



Thomas J.

**Stephens & Associates Inc.**

Clinic  
Laboratory  
Consulting  
Claim Substantiation

A Global Research Organization

**ASSESSMENT OF THE POTENTIAL OF TEST  
PRODUCTS TO INDUCE PHOTOTOXICITY**

**Prepared For**

**CoreTex Products, Inc.**  
(Formula Owner)

**TESTING RESULTS  
FOR THE FOLLOWING PRODUCTS:**

SunX SPF 30 Sunscreen  
SunX SPF 30 Lip Balm  
ProDerma SPF 30 Face Stick  
ProDerma SPF 18 Body Lotion  
ProDerma SPF 18 Facial Moisturizer

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**Stephens & Associates Study Number: C02-D096**

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**PURPOSE**

This clinical study was conducted to assess the potential of the Sponsor's test materials to induce phototoxicity (PHO) or primary skin irritation in subjects.

**GENERAL INFORMATION**

Stephens & Associates Study Number: C02-D096

Test: Assessment of the Potential of Test Products to Induce Phototoxicity

Test Materials: Lip Balm SPF 30  
Face Stick SPF 30  
Body Lotion SPF 18  
Facial Moisturizer SPF 18  
Sun Screen SPF 30

Investigator: Thomas J. Stephens, Ph.D.

Sub-Investigator/Study Physician: James H. Herndon, Jr., M.D., FAAD, Board Certified Dermatologist

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Testing and Administrative Facility: Thomas J. Stephens & Associates, Inc.  
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Experiment Start Date: May 28, 2002

Experiment End Date: May 31, 2002

Sponsor Contact: CoreTex Products, Inc.  
5307 Cameron Court  
Bakersfield, CA 93309

## **SUMMARY**

This clinical study was conducted to assess the potential of the Sponsor's test materials to induce phototoxicity (PHO) or primary skin irritation in subjects. Twenty-six subjects, with a Fitzpatrick Skin Classification of II or III, completed the study.

At Visit 1, qualified subjects were occlusively patched with duplicate sets of patches dosed with the test materials:

- Lip Balm SPF 30
- Face Stick SPF 30
- Body Lotion SPF 18
- Facial Moisturizer SPF 18
- Sun Screen SPF 30

One set of patches was designated for irritation testing and the other set of patches was designated for phototoxicity testing. A blank patch (untreated control) was also included in the phototoxicity set of patches.

Subjects returned to the clinic for Visit 2, approximately 24 hours after patch application at Visit 1. All of the patches (irritation and phototoxicity sets) were removed by clinic staff and graded for skin irritation. The phototoxicity patch set test sites (including the untreated control) were irradiated with 4.0 Joules per square centimeter ( $J/cm^2$ ) of UVA.

Subjects returned to the clinic for Visit 3 and Visit 4, approximately 24 and 48 hours after Visit 2, respectively. At each of these visits, test sites were graded for irritation and phototoxicity.

Based on the results of this study, none of the Sponsor's test materials (Lip Balm SPF 30, Face Stick SPF 30, Body Lotion SPF 18, Facial Moisturizer SPF 18, or Sun Screen SPF 30) induced phototoxicity or primary skin irritation in the subject population.

### **STORAGE, HANDLING, AND DOCUMENTATION OF TEST MATERIALS**

The receipt of test materials by Stephens & Associates was documented in a logbook, which serves as a permanent record of the receipt, storage, return, and disposition of all study materials. All study materials were kept in a locked product storage room accessible to clinical staff members only. At the conclusion of the clinical study, the remaining study materials were returned to the Sponsor.

#### **TEST MATERIAL DESCRIPTIONS**

Test material identification number (TMIN): 0217-02C  
Sponsor test material identification: Lip Balm SPF 30  
Physical description: Eggshell, opaque solid

Test material identification number (TMIN): 0218-02C  
Sponsor test material identification: Face Stick SPF 30  
Physical description: Eggshell, opaque solid

Test material identification number (TMIN): 0219-02C  
Sponsor test material identification: Body Lotion SPF 18  
Physical description: White, opaque cream

Test material identification number (TMIN): 0220-02C  
Sponsor test material identification: Facial Moisturizer SPF 18  
Physical description: White, opaque cream

Test material identification number (TMIN): 0221-02C  
Sponsor test material identification: Sun Screen SPF 30  
Physical description: White, opaque cream

#### **INFORMED CONSENT**

Written informed consent conforming to 21 CFR 50.25 was obtained from each subject prior to enrollment in the study. An original signed copy for each subject participating in the study will be retained in the study file. Each subject received a copy of the agreement. Please see Appendix III for a sample form.

#### **ATTRITION**

Twenty-six subjects completed the study. Twenty-eight subjects enrolled for study participation and two subjects were discontinued because they did not qualify for the study according to protocol specifications. Please see Appendix IV for a copy of the Attrition Form, which documents the dates of and reasons for the attrition of the two subjects.

