TEST REPORT

2025CS1140

DATE OF RECEPTION
Date Format: dd/MM/yyyy 26/05/2025

DATE TESTS
Starting: 26/05/2025
Ending: 11/06/2025

APPLICANT

KRAES ApS
Peder Skrams Gade 39, st
DK-8200 Arhus N
Denmark

Att. Nina Wejdemann

IDENTIFICATION AND DESCRIPTION OF SAMPLES

Reference by AITEX	Reference by customer	AITEX sample description
2025CS1140-S01	Batch 1001205	Emulsion/Cream

TESTS CARRIED OUT

- DETERMINATION OF THE FACTOR OF SUN PROTECTION (SPF) IN VIVO.

RESULTS

DETERMINATION OF THE FACTOR OF SUN PROTECTION (SPF) IN VIVO

1. OBJECTIVE AND PRINCIPLE OF THE STUDY.

Main objective

The level of sun protection of products with sunscreen is estimated using the erythematous response of the skin to ultraviolet (UV) radiation .

The sun protection factor (SPF) is the ratio of the energy needed to elicit a minimal erythematous response with and without sunscreen applied to the skin of a volunteer

2. TYPE OF STUDY.

ISO 24444:2019/A1:2022

The method uses a solar simulator with a lamp in xenon arc (or equivalent) with a defined and known output. The UV light is emitted on a section of the skin of each volunteer without any protection, while another section is exposed after the application of the product with the sunscreen that is being tested. For the validation of the test, a section of the additional skin is exposed to UV light after the application of a sunscreen product whose SPF is of reference

The response of the skin is visually evaluated according to the presence of redness in a period between 16-24 h after exposure to UV radiation, according to the opinion of the dermatologist investigator

The minimum erythematous dose for unprotected skin (MEDu) and the minimum erythematous dose for protected skin (MEDp), that is, after the application of a product with sunscreen, are the parameters obtained after the test

The minimum erythematous dose (MED) is expressed in terms of energy (mJ x cm-2), or MED units or in units of time (seconds)

The individual sun protection factor (SPFi) for each subject tested is determined as an individual ratio of MEDu / MEDp. The SPF of the product is the arithmetic mean of all the SPFi obtained.

3. TECHNICAL TEAM.

Asociación de investigación de la industria textil y cosmética - AITEX
Technician: ABLD

4. DATE TEST

Starting 26/05/2025
Ending 11/06/2025

5. TESTED PRODUCT REFERENCE

Reference: 2025CS1140-S01

6. RESULTS

The experimental conditions have been the following:

METHODOLOGICAL CRITERIA

- Given the idiosyncrasy of the product under study, the participants met a series of methodological criteria throughout their development, to avoid biases in the data.
- All the participants followed the recommendations that were provided to them at the beginning of the study by the Principal Investigator
- No other product was used that could interfere in the study, in the areas to be tested during the realization of the same

VOLUNTEERS

The number of volunteers whose data have been treated at the end of the trial has been 10. Each of them read, understood and signed an Authorization and Commitment Form

Amount of product applied: 2.00 ± 0.05 mg/cm^2

Gradual progression of the UV dose:

Unprotected sites: an estimated MEDu is used and 6 zones are exposed at increasing UV doses, with a geometrical increase of 1.15

Protected sites: the product to be evaluated is applied and the UV dose is defined based on the expected MEDp. 6 zones are exposed at increasing doses of UV, with a geometrical increase of 1.15

INCLUSION CRITERIA

- Number of volunteers: 10
- Age: 18-65 years
- Gender : Both
- Phototype: I-II-III
- Agree to voluntarily participate in the study and give written informed conse

CRITERIA OF NOT INCLUSION

The criteria for non-inclusion were the following:

The presence of at least one of the following criteria was excluded from the clinical trial:

1. Subjects with acute illness during the study and in the week before the start of this study
2. Presenting cutaneous pathologies in the week before the start of the study
3. Pregnant or lactating women
4. Subjects with allergies to any of the components of the product in

All the volunteers included in this study are aware and exempt from the previous actions, so they are accepted in said study

INFORMATION OF THE SAMPLE

Qualitative composition (INCI) and expected SPF
The customer is responsible for compliance with the data provided

Theoretical protection factor: 30
INCI: Unknown

RESULTS AFTER EVALUATION

Skin reactions observed by the researcher:

TABLE 1: Data of the reference product used in this test.

Standard	Average SPF	Acceptance limit (Average ± 2SD)		Conformity
		Lower limit	Upper limit	
P5	63,1	43,9	82,3	Compliance
P2	14,8	13,7	18,5	Compliance

TABLE 2: Data of the tested producto

VOLUNTEERS				SIM	SPF RESULTS							
Nº	Age	Gender	ITA º	watts/m²	MED_u		MED_s	MED_p		Standad	SPFs	SPFp
					mm:ss	J/m² eff		mm:ss	J/m² eff			
1	25	F	46	1582	31:00	244,2	3760,8	00:16	7326,2	P2	15,4	**30**
2	59	F	45	1582	33:00	250,3	3579,1	00:18	8259,4	P2	14,3	**33**
3	21	F	55	1582	25:00	194,1	2950,4	00:14	6405,5	P2	15,2	**33**
4	27	F	53	1582	26:00	204,5	2904,3	00:14	6708,4	P2	14,2	**32,8**
5	20	F	41	1582	36:00	275,6	4051,5	00:20	9177,9	P2	14,7	**33,3**
6	32	M	49	1582	29:00	226,6	6525,8	00:18	8157,2	P5	28,8	**36**
7	54	M	55	1582	25:00	194,1	5163,2	00:14	6638,4	P5	26,6	**34,2**
8	36	F	54	1582	26:00	199,3	5061,3	00:14	6695,3	P5	25,4	**33,6**
9	18	F	39	1582	37:00	288,9	8637,8	00:21	9793,3	P5	29,9	**33,9**
10	22	M	58	1582	23:00	179,2	4283,8	00:14	6291,3	P5	23,9	**35,1**

Remarks:

SPFs= MEDs/MEDu
SPFi= MEDp/MEDu
MEDu= Minimum erythematous dose (MED) for unprotected skin.
MEDs= Minimum erythematous dose (MED) for standard-protected skin.
MEDp= Minimum erythematous dose (MED) for skin protected with investigational product
SPFs= standard sun protection factor
SPFp= Sun protection factor of the product to be investigated
F = Female
M = Male

CONCLUSION

Results	
Static SPF average	**33,5**
Standard desviation	1,6
Coef "c"	1,1
95% CI	2,0
Conclusion	CI ≤ 17%

Of the 10 volunteers who start the study, they have completed 10

Based on the tables in the previous section, we can conclude that the product referenced as "2025CS1140-S01" evaluated with the UNE EN ISO 24444:2019/A1:2022 standard has obtained the following mean SPF value in vivo carried out in 10 volunteers

SPF 33,5

According to 2006/647/CE, the following labeling is recommended depending on the range of protection factors:

TABLE. Labeling of the sun protection product.

CATEGORY	SPF LABELED	SPF MEASURED
LOW PROTECTION	"6"	6-9.9
	"10"	10-14.9
MEDIUM PROTECTION	"15"	15-19.9
	"20"	20-24.9
	"25"	25-29.9
HIGH PROTECTION	"30"	30-49.9
	"50"	50-59.9
VERY HIGH PROTECTION	"50+"	≥ 60

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Nuria Jorda
Senior Cosmetic Lab. Technician

Date: 12/06/2025 13:13:24
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