REPORT OF ANALYSIS No. 143426-3/23/GDA

Client:		Sample *(according to declaration of the Client)*
KRAES ApS **Peder Skrams Gade 39, st** **8200 Aarhus N** **Denmark**		**KRAES solcreme 30SPF** **125 ml tube** **batch/lot: 09234560**
Sample received:	17.03.2023	
Analysis completed:	31.05.2023	
Report date:	31.05.2023	

IN VIVO DETERMINATION OF THE SUN PROTECTION FACTOR (SPF)

ACCORDING TO THE INTERNATIONAL NORM ISO 24444:2019/AMD 1:2022 - Cosmetics — Sun protection test methods — In vivo determination of the sun protection factor (SPF) — Amendment 1

AND OF THE WATER RESISTANCE

ACCORDING TO INTERNATIONAL NORM ISO 16217:2020 AND ISO 18861:2020

Authorised by: Monika Symonowicz, Project Manager (qualified electronic signature),
Karolina Osiecka, Dermatologist, 2487308.

J.S. HAMILTON POLAND Sp. z o.o.
ul. Chwaszczyńska 180, 81-571 Gdynia, Poland, tel. +48 58 766 99 00

REPORT OF ANALYSIS No. 143426-3/23/GDA

SCOPE OF TEST COMPLIES WITH:

- EN ISO 24444:2019/AMD 1:2022 - Cosmetics — Sun protection test methods — In vivo determination of the sun protection factor (SPF) — Amendment 1.
- EN ISO 16217:2020- Cosmetics — Sun protection test methods — Water immersion procedure for determining water resistance.
- EN ISO 18861:2020- Cosmetics — Sun protection test methods — Percentage of water resistance.
- Regulation of the European Parliament and of the Council (EC) no. 1223/2009 of 30 November 2009 on cosmetic products.
- Recommendation No. 2006/647/EC on the efficacy of sunscreen products and the claims made relating thereto.

Authorised by: Monika Symonowicz, Project Manager (qualified electronic signature),
Karolina Osiecka, Dermatologist, 2487308.

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REPORT OF ANALYSIS No. 143426-3/23/GDA

CONTENT OF THE REPORT:

1. The basis of the study.
2. Subject of test.
3. Qualitative composition of the product.
4. Purpose of the test.
5. Samples and testing conditions.
6. Inclusion criteria.
7. Non-inclusion criteria.
8. Testing equipment.
9. Laboratory staff.
10. Description of the methodology.
11. SPF and WR reference standards.
12. Product labeling method.
13. Date of performance of the study.
14. Test results.
15. Conclusion.
16. Signatures.

Authorised by: Monika Symonowicz, Project Manager (qualified electronic signature),
Karolina Osiecka, Dermatologist, 2487308.

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REPORT OF ANALYSIS No. 143426-3/23/GDA

1. THE BASIS OF THE STUDY

- Test samples delivered by the Client.
- The qualitative composition of the product delivered by the Client.
- The results of microbiological purity of the product made in J.S. Hamilton (Report of analysis no.: 143426-5/23/GDA).
- Negative results of the dermatological test of the product made in J.S. Hamilton (Report no.: 143427-1/23/GDA).
- Declared a sun protection factor: 30.

2. SUBJECT OF TEST

Parameter	Description
Appearance	Emulsion
Color	Yellow
Fragrance	Characteristic for used raw materials
Packaging	Repackaging covered with a label containing the name of the product

3. QUALITATIVE COMPOSITION OF THE PRODUCT

Caprylic/Capric triglycerides*, Helianthus Annuus Seed Oil**, Zinc Oxide*, Cera Alba*, Avena Sative Kernel Oil*
*natural **organic

The Client is responsible for compliance with the declared qualitative composition of the product and microbiological purity of sent samples for testing.

4. PURPOSE OF THE TEST

Confirmation / exclusion declared by the Manufacturer the Sun Protection Factor level and water resistance.

5. SAMPLES AND TESTING CONDITIONS

Upon arrival, all products are registered on the HAMILTON LIMS System and kept at room temperature (unless otherwise requested). The test is performed in an air-conditioned room, with the room temperature maintained at 23 ± 3°C and the relative humidity 50 ± 10%.

Authorised by: Monika Symonowicz, Project Manager (qualified electronic signature),
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REPORT OF ANALYSIS No. 143426-3/23/GDA

6. INCLUSION CRITERIA

Healthy subjects,
Subject having given her/his informed, written consent,
Subject that is willing to cooperate and aware of the necessity and duration of controls so that perfect adhesion to the protocol established by the clinical trial center could have been expected,
Age between 18 and 70,
Type: Caucasian,
Phototype: I to III,
Untanned skin on the test area.

