

APPENDIX 4

APPENDIX 4: PROTECTION FACTOR A: STUDY RESULTS

PFA DATA SUMMARY FROM CPTC



EST. 1975

Consumer Product Testing Co.

FINAL REPORT

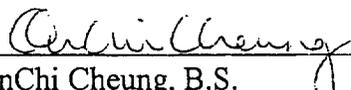
CLIENT: CTFA SPF Task Force
Round Robin Testing
1101 17th Street, N.W.
Washington DC 20036

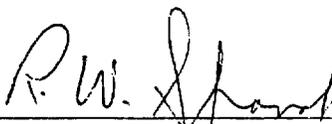
ATTENTION: Gerald McEwen, Jr., Ph.D., J.D.
Vice President – Science

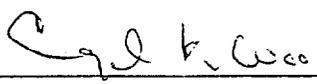
TEST: Determination of the Static UVA Protection Factors (PFA)

TEST MATERIALS: .01) Product A
.02) CTFA Sunscreen Sample E
.03) CTFA Sunscreen Sample F
.04) CTFA Sunscreen Sample G
.05) CTFA Sunscreen Sample H
.06) CTFA Sunscreen Sample I
.07) CTFA Sunscreen Sample J

**EXPERIMENT
REFERENCE NUMBER:** S00-0259


OnChi Cheung, B.S.
Quality Assurance Associate


Robert W. Shanahan, Ph.D.
Vice President, Technology


Caryl K. Wood
Director of Photobiology

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QUALITY ASSURANCE UNIT STATEMENT

Study No.: S00-0259

The objective of the Quality Assurance Unit (QAU) is to monitor the conduct and reporting of clinical laboratory studies. The QAU maintains copies of study protocols and standard operating procedures and has inspected this study on the date(s) listed below. Studies lasting six months or more are inspected at time intervals to assure the integrity of the study. The findings of such inspections are reported to management and the Study Director. All materials and data pertinent to this study will be stored or disposed of in accordance with current Standard Operating Procedures.

Date(s) of inspection: April 10, 2000
April 11, 2000
April 12, 2000
April 17, 2000

Senior personnel involved:

Caryl K. Wood	-	Director of Photobiology
Robert W. Shanahan, Ph.D.	-	Vice President, Technology
Michael Lutz, B.S.	-	Technical Supervisor of Photobiology
Kathleen Alworth, B.A.	-	Director of Quality Assurance
Laura Artiles, M.A.	-	Supervisor, Administrative Services, Photobiology

The representative signature of the Quality Assurance Unit on the front page signifies that this study has been performed in accordance with standard operating procedures and study protocol as well as government regulations regarding such procedures and protocols as outlined in the Federal Register (Vol. 46, No. 17 of Tuesday, January 27, 1981).

Objective: To determine the static UVA Protection Factor (PFA) of sunscreen formulas.

Test Samples:

.01) Product A	(expected PFA = 2-4)
.02) CTFA Sunscreen Sample E	(expected PFA = 1-3)
.03) CTFA Sunscreen Sample F	(expected PFA = 2-4)
.04) CTFA Sunscreen Sample G	(expected PFA = 3-5)
.05) CTFA Sunscreen Sample H	(expected PFA = 3-5)
.06) CTFA Sunscreen Sample I	(expected PFA = 1-3)
.07) CTFA Sunscreen Sample J	(expected PFA = 9-11)

Control Sample: A control standard formulated to provide an approximate Protection Factor of UVA (PFA) of 3.75 was run concurrently with the test material.

