1.30		-2.33	-0.42	3.10		4.78	1.43	-0.33	-3.60	-1.93	0.45	-2.30	3.60	-0.65		0.25	4.40	2.03	0.52		-0.90	3.63	-2.18	0.93		2 20	-0.38	2.08	-3.38		Mean
	0.14	0.46	1.59	0.14		2.30	0.74	0.07		0.18	0.11	0.32	0.35	0.25	28	0.21	0.35	0.07		0.42	0.42	0.04	8		0.35	0.18	0.88	0.67		0.57	0.32	0.46	1.52		SD
	=	2.2	3.2	1.8		9.9	2.6	0.7	-	5.2	4.7	0.3	-2.4	3.5	2.5	-1.7	1.5	<u>6</u> .0		0.5		Ξ	0.0		5.1	0.1	-5.0	0.7		29	1.00	1.6	2.0		Week 12 vs. Baseline Measurement 1 Measurement 2
Mean SD Median N	1.3	0.5	6	0.6		6.7	.ω	÷		4.6	3.2	-0.4	-3.4	3.2	1.0	-1.7	4.60	3.5		-0.9		==	1.5		5.0	-0.6	-5.7	1.2		23	1.4	2.0	0.0		Measurement 2
0.70 3.03 1.05 27	1.18	.38	4.63	1.20		8.28	1.93	-0.20		4.85	3.93	-0.08	-2.88	333	1.73	-165	3.14	-3.20		-0.23		1.05	-0.75		5.05	-0.30	-5.33	0.93		2.55	1.55	1.80	1.03		Mean
	0.18	1.17	2.09	0.85		2.23	0.88	1.27		0.42	1.03	0.53	0.74	0.21	1.10	0.00	2.37	0.35		1.03		0.00	1.06		0.07	0.35	0.53	0.39		0.42	0.28	0.28	1.38		SD

				_			_						_	_				_	8	_	_		-3	×.				2	_			- 8	1	•
28	4.52 4.52	8,30	21.30	12.65	830	12.30	5.75	10.70	3.45	8.45	7.25	12.85	20.05	17.35	11.40	10.10	21.15	13.15		10.55	10.40	000	6.05	- 15	7.75	2 2 2	0.00	10 15	6.75	4.75	11.00	14 55	985	Mean
		0.99	.82	0.21	0.28	1.13	0.21	1.13	0.07	0.07	0.35	0.92	0.78	0.49	0.99	0.42	į,	0.35		0.78	0.28	0.71	20	ş	0 9	2 0	0.49	20.7	1.06	0.35	0.00	1.06	0.35	SD
		11.8	16.7	12.0		15,5	6.3	21.5	8.5	11.9	5.7	10.0	14.6	25.6	12.8	8.0	10.4	21.3		10.0	12.8	8.7	7.3			3 0	12.0	;	6.3	4.0	12.8	14.6	The state of the s	Week 2 Measurement 1 Measurement 2
Z	Mean SD	12.0	16.8	14.0		15.9	7.0	22.3	7.8	13.0	5.8	10.5	14.6	28.6	13.5	8.7	12.8	22.8		10.4	13.0	9.0	6.6		3	<del>л</del> с	1 4	;	5.4	4.0	10.8	15.3		K 2
28	12.77 5.45	11.90	16.75	13.00		15.70	6.65	21.90	8.15	12.45	5.75	10.25	14.60	27.10	13.15	8.35	1.60	22.05		10.20	12.90	8.85	6.95		20.0	5,0	1730	3 36	6.35	4.00	11.80	14.95		Mean
		0.78	0.07	1.41		0.28	0.49	0.57	0.49	0.78	0.07	0.35	0.00	2.12	0.49	0.49	1.70	1.06		0.28	0.14	0.21	0 49		0.40	2 .	1 1	ì	0.07	0.00	1.41	0.49		g
		9.1	15.0	11.7		11.3	7.1	11.6		13.6	7.8	12.4	9.3	21.3	11.8	6.6	11.8	20.5		12.0	9.4	9.0	5.6		0	100	, n	3 3	6.1	3.8	12.5	12.2		Week
Z	Mean SD Median	10.8	17.8	12.3		<b>1</b> 1.1	8.3	13.5		15.0	8.5	13.1	9.7	24.1	12.6	6.3	14.9	19.9		12.9	9,6	8.9	6.2		10.3	3 5	50 10	÷5.	6.3	3.8	13.7	11.0		k 4 Measurement 2
28	11.71 4.16	9.95	16.40	12.00		11.20	7.70	12.55		14.30	8.15	12.75	9.50	22.70	12.20	6,45	13.35	20.20		12.45	9.50	8,95	5.90		10.05	12 75	16.05	13 70	6.20	3.80	13.10	11.68		Mean
		1.20	1.98	0.42		0.14	0.85	:34		66.0	0.49	0.49	0.28	1.98	0.57	0.21	2.19	0.42		0.64	0.14	0.07	0.42		0.35	206	1 2	3	0.14	0.00	0.85	0.85		SD
		7.8	9.7	9.6		12.3	4.6	6.6		13.5	8.7	7.4	13.1	14.5	9.8	7.0	14.5	13.1		9.1	6.5	8.2	4.9		7.4	126	127	501	8.9	4.0	12.1	10.1		Week 8 Measurement 1 Measurement 2
Z	Mean SD Median	77 5	11.0	10.3		9.3	5.1	8.7		14.6	8.7	11.3	13.7	16.1	10.6	7.7	16.2	14.2		10.3	8.8	8.5	4.9		80	13.0	129	110	8.9	4.7	14.0	9.3		k 8 Measurement 2
28	3.02	7.75	10,35	9.95		10.80	4.85	7.65		14.05	8.70	11.35	13.40	15.30	10.20	7.35	15.35	13.65		9.70	7.65	8.35	8		7.70	12.80	12.80	3	9.93	4.35	13.05	9.70		Mean
		0.07	0.92	0.49		212	0.35	1.48		0.78	0.00	0.07	0.42	1.13	0.57	0.49	2	0.78		0.85	.63	0.21	0.00		0.42	0.28	0 1	1 27	9	0.49	3	0.57		SD
		8.0	16.3	12.3		18.9	7.0	11.5		11.1	121	12.6	15.8	12.0	13.3	8.6	16.4	11.8		8.7		9.8	5.2		14.3	10.6	8 2	10.5	0.0		13.2	15.4		Week 12 Measurement 1 Measurement 2
z	Mean SD Median	8.2	15.5	11.7		- <del>1</del> 8.5	5,5	10.5		12.5	10.1	12.3	15.5	13.2	13.1	9.3	18.1	12.3		9.3		10.3	4.ω		15,3	9.8	9.8	125	9.4		13.4	15.2		k 12 Measurement 2
27	3.52 11.80	8.10	15,95	12.00		18.70	6.25	11.00		11.80	11.10	12.45	15.65	12.60	13.20	8.95	17.24	12.05		9.00		10.05	4.75		14.80	10.20	9.35	± 8	0.40	9.50	13.30	15.30		Mean
		0.14	0.49	0.42		0.28	1.06	0.71		0.99	1.41	0.21	0.21	0.85	0.14	0.49	1.16	0.35		0.42		0.35	0.64		0.71	0.57	0.64	141	0.07	0.42	0.14	0.14		SD

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MEE BAM MEE BA

# Data Listing 4 A CLINICAL STUDY OF TOPICAL ZEATIN FOR IMPROVING THE APPEARANCE OF PHOTODAMAGED SKIN

Intra-Subject Change in TEWL Values (g/m²/hr) of the Right Cheek

	67	28	g.	61	60	55	57	57	51	46	47	46	4	40	35	32	4	28	27	26	24	21	20	19	18	17	12	9	8	7	3	2 .	_	Subject Number
0																						-									s S	Ζ :		
8	AMM																					-					-							
	37		_				_												_			-		_			-			52	47	50	8	.S.
	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Gender
	10.0 4.2	داراء	-0.		4.1	.0	<u> </u>	Çī,	ω	<u>.</u>	-2	4	8.8	2.	<u>.</u>		.8.		0.0	2.	-0	1.7		2.0	2.0	3.2	2.2		0.3	<u>.</u>	1.8	3.0		Week 2 Measurement 1
	~ c	, ω	5			-	6	_	0.	ω	2	θ	0,	_	σ.	7	_			,.	ω				_	_	, .		-	01	_	٠.		Week 2 vs. Baseline ement 1 Measure
Mean SD Mediai N	ည ထ	.5	<u>-</u> -		2.1		10.	4.	4.	<u>.</u>	ىي	<u>.</u> б	10.	-	<u></u>	-7.	9.		-0.	2.8	<u>.</u>	0.		9.0	ω	5.5	2		-	<u></u>	6	0.0		Baseline Measurement 2
ian	0 6		2		ω		·	ω	U1	7	•	0	9		7	4	_		7		51			0.		<u> </u>				_	2			ment 2
1.57 4.56 0.90 29	9.45 3.60	4.55	0.35		3.40	0.90	11.20	4.70	4.00	-1.50	-2.60	-5.45	9.75	1.75	-1.75	-9.55	8.90		-0.35	2.50	-1.15	0.90		1.25	2.65	4.45	2.70		-0.40	-0.75	0.80	0.40		Mean
	0.78	1.77	1.20		0.85	0.71	0.57	0.57	0.71	0.28	0.57	0.78	1.63	0.49	0.07	3.04	0.71		0.49	0.42	0.49	1.13		1.06	0.92	1.48	0.71		0.99	0.35	1.41	0.57		SD
	N				_		_		(7)	_	_		_		3.		_		N		_	_		(4)	_	N			_	_	_	-		Measu
	1.5	5.0	3.8		0.2	2	.7		2	.8	).2	0.2	ω	=	3.2	0.3	6		6	1.2	),5	0.0		.0	2	5	.9		Ξ	).7	Ċ	<u>.</u> 6		Week 4 v Measurement 1
_ Me (s M	(u	, L	<u>.</u>		Ł,	2	2		6		_	7	6	0	٦.	۸.	6			<u> </u>	_	_		2	_	u	4			<u>.</u>	N	L		Week 4 vs. Baseline ement 1 Measure
Mean SD Median N	œ Ñ	. 20	).5		0.0	.7	0		Ġ	.0	.4	0.9	4	Ġ	Ξ	ິພ	Ċħ		.80	.6	.6	.3		.6	Ċ	.9	2		Ю	2	.7	:3		Baseline Measurement 2
0.24 3.79 0.83 28	1.65	4.90	-0.65		-1.10	1.95	1.85		5.85	0.90	-0.10	-10.55	5.35	0.80	-3.65	-7.80	7.05		1.90	-0.90	-1.05	-0.15		2.80	0.85	3.20	3.05		-0.55	-0.95	2.10	-2.95		Mean
	0.71	0.14	0.21		1.27	1.06	0.21		0.92	0.14	0.42	0.49	1.48	0.42	0.64	3.54	0.78		0.14	0.42	0.78	0.21		0.28	0.92	0.99	1.63		0.92	0.35	0.85	1.91		SD
					0	٠.	2.		ćn	_	_	<u>_</u>		_		٠.			_		٠.	<u>_</u>		0	0	_	_		N	_	_	25		Week 8 Measurement
	0.2	. 3	.9		.80	ω	ັພ		_	.7	.8	.4	5	.6	8	6	2		.9		نى	-0.7		.60	œ	.4	2		9	Ç,		.7		1 %
Mean SD Mediar N	-1.3	-11.6	-2.5		-3.8	-0.5	-2.8		6.1	1.2	-2.2	-6.9	-1.6	-1.5	-2.7	-4.0	0.8		-0.8	-1.4	-2.0	-1.6		0.3	1.0	0.3	0.9		1.4	-0.3	3.0	-6.0		vs. Baseline Measurement 2
,																																		-
-1.37 3.11 -1.03 28	-0.55	10.95	-2.70		-1.50	-0.90	3.05		5.60	1.45	-1.50	-6.65	-2.05	-1.20	-2.75	-5.80	0.50		-0.85	-2.75	-1.65	-1.15		0.45	0.90	0.05	0.35		2.15	-0.40	2.05	4.85		Mean
	1.41	0.92	0.28		3.25	0.57	0.35		0.71	0.35	0.99	0.35	0.64	0.42	0.07	2.55	0.42		0.07	1.91	0.49	0.64		0.21	0.14	0.49	0.78		1.86	0.14	1.34	1.63		SD
	0.4	-3.7	-0.2		7.4	=	1.6		2.7	5.1	0.4	-3.7	-5.0	2.6	-1.2	-5.7			-1.3		0.3	-0.4		7.5	-1.2	4.2	0.2		2.5	1.4	2.2	1.6		Week 12 v Measurement 1
																																		Week 12 vs. Baseline irement 1 Measuren
Mean SD Median N	-0.8	-7.0	-1.1		5.4	-0.1	-1.0		4.0	2.6	-1.2	-5.1	4.5	1.0	<u>.</u>	-2.1	-1.1		-1.8		-0.2	-22		7.6	-2.2	-2.8	1.5		0.9	0.3	2.4	-0.1		s. Baseline Measurement 2
0.15 3.16 0.05 27	-0.2	6.0	-0.6		6.4	0.50	0.3		ယ္သ	3.8	-0.4	-4.4	4.7	1.8		-3.5	-1.10		-1.55		0.0	-1.30		7.5	-1.7	-3.5	0.85		1.7	0.8	2.30	0.7.		t 2 Mean
						0 0.85													55 0.35															
	0.57	: 23	2		41	85	84		92	77	3	99	35	13	07	50	0.00		35		35	1.27		0.07	71	99	92		ಭ	78	0.14	20		SD

