

Sun Protection Factor Final Report

Report Date: 10/15/2021	FSTI Study/Sample #: 21-1181
Sponsor Formula #: [REDACTED]	Sponsor Lot #: 210134-13
Sponsor: [REDACTED]	Sample Description: SPF 30

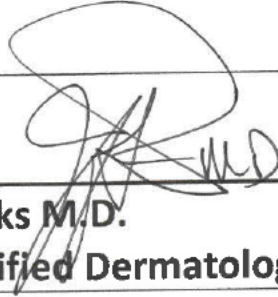
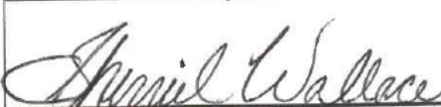
Summary:

The sponsor test product sample, Formula [REDACTED] was tested under FSTI (Florida Suncare Testing, Inc.) SOP # 2011-04, Static SPF Testing, as set forth by the FDA, 21 CFR Sec. 201.327, subpart (i), SPF Test Procedure, Sunscreen Drug Products for Over-the-Counter Human Use, Final Monograph, Federal Register, Vol. 76, No. 117, June 17, 2011.

The ten (10) subject test panel study yielded a mean Static SPF value of **32.83**, with an X-A value of 30.49, **Label SPF 30**. See Page 8 (Table 1) of this report for a summary of all test results obtained in this study.

The FDA Standard Sunscreen Product tested concurrently with the experimental test sample yielded a mean Static SPF value of 18.11, within the allowable guidelines of 16.3 ± 3.43 .

Approvals:

 Jeffrey Parks M.D. Board Certified Dermatologist	<u>10/15/21</u> Date
 Sherriel Wallace FSTI Clinical Research Director	<u>10/15/2021</u> Date

FSTI STUDY NUMBER: 21-1181

SPONSOR: [REDACTED]

SPONSOR FORMULA #: [REDACTED]

STUDY START DATE: September 20, 2021

DATE COMPLETED: October 6, 2021

I. OBJECTIVE

To measure the Sun Protection Factor (SPF) value for a sunscreen formula Static (without water immersion) under the guidelines of FSTI SOP# 2011-04 in accordance with FDA, 21 CFR Sec. 201.327, subpart (i), SPF Test Procedure, Sunscreen Drug Products for Over-the-Counter Human Use, Final Monograph, Federal Register, Vol. 76, No. 117, June 17, 2011.

II. STUDY TYPE

Ten (10) subject Static SPF study, with a final report furnished to the sponsor, which includes subject demographics, individual, mean and Label SPF values for the sponsor test sample in this study.

III. SAMPLE DESCRIPTION

SPF 30, Formula [REDACTED] Lot # 210134-13, FSTI Sample # 21-1181

IV. TEST MATERIAL HANDLING

The [REDACTED] test sample, Formula [REDACTED] Lot # 210134-13, was assigned Florida Suncare Testing, Inc. sample number 21-1181 and entered into the SPF test submission log. The FDA standard 15 SPF sunscreen, as described in FDA, 21 CFR, Sec. 201.327, subpart (i) (2), SPF Standard, was used concomitantly as the control test product for this study.

V. ARCHIVING

All original protocols, raw data sheets, and copies of final reports are maintained on the premises of Florida Suncare Testing, Inc., in limited access storage files in accordance with FSTI SOP# 2008-10. A duplicate copy of all final reports is kept on a secured, password-protected, Florida Suncare Testing, Inc. computer hard drive.

QUESTION

1. The following table shows the number of people who attended a concert in each of the five years from 2000 to 2004.

Year	Number of people
2000	1200
2001	1500
2002	1800
2003	2100
2004	2400

2. The following table shows the number of people who attended a concert in each of the five years from 2000 to 2004.

Year	Number of people
2000	1200
2001	1500
2002	1800
2003	2100
2004	2400

3. The following table shows the number of people who attended a concert in each of the five years from 2000 to 2004.

Year	Number of people
2000	1200
2001	1500
2002	1800
2003	2100
2004	2400

4. The following table shows the number of people who attended a concert in each of the five years from 2000 to 2004.

Year	Number of people
2000	1200
2001	1500
2002	1800
2003	2100
2004	2400

5. The following table shows the number of people who attended a concert in each of the five years from 2000 to 2004.

Year	Number of people
2000	1200
2001	1500
2002	1800
2003	2100
2004	2400

6. The following table shows the number of people who attended a concert in each of the five years from 2000 to 2004.

Year	Number of people
2000	1200
2001	1500
2002	1800
2003	2100
2004	2400

7. The following table shows the number of people who attended a concert in each of the five years from 2000 to 2004.

Year	Number of people
2000	1200
2001	1500
2002	1800
2003	2100
2004	2400

8. The following table shows the number of people who attended a concert in each of the five years from 2000 to 2004.

Year	Number of people
2000	1200
2001	1500
2002	1800
2003	2100
2004	2400

9. The following table shows the number of people who attended a concert in each of the five years from 2000 to 2004.

Year	Number of people
2000	1200
2001	1500
2002	1800
2003	2100
2004	2400

10. The following table shows the number of people who attended a concert in each of the five years from 2000 to 2004.

Year	Number of people
2000	1200
2001	1500
2002	1800
2003	2100
2004	2400

11. The following table shows the number of people who attended a concert in each of the five years from 2000 to 2004.

Year	Number of people
2000	1200
2001	1500
2002	1800
2003	2100
2004	2400

12. The following table shows the number of people who attended a concert in each of the five years from 2000 to 2004.

Year	Number of people
2000	1200
2001	1500
2002	1800
2003	2100
2004	2400

Dear Sirs,

I am writing to you regarding the recent developments in the project. We have successfully completed the initial phase of the research and are now moving forward with the next steps. The data collected so far is promising and indicates a strong correlation between the variables we are studying.

