SUN PRODUCTS EFFICACY

MARC PISSAVINI – COTY LANCASTER

In Vivo Veritas determination

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Why do we need photoprotection?

- 19th century: life expectancy ~40 years old
- 21st century: ~80 years old
- Paid leave + reduction of working time + democratization of the means of rapid transit = travels to warm and sunny climates
- Sun exposure increase
- Health risk increase
- Need to protect the skin
What is the SPF?
Which SPF shall I use this summer?
Why 2mg/cm²?
SPF are in line with reality?
The SPF is a relative ranking scale of effectiveness against erythema, which serves as a benchmark for consumer choice.

We cannot claim that the SPF indicated on the product will be the effective SPF for each individual, for all conditions of sun exposure and product application.

This indicator is evaluated under controlled laboratory conditions, where reproducibility is essential, but is not directly relevant to real-life situations.
WHY 2 MG/CM² ?

- 1) To have a round number?
- 2) To make more profit?
- 3) For validation reasons?
Which SPF shall I use?

a) SPF 50
b) SPF 15
c) SPF 30

SPF 30
SPF 20
SPF 30

SPF 15
SPF 30
SPF 30
Which SPF shall I use?
Which SPF shall I use?

Too low

Too high (?)

Right SPF (?)
PROTECTION FACTOR CORRELATION

Myth or Reality?
Successful first step with the UVA in vitro method

- Starting in 2007 with Colipa
- Updated in 2009 & 2011
- Published as ISO 24443 in 2012
- Thanks to a mathematical adjustment
And for the *in vitro* SPF?

- Based on spectrophotometry transmittance on a high roughness (5μm) surface (PMMA)

And for the *in vitro* SPF?

- Progress has been made
- Substantial resources are deployed (ISO, industrials ...)
- The influence of roughness, pressure, experience, temperature, pre-treatment (chemical, physical) ... are studied.
And for the *in vitro* SPF?

- NO *in vitro* SPF method is validated internationally currently.

- The *in vitro* SPF can only be used, for the moment, as an internal screening method.
Are there any other possibilities?
IN VIVO?

- Refers to procedures performed on human subjects
- The SPF is measured under laboratory conditions as carefully as possible, where reproducibility is essential, but does not necessarily correspond to real-life conditions.

*In Vivo ≠ real-life conditions*
WHERE THE EFFICACY COMES FROM?
UV Efficacy

- Spectral absorbance of product
- Uniformity of application
- Quantity applied
SPF IN VIVO EFFICACY

Spectral absorbance of product
Variable - 100%

Uniformity of application (Procedure)
Fixed - 0%

Quantity applied = 2 mg/cm²
Fixed - 0%
Application - Protection

Sunscreen applied haphazardly and non-uniformly

B. Diffey, London Sun Conference, 2009
Application - Protection

Product with the same SPF and same substrate

SPF: 30

Application different
SPF different

SPF: 15
Application - Protection

SPF:30

SPF:15
Application - Protection

L Ferrero, M Pissavini, O Doucet “How a calculated model of sunscreen film geometry can explain in vitro and in vivo SPF variation” Photochem Photobiol Sci, 2010
Crude spreading of sunscreen over exposed skin

<table>
<thead>
<tr>
<th>% sunscreen users where at least one area of their skin receives an exposure of ≥ 3 SED (minimal erythema or greater)</th>
<th>SPF 15</th>
<th>SPF 30</th>
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<tr>
<td>78</td>
<td>73</td>
<td></td>
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Careful spreading of sunscreen over exposed skin

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Crude spreading of sunscreen over exposed skin

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<tr>
<th>% sunscreen users where at least one area of their skin receives an exposure of ≥ 9 SED (marked erythema or greater)</th>
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<tr>
<td>44</td>
<td>26</td>
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<tbody>
<tr>
<td>4</td>
<td>0</td>
<td></td>
</tr>
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</table>