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																				-					21			_		- 8	0 (		7 0	۱ د	ა "	di Dei	Subject	
		Discontinu	AMM	CYR	MM	죾	GEP	Ę	GFM	MDS	SWI	PCB	ž	Ω P	≨	GSR	Σ	8	TML	JAC	F 5	MMS	PKM	ĕ	69	R A	Š	Ę	P :	FF.	Ö	2		ž	<u>Σ</u> ε	CIDUIT		
		ed	37	39	39	36	ន	33	64	52	8	59	58	47	g	స	43	5	38	g	88	59	46	52	57	45	58	58	59	57	ָ בּ	2	₹;	47	5 8	Aue	Subject's	
			Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female		Gender	
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N Necial	. 0	Mean	7.6	15.8	19.6	12.3	12.2	13.0	5.5	12.4	4.9	10.5	6.5	11.2	18.2	17.5	11.6	11.2	15.3	20.3		12.3	15.0	11.5	7.7		12.6	9.0	15.5	8.8	100	6.	မ	11.4	13.5	100	line Measurement	
-			L								_	_			_		_					<u>-</u>	<del>-</del>	<u>-</u>	7		=	8	7	9	_	<b>o</b>	ω		7. 7	ł	V.	
29	7 6	1.40																							7.40					900					13.40		Mean	-
			0.64	0.35	1.63	0.35	1.56	1.27	0.14	0.64	0.35	1.41	0.14	0.14	0.57	0.49	1.34	0.28	1.06	0.14		0.92	0.99	0.00	0.42		0.42	0.07	1.77	0.14	0.85	0.14	0.07	0.21	0.14		SD	
			10.6	21.2	20.1	11.6		21.6	7.3	26.3	8.9	11.3	4.8	11.7	14.8	22.1	12.8	8.5	9.8	19.1		10.4	11.0	8.0	5.1		11.3	14.3	12.3	13.1		9.6	4.9	8.5	12.1		We feasurement 1	
																																					Week 2	
N Neg		Mean	10.3	22.0	19.5	12.0		20.2	6.6	28.4	10.0	12.5	5.3	13.6	16.6	24.4	13.7	8.2	10.6	19.6		11.3	11.2	9.1	5.4		12.3	13.2	12.5	12.0		9.4	5.3	10.6	12.5		ek 2 Measurement 2	
29	1 9	5 1	_ 10	21	19	111.		20.	6.6	27.	9.4	11	5.0	12.0	5	23.	<u>1</u>	8.3	10	19.3		10.8	11.1	8	5.2		11.6	13.7	12.4	12.55		9.5	ر ن	9.5	12:3		Mean	1
Ψ ξ	5 -	7 /8			0.42			000000000000000000000000000000000000000												0.35		o de la composição de l			5 0.21				0 0.14			0 0.14			0000000		n SD	
			21	. 0	13	28		8	- 6	: #a	2	8	3	4	27	23	4	12	57	Ğ		*	4	à	-		-3	8	4	æ		4	ä		8		_	1
			11.1	13.0	14.3	11.3		11.2	6.1	13.7		13.9	6.3	14.1	12.2	14.5	10.2	9.8	10.3	14.5		12.0	93		8.7		13.6	11.9	12.0	11.6		7.1	6.1	11.5	11.1		/easurement	
																																			0000		1 VVeer	Wark A
z	Median	SD	10.8	13.9	16.0	12.0	5	11.0	5.	14.8		15.0	7.0	5.5	12.4	5.4	10.8	10.4	11.4	14.2		12.1	9	0.0	7.8		13.8	13.1	12.5	12.1		7.5	5.2	12.2	11.3		Measurement 2	
:	÷ ,	N =	-						. 0	1 T		7						-		4 3		12	· ·		- 00		ä	12	- 13	=======================================		7	ρ'n		11.20		_	-
28	75	77 20	ı				8																		8.25					11.85 C				-			Mean	
			- 12	1	2 2	4	5	2	2 2	2	3	۵	46	8	4	4	4	4	à	12		0	4	÷ .	0.64		14	ď	3	35		28	64	49	4		SD	
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#### Baseline to Week 2 Diary Comments

Subject No.	Initials	Age	Sex	Diary Comments (Baseline-Week Two Visit)
4	SKH	46	F	Disappears quickly. Skin feeling much smoother. Skin seems to be getting tighter.
10	JCL	41	F	Have noticed no difference.
11	TLM	50	F	Goes a long way. Helps make-up come off more easily.
15	NHK	56	F	Skin feeling sticky and tacky. Tacky in p.m. Dry in a.m. Blemishes present. Skin rough and dry.
16	VLH	57	F	Went on smooth.
25	TJJ	40	F	Make-up looks cakey after sunblock. Chin broke out.
29	DSE	59	F	Fast-absorbing; non-greasy; smooth.
36	MAE	51	F	Gentle and mild.
42	KAM	52	F	Skin felt tight.
43	CGC	48	F	Makes my face very dry.
45	TDC	48	F	Redness still there but no worse. Redness still on right cheek. Redness still there.
48	JLL	47	F	Notice blemishes.
50	DKH	49	F	Feels tight, but not uncomfortable. Feels more moist but firm. My face is feeling smoother.
52	CJL	53	F	Seems to clear skin up.
53	DSB	54	F	Improved wrinkles. Dryness, tight, tingling, redness-blotchy. Skin clearer. I can tell a marked difference in appearance.
55	SKR	57	F	Too dry. My skin doesn't feel moisturized after it dries.
58	CZR	49	F	Feels kind of greasy. Feels o.k. Feels good. Feels like face is tight. Feels O.K. Smooth.
70	CAC	62	F	Slight burning; face slightly red, felt soft. Slight swelling under right eye.
72	NRC	56	F	No irritation.
73	NLW	47	F	Jaw area began to breakout. Notice dry patches. Dryness continued. Skin very dry.

#### Week 2 to Week 4 Diary Comments

Subject No.	Initials	Age	Sex	Diary Comments (Baseline-Week Four Visit)
5	LMP	45	F	Starting to feel a little greasy.
10	JCL	41	F	Product absorbs well. Still haven't noticed improvement.
11	TLM	50	F	Burns your eyes when you wash it off.
29	DSE	59	F	No complications; continues to go on smoothly and absorb fast. Non-greasy; sunscreen is slightly greasy.
43	CGC	48	F	Makes my face very dry.
50	DKH	49	F	Face feels smoother after use.
53	DSB	53	F	Dryness. Put vaseline at eyes.
55	SKR	57	F	I noticed a little improvement.

#### Week 4 to Week 8 Diary Comments

Subject No.	Initials	Age	Sex	Diary Comments (Baseline-Week Two Visit)
5	LMP	45	F	Greasy feeling, but dry after a few minutes.
43	CGC	48	F	Moisturizes and sunblock is feeling better. Skin not as dry
45	TDC	48	F	Redness on right cheek.
50	DKH	49	F	Face feels firm and moist. Starting to get blemishes. Still feels smooth, but causing break-outs.
55	SKR	57	F	I can tell some difference for the better.

# $Data\ Listing\ 5$ A Clinical Study of Topical Zeatin for Improving the Appearance of Photodamaged Skin

## Week 8 to Week 12 Diary Comments

Subject No.	Initials	Age	Sex	Diary Comments (Baseline-Week Two Visit)
29	DSE	59	F	Makes my skin softer.
43	CGC	48	F	Skin dry.
50	DKH	49	F	Face feels smooth and moist. Face has dewy look.
55	SKR	57	F	Really like product!
69	GHD	55	F	The sunscreen clogs my pores.

#### Baseline to Week 2 Diary Comments

Subject No.	Initials	Age	Sex	Diary Comments (Baseline-Week Four Visit)
3	SKH	47	F	Soaks in skin quick. Started noticing some dryness around eye area. Quit putting so close to eye (outside). Like how it goes on skin-few minutes after, you can put make-up on. Like it.
7	DBK	52	F	Clear, cool, feels good. Don't like the sunblock. Sunblock burns my eyes.
8	JCF	54	F	Liked creaminess - no irritation. Dries fairly quickly.
17	BFH	59	F	I like the cream; it makes your face feel good, not greasy. I really like this product.
18	LJR	58	F	Skin feels tighter after application of product.
19	D-M	58	F	Feels soft, but not greasy. Feels and acts more like a hand lotion. I can tell my face is drying. Face is very dry. There are a couple of rough spots. Face feels like it's sloughing.
27	SMM	59	F	Soaks in quickly.
32	TML	38	F	Recurring blemishes.
39	DKD	50	F	Dries fast! Doesn't glide on slippery. Feels kind of stiff on skin. Easy to put make-up over, because it dries so fast.
49	L-R	58	F	Skin seems somewhat tightened.
59	GFM	64	F	Goes on smooth. No odor (great), no burn, and doesn't feel heavy.
60	JLF	32	F	I like how soft my face feels and the fact that the lotion does not smell bad.
65	EMM	39	F	Dryness.
66	CYR	39	F	The product feels soft.
67	AMM	37	F	Make-up went on smoother.

# $\label{eq:DataListing} Data\ Listing\ 6$ A Clinical Study of Topical Zeatin for Improving the Appearance of Photodamaged Skin

Week 2 to Week 4 Diary Comments

Subject No.	Initials	Age	Sex	Diary Comments (Baseline-Week Four Visit)
3	SKH	47	F	Like the tightness. Needs a little moisturizer in product.
17	BFH	59	F	Skin felt tight after study but it is now back to normal.
19	D-M	58	F	Face is peeled. Face is getting smoother. Face feels very smooth. Had a pimple-type bump. Face is drying again. Bump is gone.
40	CLM	43	F	It makes my face break out.
59	GFM	64	F	Goes on smooth. Slight redness. Feels o.k. Lines at eyes look less. Skin feels dry.