We have also identified several key areas for further investigation. These include the impact of external factors on the system's performance and the long-term sustainability of the proposed solution. We are currently working on a detailed plan to address these issues and will provide you with a comprehensive report by the end of the month.

In the meantime, we would appreciate your continued support and feedback. Your insights are invaluable and help us refine our approach. Please do not hesitate to reach out if you have any questions or concerns. We are committed to ensuring that the project meets your expectations and delivers the highest quality results.

Thank you for your time and attention. We look forward to your response and to the successful completion of the project. Your cooperation is essential to our success.

Yours faithfully,
[Signature]

[Name]
[Title]
[Company Name]

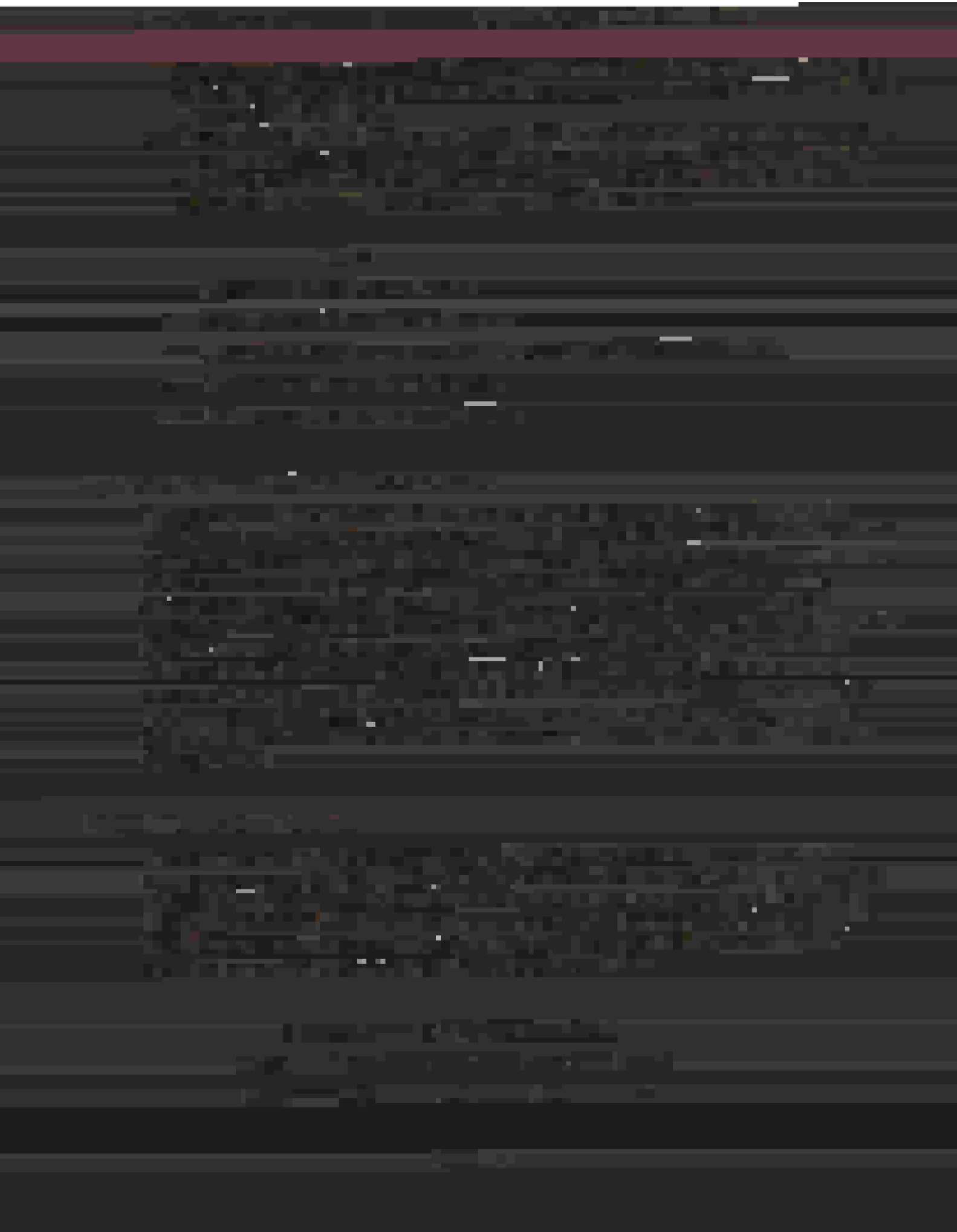
[Address]
[City, State, Zip]