7. NON-INCLUSION CRITERIA

Subjects below the age of consent or >70 years,
Pregnant or lactating women,
Subjects using medication with photo-sensitizing potential,
Subjects using anti-inflammatory medication,
Subjects with dermatological conditions,
Subjects with a history of abnormal response to the sun,
Subjects accustomed to using tanning beds,
Subjects having had sun exposure on the back area in the previous eight weeks prior to SPF testing,
Subjects having marks, blemishes or nevi or presenting existing sun damage in the test area,
Subjects having excessive hair in the area of the test.
Subjects having skeletal protrusions and extreme areas of curvature in the test area.

Authorised by: Monika Symonowicz, Project Manager (qualified electronic signature),
Karolina Osiecka, Dermatologist, 2487308.

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REPORT OF ANALYSIS No. 143426-3/23/GDA

8. TESTING EQUIPMENT

UV source:	Xenon lamp: Solar Light type Multiport 601
	Spectrum: 290 - 400 nm
	Power of the lamp: 300 W.
	Elimination of IR and visible radiation: UG11 (1mm) and dichroic mirror.
	Radiated surface: Six holes (diameter 8 mm).
UV Light Radiometer:	Solar Light Co. DCS 2.0.
Detector:	Solar Light Co. Erythema detector PMA2108.LLG.
Bath:	For water immersion test.

The documents for latest calibration and statement of compliance for solar simulators used in this study are attached below.

Authorised by: Monika Symonowicz, Project Manager (qualified electronic signature),
Karolina Osiecka, Dermatologist, 2487308.

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REPORT OF ANALYSIS No. 143426-3/23/GDA

ACCREDITED TESTING LABORATORY (NR. 312)
for Laser, LED and Lamp Safety
Akkreditierung Austria is a full member of the International Laboratory Accreditation Cooperation ILAC and a signatory of the MRA for "Testing, Calibration and Inspection"

TEST REPORT No. LE-L25/23

Scope: Measurement of spectral irradiance of a solar simulator according to the "Guidelines for Monitoring UV Radiation Sources" (Cosmetics Europe, 2007) to evaluate the UV source compliance with various test methods and determination of correction factors for handheld UV radiometers

Customer: Hamilton (Poland)

Ordered by: SAM MONADERM
5, rue des violettes, 98000 Monaco, MONACO

Device under test: Solar Light Multiport 601-300W V2.5
serial number 23338

Status of compliance: The device under test and all investigated settings are compliant with the relevant international standards (see summary on page 2)

Authorised person: Marko Weber, M.Eng.
Test performed by: DI Wolfgang Müllner

Date: 09.03.2023
Number of pages: 15
Internal Order Number: L-2635

Comments:
This test report refers exclusively to the device under test and settings thereof at the date of test. Subsequent changes to the device under test are not covered by this report.
The production or transmission of extracts of the present report is subject to authorisation by the testing laboratory.

Table 6 Integral irradiance in various wavelength ranges and the most relevant ratios

Irradiance [W·m^{-2}]	Port 1	Port 2	Port 3	Port 4	Port 5	Port 6
< 290 nm	0.01	0.01	<0.01	0.01	0.01	0.01
UVB (290-320 nm)	134	164	141	157	152	156
UVA (320-400 nm)	1218	1496	1274	1445	1387	1462
UVA-2 (320-340 nm)	366	455	386	436	413	431
UVA-1 (340-400 nm)	852	1041	888	1010	975	1031
UV (290-400 nm)	**1352**	**1660**	**1415**	**1603**	**1539**	**1618**
erythemal UV (250-400 nm)	8.6	10	9.1	10	10	10
Visible (400-780 nm)	13	15	13	15	14	14
Total (290-1600 nm)	1365	1676	1429	1619	1554	1633
Ratio UVA / UVB	9.1	9.1	9	9.2	9.1	9.4
Ratio UVA-1 / UVA-2	2.3	2.3	2.3	2.3	2.4	2.4

Table 7 Compliance of the device under test with the specifications of various in-vivo SPF test methods (ISO 24444, FDA 2021)