# $\label{eq:DataListing} Data\ Listing\ 6$ A Clinical Study of Topical Zeatin for Improving the Appearance of Photodamaged Skin

Week 4 to Week 8 Diary Comments

Subject No.	Initials	Age	Sex	Diary Comments (Baseline-Week Four Visit)
7	DBK	52	F	I see no change. I used both. Tanning one burns my eyes. The other is o.k. I don't like either cream. They don't feel the same as before. Sunscreen burns my eyes.
8	JCF	54	F	This face cream feels more creamy and not as drying as the other. I really like this cream - has no irritation.
17	BFH	59	F	Felt good to apply cream. Feels better than my cream. Absorbs quickly. Not at all greasy.
19	D-M	58	F	Seems like brown spots are disappearing. Face feels real smooth. My face looks really good - no more bumps or peeling.
27	SMM	59	F	Skin getting oily.
59	GFM	64	F	Face appears to look better.
67	AMM	37	F	Face clearing some. Face not completely clear, but looking better. 5.25.05 Face completely clear.

# Data Listing 6 A Clinical Study of Topical Zeatin for Improving the Appearance of Photodamaged Skin

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#### Week 8 to Week 12 Diary Comments

Subject No.	Initials	Age	Sex	Diary Comments (Baseline-Week Four Visit)
7	DBK	52	F	I used both. I still don't care for sunblock. I can see some difference but not as much as I thought I would have.
8	JCF	54	F	Soft and creamy.
17	BFH	59	F	I love this product. Don't like the sunscreen. It's helping my wrinkles. Sunscreen is pasty when used with the cream but I like it. I like the sunscreen a little better since I used the creamit gets kind of pasty. I like the feel of this cream. I have grown to like the sunscreen and have used it more if out in the sun. I would love to know how to purchase this cream.
19	D-M	58	F	Face feels really smooth. People are making comments, -"I really look rested." etc.

istributed to Subject No:	Sample Number	Date Distributed	Weight (in grams) at Time of Distribution	Weight (in grams) at Time of Turning in the Sample:	Date Product Turned In for Weighing	Days Used	Amount Used (in grams)	Use up Rat (in grams)
	4	4/11/2005	99.15	59.87	5/9/2005	28	39.28	1.40
4	1	5/9/2005	97.29	82.02	6/6/2005	28	15.27	0.55
	57	6/6/2005	97.47	55.60	7/1/2005	25	41.87	1.67
_	5	4/11/2005	97.33	72.48	5/9/2005	28	24.85	0.89
5	2	5/9/2005	97.45	43.59	6/6/2005	28	53.86	1.92
	56	6/6/2005	96.82	43.75	7/1/2005	25	53.07	2.12
6	6	4/11/2005	97,44	93.08	4/18/2005	7	4,36	0.62
10	10	4/12/2005	97.27	52.74	5/10/2005	28	44.53	1.59
10	7	5/10/2005	96.84	61.10	6/7/2005	28	35.74	1.28
	59	6/7/2005 4/12/2005	96.98	68.17	7/5/2005	28	28.81	1.03
11	11		97.43	71.06	5/10/2005	28	26.37	0.94
'' I	3 60	5/10/2005	97.47	62.65	6/7/2005	28	34.82	1.24
		6/7/2005	97.41	54.72	7/5/2005	28	42.69	1.52
13	13 8	4/12/2005 5/10/2005	97.60 98.09	54.93 55.16	5/10/2005	28	42.67	1.52
,,,	66		97.48		6/7/2005	28	42.93	1.53
	14	6/7/2005 4/12/2005	98.24	52.93	7/5/2005	28	44.55	1.59
14	9	5/10/2005		86.58	5/10/2005	28	11.66	0.42
'" <b>}</b>	67		97.26	91.28	6/7/2005	28	5.98	0.21
		6/7/2005	97.06	90.76	7/5/2005	28	6.30	0.23
15	15	4/12/2005	97.66	88,38	4/26/2005	14	9.28	0.66
16	16	4/12/2005	97.23	78.99	5/10/2005	28	18.24	0.65
10	12	5/10/2005	97.23	83.05	6/7/2005	28	14.18	0.51
	61	6/7/2005	96.91	83.30	7/5/2005	28	13.61	0.49
23	23	4/14/2005	97.45	47.41	5/12/2005	28	50.04	1.79
۷۵	20	5/12/2005	97.21	70.56	6/9/2005	28	26.65	0.95
	80	6/9/2005	97.10	84.96	7/7/2005	28	12.14	0.43
25	25	4/14/2005	97.10	77.81	5/12/2005	28	19.29	0.69
۷ ا	22	5/12/2005	98.29	82.46	6/9/2005	28	15.83	0.57
	75	6/9/2005	97.48	36.29	7/7/2005	28	61.19	2.19
29	29	4/15/2005	97.87	77.40	5/13/2005	28	20.47	0.73
29	21	5/13/2005	99.71	79.26	6/10/2005	28	20.45	0.73
	82	6/10/2005	97.07	76.57	7/8/2005	28	20.50	0.73
	30	4/15/2005	97.15	30.07	5/13/2005	28	67.08	2.40
30	27	5/13/2005	96.90	24.84	6/10/2005	28	72.06	2.57
	76	6/10/2005	96.77	23.40	7/8/2005	28	73.37	2.62
	35	4/18/2005	96.95	68.17	5/17/2005	29	28.78	0.99
35	54	5/17/2005	97.63	73.17	6/13/2005	27	24.46	0.91
	83	6/13/2005	97.22	74.30	7/11/2005	28	22.92	0.82
	36	4/18/2005	97.47	44.38	5/16/2005	28	53.09	1.90
36	38	5/16/2005	97.53	41.98	6/14/2005	29	55,55	1.92
i	88	6/14/2005	97.00	51.50	7/12/2005	28	45.50	1.63
	37	4/18/2005	96.75	45.65	5/17/2005	29	51.10	1.76
37	44	5/17/2005	97.26	63.86	6/13/2005	27	33.40	1.24
	84	6/13/2005	96.93	38.30	7/11/2005	28	58.63	2.09
	41	4/19/2005	97.03	55.79	5/17/2005	28	41.24	1.47
41	46	5/17/2005	97.21	35.51	6/14/2005	28	61.70	2.20
	86	6/14/2005	97.30	34.77	7/12/2005	28	62.53	2.23
	42	4/19/2005	95.89	74.78	5/17/2005	28	21.11	0.75
42	51	5/17/2005	97.21	76.52	6/14/2005	28	20.69	0.74
ſ	89	6/14/2005	97.61	76.19	7/12/2005	28	21.42	0.77
	43	4/13/2005	97.56	72.56	5/11/2005	28	25.00	0.89
43	17	5/11/2005	97.09	70.58	6/8/2005	28	26.51	0.95
1	64	6/8/2005	97.15	82.76	7/6/2005	28	14.39	0.51
	45	4/13/2005	98.14	82.40	5/11/2005	28	15.74	0.56
45	18	5/11/2005	97.17	82.25	6/8/2005	28	14.92	0.53
ľ	65	6/8/2005	97.27	81.81	7/6/2005	28	15.46	0.55
	48	4/13/2005	97.08	82.48	5/11/2005	28	14.60	0.52
48	19	5/11/2005	97.43	82.15	6/8/2005	28	15.28	0.55
İ	79	6/8/2005	97.33	77.45	7/6/2005	28	19.88	0.71
	50	4/14/2005	99.17	52.85	5/16/2005	32	46.32	1.45
50	33	5/16/2005	97.14	46.76	6/10/2005	25	50.38	2.02
ľ	87	6/10/2005	97.20	44.13	7/8/2005	28	53.07	1.90
	52	4/15/2005	97.81	57,53	5/13/2005	28	40.28	1.44
52	34	5/13/2005	97.17	56.01	6/10/2005	28	41.16	1.47
f	77	6/10/2005	97.33	45.74	7/8/2005	28	51.59	1.84
	53	4/15/2005	97.00	54.74	5/13/2005	28	42.26	1.51
53	26	5/13/2005	97.42	40.54	6/10/2005	28	56.88	2.03
	78	6/10/2005	96.98	52.25	7/8/2005	28	44.73	1.60
	55	4/15/2005	97.34	87.32	5/13/2005	28	10.02	0.36
55	28	5/13/2005	96.68	87.06	6/10/2005	28	9.62	0.34
	81	6/10/2005	97.22	74.80	7/8/2005	28	22.42	0.80
	58	4/18/2005	97.32	28.26	5/16/2005	28	69.06	2.47
58	31	5/16/2005	97.49	57.35	6/14/2005	29	40.14	1.38
	90	6/14/2005	97.15	45.72	7/12/2005	28	51.43	1.84
	62	4/18/2005	97.13	66.93	5/16/2005	28	30.19	1.04
62				66.23	6/13/2005	28	31.05	
02	32	5/16/2005	97.28					1.11
	94	6/13/2005	97.22	67.57	7/11/2005	28	29.65	1.06
63	63	4/18/2005	98.52	NR 63.00	E 14.7 10005	00	24.00	4.00
۵, ا	68	4/19/2005	97.11	63.09	5/17/2005	28	34.02	1.22
68	39	5/17/2005	97.34	53.14	6/14/2005	28	44.20	1.58
	95	6/14/2005	97.31	52.46	7/12/2005	28	44.85	1.60
l l	69	4/19/2005	97.45	74.15	5/17/2005	28	23.30	0.83
69	40	5/17/2005	97.10	64.85	6/14/2005	28	32.25	1.15

Distributed to Subject No:	Sample Number	Date Distributed	Weight (in grams) at Time of Distribution	Weight (in grams) at Time of Tuming in the Sample:	Date Product Turned In for Weighing	Days Used	Amount Used (in grams)	Use up Rate (in grams)
	70	4/19/2005	97.19	29.73	5/13/2005	24	67.46	2.81
70	24	5/13/2005	97.47	29.41	6/7/2005	25	68.06	2.72
′° [	74	6/7/2005	97.38	53,46	6/23/2005	16	43.92	2.75
	96	6/23/2005	97.40	33.55	7/11/2005	18	63.85	3.55
	71	4/19/2005	97.14	74.52	5/17/2005	28	22.62	0.81
71	47	5/17/2005	97.36	63.98	6/14/2005	28	33.38	1.19
	92	6/14/2005	97.13	61.96	7/12/2005	28	35.17	1.26
	72	4/19/2005	97.10	73.23	5/17/2005	28	23.87	0.85
72	49	5/17/2005	97.11	78.50	6/14/2005	28	18.61	0.66
	93	6/14/2005	97.52	80.43	7/12/2005	28	17.09	0.61
73	73	4/19/2005	97.37	77.13	5/3/2005	14	20.24	1.45
	91*		97.50					
	97*		97.30					
	98*		97.06					
	99*		96.65					
]	Discontinued						Mean	1.29
Product never	distributed						SD	0.70
NR-product was	s not returne	ed					Median	1.22
•								