[Phone Number]
[Email Address]

[Website]

[Additional Information]

[Closing Remarks]



THE ETHICAL CHALLENGES OF THE FUTURE

W. G. W. KEMP, M. J. VAN DIJK and M. J. VAN OORT

W. G. W. KEMP, M. J. VAN DIJK and M. J. VAN OORT

ABSTRACT. This article discusses the ethical challenges of the future. It starts with a general overview of the ethical challenges of the future. It then discusses the ethical challenges of the future in more detail. The article concludes with a discussion of the ethical challenges of the future in the context of the business system.

INTRODUCTION

The future is a time of great change and challenge.

As we look to the future, we see a world that is

changing rapidly. The pace of change is accelerating, and the challenges are becoming more complex. We are living in a time of great uncertainty, and we need to be prepared for what the future may bring. This article discusses the ethical challenges of the future, and how we can best prepare ourselves for them.

One of the most significant challenges of the future is the rapid pace of technological change. As new technologies are developed, they create new opportunities, but also new ethical challenges. For example, the development of artificial intelligence raises questions about the rights of machines and the potential for job displacement.

Another major challenge is the growing global inequality. As the world's population grows, the gap between the rich and the poor is widening. This creates ethical challenges for businesses and governments alike.

Finally, the future will be shaped by the actions of individuals and organizations today. We have a responsibility to act ethically and responsibly, so that we can create a better future for ourselves and for the world.

In this article, we will discuss the ethical challenges of the future in more detail, and explore some ways in which we can best prepare ourselves for them.

The future is a time of great change and challenge. As we look to the future, we see a world that is changing rapidly. The pace of change is accelerating, and the challenges are becoming more complex. We are living in a time of great uncertainty, and we need to be prepared for what the future may bring.

THE ETHICAL CHALLENGES OF THE FUTURE

Data from ten (10) subjects was used for calculating the test product's label SPF value. The mean SPF value (\bar{x}) and the Standard Deviation (s) for these subjects was computed. Based on a full 10 subject test panel, the upper 5-percent point from the student distribution table (denoted by t) with $n-1$ degrees of freedom was obtained. The quantity A was computed using the Formula $A = ts/\text{Square root } n$ (with n representing the number of test subjects (10) in a full study). A label SPF value was calculated by determining the largest whole number less than $\bar{X} - A$. Any test product with a label SPF less than 2 is not a sunscreen drug product and will not display an SPF value.

XII. REJECTION OF STUDY DATA

There are three (3) primary reasons for rejection of study data as noted in 21 CFR, Sec. 201.327, subpart (5)(v), Invalid Test Data. The exposure series fails to elicit an MED response on either the protected or unprotected test sites; an MED response was noted on all the protected test sites, or the test subject was non-compliant (failed to follow instructions or withdrew from the study).

XIII. RESULTS

A total of ten (10) healthy subjects who fulfilled the test panel participation criteria were inducted into this investigation. The demographic data is shown in Section V., Panel Design. The individual, mean and label SPF values of the [REDACTED] test sample, SPF 30, Formula # [REDACTED] Lot # 210134-13, FSTI Sample # 21-1181, are shown in Table 1, page 8.

XIV. ADVERSE EXPERIENCES

No adverse experiences were reported during this study.

XV. CONCLUSIONS

The Sun Protection Factor (SPF) of the above sample described herein; tested under Static (without water immersion) conditions, yielded the following SPF values:

Formula Number	FSTI Sample Number	Mean Static SPF	Label SPF
[REDACTED]	21-1181	32.83	30

The FDA standard for this study had a mean static SPF value of 18.11 and satisfied all statistical criteria as specified in FDA, 21 CFR, Sec. 201.327, subpart (6)(i).

References:

U.S. Food and Drug Administration, Sunscreen Drug Products for Over-The-Counter Human Use; Final Monograph, 21 CFR Sec. 201.327, subpart (i), SPF Test Procedure, Sunscreen Drug Products for Over-the-Counter Human Use, Federal Register, Vol. 76, No. 117, June 17, 2011.

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MEMORANDUM

TO :

FROM :

SUBJECT :

DATE :

BY :

FOR :

RE :

CC :

NOTES :

Item	Description	Quantity	Unit Price	Total
1	Item 1	10	100	1000
2	Item 2	5	200	1000
3	Item 3	20	50	1000
4	Item 4	15	70	1050
5	Item 5	8	125	1000
6	Item 6	12	80	960
7	Item 7	3	300	900
8	Item 8	7	140	980
9	Item 9	4	250	1000
10	Item 10	6	160	960
11	Item 11	9	110	990
12	Item 12	11	85	935
13	Item 13	14	65	910
14	Item 14	18	50	900
15	Item 15	22	40	880
16	Item 16	25	35	875
17	Item 17	30	30	900
18	Item 18	35	25	875
19	Item 19	40	22	880
20	Item 20	45	20	900