Parameter	Limits		Measurement results					
	Lower	Upper	Port 1	Port 2	Port 3	Port 4	Port 5	Port 6
RCEE% (< 290 nm)	-	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%
RCEE% (290 - 300 nm)	1%	8%	3.7%	3.6%	3.8%	3.7%	3.9%	3.9%
RCEE% (290 - 310 nm)	49%	65%	52.1%	51.5%	52.5%	52.0%	53.0%	52.4%
RCEE% (290 - 320 nm)	**85%**	**90%**	**85.3%**	**85.0%**	**85.4%**	**85.1%**	**85.6%**	**85.1%**
RCEE% (290 - 330 nm)	91.5%	95.5%	91.9%	91.8%	92.0%	91.8%	92.0%	91.7%
RCEE% (290 - 340 nm)	94%	97%	94.6%	94.6%	94.7%	94.6%	94.7%	94.5%
RCEE% (290 – 400 nm)	99.9%	100%	99.9%	99.9%	99.9%	99.9%	99.9%	99.9%
Ratio UVA2 / UV	20%	-	27.0%	27.4%	27.3%	27.2%	26.8%	26.6%
Ratio UVA1 / UV	60%	-	63.0%	62.7%	62.8%	63.0%	63.3%	63.7%
Total irradiance ISO [W·m^{-2}]	-	1600	1 365	1 676	1 429	1 619	1 554	1 633
Total irradiance FDA [W·m^{-2}]	-	1500						
ISO 24444			Pass	Pass	Pass	Pass	Pass	Pass
FDA (2021)			Pass	Pass	Pass	Pass	Pass	Pass

Remark: SPF specifications include an irradiance limitation of 1600 W m^{-2} (1500 W m^{-2} for FDA). To meet this requirement, it might be necessary to reduce the intensity manually by closing individual ports partially. The values not to be exceeded are reported in section 5.3 of this Test Report.

SEIBERSDORF LABORATORIES
Laser, LED and Lamp Safety
Test Report No. LE-L26/23

ACCREDITED TESTING LABORATORY (NR. 312)
for Laser, LED and Lamp Safety
Akkreditierung Austria is a full member of the International Laboratory Accreditation Cooperation ILAC and a signatory of the MRA for "Testing, Calibration and Inspection"

TEST REPORT No. LE-L26/23

Scope: Measurement of spectral irradiance of a solar simulator according to the "Guidelines for Monitoring UV Radiation Sources" (Cosmetics Europe, 2007) to evaluate the UV source compliance with various test methods and determination of correction factors for handheld UV radiometers

Customer: Hamilton (Poland)

Ordered by: SAM MONADERM
5, rue des violettes, 98000 Monaco, MONACO

Device under test: Solar Light Multiport 601-300W V2.5
serial number 25087

Status of compliance: The device under test and all investigated settings are compliant with the relevant international standards (see summary on page 2)

Authorised person: Marko Weber, M.Eng.
Test performed by: DI Wolfgang Müllner

Date: 09.03.2023
Number of pages: 15
Internal Order Number: L-2635

Comments:
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Table 6 Integral irradiance in various wavelength ranges and the most relevant ratios

Irradiance [W·m^{-2}]	Port 1	Port 2	Port 3	Port 4	Port 5	Port 6
< 290 nm	0.01	0.01	0.01	0.02	0.01	0.02
UVB (290-320 nm)	168	143	170	232	199	211
UVA (320-400 nm)	1452	1324	1494	2035	1817	1869
UVA-2 (320-340 nm)	436	389	447	612	531	554
UVA-1 (340-400 nm)	1017	935	1047	1423	1286	1315
UV (290-400 nm)	**1620**	**1467**	**1664**	**2267**	**2016**	**2080**
erythemal UV (250-400 nm)	11	9.3	11	15	13	14
Visible (400-780 nm)	11	10	12	15	15	14
Total (290-1600 nm)	1632	1478	1676	2283	2032	2096
Ratio UVA / UVB	8.6	9.2	8.8	8.8	9.1	8.8
Ratio UVA-1 / UVA-2	2.3	2.4	2.3	2.3	2.4	2.4

Table 7 Compliance of the device under test with the specifications of various in-vivo SPF test methods (ISO 24444, FDA 2021)