Distributed to Subject No:	Sample Number	Date Distributed	Weight (in grams) at Time of Distribution	Weight (in grams) at Time of Turning in the Sample:	Date Product Turned In for Weighing	Days Used	Amount Used (in grams)	Use up Rate (in grams)
1	2	4/11/2005	96.78	NR				
2	1 1	4/11/2005	97.44	59.85	5/10/2005	29	37.59	1.30
-	13 68	5/10/2005 6/6/2005	97.57 97.42	69.17 39.55	6/6/2005 7/1/2005	27	28.40	1.05
	3	4/11/2005	97.55	39.55	5/9/2005	25 28	57.87 66.26	2.31
3	5	5/9/2005	97.53	40.96	6/6/2005	28	56.57	2.37 2.02
	52	6/6/2005	97.51	39.15	7/1/2005	25	58.36	2.33
***************************************	7	4/11/2005	97.66	70.97	5/10/2005	29	26.69	0.92
7	11	5/10/2005	97,64	59.50	6/6/2005	27	38.14	1.41
	53	6/6/2005	97.60	59.40	7/1/2005	25	38.20	1.53
	8	4/11/2005	97.82	52.10	5/9/2005	28	45.72	1.63
8	6	5/9/2005	98.35	71.62	6/6/2005	28	26.73	0.95
	55	6/6/2005	97.64	49.79	7/1/2005	25	47.85	1.91
9	9 12	4/11/2005	97.79	NR	F/40/0005			
12	14	4/12/2005 5/10/2005	98.12 97.46	63.66 57.59	5/10/2005 6/7/2005	28 28	34.46	1.23
'-	56	6/7/2005	97.89	50.50	7/5/2005	28	39.87 47.39	1.42 1.69
	17	4/12/2005	97.71	70.26	5/10/2005	28	27.45	0.98
17	15	5/10/2005	97.49	76.23	6/7/2005	28	21.26	0.76
	58	6/7/2005	97.66	71.24	7/5/2005	28	26.42	0.94
	18	4/12/2005	97.85	39.19	5/10/2005	28	58.66	2.10
18	16	5/10/2005	97.96	48.40	6/7/2005	28	49.56	1.77
	62	6/7/2005	97.45	51.66	7/5/2005	28	45.79	1.64
46	19	4/12/2005	97.32	50.87	5/10/2005	28	46.45	1.66
19	10	5/10/2005	97.59	50.12	6/6/2005	27	47.47	1.76
	69	6/7/2005	97.59	40.20	7/5/2005	28	57.39	2.05
21	21	4/14/2005	97.56	78.38	5/12/2005	28	19.18	0.69
21	23 76	5/12/2005 6/9/2005	97.71 96.88	79.88 67.57	6/9/2005 7/7/2005	28	17.83	0.64
	24	4/14/2005	96.88	69.99	5/12/2005	28 28	29.31 26.85	1.05 0.96
24	28	5/12/2005	97.58	74.35	6/9/2005	28	23.23	0.83
- '	77	6/9/2005	97.60	66.06	7/7/2005	28	31.54	1.13
	26	4/14/2005	97.56	69.31	5/13/2005	29	28.25	0.97
26	33	5/13/2005	97.24	66.55	6/15/2005	33	30.69	0.93
	74	6/15/2005	97.77	NR				
	27	4/14/2005	98.01	63.08	5/12/2005	28	34.93	1.25
27	25	5/12/2005	97.77	58.26	6/9/2005	28	39.51	1.41
	71	6/9/2005	97.85	61.77	7/7/2005	28	36.08	1.29
	31	4/18/2005	96.75	65.73	5/13/2005	25	31.02	1.24
31	29	5/13/2005	98.07	60.16	6/10/2005	28	37.91	1.35
	72 32	6/10/2005 4/15/2005	97.79 97.48	47.39	7/8/2005	28	50.40	1.80
32	38	5/13/2005	97.80	63.07 59.34	5/13/2005 6/10/2005	28 28	34.41 38.46	1.23 1.37
, J	79	6/10/2005	97.77	57,38	7/8/2005	28	40.39	1.44
	39	4/19/2005	98.09	59.81	5/17/2005	28	38.28	1.37
39	45	5/17/2005	97.80	52.79	6/14/2005	28	45.01	1.61
- 1	92	6/14/2005	97.89	50.58	7/12/2005	28	47.31	1.69
	40	4/18/2005	97.53	85.00	5/17/2005	29	12.53	0.43
40	50	5/17/2005	97.86	92.63	6/13/2005	27	5.23	0.19
	86	6/13/2005	97.53	86.95	7/11/2005	28	10.58	0.38
	44	4/19/2005	97.19	64.15	5/17/2005	28	33.04	1.18
44	48	5/17/2005	97.40	62.38	6/14/2005	28	35.02	1.25
	81	6/14/2005	97.39	48.52	7/12/2005	28	48.87	1.75
46	46	4/13/2005	97.29	70.51	5/11/2005	28	26.78	0.96
40	20	5/11/2005	99.99 97.75	81.86	6/8/2005	28	18.13	0.65
	63 47	6/8/2005 4/13/2005	97.75 97.16	73.46 80.56	7/6/2005 5/11/2005	28 28	24.29 16.60	0.87 0.59
47	22	5/11/2005	97.60	49.38	6/8/2005	28	48.22	1.72
1	70	6/8/2005	97.95	52.09	7/6/2005	28	45.86	1.64
	49	4/14/2005	97.83	60.71	5/13/2005	29	37.12	1.28
49	34	5/13/2005	97.63	33.75	6/13/2005	31	63.88	2.06
l	90	6/13/2005	97.88	37.04	7/11/2005	28	60.84	2.17
	51	4/15/2005	97.50	39.22	5/13/2005	28	58.28	2.08
51	30	5/13/2005	97.47	40.43	6/10/2005	28	57.04	2.04
	73	6/10/2005	97.81	38.76	7/8/2005	28	59.05	2.11
54	54 57	4/15/2005	97.45	68.62	5/11/2005	26	28.83	1.11
57	57 35	4/18/2005 5/16/2005	97.78 97.61	73.55 70.38	5/16/2005 6/13/2005	28 28	24.23 27.23	0.87 0.97
31	97	6/13/2005	97.61	70.38 59.78	7/11/2005	28	37.71	1.35
	59	4/18/2005	97.96	31.71	5/16/2005	28	66.25	2.37
59	4	5/16/2005	97.54	53.97	6/13/2005	28	43.57	1.56
	83	6/13/2005	97.31	45.76	7/11/2005	28	51.55	1.84
	60	4/18/2005	97.62	64.41	5/16/2005	28	33.21	1.19
60	36	5/16/2005	101.65	75.28	6/13/2005	28	26.37	0.94
	82	6/13/2005	97.74	66.39	7/11/2005	28	31.35	1.12
61	61	4/18/2005	96.95	NR				
	64	4/19/2005	97.78	83.38	5/16/2005	27	14.40	0.53
64	37	5/16/2005	97.61	73.58	6/13/2005	28	24.03	0.86
	91	6/13/2005	97.30	80.55	7/11/2005	28	16.75	0.60
1	65	4/19/2005	97.77	51.51	5/17/2005	28	46.26	1.65
65	41	5/17/2005	96.63	55.63	6/14/2005	28	41.00	1.46
	87	6/14/2005	97.57	56.88	7/12/2005	28	40.69	1.45
66	66 42	4/19/2005 5/17/2005	97.93 97.74	49.31 57.07	5/17/2005 6/14/2005	28 28	48.62 40.67	1.74 1.45

Distributed to Subject No:	Sample Number	Date Distributed	Weight (in grams) at Time of Distribution	Weight (in grams) at Time of Tuming in the Sample:	Date Product Turned In for Weighing	Days Used	Amount Used (in grams)	Use up Rate (in grams)
	67	4/19/2005	98.41	50.77	5/17/2005	28	47.64	1.70
67	43	5/17/2005	97.55	68.08	6/14/2005	28	29.47	1.05
	80	6/14/2005	97.79	62.27	7/12/2005	28	35.52	1.27
	75*		97.87					
	78*		98.02					
	84*		97.67					
	88*		97.86					
	89*		97.67					
	93*		98.02					
	94*		97.43					
	95*		97.71					
	96*		97.32					
	98*		97.47					
	99*		97.68					
	Discontinued						Mean	1.37
Droduct nover	dietributed						Madian	1 27