Study Schedule:

<u>Initiation Date</u>	<u>Completion Date</u>
March 23, 2000	April 11, 2000

Inclusion Criteria: Healthy male or female volunteers:

- 18 to 65 years of age;
- With Skin Types I - III, determined by the following guidelines:

<u>Skin Type</u>	<u>Sunburn and Tanning History</u>
I	Always burns easily; never tans (sensitive)
II	Always burns easily; tans minimally (sensitive)
III	Burns moderately; tans gradually (normal)
IV	Burns minimally; always tans well (normal)
V	Rarely burns; tans profusely (insensitive)
VI	Never burns; deeply pigmented (insensitive)

- Considered dependable and capable of following directions;
- Having completed a Medical History Form;
- Having read, understood and signed an Informed Consent Form.

Exclusion Criteria:

- a) Subjects with a history of abnormal response to sunlight;
- b) Subjects exhibiting current sunburn, suntan or uneven skin tone which might be confused with a reaction from the test material or interfere with the evaluation of test results;
- c) Subjects with diabetes, Addison's disease, or thyroid conditions;
- d) Subjects taking medication which might produce an abnormal response to sunlight or interfere with the results of the test;
- e) Subjects with allergies or sensitivities to cosmetic products, toiletries, sunscreens (i.e., Padimate O, PABA, oxybenzone, or octyl methoxycinnamate) and/or topical drugs; or
- f) Subjects exhibiting any visible skin disease which could be considered to affect the purpose or integrity of the study.
- g) Subjects participating in any other clinical study (i.e., dermal patch, use tests, etc.) during the period required to complete the study.

Test Method:

A total of twenty-six (26) subjects who met the inclusion criteria were selected for participation. Twelve (12) subjects tested samples .01 - .03 and fourteen (14) subjects tested sample .04 - .07.

Light Source: A Xenon Arc Multiport Solar Simulator* (150w) was used as the source of ultraviolet light. A continuous emission spectrum in the UVA range (320-400 nanometers), using Schott WG 335/2 mm and UG11/1 mm filters, was produced during the testing procedure by this instrument.

Determination of Minimal Response Dose (MRD): Prior to the testing phase, the MRD of the unprotected skin of each subject was determined by a progressive sequence of timed UVA light exposures, graduated incrementally by 25% over that of the previous exposure. For subjects of unknown sensitivity, the dose series was 10, 12.5, 15.6, 19.5, and 24.4 J/cm². For subjects with predetermined UVA MRD values, the dose series was centered around the previously determined MRD.

*Manufactured by Solar Light Company, Philadelphia, PA

**Test Method
(continued):**

MRD values were determined by visual examination of the sites made sixteen (16) to twenty-four (24) hours after irradiation using the following scoring system:

- 0 = No reaction
- 0.5 = Minimal tanning or erythema, barely perceptible
- 1 = Light brown or red color with definite borders
- 1.5 = Medium brown or red, well-defined
- 2 = Dark brown or red with edema

Determination of PFA: A sufficient number of 5 x 7 cm test site areas were outlined with a surgical marking pen on the subject's back between the scapulae and the beltline, lateral to the midline. These areas were designated for the Test Material and Standard, with an adjacent site designated for a concurrent MRD determination (unprotected control). The test and control material(s) were applied using a randomization scheme supplied by Consumer Product Testing Co.

A 2mg/cm² portion of the Test Material and of the Standard was applied to the appropriate designated test site and spread evenly over the site using a fingertip. After product application, the test areas were divided into five (5) sub-sites which were used for serial UVA light exposures. Irradiation of the sites was begun 20 minutes after application.

Exposure times were selected for each sub-site based upon the previously determined MRD of the unprotected skin and the expected PFA of the Test Article or the Standard. After irradiation was completed for each area, responses for tanning, reddening, and heat response were recorded as absent (0) or present (1).

All test sites were evaluated sixteen (16) to twenty-four (24) hours post-irradiation to determine Minimal Response Dose (MRD).

Calculation of the PFA - The PFA for the Test Material and Standard was calculated as follows:

$$\text{PFA} = \frac{\text{MRD Test Material or Standard}}{\text{MRD Unprotected Skin}}$$

Test Results:

PFA calculations for each subject are represented in Tables 1-7.