Parameter	Limits		Measurement results					
	Lower	Upper	Port 1	Port 2	Port 3	Port 4	Port 5	Port 6
RCEE% (< 290 nm)	-	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%
RCEE% (290 - 300 nm)	1%	8%	4.1%	3.8%	4.0%	4.0%	3.9%	4.2%
RCEE% (290 - 310 nm)	49%	65%	54.0%	52.4%	53.3%	53.2%	53.0%	53.8%
RCEE% (290 - 320 nm)	**85%**	**90%**	**86.3%**	**85.3%**	**86.0%**	**85.9%**	**85.7%**	**86.1%**
RCEE% (290 - 330 nm)	91.5%	95.5%	92.5%	91.9%	92.3%	92.3%	92.1%	92.4%
RCEE% (290 - 340 nm)	94%	97%	95.0%	94.6%	94.9%	94.9%	94.7%	94.9%
RCEE% (290 – 400 nm)	99.9%	100%	99.9%	99.9%	99.9%	99.9%	99.9%	99.9%
Ratio UVA2 / UV	20%	-	26.9%	26.5%	26.9%	27.0%	26.3%	26.6%
Ratio UVA1 / UV	60%	-	62.7%	63.7%	62.9%	62.8%	63.8%	63.2%
Total irradiance ISO [W·m^{-2}]	-	1600	1 632	1 478	1 676	2 283	2 032	2 096
Total irradiance FDA [W·m^{-2}]	-	1500						
ISO 24444			Pass	Pass	Pass	Pass	Pass	Pass
FDA (2021)			Pass	Pass	Pass	Pass	Pass	Pass

Remark: SPF specifications include an irradiance limitation of 1600 W m^{-2} (1500 W m^{-2} for FDA). To meet this requirement, it might be necessary to reduce the intensity manually by closing individual ports partially. The values not to be exceeded are reported in section 5.3 of this Test Report.

Authorised by: Monika Symonowicz, Project Manager (qualified electronic signature),
Karolina Osiecka, Dermatologist, 2487308.

Laboratory: ul. Bajana 3D, 80-463 Gdańsk, Poland

The results relate to the analysed samples only.

J.S. HAMILTON POLAND Sp. z o.o.
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REPORT OF ANALYSIS No. 143426-3/23/GDA

SEIBERSDORF LABORATORIES
Laser, LED and Lamp Safety
Test Report No. LE-L27/23

SEIBERSDORF LABORATORIES

ACCREDITED TESTING LABORATORY (NR. 312)
for Laser, LED and Lamp Safety
Akkreditierung Austria is a full member of the International Laboratory Accreditation Cooperation ILAC and a signatory of the MRA for "Testing, Calibration and Inspection"

TEST REPORT No. LE-L27/23

Scope: Measurement of spectral irradiance of a solar simulator according to the "Guidelines for Monitoring UV Radiation Sources" (Cosmetics Europe, 2007) to evaluate the UV source compliance with various test methods and determination of correction factors for handheld UV radiometers

Customer: Hamilton (Poland)

Ordered by: SAM MONADERM
5, rue des violettes, 98000 Monaco, MONACO

Device under test: Solar Light Multiport 601-300W V2.5
serial number 27595

Status of compliance: The device under test and all investigated settings are compliant with the relevant international standards (see summary on page 2)

Authorised person: *Marko Weber, M.Eng.*
Test performed by: *DI Wolfgang Müllner*

Date: 09.03.2023
Number of pages: 15
Internal Order Number: L-2635

Comments:
This test report refers exclusively to the device under test and settings thereof at the date of test. Subsequent changes to the device under test are not covered by this report.
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Table 6 Integral irradiance in various wavelength ranges and the most relevant ratios

Irradiance [W·m⁻²]	Port 1	Port 2	Port 3	Port 4	Port 5	Port 6
< 290 nm	0.02	0.02	0.02	0.02	0.02	0.02
UVB (290-320 nm)	268	252	279	274	281	281
UVA (320-400 nm)	2405	2250	2491	2487	2666	2569
UVA-2 (320-340 nm)	703	663	733	725	768	753
UVA-1 (340-400 nm)	1702	1587	1759	1762	1897	1816
UV (290-400 nm)	**2673**	**2502**	**2770**	**2761**	**2947**	**2850**
erythemal UV (250-400 nm)	18	17	18	18	18	18
Visible (400-780 nm)	28	26	28	28	31	28
Total (290-1600 nm)	2704	2531	2801	2792	2981	2881
Ratio UVA / UVB	9	8.9	8.9	9.1	9.5	9.1
Ratio UVA-1 / UVA-2	2.4	2.4	2.4	2.4	2.5	2.4

s/n 27595 (bulb s/n 28082)

Table 7 Compliance of the device under test with the specifications of various in-vivo SPF test methods (ISO 24444, FDA 2021)