\*Product never distributed NR-product was not returned 
 Mean
 1.37

 Median
 1.37

 SD
 0.50

 N
 81

Distributed to Subject No:	Sample Number	Date Distributed	Weight (in grams) at Time of Distribution	Weight (in grams) at Time of Turning in the Sample:	Date Product Turned in for Weighing	Days Used	Amount Used (in grams)	Use up Rate (in grams)
1	82	4/11/2005	152,62	NR				
2	2	4/11/2005 5/10/2005	151.62	133.28	5/10/2005	29	18.34	0.63
2	38 129	6/6/2005	155.89 156.39	140.63	6/6/2005	27	15.26	0.57
***************************************	123	4/11/2005	157.30	118.37 98.41	7/1/2005 5/9/2005	25 28	38.02	1.52
3	5	5/9/2005	154.48	102.98	6/6/2005	28	58.89 51.50	2.10
	125	6/6/2005	151.33	112.60	7/1/2005	25	38.73	1.84 1.55
	119	4/11/2005	156.79	114.23	5/9/2005	28	42.56	1.52
4	1	5/9/2005	152.70	118.86	6/6/2005	28	33.84	1.21
	128	6/6/2005	155.26	97.93	7/1/2005	25	57.33	2.29
	92	4/11/2005	156.05	91.29	5/9/2005	28	64.76	2.31
5	3	5/9/2005	151.09	118.28	6/6/2005	28	32.81	1.17
	126	6/6/2005	153.59	64.63	7/1/2005	25	88.96	3.56
6	6	4/11/2005	155.12	153.81	4/18/2005	7	1.31	0.19
7	7	4/11/2005	151.73	82.79	5/10/2005	29	68.94	2.38
	130	6/6/2005	153.30	123.83	7/1/2005	25	29.47	1.18
	8	4/11/2005	155.07	127.97	5/9/2005	28	27.10	0.97
8	4	5/9/2005	150.94	134.23	6/6/2005	28	16.71	0.60
	131	6/6/2005	155.89	142.52	7/1/2005	25	13.37	0.53
9	9	4/11/2005	151.93	NR				
10	10	4/12/2005	152.33	125.97	5/10/2005	28	26.36	0.94
10	74	5/10/2005	153.00	143.53	6/7/2005	28	9.47	0.34
	140	6/7/2005	155.71	143.17	7/5/2005	28	12.54	0.45
11	11 28	4/12/2005	156.28	151.30	5/10/2005	28	4.98	0.18
* *		5/10/2005	155.14	110.64	6/7/2005	28	44.50	1.59
	133	6/7/2005 4/12/2005	154,96	142.52	7/1/2005	24	12.44	0.52
12	12 34		150.13	141.24	5/10/2005	28	8.89	0.32
14	141	5/10/2005	155,68	139.47	6/7/2005	28	16.21	0.58
	13	6/7/2005 4/12/2005	153,91 153,27	126.80	7/5/2005	28	27.11	0.97
13	56	5/10/2005	153.27 151.87	140.66 136.92	5/10/2005 6/7/2005	28 28	12.61 14.95	0.45
	160	6/7/2005	156.05	139.83	7/5/2005	28	16.22	0.53
	14	4/12/2005	156.96	148.21	5/10/2005	28	8.75	0.58
14	68	5/10/2005	150.21	144.29	6/7/2005	28	5.92	0.31
	146	6/7/2005	155.22	151,22	7/5/2005	28	4.00	0.21 0.14
15	15	4/12/2005	150.61	144.34	4/26/2005	14	6,27	0.14
,,,	16	4/12/2005	152.74	148.12	5/10/2005	28	4.62	0.17
16	75	5/10/2005	153.34	148.65	6/7/2005	28	4.69	0.17
	145	6/7/2005	154.91	144.44	7/5/2005	28	10.47	0.17
	17	4/12/2005	151.46	95.83	5/10/2005	28	55.63	1.99
17	76	5/10/2005	154.60	110.35	6/7/2005	28	44.25	1.58
	147	6/7/2005	155.71	40.47	7/5/2005	28	115.24	4.12
	18	4/12/2005	156.85	109.42	5/10/2005	28	47.43	1.69
18	77	5/10/2005	155.14	106.27	6/7/2005	28	48.87	1.75
	132	6/7/2005	153.69	118.94	7/5/2005	28	34.75	1.24
	19	4/12/2005	154.90	139.79	5/10/2005	28	15.11	0.54
19	22	5/10/2005	154.12	139.95	6/7/2005	28	14.17	0.51
	127	6/7/2005	153.73	137.84	7/5/2005	28	15.89	0.57
	21	4/14/2005	156.29	117.97	5/12/2005	28	38.32	1.37
21	84	5/12/2005	149.49	116,67	6/9/2005	28	32.82	1.17
	156	6/9/2005	155.46	118.76	7/7/2005	28	36.70	1.31
	23	4/14/2005	157.08	96.16	5/12/2005	28	60.92	2.18
23	85	5/12/2005	154.52	128.68	6/9/2005	28	25.84	0.92
	142	6/9/2005	155.79	141,16	7/7/2005	28	14.63	0.52
٠, ١	24	4/14/2005	156.20	136.58	5/12/2005	28	19.62	0.70
24	86	5/12/2005	160.65	150.32	6/9/2005	28	10.33	0.37
	143	6/9/2005	154.75	144.79	7/7/2005	28	9.96	0.36
25	25	4/14/2005	156.27	150.75	5/12/2005	28	5.52	0.20
25	87	5/12/2005	155.62	153.78	6/9/2005	28	1.84	0.07
	161	6/9/2005	154.57	139.83	7/5/2005	26	14.74	0.57
26	26 97	4/14/2005 5/13/2005	155.51	145.79	5/13/2005	29	9.72	0.34
20		6/15/2005	155.88	144.32	6/15/2005	33	11.56	0.35
	177		156,20 154,81	NR 139.01	E/40/000E	20	46.00	0.00
27	27 88	4/14/2005 5/12/2005	154.81	138.01 127.84	5/12/2005	28	16.80	0.60
	149	6/9/2005	152.32		6/9/2005	28	24.48	0.87
	29	4/15/2005	155.11	132.94	7/7/2005 5/13/2005	28	21.55	0.77
29	29 89	5/13/2005	155.66	148.99 149.30	6/10/2005	28 28	6.12	0.22
	150	6/10/2005	156.43	151.57	7/8/2005	28	6.36 4.86	0.23
	30	4/15/2005	150.62	131.60	5/13/2005	28	19.02	0.17 0.68
30	90	5/13/2005	157.74	124.70	6/10/2005	28	33.04	1.18
	151	6/10/2005	155.07	122.77	7/8/2005	28	32.30	1.15
	31	4/18/2005	157.84	145.50	5/13/2005	25	12.34	0.49
31	91	5/13/2005	156.00	146.57	6/10/2005	28	9.43	0.49
- 1	144	6/10/2005	153.96	145.80	7/8/2005	28	8.16	0.29
32	32	4/15/2005	149.47	134.72	4/29/2005	14	14.75	1.05
33	33	5/10/2005	154.39	80.37	6/6/2005	27	74.02	2.74
	35	4/8/2005	155,85	131.21	5/17/2005	39	24.64	0.63
35	124	5/17/2005	153.76	136.50	6/13/2005	27	17.26	0.64
Ì	148	6/13/2005	156.99	133.41	7/11/2005	28	23.58	0.84
	36	4/18/2005	155.26	146.62	5/16/2005	28	8.64	0.31
36	103	5/16/2005	154.37	113.61	6/14/2005	29	40.76	1.41
1	166	6/14/2005	156.81	107.55	7/12/2005	28	49.26	1.76
	37	4/18/2005 I	153.87	119.53 I	5/17/2005 I	29	34.34	1 18
37	37 111	4/18/2005 5/17/2005	153.87 155.06	119.53 123.11	5/17/2005 6/13/2005	29 27	34.34 31.95	1.18 1.18

Distributed to Subject No:	Sample Number	Date Distributed	Weight (in grams) at Time of Distribution	Weight (in grams) at Time of Turning in the Sample:	Date Product Turned In for Weighing	Days Used	Amount Used (in grams)	Use up Rate (in grams)
	39	4/19/2005	153.10	114.49	5/17/2005	28	38.61	1.38
39	114	5/17/2005	156.37	115.72	6/14/2005	28	40.65	1.45
······	176 40	6/14/2005	154.77	95.88	7/12/2005	28	58.89	2.10
40	117	4/18/2005 5/17/2005	151.23 155.15	133.72	5/17/2005	29	17.51	0.60
-10	171	6/13/2005	153.60	149.66 128.60	6/13/2005 7/11/2005	27 28	5.49 25.00	0.20 0.89
	41	4/19/2005	154.43	148.22	5/17/2005	28	6.21	0.89
41	118	5/17/2005	155.46	150.98	6/14/2005	28	4.48	0.16
71	165	6/13/2005	156.10	119.85	7/12/2005	29	36.25	1.25
	154	6/14/2005	153.71	153.21	7/12/2005	28	0.50	0.02
40	42	4/19/2005	155.55	150.20	5/17/2005	28	5.35	0.19
42	122	5/17/2005	159.38	153.39	6/14/2005	28	5.99	0.21
	168 43	6/14/2005 4/13/2005	154.01 154.23	145.63 145.51	7/12/2005	28	8.38	0.30
43	78	5/11/2005	149.38	145,51 NR	5/11/2005	28	8.72	0.31
	134	6/8/2005	155.87	149.83	7/6/2005	28	6.04	0.22
	44	4/19/2005	151.98	119.69	5/17/2005	28	32.29	1.15
44	116	5/17/2005	153.50	102.38	6/14/2005	- 28	51.12	1.83
	153	6/14/2005	156.05	139.72	7/12/2005	28	16.33	0.58
45	45	4/13/2005	156.52	150.34	5/11/2005	28	6.18	0.22
45	79	5/11/2005	155.96	148.90	6/8/2005	28	7.06	0.25
	135	6/8/2005	155.75	141.05	7/6/2005	28	14.70	0.53
46	46 80	4/13/2005 5/11/2005	155.27	136.00	5/11/2005	28	19.27	0.69
	136	6/8/2005	150.69 155.12	125.65 121.99	6/8/2005 7/6/2005	28 28	25.04 33.13	0.89
~	47	4/13/2005	155.12	121.99	5/11/2005	28	5.47	1.18 0.20
47	83	5/11/2005	155.51	145.18	6/8/2005	28	10.33	0.20
	138	6/8/2005	156.58	148.24	7/6/2005	28	8.34	0.37
	48	4/13/2005	153,60	150.29	5/11/2005	28	3.31	0.12
48	81	5/11/2005	150.23	147.36	6/8/2005	28	2.87	0.10
	137	6/8/2005	157.45	154.57	7/6/2005	28	2.88	0.10
	49	4/14/2005	153.92	137.61	5/13/2005	29	16.31	0.56
49	99	5/13/2005	149.90	81.67	6/13/2005	31	68.23	2.20
	164	6/13/2005	155.83	72.07	7/11/2005	28	83.76	2.99
50	50	4/14/2005	152.25	136.51	5/16/2005	32	15.74	0.49
50	107 157	5/16/2005 6/10/2005	153.47 155.50	103.51	6/10/2005	25	49.96	2.00
	51	4/15/2005	149.80	83.49 138.71	7/7/2005 5/13/2005	27 28	72.01 11.09	2.67 0.40
51	93	5/13/2005	161.35	151.24	6/10/2005	28	10.11	0.40
•	158	6/10/2005	155.73	144,05	7/8/2005	28	11.68	0.30
	52	4/15/2005	150.69	95.42	5/13/2005	28	55.27	1.97
52	94	5/13/2005	157.54	104.23	6/10/2005	28	53.31	1.90
	155	6/10/2005	155.19	70.61	7/8/2005	28	84.58	3.02
	53	4/15/2005	155.84	145.14	5/13/2005	28	10.70	0.38
53	96	5/13/2005	154.96	141.23	6/10/2005	28	13.73	0.49
	159	6/10/2005	154.12	NR :	7.0.0005			
54	178 <b>54</b>	7/1/2005 4/15/2005	156.66 151.33	154.94 143.42	7/8/2005	7 26	1.72	0,25
34	55	4/15/2005	154.94	146.67	5/11/2005 5/13/2005	28	7.91 8.27	0.30
55	98	5/13/2005	155.93	145.72	6/10/2005	28	10.21	0.36
	170	6/10/2005	155.72	136.11	7/8/2005	28	19.61	0.70
	57	4/18/2005	157.07	147.57	5/16/2005	28	9.50	0.34
57	101	5/16/2005	155.87	150.03	6/13/2005	28	5.84	0.21
	173	6/13/2005	155.52	148.91	7/11/2005	28	6.61	0.24
58	58	4/18/2005	152.17	92.62	5/16/2005	28	59.55	2.13
	102	5/16/2005	153.26	74.86	6/14/2005	29	78.40	2.70
59	59	4/18/2005	156.24	77.22	5/16/2005	28	79.02	2.82
29	104 152	5/16/2005 6/13/2005	154.61 153.22	90,07 107.58	6/13/2005 7/11/2005	28 28	64.54 45.64	2.31 1.63
	60	4/18/2005	153.22	107.58	5/16/2005	28	22.22	1.03
60	105	5/16/2005	154.75	139.63	6/13/2005	28	32.22 15.12	0.54
	172	6/13/2005	155.85	143.55	7/11/2005	28	12.30	0.44
61	61	4/18/2005	154.18	NR				
	62	4/18/2005	156.84	120.09	5/16/2005	28	36.75	1.31
62	106	5/16/2005	154.29	101.25	6/13/2005	28	53.04	1.89
	174	6/13/2005	154.75	126.68	7/11/2005	28	28.07	1.00
	64	4/18/2005	152.30	145.68	5/16/2005	28	6.62	0.24
64	108	5/16/2005	152.91	134.40	6/13/2005	28	18.51	0.66
	169	6/13/2005	156.40 153.13	149.76	7/11/2005	28	6.64	0.24
65	65 109	4/18/2005 5/17/2005	156.38	148.69 129.44	5/17/2005 6/14/2005	29 28	4.44 26.94	0.15
	66	4/18/2005	155.72	104.39	5/17/2005	29	51.33	1.77
66	110	5/17/2005	155.59	118.94	6/14/2005	28	36.65	1.31
	182	6/14/2005	157.85	76.19	7/12/2005	28	81.66	2.92
	67	4/19/2005	150.36	145.80	5/17/2005	28	4.56	0.16
67	112	5/17/2005	151.93	149.94	6/14/2005	28	1.99	0.07
	183	6/14/2005	153.93	151.78	7/12/2005	28	2.15	0.08
	63	4/18/2005	153.34	146.31	5/17/2005	29	7.03	0.24
	113	5/17/2005	153.18	125.02	6/14/2005	28	28.16	1.01
68		6/14/2005	156.40	140.18	7/12/2005	28	16.22	0.58
68	184				CHZIOOOE	28	1606	0.57
	69	4/19/2005	153.60	137.54	5/17/2005		16.06	
68 69	69 115	5/17/2005	155.10	138.40	6/14/2005	28	16.70	0.60
	69 115 139	5/17/2005 6/14/2005	155.10 154.71	138.40 87.92	6/14/2005 7/12/2005	28 28	16.70 66.79	0.60 2.39
	69 115	5/17/2005	155.10	138.40	6/14/2005	28	16.70	0.60

