Thomas J.
Stephens & Associates Inc.
A Global Research Organization

Clinic
Laboratory
Consulting
Claim Substantiation

STATIC AND VERY WATER RESISTANT SPF DETERMINATION TEST

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

Stephens & Associates Study Number: C02-D097

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PURPOSE

This clinical study was conducted to estimate the sun protection factor (SPF) and product category designation (PCD) of sunscreen test materials under static and very water resistant test conditions.

GENERAL INFORMATION

Stephens & Associates Study Number:	C02-D097
Test:	Static and Very Water Resistant SPF Determination Test
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., Board Certified Dermatologist
Sub-Investigator:	Monya L. Sigler, Ph.D.
Clinic Supervisor:	Colleen Banas
Biostatistics Manager:	Lorena M. Rodriguez Fernandez, M.S.
Quality Assurance Manager:	Patricia G. Pierce, M.Ed.
Testing and Administrative Facility:	Thomas J. Stephens & Associates, Inc. 3310 Keller Springs Road, Suite 130 Carrollton, Texas 75006
Experiment Start Date:	August 5, 2002
Experiment End Date:	October 11, 2002
Sponsor Contact:	CoreTex Products, Inc. 5307 Cameron Court Bakersfield, CA 93309

SUMMARY

This clinical study was conducted to estimate the sun protection factor (SPF) and product category designation (PCD) of sunscreen test materials under static and very water resistant test conditions. Ten subjects completed the pilot portion of the study and forty subjects completed the standard portion of the study. For both the pilot and standard studies, half of the subjects tested Lip Balm SPF 30 and Face Stick SPF 30, and the other half of the subjects tested Sun Screen SPF 30, Body Lotion SPF 18, and Facial Moisturizer SPF 18. All subjects participated in the procedures described below.

MED Determination (Visit 1 and Visit 2)

At Visit 1 and Visit 2, each subject's inherent or unprotected MED (minimal erythema dose) was determined on the lower back.

Test Material Evaluation (Visit 3 and Visit 4)

Test sites (50 cm^2) were selected on each subjects' back and outlined in ink using a marking pen and a template. Each test site was subdivided into 3 to 7 sub-sites, of approximately 1 cm in size. Subjects received application of one of the following sets of test materials (one test material per site). Approximately 100 milligrams (mg) of test material was applied to test sites (water immersion sites):

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

At least 15 minutes after test material application, subjects participated in test site immersion procedures. Subjects in the pilot study immersed test sites for a total of 40 minutes, and subjects in the standard study immersed test sites for a total of 80 minutes (20 minutes submersion followed by 20 minutes rest for four cycles). After completion of the immersion procedures, the remaining test sites for each subject received application of the test materials as previously described (static sites) and one site for each subject received application of SPF 4 standard[1] (8% Homomethyl Salicylate).

One unprotected area on the subject's lower back (not a test site) was irradiated with a confirmatory dose of the subject's unprotected MED. At least 15 minutes after application of the test materials and SPF 4 standard, all test sites (water immersion sites and static sites) received UV exposures. Subjects returned to the clinic approximately 22 to 24 hours after UV exposures at Visit 3 and the test sites were examined for erythema.

The following chart presents the calculated SPF Label values and the PCD for the static and water resistant determination tests:

	Static SPF (n=20)	Water Immersion SPF (40 Minutes) "Water Resistant" (n=5)	Water Immersion SPF (80 Minutes) "Very Water Resistant" (n=20)	PCD
Lip Balm SPF 30	36.00	35.00	33.00	High
Face Stick SPF 30	37.00	34.00	35.00	High
Sun Screen SPF 30	36.00	30.00	31.00	High
Body Lotion SPF 18	20.00	19.00	19.00	Moderate
Facial Moisturizer SPF 18	20.00	19.00	19.00	Moderate

STORAGE, HANDLING, AND DOCUMENTATION OF TEST MATERIALS

The receipt of test materials by Stephens & Associates was documented in a log book, 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

Fifty subjects completed the study. A total of fifty-four subjects were enrolled for study participation and four subjects (010, 011, 014, 024) were discontinued for failure to attend a scheduled visit. Please see Appendix IV for a copy of the Attrition Form, which documents the dates of and reasons for the attrition for the four subjects.

ADVERSE EVENTS

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

SUBJECT DEMOGRAPHICS

Fifty Caucasian subjects completed the study. Ethnicity information was obtained from each subject's health and eligibility questionnaire. Table 1 presents each subject's gender, date of birth, and Fitzpatrick skin classification*.