Parameter	Limits		Measurement results					
	Lower	Upper	Port 1	Port 2	Port 3	Port 4	Port 5	Port 6
RCEE% (< 290 nm)	-	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%
RCEE% (290 - 300 nm)	1%	8%	4.3%	4.0%	4.0%	4.1%	3.6%	3.7%
RCEE% (290 - 310 nm)	49%	65%	54.4%	53.6%	53.6%	53.8%	51.9%	52.6%
RCEE% (290 - 320 nm)	**85%**	**90%**	**86.2%**	**86.0%**	**86.0%**	**86.0%**	**85.1%**	**85.5%**
RCEE% (290 - 330 nm)	91.5%	95.5%	92.4%	92.3%	92.3%	92.3%	91.7%	92.0%
RCEE% (290 - 340 nm)	94%	97%	94.9%	94.9%	94.9%	94.8%	94.4%	94.7%
RCEE% (290 – 400 nm)	99.9%	100%	99.9%	99.9%	99.9%	99.9%	99.9%	99.9%
Ratio UVA2 / UV	20%	-	26.3%	26.5%	26.4%	26.3%	26.1%	26.4%
Ratio UVA1 / UV	60%	-	63.7%	63.4%	63.5%	63.8%	64.4%	63.7%
Total irradiance ISO [W·m⁻²]	-	1600	2 704	2 531	2 801	2 792	2 981	2 881
Total irradiance FDA [W·m⁻²]	-	1500						
ISO 24444			Pass	Pass	Pass	Pass	Pass	Pass
FDA (2021)			Pass	Pass	Pass	Pass	Pass	Pass

s/n 27595 (bulb s/n 28082)

Remark: SPF specifications include an irradiance limitation of 1600 W m⁻² (1500 W m⁻² for FDA). To meet this requirement, it might be necessary to reduce the intensity manually by closing individual ports partially. The values not to be exceeded are reported in section 5.3 of this Test Report.

SEIBERSDORF LABORATORIES
Laser, LED and Lamp Safety
Test Report No. LE-L24/23

SEIBERSDORF LABORATORIES

ACCREDITED TESTING LABORATORY (NR. 312)
for Laser, LED and Lamp Safety
Akkreditierung Austria is a full member of the International Laboratory Accreditation Cooperation ILAC and a signatory of the MRA for "Testing, Calibration and Inspection"

TEST REPORT No. LE-L24/23

Scope: Measurement of spectral irradiance of a solar simulator according to the "Guidelines for Monitoring UV Radiation Sources" (Cosmetics Europe, 2007) to evaluate the UV source compliance with various test methods and determination of correction factors for handheld UV radiometers

Customer: Hamilton (Poland)

Ordered by: SAM MONADERM
5, rue des violettes, 98000 Monaco, MONACO

Device under test: Solar Light Multiport 601-300W V2.5
serial number 20427

Status of compliance: The device under test and all investigated settings are compliant with the relevant international standards (see summary on page 2)

Authorised person: *Marko Weber, M.Eng.*
Test performed by: *DI Wolfgang Müllner*

Date: 09.03.2023
Number of pages: 15
Internal Order Number: L-2635

Comments:
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Table 6 Integral irradiance in various wavelength ranges and the most relevant ratios

Irradiance [W·m⁻²]	Port 1	Port 2	Port 3	Port 4	Port 5	Port 6
< 290 nm	0.01	0.01	0.01	0.01	0.01	0.01
UVB (290-320 nm)	135	139	173	173	179	139
UVA (320-400 nm)	1129	1113	1398	1447	1451	1153
UVA-2 (320-340 nm)	331	330	417	423	433	339
UVA-1 (340-400 nm)	799	783	980	1024	1018	814
UV (290-400 nm)	**1264**	**1251**	**1571**	**1620**	**1630**	**1292**
erythemal UV (250-400 nm)	9.9	10	13	13	13	10
Visible (400-780 nm)	11	12	13	14	14	12
Total (290-1600 nm)	1276	1264	1584	1635	1645	1304
Ratio UVA / UVB	8.4	8	8.1	8.4	8.1	8.3
Ratio UVA-1 / UVA-2	2.4	2.4	2.3	2.4	2.3	2.4

s/n 20427 (bulb s/n ZA 1993)

Table 7 Compliance of the device under test with the specifications of various in-vivo SPF test methods (ISO 24444, FDA 2021)