#### **ADVERSE EVENTS**

There were no adverse events reported by subjects during the course of the study.

**SUBJECT DEMOGRAPHICS**

Twenty-six subjects completed the study. Table 1 lists each subject's ethnicity, gender, date of birth, and Fitzpatrick Skin Classification\*. Ethnicity information was obtained from each subject's eligibility and health questionnaire.

**TABLE 1  
 SUBJECT DEMOGRAPHICS**

| Subject Number | Ethnicity | Gender | Date of Birth | Fitzpatrick Classification |
|----------------|-----------|--------|---------------|----------------------------|
| 001            | Caucasian | Male   | 11/16/47      | III                        |
| 003            | Caucasian | Female | 03/05/70      | III                        |
| 004            | Caucasian | Male   | 03/25/56      | III                        |
| 005            | Caucasian | Female | 07/30/58      | III                        |
| 007            | Caucasian | Female | 07/15/64      | III                        |
| 008            | Caucasian | Female | 09/13/52      | III                        |
| 009            | Caucasian | Female | 08/06/54      | III                        |
| 010            | Caucasian | Male   | 12/03/52      | II                         |
| 011            | Caucasian | Female | 11/10/59      | III                        |
| 012            | Caucasian | Male   | 05/20/53      | III                        |
| 013            | Caucasian | Male   | 06/06/58      | II                         |
| 014            | Caucasian | Female | 04/15/50      | III                        |
| 015            | Caucasian | Female | 02/13/59      | II                         |
| 016            | Caucasian | Female | 01/13/50      | III                        |
| 017            | Caucasian | Male   | 03/24/49      | III                        |
| 018            | Caucasian | Female | 07/28/49      | II                         |
| 019            | Caucasian | Female | 01/28/51      | III                        |
| 020            | Caucasian | Female | 04/11/83      | III                        |
| 021            | Caucasian | Male   | 05/27/83      | II                         |
| 022            | Caucasian | Female | 10/29/47      | III                        |
| 023            | Caucasian | Female | 07/24/57      | II                         |
| 024            | Hispanic  | Female | 06/20/58      | III                        |
| 025            | Caucasian | Female | 10/28/77      | III                        |
| 026            | Caucasian | Female | 05/24/61      | III                        |
| 027            | Caucasian | Female | 12/28/44      | III                        |
| 028            | Caucasian | Male   | 11/18/48      | III                        |

\* The Fitzpatrick Skin Classification is based on the skin's unprotected response to the first 30 to 45 minutes of sun exposure after a winter season without sun exposure.

- I Always burns easily; never tans
- II Always burns easily; tans minimally
- III Burns moderately; tans gradually

## PROCEDURES AND METHODS

At Visit 1, prospective subjects were examined on the back for the presence of scars, birthmarks, moles, vitiligo, keloids, skin abnormalities, tanning, erythema (due to sunburn), or any other dermal markings that would interfere with the conduct of the study. Subjects who qualified for study participation based on the initial examination completed a health and eligibility questionnaire and signed an informed consent agreement.

Subjects were occlusively patched with duplicate sets of patches dosed with the test materials:

- Lip Balm SPF 30
- Face Stick SPF 30
- Body Lotion SPF 18
- Facial Moisturizer SPF 18
- Sun Screen SPF 30

One set of patches was designated for irritation testing and the other set of patches was designated for phototoxicity testing. A blank patch (untreated control) was also included in the phototoxicity set of patches.

Subjects returned to the clinic for Visit 2, approximately 24 hours after patch application at Visit 1. All of the patches (irritation and phototoxicity sets) were removed by clinic staff, wiped with dry gauze, and graded for skin irritation approximately 15 minutes after patch removal using the grading scale listed below. The phototoxicity patch set test sites (included the untreated control) were irradiated with 4.0 Joules per square centimeter ( $J/cm^2$ ) of UVA\*.

Subjects returned to the clinic for Visit 3 and Visit 4, approximately 24 and 48 hours after Visit 2, respectively. At each of these visits, test sites were graded for irritation and phototoxicity.

Results of the irritation and phototoxicity assessments were recorded using the following grading scale:

- 0 Negative, no response
- ± Equivocal reaction, barely perceptible erythema with no clearly defined border
- 1 Mild but definite erythema with no clearly defined border
- 2 Moderate clearly defined erythema
- 3 Strong erythema or edema
- 4 Vesiculation, bullous reactions and/or wheal and flare responses

\* UV radiation was supplied by an artificial source, which has a spectral output in the ultraviolet range comparable to that of the natural solar spectrum. A single port solar simulator with a 150-watt xenon arc lamp (Model 16S, Solar UV Simulator, Solar Light Co., Philadelphia) was used for irradiation. UVA radiation was obtained by placing the WG-360 filter (in addition to the UG-5 or UG-11 and WG-320 filters) in the radiation patch of the solar simulator. At a distance of 3 inches from the lamp housing (the distance at which radiation will strike the skin), the lamp emits a 1 cm diameter "spot" of radiation. The radiation of the xenon bulb was measured using the 3D-600 meter (Solar light Co.) and measurements were taken at least 30 minutes after lamp warm-up.