TABLE 1
SUBJECT DEMOGRAPHICS

Subject Number	Gender	Date of Birth	Fitzpatrick Classification	Subject Number	Gender	Date of Birth	Fitzpatrick Classification
001	Female	02/26/44	II	030	Female	06/07/80	II
002	Female	10/22/47	II	031	Female	08/02/53	II
003	Female	03/14/54	II	032	Female	03/23/52	II
004	Female	04/27/42	II	033	Male	04/02/75	II
005	Male	07/15/44	III	034	Female	06/01/82	II
006	Female	06/26/50	III	035	Female	12/23/64	II
007	Female	09/02/54	II	036	Female	09/20/53	III
008	Female	04/22/84	II	037	Female	12/14/74	II
009	Male	05/20/53	III	038	Female	11/07/59	III
012	Female	06/22/62	III	039	Female	04/18/56	III
013	Male	06/25/62	III	040	Female	02/05/52	III
015	Female	10/24/53	II	041	Female	04/22/65	II
016	Female	01/29/65	II	042	Female	01/28/70	III
017	Female	11/14/64	III	043	Female	12/22/56	II
018	Female	06/02/71	II	044	Female	02/18/70	II
019	Male	02/07/69	III	045	Male	12/19/72	III
020	Female	03/24/82	III	046	Female	04/19/82	III
021	Female	10/06/77	II	047	Female	10/16/74	II
022	Female	12/28/53	II	048	Male	12/17/56	III
023	Female	11/13/70	II	049	Female	10/29/47	III
025	Female	12/01/61	II	050	Female	11/30/60	III
026	Female	08/29/65	II	051	Female	02/03/59	II
027	Female	05/24/61	III	052	Female	09/22/78	II
028	Female	01/04/61	III	053	Female	04/01/60	II
029	Female	06/17/61	II	054	Female	04/12/58	II

* 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

PROTOCOL AMENDMENTS

Affected Section of Protocol:	**PROTOCOL TITLE** (Cover Page)
Original Wording:	Static and Water Resistant (Formerly Sweat Proof) SPF Determination Test
Revised Wording:	Static and Very Water Resistant SPF Determination Test
Reason for Change:	Investigator's request
Affected Section of Protocol:	**SUBJECT ENROLLMENT**, Number of Subjects
Original Wording:	Five subjects will be required for the pilot study.
Revised Wording:	Ten subjects will be required for the pilot study. Five (5) subjects will evaluate the static and water resistant properties ***of each test material***.
Reason for Change:	Investigator's request
Affected Section of Protocol:	**CONDUCT OF THE STUDY**, Procedures, Visit 3
Original Wording:	For a "water resistant" claim, immersion will be for 40 minutes. The subject will enter the water for 20 minutes of moderate activity and then will rest for 20 minutes to allow the skin to air dry. The subjects will re-enter the water for 20 minutes and air dry the sites (no toweling of test areas).
Revised Wording:	For a "very water resistant" claim, immersion will be for 80 minutes. The subject will enter the water for 20 minutes of moderate activity and then will rest for 20 minutes to allow the skin to air dry (no toweling of test areas). This cycle will be repeated until the total immersion time has been completed.
Reason for Change:	Investigator's request
Affected Section of Protocol:	**CONDUCT OF THE STUDY**, Procedures, Visit 4
Original Wording:	The test sites will be examined for reactions 22 to 24 hours after the completion of the irradiation exposures.
Revised Wording:	The test sites will be examined for reactions at approximately 22 to 24 hours after the completion of the irradiation exposures.
Reason for Change:	This change was implemented at the request of the Investigator to accommodate the work schedules of subjects 002, 003, 005, 006, 027, and 035.

PROCEDURES AND METHODS

Ten subjects (001 through 012) completed the pilot portion of this study, conducted between August 5 and August 14, 2002. Forty subjects (013 through 054) completed the standard portion of the study, conducted between August 19 and October 11, 2002. For both the pilot and standard studies, half of the subjects tested Lip Balm SPF 30 and Face Stick SPF 30, and the other half of the subjects tested Sun Screen SPF 30, Body Lotion SPF 18, and Facial Moisturizer SPF 18. All subjects participated in the procedures described below. Please note that subjects 045 through 054 only participated in the very water resistant determination test.

MED Determination (Visit 1 and Visit 2)

At Visit 1, prospective subjects were examined on the back for the presence of scars, birthmarks, moles, vitiligo, keloids, skin abnormalities, tanning, erythema, or any other dermal markings. Subjects who did not exhibit a skin condition that would interfere with the study qualified for study participation. Subjects completed a health and eligibility questionnaire and signed an informed consent agreement.

PROCEDURES AND METHODS (Continued)
Each subject's inherent or unprotected MED (minimal erythema dose) was determined on the lower back. To determine the MED, each subject received approximately seven irradiation exposures on seven adjacent unprotected skin sites on the lower back. Each exposure represented a 25% increase in energy over the previous exposure. The sites were examined by a clinical grader for immediate erythema and immediate pigment darkening after the completion of each exposure.