Distributed to Subject No:	Sample Number	Date Distributed	Weight (in grams) at Time of Distribution	Weight (in grams) at Time of Turning in the Sample:	Date Product Turned In for Weighing	Days Used	Amount Used (in grams)	Use up Rate (in grams)
T	71	4/19/2005	156.92	150.54	5/17/2005	28	6.38	0.23
71	120	5/17/2005	156.36	133,12	6/14/2005	28	23.24	0.83
	167	6/14/2005	156.44	124.80	7/12/2005	28	31.64	1.13
L	72	4/19/2005	154.93	148.39	5/17/2005	28	6.54	0.23
72	121	5/17/2005	156.91	92.52	6/14/2005	28	64.39	2.30
	175	6/14/2005	156.86	131,48	7/12/2005	28	25.38	0.91
73	73	4/19/2005	155.44	147.18	5/3/2005	14	8.26	0.59
90	185	6/14/2005	152.57	81.73	7/12/2005	28	70.84	2.53
R	100		155.33					
	20*		153.29					
	179*		153.48					
	180*		155.20		***************************************			
	181*		154.10		***************************************			
	Discontinued			· · · · · · · · · · · · · · · · · · ·	***************************************	· · · · · · · · · · · · · · · · · · ·	Mean	0.96
Product never o	distributed						Median	0.63

\*Product never distributed NR-product was not returned 
 Mean
 0.96

 Median
 0.63

 SD
 0.82

 N
 167

#### Adverse Events

								Adverse Events			
Subject Number	Subject's Initials	Age	Gender	Group	Description of Adverse Event	Severity	Date of Onset	Frequency	Outcome of Event	Action Taken	Comments
4	SKH	46	F	А	Tightness	Mild (aware or unaware of event, but easily tolerated)	4/20/2005	Event occurred one time	Resolved without treatment	None	Panelist described a tight sensation after 9 days of use. The sensation lasted about an hour before subsiding and has not occurred again.
5	LMP	45	F	A	Bump	Mild (aware or unaware of event, but easily tolerated)	5/8/2005	Event occurred intermittently	Resolved without treatment	None	Panelist currently has a small bump on her chin. It will appear for a few days then go away. RCTS was notified at her Week 8 visit. Follow up is needed. 7/1/05 - Week 12 visit - no bumps or breakouts have recurred since the last one cleared up on 6/10.
6	PJW	43	,	٠	Dryness	Moderate (discomfort enough to cause interference with usual activity)	4/14/2005	Event occurred one time	Resolved with treatment (explain in comment section)	Dropped subject from study	The subject called her doctor on Friday morning and got a prescription. The subject normally uses the cream on the reczema (not on the facial area). She is going to call back with the name of the cream. The subject used Desonide0.55% toton GLA to help with the redness and dyness. AED 4/1905. Spoke with panellst and she said that all riftation went away as of 4/24/05 and she didn't have any more problems. MR 5/19/05
8	FJW	43	F	A	Redness with Bumps	Moderate (discomfort enough to cause interference with usual activity)	4/14/2005	Event occurred one time	Resolved with treatment (explain in comment section)	Dropped subject from study	The subject called her doctor on Friday morning and got a prescription. The subject normally uses the cream on her eczema (not on the facial area). She is going to call back with the name of the cream. The subject used
7	DBK	52	F	В	Eyes Burning	Mild (aware or unaware of event, but easily tolerated)	4/12/2005	Event occurred with each installation for 80 days	Resolved without treatment	None	Subject states that her eyes burn with every application of the sunscene since 4/1205. This event lasted for 10-00 seconds. Subject confinues to experience this problem. Follow up is needed. DS 4/27/05. Still engoin, 5/1005. Subject has glaucome and says that she obsert use the product close to her eyes to avoid the burning sensation. If panellist doe use product around eyes the still experiences burning. Panellist Is not taking medication and hash't consulted a doctor. MR 5/19/05 66 Weel 8 valt – AE still orgoing. DS. Panellist reports that due to a pre-existing condition, her eyes have been burning intermittently since before she began the study. DS 7/1/105
11	TLM	50	F	A	Burns Eyes	Mild (aware or unaware of event, but easily tolerated)	4/28/2005	Event occurred with each installation for 2 days	Resolved without treatment	None	Panelist described a burning sensation to her eyes whenever the would shower at night and the product would rinse off into her eyes from the previous am application. She said it happened a couple of limes before began rinsing more carefully with her eyes closed. RCTG was notified at her Week 4 visit. Praelist reports that after the first two times she would close her eyes while in the shower and has not experienced the burning sensation since. FJ 07576 with the the burning sensation since. FJ 07576 with the production of the production of the production of the production of the production of the production of the production of the production of the production of the production of the production of the production of the production of the production of production of
15	NHK	56	F	A	Blemishes (breakout)	Mild (aware or unaware of event, but easily tolerated)	4/15/2005	Event occurred with each installation for {ongoing}	Panelist lost to follow- up, no further data available	None	Subject has had a few breakouts above her eyebrows, on her chin, left temple and left cheek bone. She is still breaking out. Follow up is needed. DS 42805. Followed up with 5/1905 and parelist said that the breakouts on her chin and left cheek bone are gone but the breakouts above her eyebrows and left temple are still fiver. Penalist has not use any creams but has gone back to using her regular cleaning soap on he face. Needs follow up. MR 5/1909.
17	BFH	59	F	В	Tightness	Mild (aware or unaware of event, but easily tolerated)	4/27/2005	Event occurred one time	Resolved without treatment	None	Panelist described a tight sensation on 4/27. The sensation lasted until she was able to apply the product. She says it feels tight because she was unable to apply the product because that was the day of her visit. RCTS was notified at her Week 4 visit.
18	LJR	58	F	В	Tightness	Mild (aware or unaware of event, but easily tolerated)	4/15/2005	Event occurred one time	Resolved without treatment	None	Panelist described a tight feeling upon application after the second use. She said it was not a negative sensation and it did not happen again. RCTS was notified at her Week 2 visit.
19	D-M	58	F	В	Peeling/Sloughing	Mild (aware or unaware of event, but easily tolerated)	4/24/2005	Event occurred intermittently	Resolved without treatment	None	Panelist noticed some sloughing on 4/24 and it tends to last for a couple days before her face becomes smooth again. Sloughing/peeling is occurring internitently; follow up is needed. Panelist called and left a message on 5/24 stating that the peeling/sloughing has subsided.
					Breakout	Mild (aware or unaware of event, but easily tolerated)	5/6/2005	Event occurred one time	Resolved without treatment	None	Panelist got a pimple on 5/6 and it lasted until 5/8. She thinks it could be due to the sunscreen since it is a very greasy product. RCTS was notified at her week 4 visit.
25	TJJ	40	F	В	Breakout	Mild (aware or unaware of event, but easily tolerated)	4/21/2005	Event occurred with each installation for {ongoing}	Resolved without treatment	None	Panelist noticed some breakouts on her cheeks on 4/21/05. Since then her cheeks have cleared up but her chin is currently broken out. RCTS was notified at her Week 2 visit. Follow up is needed. DS 4/28. Week 4 visit - panelist states breakout is almost gone. DS 5/12. Follow up still needed. Followed up with panelist on 5/1905 and he said that the breakout was gone as of 5/15/05. They did not seek medical attention or use any creams to help with breakout. Panelist said she thought it was because she was using too much sunscreen on her face. MR 5/19/05
26	РКМ	47	F	В	Surgery on Hand	Moderate (discomfort enough to cause interference with usual activity)	6/28/2005	Event occurred one time	Panelist lost to follow- up, no further data available	Dropped subject from study	Panelist went to the hospital for day surgery on 6/28/05 where they took cartidge from her rib and put it in her hand where she had the arthritis (arthroglashy). The medicines she is currently taking, or has taken, include: Hydroco/apap-10mg taken every 3-4 hours as needed for pain and Cephalsen's 500mg, taken every 6-4 hours for three days. The paneliscalled in on 7/8/05 to cancel her regular appointment. The surgery had nothing to do with the study because the panelist had been experiencing pain in her hand for many years. Follow up needed. MR 7/8/05
30	MMC Discontinue	64	F	Α	Headache	Severe (incapacitating; unable to work or do usual activity)	4/20/2005	Event occurred one time	Resolved with treatment (explain in comment section)	None	Panelist reported headache on 4/29/05. The headache occurred on 4/20/05 and lasted 30 minutes. Panelist was given BC Powder (1 pkg) as treatment of headache.