Parameter	Limits		Measurement results					
	Lower	Upper	Port 1	Port 2	Port 3	Port 4	Port 5	Port 6
RCEE% (< 290 nm)	-	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%
RCEE% (290 - 300 nm)	1%	8%	6.4%	6.6%	6.4%	6.2%	6.1%	6.3%
RCEE% (290 - 310 nm)	49%	65%	59.5%	60.2%	59.6%	59.2%	59.1%	59.4%
RCEE% (290 - 320 nm)	**85%**	**90%**	**88.2%**	**88.7%**	**88.4%**	**88.1%**	**88.3%**	**88.2%**
RCEE% (290 - 330 nm)	91.5%	95.5%	93.5%	93.8%	93.7%	93.5%	93.6%	93.6%
RCEE% (290 - 340 nm)	94%	97%	95.7%	95.9%	95.8%	95.6%	95.7%	95.7%
RCEE% (290 – 400 nm)	99.9%	100%	99.9%	99.9%	99.9%	99.9%	99.9%	99.9%
Ratio UVA2 / UV	20%	-	26.2%	26.4%	26.6%	26.1%	26.6%	26.2%
Ratio UVA1 / UV	60%	-	63.2%	62.5%	62.4%	63.2%	62.4%	63.0%
Total irradiance ISO [W·m⁻²]	-	1600	1 276	1 264	1 584	1 635	1 645	1 304
Total irradiance FDA [W·m⁻²]	-	1500						
ISO 24444			Pass	Pass	Pass	Pass	Pass	Pass
FDA (2021)			Pass	Pass	Pass	Pass	Pass	Pass

s/n 20427 (bulb s/n ZA 1993)

Remark: SPF specifications include an irradiance limitation of 1600 W m⁻² (1500 W m⁻² for FDA). To meet this requirement, it might be necessary to reduce the intensity manually by closing individual ports partially. The values not to be exceeded are reported in section 5.3 of this Test Report.

Authorised by: Monika Symonowicz, Project Manager (qualified electronic signature),
Karolina Osiecka, Dermatologist, 2487308.

Laboratory: ul. Bajana 3D, 80-463 Gdańsk, Poland

The results relate to the analysed samples only.

J.S. HAMILTON POLAND Sp. z o.o.
ul. Chwaszczyńska 180, 81-571 Gdynia, Poland, tel. +48 58 766 99 00

REPORT OF ANALYSIS No. 143426-3/23/GDA

9. LABORATORY STAFF

The application of the product and visual skin assessment of the responses are made by technically qualified and trained persons.

10.DESCRIPTION OF METHODOLOGY

The matter is to compare the Sun Protection Factor of the product applied at 2.00 ± 0.05 mg/cm² obtained after 2 immersions of 20 minutes in a bath of water at 30 ± 2°C (room temperature between 23± 3°C), to that obtained without immersion.
After product is applied to the skin, exposure of the test site begins after a waiting period of 15-30 minutes. The application method is matched to the product type:

Product form	Application method	Description
Fluid products: lotion, cream, oil, liquid, gel, pump spray	A	Droplets (at least 15 per 30 cm^2) of the product are deposited within the test site using a pipette at one time, then spreaded over the whole test site (using a finger with or without a finger cot), first with circular movements to gather the droplets and second in horizontal and vertical directions using light pressure. During the whole process, the application finger stays in contact with the skin.

Tested product was applied with finger cot. Drying time between application and UV exposure: exposure of the test site to the sequence of UV doses shall start 15 min to 30 min after the application of the products.
The Sun Protection Factor is the ratio of the Minimal Erythemal Dose obtained in presence of the product (MEDp) to the Minimal Erythemal Dose obtained without the product (MEDu).

$$SPF = MEDp/MEDu$$

The Minimal Erythemal Dose is defined as the quantity of energy necessary to produce the first perceptible unambiguous redness reaction with clearly defined borders, evaluated 16 to 24 hours after exposure to a solar simulator, with 6 increasing doses of UV (15% progression).
The study must be carried out on at least 10, and not more than 20 subjects and must satisfy the statistical criterion on the SPF (95% CI < 17% Average SPF) and on the water resistance (WR% - d ≥ 50%).

11.SPF AND WR REFERENCE STANDARDS

The SPF method was controlled using reference sunscreen formulations to verify the test procedure. The mean SPF and the acceptance limits for the reference sunscreen formulations were:

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Reference Sunscreen Formulation		Mean SPF	Acceptance limits	
			Lower limit	Upper limit
P2		16.1	13.7	18.5
P5		30.6	23.7	37.4
P8		63.1	43.9	82.3

The WR method was controlled using reference sunscreen formulation to verify the test procedure. The mean SPF after immersion, WR and the acceptance limits for the reference sunscreen formulation were:

Reference Sunscreen Formulation	Parameter after 40 min immersion	Mean	Acceptance limits	
			Lower limit	Upper limit
P2	SPF	11.5	9.0	15.0
	WR%	68.1	50.0	85.0