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 + UVB radiation was obtained by using a combination of the UG-5 or UG-11 and WG-320 filters (Schott Glass Technologies) placed in the radiation path 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 output of the xenon bulb was measured using the 3D-600 meter (Solar Light Co.).

At Visit 2, approximately 22 to 24 hours after completion of irradiation at Visit 1, the irradiated sites were examined for erythema using the following scale:

-	No visible erythema
?	Questionable response; unclear
+	Erythema, extending to the borders (MED)
++	Erythema, with or without edema present

The site receiving the lowest dose of UV, which produced the first perceptible redness reaction with clearly defined borders (+), was selected as the MED for the subject.

Test Material Evaluation (Visit 3 and Visit 4)
Test sites, 50 square-centimeters (cm^2) in size, were selected on each subject's back, between the beltline and shoulder blades on either side of the lateral midline, and outlined in ink using a marking pen and a template. Each test site was subdivided into 3 to 7 sub-sites, of approximately 1 centimeter (cm) in size.

Subjects received application of one of the following sets of test materials (one test material per site) according to a site rotational randomization design. Approximately 100 milligrams (mg) of test material was applied to test sites (water immersion sites):

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

Neither the grader nor the subject was aware of the test material/standard assignment.

At least 15 minutes after test material application, subjects immersed the test sites in a whirlpool which circulated the water gently at all times. Test sites were submersed for 20 minutes and then subjects rested for 20 minutes to allow the skin to air dry. For the ten subjects in the pilot study, this cycle was repeated once for a total of 40 minutes immersion time. For the subjects in the standard study, this cycle was repeated three times until a total submersion time of 80 minutes was achieved.

After completion of the immersion procedures, the remaining test sites (static sites) for each subject received application of the test materials as previously described and one site for each subject received application of SPF 4 standard[1] (8% Homomethyl Salicylate).

One unprotected area on the subject's lower back (not a test site) was irradiated with a confirmatory dose of the subject's unprotected MED. At least 15 minutes after application of the test materials and SPF 4 standard, all test sites (water immersion sites and static sites) received UV exposures.

PROCEDURES AND METHODS (Continued)
The exact series of energy levels to be given to the test sites was determined by the previously established unprotected MED for each subject times the expected SPF of the test sunscreen times the multiplication factors published in the Final Monograph[1]. The exact number of exposures for each subject varied from 3 to 7 sub-sites and bracketed the expected SPF of the test material. Any immediate erythema or immediate pigment darkening responses at sub-sites were recorded on each subject's case report form.

Subjects returned to the clinic for Visit 4 approximately 22 to 24 hours after completion of the UV exposures at Visit 3. The test areas were examined for erythema and graded using the scale listed for Visit 2.

BIOSTATISTICS AND DATA MANAGEMENT
Approximate SPF values and PCD were determined for the test materials (water immersion and static sites) and the untreated site using the statistical procedures published in the Final Monograph. Results are reported in Table 2. Please see Appendix I for biostatistics.

MAINTENANCE OF RECORDS
All original records (including the study protocol, observation records, medical histories, informed consent agreements, 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 from the date of study completion. When the archive time has expired, the study files will be either destroyed or sent to the Sponsor upon the Sponsor's notification.

RESULTS
Table 2 presents the Sun Protection Factor (SPF) values and Product Category Designation (PCD) calculated for the static and water immersion sites for each test material. Please note that water immersion values were calculated separately for pilot study subjects who participated in 40 minutes water immersion (water resistant) and for standard study subjects who participated in 80 minutes water immersion (very water resistant). Shaded cells indicate that the subject did not participate in the specified test.

TABLE 2
SUMMARY TABLE OF CALCULATED SPF LEVEL AND PCD FOR EACH TEST SITE

	Results of Water Immersion Test: "Water Resistant" (40 minutes)				
	Lip Balm SPF 30	Face Stick SPF 30	Sun Screen SPF 30	Body Lotion SPF 18	Facial Moisturizer SPF 18
001			34.50	20.50	20.50
002	34.42	34.42			
003			34.50	20.50	19.50
004			34.50	20.50	20.50
005	39.47	39.47			
006			32.00	19.20	20.80
007	39.60	39.60			
008	39.60	39.60			
009			30.00	19.20	20.80
012	39.47	34.42			
Average SPF	38.51	37.50	33.10	19.98	20.42
SPF Label	35.00	34.00	30.00	19.00	19.00
PCD	High	High	High	Moderate	Moderate

RESULTS (Continued)