Discontinued due to adverse event

32 40 42	Subject's Initials  TML  CLM  KAM	Age 38	Gender F	Group	Description of Adverse Event	Severity	Date of Onset	Frequency	Outcome of Event	Action Taken	Comments
40	CLM		F	В	Blemishes						
42		43				Mild (aware or unaware of event, but easily tolerated)	4/17/2005	Event occurred intermittently	Resolved without treatment	Discontinued test article (sunscreen) permanently	Panelis is breaking out. She thinks it is due to the suncroren because he has been known to breakout to sunscreens in the past. She quit using the suncreen for a few days and the blemshes seemed to clear urusifia she spoke with me and instructed her to continue using it and this resulted in more blemishes. Sub-Investigator instructed panelist to discontinue use of the sunscreen permanently. Follow up is needed. Since panelist has discontinued use of the sunscreen, her blemishes cleared up around May 1st and have not recocured. Als completes.
	KAM	L	F	В	Breakout	Mild (aware or unaware of event, but easily tolerated)	4/26/2005	Event occurred intermittently	Resolved without treatment	None	Panelist noticed her face breaking out after the first week of use. She thought it was just hormonal until the breakouts kept coming up. RCTS was notified at her week 4 vist. Follow up is needed. Breakouts still ongoing, intensity is still the same AD 6/14/05. Panelist stated she has not had a breakout during the list! 4 veeks. Her breakout would take 4 days before clearing up. AE resolved without breatment. RCTS was notified at her Week. 12 vist.
43		52	F	А	Tightness	Mild (aware or unaware of event, but easily tolerated)	4/20/2005	Event occurred one time	Resolved without treatment	None	Panelist described a tight sensation upon the 2nd day of use. Sensation lasted 10 seconds and resolved on its own. DS 5/3/05
	CGC	48	F	А	Breakout	Mild (aware or unaware of event, but easily tolerated)	5/25/2005	Event occurred intermittently	Resolved without treatment	None	Panelist is experiencing intermittent breakouts that last for about a weel and a half before clearing up. She says she hasn't broken out in 20 years. Follow up is needed. Panelist is still breaking out intermittently. Follow up is still needed. DS 7/6.
45	TDC	48	F	Α	Redness	Mild (aware or unaware of event, but easily tolerated)	5/4/2005	Event occurred one time	Panelist lost to follow- up, no further data available	None	Panelist states that redness on her face has become more intense this last week. RCTS was notified at her Week 4 visit. Follow up is needed Redness is still there and hardly other any worse, and panelist hash't used any creams or visited a doctor. MR 5/19/05; Wk 8 Visit. AE still ongoing. Follow up still needed. DS 68. Wk 12 visit. AE still ongoing. Follow up still needed. FJ 07/06/05
48	JLL	47	F	А	Blemishes	Mild (aware or unaware of event, but easily tolerated)	4/20/2005	Event occurred intermittently	Resolved without treatment	None	Panelist noticed blemishes on her chin and forehead on 4/20/05. RCTS was notified on her Week 2 visit. Spoke to panelist on her Week 4 visit and she stated the blemishes cleared up by 4/30/05.
49	L-R	58	F	В	Tightness	Mild (aware or unaware of event, but easily tolerated)	4/15/2005	Event occurred one time	Resolved without treatment	None	Panelist described a tight feeling upon application after the second use. She said it was not a negative sensation and it did not happen again. RCTS was notified at her Week 2 visit.
50	DKH	49	F	А	Breakouts	Mild (aware or unaware of event, but easily tolerated)	5/21/2005	Event occurred intermittently	Resolved without treatment	None	Panelist is getting breakouts starting on 5/21. She is not treating the breakouts. RCTS was notified on her Week 8 visit. Still ongoing at Wee 12 Visit. Follow up needed. Panelist stated at Week 12 visit that she's no sure the product is the cause of her breakouts. She thinks they might be due to stress. She is currently broken out so follow up is needed. DS 7/
53	DSB	54	F	A	Bronchitis	Moderate (discomfort enough to cause interference with usual activity)	4/19/2005	Event occurred one time	Resolved with treatment (explain in comment section)	Discontinued test article temporarily	Panelist came down with bronchitis on 4/19 and was treated with Aveloc 400 mg (antibiotic 1 tablet), then amoxicillin 500mg BID for 10 days; claritin 1 tablet SID for 10 days and Duraphen Forter 1 tablet BID or as needed. Bronchitis was resolved by 4/28/05. On 4/19 pm and 4/20 am panelist was in bed and did not apply any test article
30	555				Tightness	Mild (aware or unaware of event, but easily tolerated)	4/24/2005	Event occurred with each installation for 10 days	Resolved with treatment (explain in comment section)	None	Panelist experienced a tight sensation on 4/24 and 4/25. The sensation lasted about 10 minutes before subsiding. Panelist did treat sightness with her own moisturizers (Oil of Olay and another product) until instructed otherwise. The tightness has not reoccurred and she will no longer use any other moisturizers besides the test article
54	TWS	55	F	В	Rash (bumps)	Mild (aware or unaware of event, but easily tolerated)	5/9/2005	Event occurred one time	Resolved with treatment (explain in comment section)	Dropped subject from study	Panelist has broken out in a rash. Small red bumps (rash) and pimples are present not both sides of her face. RCTS was notified 1 day before her Week 4 visit (5/11). She will treat the rash with her normal moisturizer (10 di Clay) and a steroid or arbibitior cream. Panelist is dropped from the study due to this AE per Sub-Investigator. Still two areas with a rash located under left eye. Panelist has used a cream an will call back with name of cream. Panelist and that the rash is going away and the rash under her right eye has gone away dody, 5/19/05. Still needs follow up. ME 5/19/05 Panelist is using Psorzon Diforosone Diacetist to treat.
58	CZR	49	F	А	Tightness	Mild (aware or unaware of event, but easily tolerated)	4/26/2005	Event occurred one time	Resolved without treatment	None	Panelist experienced a tight sensation one minute after applying the product on 4/26. This event lasted three minutes before subsiding. RCTS was notified at her week 2 visit.
59	GFM	64	F	В	Slight Redness	Mild (aware or unaware of event, but easily tolerated)	5/3/2005	Event occurred one time	Resolved without treatment	None	Panelist developed slight redness on both her cheeks. Sensation didn't last more than a day and was gone by the time of the next application. RCTS was notified at her week 4 visit.
67	AMM	37	F	В	Breakout	Mild (aware or unaware of event, but easily tolerated)	5/14/2005	Event occurred one time	Resolved without treatment	None	Panelist broke out over the weekend (~5/14). She has 2 blemishes on her chin. RCTS was notified at her week 4 visit. Still ongoing. Follow u needed. Face was completely clear of breakouts by 5/25/05 AD 6/14/05
69	GHD	55	F	В	Sunscreen Clogs Pores	Mild (aware or unaware of event, but easily tolerated)	5/19/2005	Event occurred intermittently	Resolved without treatment	None	Panelist says the sunscreen is clogging her pores. RCTS was notified a her Week 12 visit. AE ongoing; follow up is needed. DS 7/12
					Redness	Mild (aware or unaware of event, but easily tolerated)	4/20/2005	Event occurred one time	Resolved without treatment	None	Panelist experienced some redness upon the first application of the test article. This event resolved without treatment by the next day and has no occurred again. RCTS was notified at her week 2 visit.
70	CAC	62	F	A	Swelling under Right Eye	Mild (aware or unaware of event, but easily tolerated)	4/21/2005	Event occurred one time	Resolved without treatment	None	Panelist described swelling under her right eye after the 2nd day of use. No action was taken to treat the swelling and it resolved on its own by th next day. RCTS was notified at her week 2 visit.
					Watery Eye	Moderate (discomfort enough to cause interference with usual activity)	4/22/2005	Event occurred intermittently	Resolved without treatment	None	Panelist stated that her right eye would become watery after applying the test article. Sensation would occur intermittently but at night the sensation would last longer. Watery eye has not occurred since 4/27/05 Panelist also stated that this same time last year, her eyes were burning and fiching and her eye doctor said it was probably due to pollen in the air.
					Breakout	Mild (aware or unaware of event, but easily tolerated)	4/22/2005	Event occurred one time	Resolved without treatment	None	Panelist noticed a breakout along her lower right jawline. After about a week the breakouts turned into dry patches. See adverse event for dryness. Panelist states that breakouts occur as a result of dry skin.
73	NLW	47	F	A	Dryness	Moderate (discomfort enough to cause interference with usual activity)	4/23/2005	Event occurred with each installation for	Resolved with treatment (explain in comment section)	Dropped subject from study	Panelist noticed some dry patches beginning on 4/23 and the dyness has since then gotten much worse. RCTS was notified on her week 2 wist. Follow up is needed.  Panelist called and left an essage stating that by 5/10 80% of the dryness had cleared up and by 5/17 all of the dryness had subsided. She was using her normal moisturizer to treat

### Group A

Group B			E OTOBT OF TOTIONE ZENTINT ON INITIATION THE ALT ENGLINGE OF THOTOBANDACED ONLY
Subj. No.	Subj. Initials	Visit	Deviation
Oubj. No.	Oubj. IIIItiais	VISIC	The room temperature (73.6°F) and relative humidity (32%) at the time of entry were not according to protocol (70+3°F, RH - 45+10%).
10	JCL	Baseline	The room temperature and relative humidity at the time of TEWL (73.9°F, 32%) and NOVA (73.6°F, 32%) measurements were not according to protocol (70±3°F, RH - 45±10%).
11	TLM	Baseline	The relative humidity (34%) of the room at the time of entry was not according to protocol (RH - 45±10%).
13	DKS	Baseline	The relative humidity (34%) of the room at the time of entry was not according to protocol (RH - 45±10%). Per diary, panelist used the product twice on the day of her baseline visit (04/12/05). Per Sub-investigator, panelist was allowed to continue with study.
19	D-M	Baseline	The relative humidity (32%) of the room at the time of entry was not according to protocol (RH - 45±10%).  The relative humidity (33%) of the room at the time of TEWL and NOVA measurements was not according to protocol (RH - 45±10%).  Per diary, panelist used the product the morning of her baseline visit on 04/12/05. Per Sub-investigator, panelist was allowed to continue with the study.
3	SKH		Panelist has not used the sunscreen since her baseline visit. She told technician she didn't use it because she never went outside. She was instructed to use the sunscreen in the morning regardless if she was inside or outside. Per Sub-investigator, panelist was allowed to continue with the study.
4	SKH		Per diary, panelist did not use the product the evening of her baseline visit.(4/11/05).  Also, she used the product on the morning before her week 2 visit on 04/25/05. Per Sub-Investigator, panelist was allowed to continue with the study.
12	EFK	Week 2	Panelist did not use the sunscreen once daily as per protocol. She told technician that she only used it when she was outside although she was told to use it every day regardless. Per Sub-Investigator, panelist was allowed to continue with the study.
18	LJR	Week 2	Per diary, panelist did not use the product in the evening before bedtime on 04/12/05. Her baseline visit was earlier that day, and she only needed to use the product once that evening. Per Sub-Investigator, panelist was allowed to continue with the study.
26	PKM	Week 2	Panelist came in one day after her scheduled week 2 visit, which was on 4/28/05. Per Sub-investigator, panelist was allowed to continue with the study.
29	DSE	Week 2	Per diary, panelist used the product twice on the day of her baseline visit (04/15/05). Per Sub-Investigator, panelist was allowed to continue with the study.
30	MMC	Week 2	Per diary, panelist used the product twice on the day of her baseline visit (04/15/05). Per Sub-Investigator, panelist was allowed to continue with the study.
31	JAC	Week 2	Per diary, panelist used the product twice on the day of her baseline visit (04/18/05). Panelist came in for her week 2 visit on 04/29/05, 3 days earlier than her scheduled visit (on 05/02/05). Per Sub-Investigator, panelist was allowed to continue with the study.
32	TML	Week 2	Per diary, panelist used the product twice on the day of her baseline visit (04/15/05). Panelist used the product at 12:30 A.M. (04/22/05 and 04/23/05) for her P.M. regime (04/21/05 and 04/22/05). Panelist discontinued use of sunscreen permanently due to breakouts that recurred after temporary disuse of product. Per Sub-Investigator, panelist was allowed to continue with the study.
37	GLJ	Week 2	Per diary, panelist did not use the product in the evening before bedtime on 04/18/05, and she used the product on the morning of her week 2 visit (05/02/05). Per Sub-Investigator, panelist was allowed to continue with the study.
40	CLM	Week 2	The room temperature at the time of entry (73.2°F), time of TEWL measurements (74.5°F) and time of NOVA measurements (74.8°F) was not according to protocol (70±3°F).  Per diary, panelist did not begin using product until the day after her baseline visit (04/19/05). Panelist came in for her week 2 visit on 05/03/05, one day later than her scheduled visit (on 05/02/05). PerSub-investigator, panelist was allowed to continue with the study.
41	E-N	Week 2	Panelist did not use the product in the morning (AM) on 4/26/05 because she inadvertently thought that was her visit day. Per Sub-investigator, panelist was allowed to continue with the study.
43	CGC	Week 2	Per diary, panelist used the product the morning of her baseline visit on 04/13/05. Per Sub-investigator, panelist was allowed to continue with the study.
45	TDC	Week 2	Per diary, panelist did not use the product on the evening of her baseline visit (04/13/05) and the evening of 04/15/05. Per Sub-Investigator, panelist was allowed to continue with the study.