Product A

Results are based on eleven (11) subjects. Under the test conditions described, Test Material: Product A, exhibited an average PFA value of 3.61.

CTFA Sunscreen Sample E

Results are based on eleven (11) subjects. Under the test conditions described, Test Material: CTFA Sunscreen Sample E, exhibited an average PFA value of <1.64.

CTFA Sunscreen Sample F

Results are based on eleven (11) subjects. Under the test conditions described, Test Material: CTFA Sunscreen Sample F, exhibited an average PFA value of 3.66.

CTFA Sunscreen Sample G

Results are based on ten (10) subjects. Under the test conditions described, Test Material: CTFA Sunscreen Sample G, exhibited an average PFA value of 4.73.

CTFA Sunscreen Sample H

Results are based on ten (10) subjects. Under the test conditions described, Test Material: CTFA Sunscreen Sample H, exhibited an average PFA value of 4.34.

CTFA Sunscreen Sample I

Results are based on ten (10) subjects. Under the test conditions described, Test Material: CTFA Sunscreen Sample I, exhibited an average PFA value of 2.36.

CTFA Sunscreen Sample J

Results are based on ten (10) subjects. Under the test conditions described, Test Material: CTFA Sunscreen Sample J, exhibited an average PFA value of 12.19.

Individual PFA Values

Table 1

Subject	CPTC#	Skin Type	Age/ Sex	Standard	Product A
BK	3371	II	54/F	3.76	3.00
JM	11714	II	42/F	3.76	3.75
BB	13995	II	41/F	5.84	4.67
TE	5838	II	35/F	3.75	2.40
EM	7000	II	42/F	3.00	3.00
DS	11919	II	45/F	3.75	2.99
BS	618	II	46/F	4.69	3.75
SM	556	II	35/F	3.75	3.00
JO	14358	II	20/M	3.75	3.75
JF	15527	II	47/M	4.69	4.69
CJ	14926	II	54/F	3.76	4.70
Average PFA (N=11)				4.05	3.61
(95% Confidence Limits)				(3.54-4.56)	(3.07-4.15)
Standard Deviation				0.76	0.81
Standard Error				0.23	0.24

Table 2

Subject	CPTC#	Skin Type	Age/ Sex	Standard	CTFA Sunscreen Sample E
BK	3371	II	54/F	3.76	2.50
JM	11714	II	42/F	3.76	1.60
BB	13995	II	41/F	5.84	<1.60*
TE	5838	II	35/F	3.75	<1.02*
EM	7000	II	42/F	3.00	1.60
DS	11919	II	45/F	3.75	1.28
BS	618	II	46/F	4.69	1.60
SM	556	II	35/F	3.75	1.28
JO	14358	II	20/M	3.75	2.00
JF	15527	II	47/M	4.69	2.00
CJ	14926	II	54/F	3.76	1.60
Average PFA (N=11)				4.05	<1.64
*calculated as actual value					

Individual PFA Values

Table 3

Subject	CPTC#	Skin Type	Age/ Sex	Standard	CTFA Sunscreen Sample F
BK	3371	II	54/F	3.76	4.69
JM	11714	II	42/F	3.76	3.01
BB	13995	II	41/F	5.84	5.84
TE	5838	II	35/F	3.75	1.92
EM	7000	II	42/F	3.00	3.75
DS	11919	II	45/F	3.75	3.74
BS	618	II	46/F	4.69	3.75
SM	556	II	35/F	3.75	3.00
JO	14358	II	20/M	3.75	3.01
JF	15527	II	47/M	4.69	3.75
CJ	14926	II	54/F	3.76	3.76
Average PFA (N=11)				4.05	3.66
(95% Confidence Limits)				(3.54-4.56)	(2.98-4.34)
Standard Deviation				0.76	1.01
Standard Error				0.23	0.30

