HELIOSCIENCE®

SunTechnology

FINAL REPPORT

SPF « Sun Protection Factor » and UVA, IN-VITRO method, with UV pre-irradiation. According to the criteria Colipa 2011

SPONSOR OF THE STUDY:	Eco Cosmetics
Monitor of the study:	Cecile Morice
Reference of the product :	Crème enfants SPF50+ Lot: 09.2013/00511
References of the study:	Eco2001. 13Eco01-0112

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The present study had be done by HELIOSCIENCE between the 10/01/12 and 14/01/12

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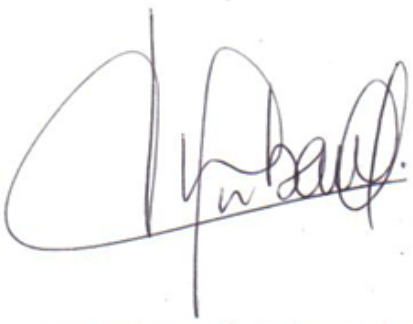
1. QUALITY INSURANCE

Helioscience, certify that a control in the spirit of the Good Laboratory Practices, has been undertaken to each stage of the described procedure initially in the protocol so as to lead to accurate investigations and the evaluation of the indicative level of protection of the concerned product(s) and to guarantee the reliability of data analyzed in accordance with this standard procedure.

The present report constitutes a precise description of the realization of the experimental tests, the processing of data and operative means which has been used



Jean Claude HUBAUD

2. SUMMARY OF THE RESULTS

Title:

Determination of the factor of solar protection, "sun protection factor " or "S.P.F", by mean a spectrophotometric initially described by B L Diffey and J Robson (J.S.C.C. 40, 127-133 May/ June 1989) then modified and improved, in view of the evaluation of the protection of the product against effects of UVB and UVA on the skin. It is today largely used and recognized by international authorities.

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Monitor of the study:	Cécile Morice
Reference of the product :	Crème enfants SPF50+ Lot: 09.2013/00511
SPF of the product:	**90,4**
PF UVA of the product:	**20,9**
Ratio SPF/UVA :	**4,31 and 2,87 when adjusted**
References of the study:	Eco2012. 13Eco01-0112

3. PRINCIPLE OF THE METHOD
Application of the protocol of the standard study

3.1 Title of the study :

" Sun Protection Factor " in vitro evaluation.

3.2 Goal of the study :

The present study has consisted in evaluating the level of protection of cosmetic product(s) containing solar filters by a spectrophotometric method so as to determine their level of protection and if possible their spreadibility which will be influencing directly the performance of the product(s).

3.3 Principle of the method :

To determine the efficiency of solar products, one evaluates their capacity to warn the erythemal reaction that appears to the surface of the skin when exposed while a certain time to a source of UV energy . The UVB represent only approximately 5% of total UV energy (UVA + UVB), but considering their energy, they have a preponderant action on the appearance of this erythemal reaction..
The used method consists in measure the flow of UV energy through the cream, expressed in energy transmission and to compare this flow to the initial flow according to the principle of all spectrophotometric methods.

$F(\lambda) = I / I0$ with l as the wavelength .

Nevertheless, the comparison of these two curves is not enough to express the level of protection of the product displayed on the skin since it will also depend on two other wavelength functions

- **The one concerning the source**. In the practice, it concerns the sun whose spectre has been defined by the international commission of energy as a function of wave G(l)
- **The other related to the skin** : as cutaneous or subcutaneous reactions depending of light energy we consider a second curve, in the form of an other function of wave H(l)

According to the same principles that the evaluation of the colour, one will express a consequent curve from the integration of the product of the three curves.
By integrating each on these 3 curves on all the UVB and UVA area, one will obtain the expression of the in vitro SPF.

This method has been initially described by B Diffey and J Robson (JSCC 40. 127-133 (1989). It is today largely used and recognized by international authorities.

4.Operative conditions of the realization of the study

4.1 Equipment used

4.1.1 Equipment of laboratory

We have used a KONTRON 930 spectrophotometer equipped with a UV source and a monochromator and capable to deliver a flow of energy between 290 and 400 nm.

We have used a precision laboratory scale to control our displays.

4.1.2 Support of application.

We have displayed products on plates following this described procedure :

PMMA PLATES (From Europlast Sa, Aubervilliers, France.; 6 micrometer roughness).

4.2 Investigators and responsible of study.

Tests, realization of calculations and the writing of the final report have been realized by Dr Jean Claude HUBAUD.

4.3 Products tested.

4.3.1 Reception of the product(s).

It has been reminded in the protocol that the promoter of studies remains responsible for the initial identification, the composition, the purity of the product, as well as all characteristics allowing to define and identify products tested before the beginning of the study.

Tests of stability will have been proceeded, in agreement to the good practice laboratory so as to insure that obtained results will be significant of the behavior of the product after been long time stocked .