# le Codes: Data Listing 11 A CLINICAL STUDY OF TOPICAL ZEATIN FOR IMPROVING THE APPEARANCE OF PHOTODAMAGED SKIN Group A Group B

Group B			
48	JLL	Week 2	Per diary, panelist used the product twice on the day of her baseline visit (04/13/05). Per Sub-Investigator, panelist was allowed to continue with the study.
49	L-R	Week 2	Panelist came in one day after her scheduled week 2 visit, which was on 04/28/05. Per Sub-investigator, panelist was allowed to continue with the study.
51	PCB	Week 2	Per diary, panelist used the product twice on the day of her baseline visit (04/15/05). Her baseline visit was earlier that day, and she only needed to use the product once that evening. Per Sub-Investigator, panelist was allowed to continue with the study.
52	CJL	Week 2	Per diary, panelist used the product twice on the day of her baseline visit (04/15/05). Per Sub-Investigator, panelist was allowed to continue with the study.
53	DSB	Week 2	Per diary, panelist did not use product the evening of 04/19/05 and the morning of 04/20/05 due to bronchitis. Per Sub-investigator, panelist was allowed to continue with the study.
57	MDS	Week 2	Per diary, panelist used the product twice on the day of her baseline visit (04/18/05). Her baseline visit was earlier that day, and she only needed to use the product once that evening. Per Sub-Investigator, panelist was allowed to continue with the study.
58	CZR	Week 2	Per diary, panelist used the product twice on the day of her baseline visit (04/18/05). Per Sub-Investigator, panelist was allowed to continue. with the study
62	KME	Week 2	Per diary, panelist did not use the product in the evening before bedtime on 04/18/05. Per Sub-Investigator, panelist was allowed to continue with the study.
64	KKF	Week 2	Per diary, panelist did not use the product in the evening before bedtime on 04/18/05. Per Sub-Investigator, panelist was allowed to continue with the study.
65	EMM	Week 2	The relative humidity (34%) of the room at the time of entry was not according to protocol (RH - 45±10%).  The room temperature (73.9°F) at the time of TEWL and NOVA measurements was not according to protocol (70±3°F).
66	CYR	Week 2	The relative humidity (34%) of the room at the time of entry was not according to protocol (RH - 45±10%).  The room temperature at the time of TEWL (74.1°F) and NOVA (74.5°F) measurements was not according to protocol (70±3°F).
68	SAM	Week 2	Per diary, panelist used the product twice on the day of her baseline visit (4/19/05).  Per Sub-Investigator, panelist was allowed to continue with the study.
70	CAC	Week 2	Panelist came in for her week 2 visit on 05/02/05, one (1) day prior to scheduled visit (05/03/05). Per Sub-investigator, panelist was allowed to continue with the study.
73	NLW	Week 2	Per diary, panelist did not use the product in the evening before bedtime on 04/19/05. Per Sub-Investigator, panelist was allowed to continue with the study.
2	MLE	Week 4	Panelist came in for her week 4 visit on 05/10/05, one day after her scheduled visit (on 05/09/05). Per Sub-investigator, panelist was allowed to continue with the study.
4	SKH	Week 4	Panelist did not use the product in pm for week 2 visit (02/25/05). Per Sub-investigator, panelist was allowed to continue with study.
7	DBK	Week 4	Per diary, panelist used the product the morning of her 4 week visit (05/10/05). Panelist came in for her week 4 visit on 05/10/05, one day after her scheduled visit (on 05/09/05). Per Sub-investigator, panelist was allowed to continue with the study.
13	DKS	Week 4	Per diary, panelist used the product in the afternoon for her morning regime on the following dates: 04/26/05 (2:30 P.M.), 05/01/05 (12:30 P.M.), and on 05/07/05 (12:40 P.M.). Per Sub-investigator, panelist was allowed to continue with the study.
27	SMM	Week 4	Per diary, panelist used the product at 12:30 A.M. (05/09/05) for her P.M. regime on 05/08/05. Per Sub-investigator, panelist was allowed to continue with the study.
32	TML	Week 4	Per diary, panelist used the product at 12:30 A.M. (05/03/05) for her P.M. regime on 05/02/05. Per Sub-investigator, panelist was allowed to continue with the study.
35	DLM	Week 4	Per diary, panelist did not use product for pm use on 5/15/05 and for am use on 5/16/05 due to personal problem.  Per Sub-investigator, panelist was allowed to continue with study.

#### le Codes: Data Listing 11 A CLINICAL STUDY OF TOPICAL ZEATIN FOR IMPROVING THE APPEARANCE OF PHOTODAMAGED SKIN Group A

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Group B			
39	DKD	Week 4	Per diary, panelist used the product the morning of her 4 week visit (05/17/05). Panelist used the product at 1:00 A.M. (05/14/05) for her PM regime (05/13/05). Panelist did not use the product the evening of 05/16/05. Per Sub-investigator, panelist will be allowed to continue with study.
47	CMP	Week 4	Per diary, panelist used the product the morning of her 4 week visit (05/11/05). Per Sub-investigator, panelist was allowed to continue with the study.
48	JLL	Week 4	Per diary, panelist used the product in the afternoon (1:30 P.M.) for her morning regime on 04/27/05. She also used the product at 1:15 P.M. for her morning regime on 05/07/05. Per Sub-investigator, panelist was allowed to continue with the study.
49	L-R	Week 4	Per diary, panelist did not use the product in the evening before bedtime on 04/29/05. Per Sub-Investigator, panelist was allowed to continue with the study. Panelist came in for her week 8 visit on 6/13/05, three days after her scheduled visit (06/10/05).
50	DHK	Week 4	Panelist came in for her week 4 visit on 05/16/05, three (3) days later than the scheduled visit (05/13/05). Per Sub-investigator, panelist was allowed to continue with the study.
66	CYR	Week 4	Per diary, panelist did not use product in the evening of her week 4 visit (05/17/05). Per Sub-investigator, panelist was allowed to continue with study.
69	GHD	Week 4	Per diary, panelist used the product in the afternoon for her morning regime on the following dates: 05/03/05 (1:00 P.M.), 05/07/05 (1:00 P.M.), and on 05/14/05 (3:00 P.M.). Per Sub-investigator, panelist was allowed to continue with the study.
70	CAC	Week 4	Panelist came in for her week 4 visit on 05/02/05, one (1) day prior to scheduled visit (05/03/05). Per Sub-investigator, panelist was allowed to continue with the study.
13	DKS	Week 8	Per diary, panelist used the product in the afternoon for her morning regime on 05/10/05 (2:35 P.M.), 05/14/05(12:30 P.M.) 05/22/05 (3:30 P.M.) and on 06/04/05 (12:15 P.M.). Per Sub-investigator, panelist was allowed to continue with the study.
25	TJJ	Week 8	Per diary, panelist used product in the afternoon (5:45 P.M.) for her evening application on 05/12/05. Per Sub-investigator, panelist was allowed to continue with the study.
26	PKM	Week 8	Panelist came in for her week 8 visit on 6/15/05, five days after her scheduled visit (06/10/05). Per Sub-investigator, panelist was allowed to continue with the study.
27	SMM	Week 8	Per diary, panelist used the product at 1:30 A.M. (05/22/05) for her P.M. regime on 05/21/05. Panelist also used the product the morning of her week 8 visit (06/09/05). Per Sub-investigator, panelist was allowed to continue with the study.
32	TML	Week 8	Per diary, panelist used the product at 12:45 A.M. (05/22/05) for her P.M. regime on 05/21/05. Per Sub-investigator, panelist was allowed to continue with the study.
39	DKD	Week 8	Per diary, panelist used the product at 1:00 A.M. (06/18/05 and 07/02/05) for her P.M. regime on 06/18/05 and 07/01/05.  Per Sub-investigator, panelist was allowed to continue with study.
40	CLM	Week 8	Per diary, panelist the product in the afternoon for her morning regime on 05/17/05 (2:00 P.M.). Per Sub-investigator, panelist was allowed to continue with the study.
48	JLL	Week 8	Per diary, panelist used the product in the afternoon (1:30 P.M.) for her morning regime on 05/11/05. Per Sub-investigator, panelist was allowed to continue with the study.
49	L-R	Week 8	Panelist came in for her week 8 visit on 6/13/05, three (3) days after her scheduled visit (06/10/05).  Panelist used the product on the morning of her week 8 visit .Per Sub-investigator, panelist was allowed to continue with the study.
50	DHK	Week 8	Panelist came in for her week 8 visit on 06/10/05, three (3) days prior to scheduled visit (06/13/05).  Per Sub-investigator panelist was allowed to continue with the study.
53	DSB	Week 8	Per diary, panelist used the product in the afternoon for her morning regime at 12:45 P.M. on 05/28/05 and 1:00 P.M. on 06/08/05.  Per Sub-investigator panelist was allowed to continue with the study.
68	SAM	Week 8	Per diary, panelist used the product in the after noon for her morning regime at 12:00 P.M. on 06/03/05 and at 12:15 P.M on 06/04/05.  Per Sub-investigator panelist was allowed to continue with the study.
70	CAC	Week 8	Panelist came in for her week 8 visit on 06/13/05, three (3) days later than the scheduled visit (06/10/05). Per diary, panelist used the product 12:15 A.M. for the evening use for 06/10/05. Per Sub-investigator, panelist allowed to continue with the study.

# le Codes: Data Listing 11 A CLINICAL STUDY OF TOPICAL ZEATIN FOR IMPROVING THE APPEARANCE OF PHOTODAMAGED SKIN Group A Group B

Gloup B			
2	MLE	Week 12	Panelist came in for her week 12 visit on 07/01/05, four (4) days prior to scheduled visit (07/04/05). Per Sub-investigator, panelist was allowed to continue with the study.
3	SKH	Week 12	Panelist came in for her week 12 visit on 07/01/05, four (4) days prior to scheduled visit (07/04/05). Per Sub-investigator, panelist was allowed to continue with the study.
4	SKH		Panelist came in for her week 12 visit on 07/01/05, four (4) days prior to scheduled visit (07/04/05). Per Sub-investigator, panelist was allowed to continue with the study.
5	LMP	Week 12	Panelist came in for her week 12 visit on 07/01/05, three (3) days prior to scheduled visit (07/04/05) because of the holiday. Per Sub-investigator, panelist was allowed to continue with the study.
13	DKS	vveek 12	Per diary, panelist used the product in the afternoon for her morning regime on 06/11/05 (12:10 P.M.), 06/13/05 (12:15 P.M.), and on 06/18/05 (12:10 P.M.). Per Sub-investigator, panelist was allowed to continue with the study.
17	BFH	Week 12	Per diary, panelist did not use the product the evening of 06/23/05. Per Sub-investigator, panelist was allowed to continue with the study.
25	TJJ	Week 12	Per diary, panelist used product in the early afternoon (4:30 P.M.) for her evening application on 06/09/05. Per Sub-investigator, panelist was allowed to continue with the study.
27	SMM	Week 12	Per diary, panelist used the product in the afternoon (1:30 P.M.) for her morning regime on 06/11/05. Also panelist used the product at 1:00 A.M. (07/03/05) for her P.M. regime (07/02/05). Per Sub-investigator, panelist was allowed to continue with study.
40	CLM	vveek 1/	Panelist came in for her week 12 visit on 07/11/05, one (1) day prior to scheduled visit (07/12/05). Per Sub-investigator, panelist was allowed to continue with the study.
42	KAM	VVPPK 12	Per diary, panelist used the product the morning of her week 12 visit on 07/12/05 (6:00 A.M.). Per Sub-Investigator, panelist was allowed to continue with the study.
48	JLL		Per diary, panelist used the product in the afternoon for her morning regime the day of her 4 week visit (06/08/05 at 2:00 P.M.). Per Sub-investigator, panelist was allowed to continue with the study.
49	L-R	Week 12	Panelist equilibrated for 12 minutes prior to TEWL and skin moisture measurements. Per Sub-investigator, panelist was allowed to continue with the study.
51	РСВ	Week 12	Per diary, panelist did not use product for evening application on 07/01/05 until 3:00 A.M. (which is actually 07/02/05). Per Sub-investigator panelist was allowed to continue with the study.
53	DSB	Week 12	Per diary, panelist used the product in the afternoon for her morning regime on 06/22/05 (12:30 P.M.). Per Sub-investigator, panelist was allowed to continue with study.
68	SAM	Week 12	Per diary, panelist used the product in the morning for her evening regime on 06/14/05 (12:30 A.M.), 06/15/05 (12:15 A.M.), 06/16/05 (12:45 A.M.), 06.17.05 (1:00 A.M.), 06/20/05 (12:00 A.M.), 06/21/05 (12:15 A.M.), 06/24/05 (12:30 A.M.), and 06/27/05 (1:00 A.M.) Panelist also used the product in the afternoon for her morning regime on 06/23/05 (12:00 P.M.) Per Sub-investigator, panelist was allowed to continue with study.
69	GHD	vveek 12	Per diary, panelist used the product in the early morning of 07/04/05 (1:00 A.M.) for her PM regime for 07/03/05. Per Sub-investigator, panelist was allowed to continue with study.
70	CAC	Week 12	Panelist was issued an extra product since she was running low during the Week 8 - Week 12 period.