Table 4

Subject	CPTC#	Skin Type	Age/ Sex	Standard	CTFA Sunscreen Sample G
HF	19302	II	22/F	3.76	5.01
AH	20154	II	53/F	4.69	5.00
BK	7839	II	50/F	3.75	4.00
AD	7691	II	48/F	3.75	5.01
JM	20378	II	29/M	4.69	5.01
JA	15396	II	37/F	3.76	4.01
CG	9638	II	34/F	3.74	3.99
CM	18105	II	44/F	3.75	4.00
CO	2849	II	47/F	3.75	6.25
JP	3656	II	46/F	3.75	4.99
Average PFA (N=10)				3.94	4.73
(95% Confidence Limits)				(3.66-4.22)	(4.21-5.25)
Standard Deviation				0.40	0.73
Standard Error				0.13	0.23

Individual PFA Values

Table 5

Subject	CPTC#	Skin Type	Age/ Sex	Standard	CTFA Sunscreen Sample H
HF	19302	II	22/F	3.76	4.01
AH	20154	II	53/F	4.69	5.00
BK	7839	II	50/F	3.75	3.20
AD	7691	II	48/F	3.75	5.01
JM	20378	II	29/M	4.69	5.01
JA	15396	II	37/F	3.76	4.01
CG	9638	II	34/F	3.74	3.20
CM	18105	II	44/F	3.75	4.00
CO	2849	II	47/F	3.75	5.00
JP	3656	II	46/F	3.75	4.99
Average PFA (N=10)				3.94	4.34
(95% Confidence Limits)				(3.66-4.22)	(3.80-4.88)
Standard Deviation				0.40	0.75
Standard Error				0.13	0.24

Table 6

Subject	CPTC#	Skin Type	Age/ Sex	Standard	CTFA Sunscreen Sample I
HF	19302	II	22/F	3.76	2.50
AH	20154	II	53/F	4.69	2.51
BK	7839	II	50/F	3.75	2.00
AD	7691	II	48/F	3.75	3.13
JM	20378	II	29/M	4.69	2.00
JA	15396	II	37/F	3.76	2.00
CG	9638	II	34/F	3.74	1.99
CM	18105	II	44/F	3.75	2.50
CO	2849	II	47/F	3.75	2.50
JP	3656	II	46/F	3.75	2.50
Average PFA (N=10)				3.94	2.36
(95% Confidence Limits)				(3.66-4.22)	(2.10-2.62)
Standard Deviation				0.40	0.37
Standard Error				0.13	0.12

Individual PFA Values

Table 7

Subject	CPTC#	Skin Type	Age/ Sex	Standard	CTFA Sunscreen Sample J
HF	19302	II	22/F	3.76	11.26
AH	20154	II	53/F	4.69	14.07
BK	7839	II	50/F	3.75	11.26
AD	7691	II	48/F	3.75	11.26
JM	20378	II	29/M	4.69	11.26
JA	15396	II	37/F	3.76	11.27
CG	9638	II	34/F	3.74	14.98
CM	18105	II	44/F	3.75	11.24
CO	2849	II	47/F	3.75	14.06
JP	3656	II	46/F	3.75	11.24
Average PFA (N=10)				3.94	12.19
(95% Confidence Limits)				(3.66-4.22)	(11.10-13.28)
Standard Deviation				0.40	1.52
Standard Error				0.13	0.48

**DATA SUMMARY FROM
TKL RESEARCH**



SUMMARY REPORT

TKL Study No. PB840200
Date of Report 5/22/2000

Protocol Title: Determination of the Static UVA Protection Factors (PFA).

Objective: To determine the static UVA Protection Factor (PFA) for sunscreen formulas.

Design of Study: UVA induced Minimal Response Dose (MRD) determination, product application and UVA irradiation followed by 16-24 hour evaluation to determine PFA values.