12.PRODUCT LABELING METHOD

The following range of sun protection factors for each category and the respective labeling is recommended (in accordance with 2006/647/EC):

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Labelled category	Labelled sun protection factor	Measured sun protection factor
"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≤

13.DATE OF PERFORMANCE OF THE STUDY

19.04.2023-26.05.2023

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14.TEST RESULTS

14.1 Characteristics of subjects

N° of subject	Identification of subject	Beginning of the study	End of the study	Age	Sex	ITA°	Phototype
1	KIE_MA	19.04.2023	21.04.2023	26	F	57.7	I
2	MUC_EW	04.05.2023	06.05.2023	40	F	45.3	II
3	BRY_MA	08.05.2023	10.05.2023	58	F	58.1	I
4	JUR_KA	09.05.2023	11.05.2023	28	F	49.5	II
5	ŁAB_KA	09.05.2024	11.05.2024	37	F	55.9	I
6	SKO_KA	10.05.2023	12.05.2023	30	F	57.0	I
7	ICE_BR	10.05.2023	12.05.2023	63	F	41.5	II
8	OSS_MA	15.05.2023	17.05.2023	33	M	53.2	II
9	BAG_PA	16.05.2023	18.05.2023	33	F	59.5	I
10	HAJ_AN	24.05.2023	26.05.2023	55	F	52.0	II

Min. age	No. F	Av. ITA°	Phototype I
26	9	53.0	5
Max. age	**No. M**		**Phototype II**
63	1		5
Av. age			**Phototype III**
40			0

Legend: ***()****: value not included in data analysis*

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14.2 Water parameters

N° of subject	Room temperature [°C]	Water temperature [°C]	Water conductivity [µS]	Water pH	Water flow [m/s]	Water hardness [°N]
1	25	32	538	6.98	0.03	15
2	25	32	540	6.90	0.03	15
3	25	32	528	7.10	0.02	15
4	25	32	545	6.92	0.02	15
5	26	32	556	3.27	0.04	15
6	25	32	572	7.38	0.02	15
7	26	32	572	7.38	0.02	15
8	26	32	541	7.12	0.02	15
9	25	32	528	7.10	0.02	15
10	26	31	559	7.21	0.03	15

Legend: ***()****: value not included in data analysis*

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14.3 Test results for reference formulation P2

SUBJECTS	TECHNICIANS			RESULTS											
No.	APPL.D0/D1	EXP.D0/D1	READ D1/D2	SIM EE (highest)	MEDu		MEDp		MEDui		MEDpi		SPFi p	SPFi pi	% WR Retention
	by	by	by	W/m² eff.	sec	J/m² eff.	sec	J/m² eff.	sec	J/m² eff.	sec	J/m² eff.			
1	25/25	25/25	23;24/23;24	11.0	32	266	513	4277	32	266	382	3188	16.1	12.0	72.8
2	24/24	24/24	23;25/23;25	9.3	37	258	586	4132	37	258	439	2695	16.0	10.4	62.7
3	25/25	25/25	23;24/23;24	11.0	33	279	535	4460	33	279	401	3345	16.0	12.0	73.3
4	23/23	23/23	24;25/24;25	11.0	27	222	428	3572	27	222	319	2662	16.1	12.0	72.8
5	25/25	25/25	23;24/23;24	11.0	29	239	460	3832	29	239	345	2874	16.0	12.0	73.3
6	23/23	23/23	24;25/24;25	11.0	25	208	402	3349	25	208	299	2496	16.1	12.0	72.8
7	25/25	25/25	23;24/23;24	9.3	29	203	459	3242	29	203	345	2432	16.0	12.0	73.3
8	25/25	25/25	23;24/23;24	9.3	26	184	418	3389	26	184	313	2542	18.4	13.8	73.6
9	25/25	25/25	23;24/23;24	11.0	41	346	663	5528	41	346	497	4146	16.0	12.0	73.3
10	23/23	23/23	24;25/24;25	11.0	27	222	425	3545	27	222	319	2659	16.0	12.0	73.3
Number of subjects (n)													10	10	10
Average value													**16.3**	**12.0**	72.1
Standard deviation													0.7	0.8	3.3
c_n													0.5	0.6	
Cl_n (100%)													3.3		
d															1.5
Mean %WRR-d															**70.7**

Date of last testing:24.05.2023

Legend: ***()****: value not included in data analysis*

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14.4 Test results for reference formulations P

