



## SUMMARY

### **EVALUATION OF THE SUN PROTECTION FACTOR** **according to the International Method (May 2006)** **and its "LONG LASTING" EFFECT after 8 hours**

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### **DAYLONG EXTREME (phase one)**

**Study N° : #08E4013**  
**Estimate: #08D4013**  
**Sponsor: SPIRIG**

#### **Study Objective**

- To evaluate the Sun Protection Factor (SPF) of a product, following the International SPF test method published by COLIPA / CTFA SA / JCIA /CTFA (May 2006).
- To evaluate the SPF of the same product, 8 hours after application. (The subjects stay in the laboratory in standardized conditions: no clothes should be in contact with the measurement areas).

#### **Method**

The Sun Protection factor is the ratio of the Minimal Erythema Dose obtained in presence of the product (2 mg/cm<sup>2</sup>) (MEDp) to the Minimal Erythema Dose obtained without the product (MEDu).

$$\text{SPF} = \text{MEDp}/\text{MEDu}$$

The Minimal Erythema 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 (12% progression).

The study must be carried out on at least 10, and not more than 20 subjects and must satisfy the statistical criterion (95% CI < 17% Average SPF).

#### **Investigators**

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## Results

### DAYLONG EXTREME

Subject / Volontaire	ITA°	Phototype	MEDnp / DEMnp	MEDp / DEMp	SPFi / FPSi
(1)*	51	II	0.955	71.904	(75,3)*
(2)*	36	III	1.709	81.480	(47,7)*
3	41	III	1.222	83.507	68.3
4	34	III	1.142	87.415	76.5
5	39	III	1.278	95.937	75.0
6	34	III	1.605	120.438	75.0
7	50	II	0.840	84.672	100.8
8	55	I	0.694	76.486	110.1
<b>Number of subjects / Nombre de sujets</b>				<b>n =</b>	<b>8</b>
<b>Average SPF / FPS moyen</b>					<b>84.3</b>
<b>Standard deviation / Ecart-type</b>					<b>16.9</b>
<b>95% confidence interval / Intervalle de confiance à 95%</b>					<b>17.7</b>
<b>Average SPF ± 17% / 17% du FPS moyen</b>					<b>14.3</b>

### DAYLONG EXTREME (8 hours after application)

Subject / Volontaire	ITA°	Phototype	MEDnp / DEMnp	MEDp / DEMp	SPFi / FPSi
1	51	II	0.955	46.977	(49,2)*
2	36	III	1.709	53.234	(31,1)*
3	41	III	1.222	61.329	50.2
4	34	III	1.142	71.904	62.9
5	39	III	1.278	61.367	48.0
6	34	III	1.605	68.785	42.9
7	50	II	0.840	81.866	97.5
8	55	I	0.694	45.852	66.0
<b>Number of subjects / Nombre de sujets</b>				<b>n =</b>	<b>8</b>
<b>Average SPF / FPS moyen</b>					<b>61.2</b>
<b>Standard deviation / Ecart-type</b>					<b>19.9</b>
<b>95% confidence interval / Intervalle de confiance à 95%</b>					<b>20.9</b>
<b>Average SPF ± 17% / 17% du FPS moyen</b>					<b>10.4</b>

Data for the subject #1 were not included in final results because all sub-sites in the exposure series showed an erythematous response

Data for the subject #2 were not included in final results because the product has been probably removed during the 8 hours.

**Reference P3**

Subject / Volontaire	ITA°	Phototype	MEDnp / DEMnp	MEDp / DEMp	SPFi / FPSi
(1)*	51	II	0.955	13.648	(14,3)*
(2)*	36	III	1.709	27.352	(16,0)*
3	41	III	1.222	21.903	17.9
4	34	III	1.142	18.278	16.0
5	39	III	1.278	20.456	16.0
6	34	III	1.605	20.472	12.8
7	50	II	0.840	16.128	19.2
8	55	I	0.694	13.937	20.1
<b>Number of subjects / Nombre de sujets</b>				<b>n =</b>	<b>8</b>
<b>Average SPF / FPS moyen</b>					<b>17.0</b>
<b>Standard deviation / Ecart-type</b>					<b>2.7</b>
<b>95% confidence interval / Intervalle de confiance à 95%</b>					<b>2.8</b>
<b>Average SPF ± 17% / 17% du FPS moyen</b>					<b>2.9</b>

**Conclusion**

Product, «**DAYLONG EXTREME** », has:

- an average SPF of **84.3**, 15 minutes after application,
- an average SPF of **61.2**, 8 hours after application.

Lyon, February 22, 2008.

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