Principal Investigator: Alan H. Greenspan, MD

Clinical Research Coordinator: Maureen Damstra, BA, CCRC

Study Sponsor: THE COSMETIC, TOILETRY, AND FRAGRANCE ASSOCIATION
1101 17th St. NW, Suite 300
Washington, DC 20036-4702
Attention: Gerald McEwen, PhD

Study Center: TKL Research, Inc.
4 Forest Avenue
Paramus, NJ 07652

Study Dates: Date Initiated: March 27, 2000
Date Completed: April 12, 2000

Study Products:

CTFA Sample # / Product ID

A: White lotion	H: White Cream
E: White lotion	I: White lotion
F: White lotion	J: White lotion
G: White lotion	

Number of Subjects: Enrolled: 22 Completed: 22

SUMMARY REPORT (Cont'd)
TKL Study No. PB840200
The Cosmetic, Toiletry, and Fragrance Association

Listing of Attached Tables:

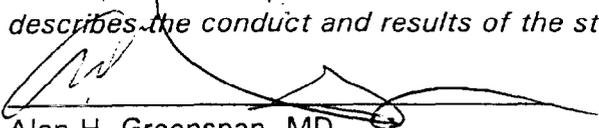
Appendix I PFA Result Tables
 Appendix II Fitzpatrick Skin Type Table
 Appendix III Study Demographics

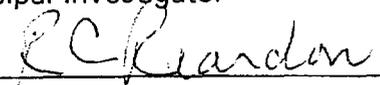
Summary - Conclusions: The following UVA-Protection factors (PFA) and associated values were obtained following UVA induced Minimal Response Dose (MRD) determination.

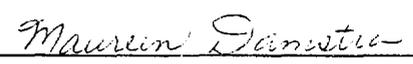
PRODUCT NUMBER	EST. PFA	PFA/STD. DEVIATION	STANDARD ERROR	5% OF MEAN	COMMENTS
A	2-4	3.23±0.54 N = 11	0.16	0.16	No unacceptable results
E	1-3	1.79±0.26 N = 11	0.08	0.09	One result rejected due to lack of protection at irradiated sub-sites
F	2-4	3.43±0.56 N = 11	0.17	0.17	No unacceptable results
G	3-5	4.40±0.83 N = 11	0.25	0.22	No unacceptable results
H	3-5	4.01±0.89 N = 11	0.27	0.20	No unacceptable results
I	1-3	2.59±0.70 N = 11	0.21	0.13	No unacceptable results
J	9-11	13.00±4.71 N = 11	1.42	0.65	No unacceptable results

Signatures:

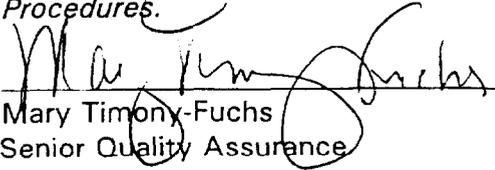
I have read this report and confirm that to the best of my knowledge it accurately describes the conduct and results of the study.

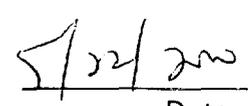

 Alan H. Greenspan, MD
 Principal Investigator


 Robert C. Reardon, PhD
 Director of Operations


 Maureen Damstra, BA, CCRC,
 Clinical Research Coordinator and
 Manager, Photobiology

All data and supporting documentation for this study and report have been audited by the TKL Quality Assurance Department and found to be accurate and complete and in compliance with all requirements of the protocol and TKL's Standard Operating Procedures.