## BIOSTATISTICS AND DATA MANAGEMENT

A frequency distribution of the irritation and phototoxicity scores for the test materials and control (phototoxicity only) was reported for each time point. See Appendix I for complete statistics.

**MAINTENANCE OF RECORDS**

All original records (including the study protocol, observation records, medical histories, informed consents, attrition form, and any other records or forms used in the study) and a copy of the final report will be retained on file in the Stephens and Associates archives for two years. When the archive time has expired, the study files will be either destroyed or sent to the Sponsor at the Sponsor's expense.

**RESULTS**

Subjects were occlusively patched with duplicate sets of the test material at Visit 1. After wearing patches for approximately 24 hours, test sites were graded for irritation at Visit 2. One set of patches (phototoxicity) were irradiated with 4.0 J/cm<sup>2</sup> of UVA at Visit 2. All patch sites were graded for irritation or phototoxicity at Visit 3 and Visit 4, approximately 24 and 48 hours after Visit 2, respectively.

Table 2 presents the frequency of irritation and phototoxicity scores for the test material and control at the assessment time points. The number of subjects with the indicated irritation/phototoxicity scores is listed.

**TABLE 2  
 FREQUENCY TABLE OF IRRITATION AND PHOTOTOXICITY SCORES**

| Treatment                 | Score | IRRITATION<br>PATCH SET |         |         | PHOTOTOXICITY<br>PATCH SET |         |         |
|---------------------------|-------|-------------------------|---------|---------|----------------------------|---------|---------|
|                           |       | Visit 2                 | Visit 3 | Visit 4 | Visit 2                    | Visit 3 | Visit 4 |
| Lip Balm SPF 30           | 0     | 25                      | 26      | 26      | 24                         | 26      | 26      |
|                           | ±     | 1                       | 0       | 0       | 2                          | 0       | 0       |
| Face Stick SPF 30         | 0     | 25                      | 26      | 26      | 26                         | 26      | 26      |
|                           | ±     | 1                       | 0       | 0       | 0                          | 0       | 0       |
| Body Lotion SPF 18        | 0     | 26                      | 26      | 26      | 26                         | 26      | 26      |
| Facial Moisturizer SPF 18 | 0     | 26                      | 26      | 26      | 26                         | 26      | 26      |
| Sun Screen SPF 30         | 0     | 26                      | 26      | 26      | 26                         | 26      | 26      |
| Untreated                 | 0     |                         |         |         | 26                         | 26      | 26      |

**DISCUSSION AND CONCLUSIONS**

Based on the results of this study, none of the Sponsor's test materials (Lip Balm SPF 30, Face Stick SPF 30, Body Lotion SPF 18, Facial Moisturizer SPF 18, or Sun Screen SPF 30) induced phototoxicity or primary skin irritation in the subject population.

### STATEMENT OF QUALITY ASSURANCE

All data and supporting documentation for this study have been audited by the Stephens & Associates, Inc., Quality Assurance Department and found to be accurate, complete, and in compliance with the requirements of the protocol and Stephens & Associates' Standard Operating Procedures. This report has been reviewed and accurately reflects all aspects of the conduct of the study.

All clinical research studies that are performed by Stephens & Associates are in accordance with federal regulations and Good Clinical Practice guidelines.

*Patricia Pierce*

Patricia G. Pierce, M.Ed.  
Quality Assurance Manager

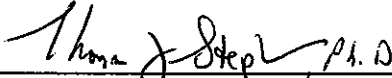
*6/19/02*

Date

**REPORT APPROVAL**

Report approved by:

THOMAS J. STEPHENS & ASSOCIATES, INC.

  
\_\_\_\_\_  
Thomas J. Stephens, Ph.D. 6/17/02  
Investigator Date

  
\_\_\_\_\_  
James H. Herndon, Jr., M.D., FAAD, Board Certified Dermatologist 6/17/02  
Sub-Investigator/Study Physician Date

## APPENDICES

- I. **Biostatistics**
- II. **Protocol: Assessment of the Potential of Test Products to Induce Phototoxicity**
- III. **Sample Forms**
  - Eligibility and Health Questionnaire
  - Informed Consent Agreement
  - Observation Record(s)
- IV. **Copy of Attrition Form**
- V. **Copies of Observation Records**