TABLE 2
SUMMARY TABLE OF CALCULATED SPF LEVEL AND PCD FOR EACH TEST SITE

	Results of Static and Water Immersion Tests: "Very Water Resistant" (80 minutes)			
	Lip Balm SPF 30		Face Stick SPF 30	
	Static Values	Water Immersion Values (Very Water Resistant)	Static Values	Water Immersion Values (Very Water Resistant)
002	34.42		34.42	
005	39.47		39.47	
007	39.60		39.60	
008	34.40		39.60	
012	39.47		39.47	
015	39.47	32.21	39.47	39.47
017	30.00	30.00	34.40	30.00
019	34.42	32.21	34.42	34.42
021	39.60	39.60	39.60	39.60
022	39.60	34.40	39.60	34.40
025	39.47	34.42	39.47	39.47
027	39.50	39.50	39.50	34.50
028	39.47	34.42	39.47	39.47
029	39.47	39.47	39.47	34.42
032	39.60	34.40	39.60	39.60
034	39.60	39.60	34.40	39.60
039	39.60	39.60	39.60	39.60
041	34.40	39.60	39.60	39.60
042	39.60	34.40	39.60	34.40
043	39.60	32.00	39.60	39.60
046		32.21		34.42
047		39.60		39.60
050		34.40		34.40
051		34.42		39.47
054		30.00		34.40
Average SPF	38.04	35.32	38.52	37.02
SPF Label	36.00	33.00	37.00	35.00
PCD	High	High	High	High

RESULTS (Continued)

TABLE 2 (Continued)
SUMMARY TABLE OF CALCULATED SPF LEVEL AND PCD FOR EACH TEST SITE

	Results of Static and Water Immersion Tests: "Very Water Resistant" (80 minutes)					
	Sun Screen SPF 30		Body Lotion SPF 18		Facial Moisturizer SPF 18	
	Static Values	Water Immersion Values (Very Water Resistant)	Static Values	Water Immersion Values (Very Water Resistant)	Static Values	Water Immersion Values (Very Water Resistant)
001	34.50		20.50		20.50	
003	34.50		20.50		18.00	
004	32.00		20.50		19.50	
006	32.00		20.80		20.80	
009	34.40		20.80		20.80	
013	39.60	30.00	20.80	18.00	20.80	18.00
016	34.40	32.00	20.80	20.80	20.80	20.80
018	39.47	34.42	20.84	20.84	20.84	20.84
020	39.47	34.42	20.84	19.26	20.84	20.84
023	39.47	32.21	20.84	19.26	20.84	20.84
026	39.60	32.00	20.80	18.00	20.80	20.80
030	39.60	32.00	20.80	20.80	20.80	19.20
031	39.60	32.00	20.80	19.20	19.20	20.80
033	39.60	32.00	20.80	20.80	19.20	20.80
035	39.50	30.00	20.75	20.75	20.75	19.25
036	39.60	32.00	20.80	18.00	20.80	19.20
037	39.50	34.50	20.50	20.50	20.50	20.50
038	39.47	32.21	20.84	18.00	20.84	19.26
040	34.40	32.00	20.80	19.20	20.80	20.80
044	39.60	30.00	20.80	18.00	20.80	18.00
045		34.40		20.80		20.80
048		32.00		20.80		20.80
049		34.40		20.80		20.80
052		32.00		20.80		19.20
053		34.40		18.00		20.80
Average SPF	37.51	32.45	20.75	19.63	20.41	20.12
SPF Label	36.00	31.00	20.00	19.00	20.00	19.00
PCD	High	High	Moderate	Moderate	Moderate	Moderate

DISCUSSION AND CONCLUSIONS

The following chart presents the calculated Sun Protection Factor (SPF) Label values and the Product Category Designation (PCD) for the static and water resistant determination tests:

	Static SPF (n=20)	Water Immersion SPF (40 Minutes) "Water Resistant" (n=5)	Water Immersion SPF (80 Minutes) "Very Water Resistant" (n=20)	PCD
Lip Balm SPF 30	36.00	35.00	33.00	High
Face Stick SPF 30	37.00	34.00	35.00	High
Sun Screen SPF 30	36.00	30.00	31.00	High
Body Lotion SPF 18	20.00	19.00	19.00	Moderate
Facial Moisturizer SPF 18	20.00	19.00	19.00	Moderate

REFERENCE

[1] "Sunscreen Drug Products for Over-The Counter Human Use." FDA Final Monograph 21 May 1999. Federal Register 64 (98).

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 — 10/29/02
Patricia G. Pierce, M.Ed. — Date
Quality Assurance Manager

REPORT APPROVAL

Report approved by:

THOMAS J. STEPHENS & ASSOCIATES, INC.

Thomas J Stephens, PhD 10/29/02

Thomas J. Stephens, Ph.D. Date
Investigator

James H Herndon MD 10-29-02

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

APPENDICES

I. **Biostatistics**

II. **Protocol: Static and Very Water Resistant SPF Determination Test**

III. **Sample Forms**
- Health and Eligibility Questionnaire
- Informed Consent Agreement
- Observation Forms

IV. **Copy of Attrition Form**

V. **Copies of Site Form and Randomization Form**

VI. **Copies of Observation Forms**