4.3.2 Stocking and evaluation of products.

Products have been stocked after being referenced as soon as received. They have been keep in ambient condition following the good practice laboratory.

Products have been evaluated as follows :

4.3.2.1 Deposit

Application had be performed by small spots all over the surface.
The product quantity applied on the substrate will be controlled by weighing it on PMMA plate (1,3 mg/cm2). To avoid the evaporation of the product, the weighing will be made before equilibration of the scale.

4.3.2.2 Spreading on the plates

The objective was to get a film as homogeneous as possible. The precise and detailed procedure used is described in a document kept in our laboratory. For confidentiality reasons, this information can't be communicated in this protocol but remains at the disposal of Authorities in case of need.

4.3.2.2 Selection of the samples

- If the mass was not respected or if the film presented great visible defects, the operation has been resumed.

4.3.2.4 Reference standard.

The SPF standard has been previously evaluated, A PMMA plate including UV filter, has been used as a reference so as to check the equipment was in good working order and to assess the relevance of carried out measures,

4.3.2.5 Irradiation

The samples have been exposed to 4 minimal erythemal dose "MED".
The MED value was selected at 550 W/cm2 erythemal effective, this value corresponding to an exposure to a zenith sun

With this standard sun light, while receiving **2 MED** the product should receive: **95O kJ/cm2**

4.1 Methode of calculation used

4.4.1 Calculation of the SPF

The IN VITRO SPF is expressed from the totality of the residual UVB and UVA specter after having crossed the same deep of cream that is displayed on the skin. Nevertheless, this function of wave T(l) has to be multiplied by

- *· A first function of wave that expresses the spectral characteristic of the sun. S(l)*
- *A second function of wave that expresses the reactivity of the skin according to the length of wave (and therefore of dissipated energy) : it is the erythemal function E(l)*

$$SPF\ in\ vitro = \frac{\sum_{280\,nm}^{400nm} E(\lambda).\ S(\lambda).\ d\lambda}{\sum_{280\,nm}^{400nm} E(\lambda).\ S(\lambda).\ T((\lambda).\ d\lambda}$$

The UVA protection IN VITRO expresses itself from the whole residual ghost UVA having crossed the same coat of cream.

$$UVA_e\ in\ vitro = \frac{\sum_{320\,nm}^{400nm} E\ (\lambda).\ S\ (\lambda).\ d\lambda}{\sum_{320\,nm}^{400nm} E\ (\lambda).\ S\ (\lambda).\ T\ (\lambda).\ d\lambda}$$

From transmission data between 290 to 400nm with a 5 nm increment , this software allows to access directly and instantaneously to calculations :

Of the SPF according to the calculation proposed by B Diffey taking into account the erythemal reply of the skin and the energy specter of the sun.

Each of these calculations is expressed as a statistic evaluation of 3 to 5 measures and given with the average value and the dispersion of results.

Each test which include 3 to 5 measures, it is equally automatically indicated the proper dispersion of the measurement wavelength by wavelength which allows to characterize the reproducibility of the measurement and therefore the reliability of the spreading.

5. **Operative results**

5.1 Presentation of the transmission value according to the incident wavelength .

Values of transmissions have been stocked and been able to be communicated and analysed in a complementary report if require by the client.

5.2 Results of the different tests :

	Crème enfants SPF50+ Lot: 09.2013/00511	
Série 1 Série 2 Série 3	96,39 88,93 86,12	21,73 20,83 20,38
SPF Means	**90,48**	**20,98**
Standard deviation	**5,31**	**0,69**

Ratio SPF/UVA = 4,31

5.3 Conclusions :

The product doesn't present any problem during the measurement. The standard deviation is normal for this level of protection. We can conclude that it's a very acceptable product.

The product has a very strong protection, and has an equilibrated protection (UVB and UVA protection).

After adjustement to the SPF display value, these results are sufficient to display the **logo UVA**, recommended by the COLIPA.

6. Results and Confidentiality

6.1 Results

Product name: **Crème enfants SPF50+;** Lot: 09.2013/00511
Values obtain

- SPF = 90,4
- PF UVA = 20,9

Ratio SPF/UVA = 4,31

For the ratio the right value for the SPF will be the value print on the product:

- SPF/UVA = 60/20,9

Ratio SPF/UVA = 2,87

These results are sufficient to display the **logo UVA**, recommended by the COLIPA.

6.2 Final report

This final report will be write in duplicate on for the promoter the other will be stay in the laboratory.

6.3 Confidentiality and Stocking of data

All information concerning products to study such that patents, formulae, raw materials, processes of manufacture etc.… provided by the promoter of the study will be considered as confidential, and will remain the property of the promoter and will not be able to be divulged without agreement of the promoter.

On the other hand the product will be destroy or returned to the promoter of the study that will have to take its dispositions to stock it to title of witness.

Information from Helioscience® will be available at any given time for an ulterior consultation of the promoter or competent authorities.

The responsible of study **Marseille 13 Janv. 12**
Jean Claude HUBAUD