SUBJECTS	TECHNICIANS			RESULTS					
No.	APPL. D0	EXP. D0	READ D1	MEDu		MEDs		SPFs (P2)	SPFs (P8)
	by	by	by	sec	J/m² eff.	sec	J/m² eff.		
1	25	25	23;24	23	146	1463	9225	-	63.2
2	25	25	23;24	32	231	513	3719	16.1	-
3	24	24	23;25	27	191	1709	12062	-	63.2
4	25	25	23;24	29	239	462	3856	16.1	-
5	23	23	24;25	24	203	1533	11116	-	54.8
6	25	25	23;24	24	197	1490	12423	-	63.1
7	24	24	22;25	41	291	1856	13097	-	45.0
8	25	25	23;24	31	218	1949	15815	-	72.5
9	25	25	23;24	26	184	418	3389	18.4	-
10	23	23	24;25	27	225	1701	14176	-	63.0
Number of subjects (n)								3	7
Average value								**16.9**	**60.7**

Legend: ***()****: value not included in data analysis*

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14.5 Test results for product

SUBJECTS	TECHNICIANS			RESULTS											
No.	APPL.D0/D1	EXP.D0/D1	READ D1/D2	SIM EE (highest)	MEDu		MEDp		MEDui		MEDpi		SPFi p	SPFi pi	% WR Retention
	by	by	by	W/m² eff.	sec	J/m² eff.	sec	J/m² eff.	sec	J/m² eff.	sec	J/m² eff.			
1	25/25	25/25	23;24/23;24	11.0	23	146	348	3836	23	168	232	2557	26.3	15.2	56.1
2	25/25	25/25	23;24/23;24	11.0	32	231	797	5775	32	266	574	4158	25.0	15.6	60.8
3	24/24	24/24	23;25/23;25	9.3	27	191	948	5818	27	220	677	3614	30.5	16.4	52.2
4	25/25	25/25	23;24/23;24	11.0	29	239	1005	7288	29	239	718	5987	30.5	25.1	81.7
5	23/23	23/23	24;25/24;25	11.0	24	203	851	6166	24	203	608	4404	30.4	21.7	70.4
6	25/25	25/25	23;24/23;24	11.0	24	197	827	6890	24	197	590	4922	35.0	25.0	70.6
7	24/24	24/24	23;25/23;25	9.3	41	291	1443	8858	41	291	1031	6327	30.4	21.7	70.4
8	25/25	25/25	23;24/23;24	9.3	31	218	1081	7628	31	218	772	5448	35.0	25.0	70.6
9	25/25	25/25	23;24/23;24	9.3	26	184	913	4874	26	184	652	3482	26.5	18.9	70.2
10	23/23	23/23	24;25/24;25	11.0	27	225	943	7863	27	225	674	4884	34.9	21.7	61.1
Number of subjects (n)													10	10	10
Average value													**30.5**	**20.6**	66.4
Standard deviation													3.7	3.9	8.7
cn													2.7	2.8	
Cln (100%)													8.7		
d															3.8
Mean %WRR-d															**62.6**

Legend: ***()****: value not included in data analysis*
***cn** = t * s / √n with: t = t value from « two-sided » Student-t test for the 95% Confidence Interval*
***d** = t * s / √n with: t = t value from « one-sided » Student-t test for the 90% Confidence Interval*
***[Mean % WRR – d]** = lower limit of 90% unilateral Confidence Interval*

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MEDu: the Minimal Erythema Dose (MED) for unprotected skin.
MEDs: the Minimal Erythema Dose (MED) for protected skin by standard sunscreen.
MEDp: the Minimal Erythema Dose (MED) for protected skin by tested sunscreen without immersion.
MEDui: the Minimal Erythema Dose (MED) for unprotected skin after immersion.
MEDpi: the Minimal Erythema Dose (MED) for protected skin by tested sunscreen after immersion.

SPF s: MEDs/MEDu
SPFi p: MEDp/MEDu
SPFi pi: MEDpi/MEDui

14.CONCLUSION

Product « **KRAES solcreme 30SPF 125 ml tube batch/lot: 09234560**»:

- has an average SPF of: 30.5.
- could support the claim «**water resistant**» because the value [Mean %WRR-d] is greater than 50% of the SPF without immersion
  - **a.** mean SPF value: 30.5.
  - **b.** standard deviation: 3.7.
  - **c.** 95%CI confidence interval: 27.8;33.2.
  - **d.** SPF value to be used in labelling (according to 2006/647/EC): 30 (High protection).
  - **e.** mean SPF value after immersion: 20.6.
  - **f.** standard deviation: 3.9.
  - **g.** % WR Retention-d: 62.6.

15.SIGNATURES

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