 Mary Timony-Fuchs
 Senior Quality Assurance


 Date

APPENDIX I

PFA RESULT TABLES

Table 1

<u>Subject Number</u>	<u>Product No.</u> <u>"A"</u>
02	3.75
03	3.00
05	3.75
06	2.40
11	3.75
12	3.00
13	2.40
15	3.75
19	3.00
20	3.00
22	3.75
Mean=	3.23
SD=	0.54
SE=	0.16
5% MEAN=	0.16
N=11	

Table 2

<u>Subject Number</u>	<u>Product No.</u> <u>"E"</u>
02	2.00
03	2.00
04	1.60
07	2.00
08	2.00
14	1.28
15	1.60
16	2.00
19	1.60
20	2.00
21	1.60
Mean=	1.79
SD=	0.26
SE=	0.08
5% MEAN=	0.09
N=11	

Table 3

<u>Subject Number</u>	Product No. <u>"F"</u>
01	3.75
02	3.75
04	3.00
05	3.00
11	3.75
12	3.00
13	3.75
15	3.00
19	3.00
20	3.00
22	4.69
Mean=	3.43
SD=	0.56
SE=	0.17
5% MEAN=	0.17
N=11	

Table 4

<u>Subject Number</u>	Product No. <u>"G"</u>
01	6.25
03	4.00
06	4.00
09	4.00
10	4.00
11	5.00
12	3.20
13	4.00
15	4.00
20	5.00
22	5.00
Mean=	4.40
SD=	0.83
SE=	0.25
5% MEAN=	0.22
N=11	

Table 5

<u>Subject Number</u>	<u>Product No.</u> <u>"H"</u>
01	5.00
02	5.00
05	5.00
11	4.00
12	4.00
13	3.20
14	2.56
15	3.20
19	3.20
20	4.00
22	5.00
Mean=	4.01
SD=	0.89
SE=	0.27
5% MEAN=	0.20
N=11	

Table 6

<u>Subject Number</u>	<u>Product No.</u>
03	3.12
04	2.50
05	2.00
06	1.60
07	3.13
08	2.50
13	2.50
16	3.12
17	1.60
18	2.50
22	3.91
Mean=	2.59
SD=	0.70
SE=	0.21
5% MEAN=	0.13
N=11	

Table 7

<u>Subject Number</u>	<u>Product No.</u> <u>"J"</u>
04	15.64
06	12.50
07	19.55
08	10.00
09	8.00
10	10.00
14	8.80
16	21.50
17	8.82
18	17.21
21	11.00
Mean=	13.00
SD=	4.71
SE=	1.42
5% MEAN=	0.65
N=11	

APPENDIX II

FITZPATRICK SKIN TYPE

FITZPATRICK SKIN TYPE

Entry No.	SKIN TYPE
01	III
02	III
03	III
04	II
05	III
06	III
07	III
08	III
09	III
10	III
11	III
12	III
13	III
14	III
15	III
16	III
17	III
18	III
19	III
20	III
21	III
22	III

Key:

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

APPENDIX III

DEMOGRAPHICS

KEY:

F = Female
M = Male

DEMOGRAPHICS

Entry No.	Subject No.	Sex	Race	Age
01	13934	F	WHITE	61
02	15355	F	WHITE	39
03	55189	F	WHITE	36
04	17711	F	WHITE	44
05	18512	F	WHITE	26
06	13884	F	WHITE	52
07	17823	F	WHITE	48
08	61695	M	HISPANIC	62
09	59391	F	WHITE	59
10	66551	F	WHITE	42
11	16801	F	WHITE	64
12	63749	F	HISPANIC	32
13	56271	F	WHITE	43
14	58366	F	HISPANIC	39
15	15784	F	WHITE	40
16	50346	F	WHITE	35
17	66375	F	WHITE	40
18	45100	M	WHITE	24
19	15109	F	WHITE	41
20	20360	F	WHITE	48
21	56637	M	WHITE	31
22	19059	F	WHITE	41

DISTRIBUTION OF AGES

Under 18	: n =	0
18 to 25	: n =	1
26 to 35	: n =	4
36 to 45	: n =	10
46 to 55	: n =	3
56 to 65	: n =	4
Over 65	: n =	0

Total	: n =	22
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Mean Age:	43
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Median Age:	41
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Age range for the study: 24 to 64