

Results

Subject number	Subject Code	Gender	Age	ITA* (Individual Typology Angle)	Phototype	MED u (unprotected)	MED p (protected)	SPFI (Individual)	SPFI Individual P2 Standard
1	RO226933	F	55	56	I	0.854	49.124	57.5	18.5
2	RO205255	F	46	49	II	0.989	65.398	66.1	16.1
3	RO238355	F	57	46	II	1.430	78.629	55.0	16.1
4	RO237600	F	37	60	I	0.852	51.101	60.0	16.1
5	RO221244	M	69	51	II	0.920	56.120	61.0	18.5
6	RO184922	F	67	49	II	0.989	70.516	71.3	16.1
7	RO223700	F	22	57	I	0.823	50.836	61.8	16.1
8	RO29015	F	64	47	II	1.230	69.197	56.3	18.5
9	RO250111	F	35	50	II	0.943	59.975	63.6	18.5
10	RO243966	M	39	55	I	0.771	49.312	64.0	16.1
Number of subjects							n=	10	10
Average SPF								61.6	17.0
Standard deviation								4.9	1.2
95% confidence interval								3.5	0.9
Average SPF \pm 17%								10.5	2.9

Adverse events /serious adverse events /pregnancy events

No adverse event, serious adverse event or pregnancy were reported.

Conclusion

The product, formula N° SUNSCREEN PRODUCT REF:988.01 has an average SPF of 61.6.

The test is valid since the average SPF value of the P2 reference was kept between the acceptability range 13.7 and 18.5.

6. RESULTS

Tables below show values of the MED (in MED units) obtained with and without the product and with the reference on ten subjects.

Product Formula N° SUNSCREEN PRODUCT REF: 988.01

Subject number	Subject Code	Gender	Age	ITA° (Individual Typology Angle)	Phototype	MED u (unprotected)	MED p (protected)	SPFi (Individual)
1	RO226933	F	55	56	I	0.854	49.124	57.5
2	RO205255	F	46	49	II	0.989	65.398	66.1
3	RO238355	F	57	46	II	1.430	78.629	55.0
4	RO237600	F	37	60	I	0.852	51.101	60.0
5	RO221244	M	69	51	II	0.920	56.120	61.0
6	RO184922	F	67	49	II	0.989	70.516	71.3
7	RO223700	F	22	57	I	0.823	50.836	61.8
8	RO29015	F	64	47	II	1.230	69.197	56.3
9	RO250111	F	35	50	II	0.943	59.975	63.6
10	RO243966	M	39	55	I	0.771	49.312	64.0
Number of subjects							n=	10
Average SPF								61.6
Standard deviation								4.9
95% confidence interval								3.5
Average SPF ± 17%								10.5

The average SPF value of the product formula n° “SUNSCREEN PRODUCT REF: 988.01” was 61.6.

P2 Reference

Subject number	Subject Code	Gender	Age	ITA° (Individual Typology Angle)	Phototype	MED u (unprotected)	MED p (protected)	SPFi individual P2 Standard
1	RO226933	F	55	56	I	0.854	15.818	18.5
2	RO205255	F	46	49	II	0.989	15.923	16.1
3	RO238355	F	57	46	II	1.430	23.017	16.1
4	RO237600	F	37	60	I	0.852	13.712	16.1
5	RO221244	M	69	51	II	0.920	17.034	18.5
6	RO184922	F	67	49	II	0.989	15.923	16.1
7	RO223700	F	22	57	I	0.823	13.244	16.1
8	RO29015	F	64	47	II	1.230	22.772	18.5
9	RO250111	F	35	50	II	0.943	17.460	18.5
10	RO243966	M	39	55	I	0.771	12.405	16.1
Number of subjects							n=	10
Average SPF								17.0
Standard deviation								1.2
95% confidence interval								0.9
Average SPF ± 17%								2.9

- The average SPF value of the P2 reference was 17.0.
P2: Acceptability if the mean of the SPF value kept between 13.7 and 18.5.

- The 95% confidence interval (for the tested product and the standard preparation) was kept within 17% of the respective mean SPF value.
- These results, for the test performed on ten subjects, are reliable.

**7. ADVERSE EVENTS /SERIOUS ADVERSE EVENTS
/PREGNANCY EVENTS**

7.1. Adverse events (AE)

No adverse event was reported by the subjects.

7.2. Serious adverse events

No serious adverse event was reported by the subjects.

7.3. Pregnancy events

No pregnancy event was reported by the female subjects.

8. CONCLUSION

The aim of the study was to evaluate the Sun Protection Factor (SPF) of a cosmetic product, applied in standardized quantity on defined zones, on healthy adult subject's back, followed by exposure to UV according to ISO/EN 24444 Cosmetics-Sun protection test methods-In vivo determination of the sun protection factor (SPF) (2010).

STUDY CONDITIONS:

Product	Reference: SUNSCREEN PRODUCT REF: 988.01	Galenic form: White emulsion	
Study date(s)	2021CRCL176: From January 14 to January 29, 2021		
Objective	Evaluation of the Sun Protection Factor (SPF) of a cosmetic product, applied in standardized quantity on defined zones, on healthy adult subject's back, followed by exposure to UV according to ISO/EN 24444 Cosmetics-Sun protection test methods-In vivo determination of the sun protection factor (SPF) (2010).		
Methodology	<ul style="list-style-type: none"> - Comparative study, - Randomized study, - With a reference product. 		
Assessment criterion	Sun Protection Factor (SPF).	Zone	Back.
		Application method	Standardized application (2mg/cm ²)
Studied population	Number of subjects analysed: 10.		
	Mean age: 49 ± 5 years old (between 22 and 69 years old).		
	<u>Main inclusion criteria:</u> skin type I, II or III (ITA°>28°).		

RESULTS

PRODUCT	Average SPF	95 % CI
SUNSCREEN PRODUCT REF : 988.01	61.6	3.5
P2 Reference	17.0	0.9

- **Product, formula n° “SUNSCREEN PRODUCT REF: 988.01” has an average SPF of 61.6.**