Sunscreens SPF 30/50/50+ TEST PROGRAM

This is a double blind study: Products were kept in their original containers. The products are covered (the whole bottle is covered with opaque stickers) for the volunteers and the lab analysts and technicians.

The study was performed between October 2018 and December 2018.

Selection of Subjects

Subjects taking part in this test are selected on the basis of Fitzpatrick's skin type table as indicated by dermatological anamnesis or on the basis of skin color typing by colorimetric measurements, respectively (ITA° > 28°). They correspond to the majority of users as far as their skin sensitivity classification is concerned. The following types result:

Phototype	Skin colour typing	expected ITA° value*
Type I	very light	> 55°
Type II	light	from 42 to 55°
Type III	intermediate	from 29 to 41°

Phototype	Skin colour typing	expected ITA° value*
Type IV	tan (or matt)	from 11 to 28°
Type V	brown	- 30 to 10°
Type VI	black	< - 30°

* ITA° = [Arc Tangent ((L*-50) / b*)] 180 / 3.14159

Number of Subjects

The number of subjects is restricted to a minimum of 10 and a maximum of 20 valid results. A minimum of 10 volunteers is sufficient if the 95 %-Confidence Interval (95 %-CI) of the mean SPF falls within a range of ± 17 % of the mean SPF. Otherwise, the number of subjects is increased from 10 until the statistical criterion is met. A maximum of five individual results may be excluded from the calculation of mean SPF. Each exclusion has to be justified. All individual results are included in the report.

1. ***In Vivo* Determination of Sun Protection Factor (SPF)**

The test is based on the international standard ISO 24444:2010(E) - Sun protection test methods -- *In vivo* determination of the sun protection factor (SPF).
Test areas on subjects' backs are coated with test product. Between product application and irradiation a waiting time of 15 minutes is realized.
Irradiation is carried out by 6 different doses. The resultant erythema is used to ascertain the minimum erythema dose (MED). The individual Sun Protection Factor (SPFi) is determined from the ratio of MEDu (MED of untreated skin) and MEDp (MED of protected skin) of the area treated with the product in question. The SPF result is expressed as the arithmetical mean of the individual SPF values obtained from the total number of subjects used.

2. **Determination of UVA Protection Factor**

This protocol describes the in vitro determination of UVA-protection of sunscreen products according to ISO 24443:2012(E) taking into account possible photo-degradation. The test is based on the assessment of UV-transmittance through a thin film of sunscreen sample spread

on a roughened substrate, before and after exposure to a controlled dose of irradiation from a defined source of sun spectrum.
In order to characterize the UVA-protection properties of the test product the ratio of the *in vivo* label SPF and the *in vitro* UVA-PF is calculated.
A ratio of ≤ 3 is recommended according to the "Commission Recommendation on the efficacy of sunscreen products and the claims made relating thereto":

$$Ratio = \frac{SPF_{Label}}{UVA\text{-}PF}$$