M. Pissavini, B. Diffey, “The likelihood of sunburn in sunscreen users is disproportionate to the SPF “Photodermatol Photoimmunol Photomed 2013; 29: 111–115
Mismatch between quantity applied and quantity used in testing procedure

- Szepietowski et al 2004
- Neale et al 2002
- Autier et al 2001
- Hart et al 2000
- Diffey et al 1997
- Bech-Thomsen et al 1993
- Stenberg et al 1985

Application thickness mg/cm²

Median application thickness

SPF determined at

Quantity applied = 2 mg/cm²
Fixed = 9%
What is the best way to apply?
What is the best amount to apply?

It’s YOU who must chose!
**SPF In vivo efficacy**

- **Spectral absorbance of product**
  - Variable – impact 100%

- **Uniformity of application (Procedure)**
  - Fixed – impact 0%

- **Quantity applied = 2 mg/cm²**
  - Fixed – impact 0%
Spectral absorbance of product: depends on product

Uniformity of application: depends on product

Quantity applied: depends on product

Efficacy in vivo veritas
Efficacy *in vivo veritas*

Spectral absorbance of product
Measured *in vivo* or *in vitro*
• there is a strong inverse relationship between the median application thickness and % CV in measured SPF from in vitro assay.

• people tend to apply a greater quantity of a product that spreads easily

• Conversely, products that are difficult to spread result in users compensating by applying smaller quantities
• There is a strong inverse relationship between the median application thickness and % CV in measured SPF from *in vitro* assay.

### SPF eff Formula

\[
\text{SPF}_{\text{eff}} = 1 + t \times \frac{[\text{SPF} - 1]}{2}
\]

### SPF in vivo veritas Table

<table>
<thead>
<tr>
<th>Sunscreen SPF30</th>
<th>% CV</th>
<th>Compliance Factor = t/2</th>
<th>SPF in vivo veritas</th>
<th>Labelled category</th>
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<tbody>
<tr>
<td>A</td>
<td>8.7</td>
<td>1.05</td>
<td>31.4</td>
<td>High Protection</td>
</tr>
<tr>
<td>B</td>
<td>43.6</td>
<td>0.50</td>
<td>15.5</td>
<td>Medium Protection</td>
</tr>
<tr>
<td>C</td>
<td>15.3</td>
<td>0.74</td>
<td>22.5</td>
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</tr>
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<td>D</td>
<td>14.3</td>
<td>0.78</td>
<td>23.7</td>
<td>Medium Protection</td>
</tr>
<tr>
<td>E</td>
<td>14.0</td>
<td>0.80</td>
<td>24.1</td>
<td>Medium Protection</td>
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<tr>
<td>F</td>
<td>22.4</td>
<td>0.55</td>
<td>17.1</td>
<td>Medium Protection</td>
</tr>
<tr>
<td>G</td>
<td>22.1</td>
<td>0.56</td>
<td>17.2</td>
<td>Medium Protection</td>
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<tr>
<td>H</td>
<td>24.3</td>
<td>0.53</td>
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</tr>
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<td>K</td>
<td>20.4</td>
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Efficacy *in vivo veritas*

**Expectation**

Equal SPF measured *in vivo*

Product A  
- Pleasant sensory perception  
- Easy to spread: Generous quantity & uniform  
- High delivered SPF with low variance  
- Delivers anticipated protection  

Product B  
- Poor sensory perception  
- Difficult to spread: low quantity & non-uniform  
- Low delivered SPF with high variance  
- Protection compromised

**Realisation**

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CONCLUSION

- *In Vivo* SPF does not reflect the real life conditions
- The amount of product applied and how it is spread are determined by the user
- Galenic has a direct influence on these parameters and so on the final in vivo “veritas” factor
- Pleasure to use: a guarantee for a better protection.
- Indices of protection should be more in line with reality

The challenge is to improve the protection and the experience.
Thank you