HelioScreen

HelioNews

News about In Vitro Sun Protection Testing

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Contents

Editorial

More than one year after the beginning of the COVID-19 pandemic, our lifestyle, health and wellbeing were considerably impacted and it changed our vision of future. From a professional point of view, the pandemic disrupted the entire world and affected many industries including the cosmetics market. Nevertheless, beyond this point, the global cosmetics market size was valued at more than $380 billion in 2019, and is projected to increase about 5% until 2027. Moreover, by category, the skin and sun care segment dominated the global market.

In the clinical testing field, a complicated situation appeared due to volunteer's restriction for health protection reasons and postponed several sun protection evaluation studies during weeks and months worldwide. However, in the same time, the number of in vitro sunscreen tests continued to increase and alternative methods demonstrated a strong resistance to such issues.

At HelioScreen, we are proud to inform our customers that our quality system policy and business continuity plan were a success to ensure the in vitro sun protection assessment of sunscreen products and the manufacture/shipment of Molded PMMA plates HD6 & Sandblasted PMMA plates SB6 during this period.

Sébastien MIKSA, General Manager

Congress & Events

16TH SUN PROTECTION CONFERENCE 2021 — 25 - 26 November 2021 Royal College of Physicians, London

Sun Protection Conference 2021 - London

Conference by **S. MIKSA** about « **Revision of ISO 24443 method for determination of sunscreen UVA photoprotection in vitro** »

cosmetotest Cosmetic Testing Symposium

Cosmetotest - January 2022, 27-28 - Lyon

Conference by **S. MIKSA** about « **Future of in vitro SPF international method: panorama of the new perspectives ISO 23675** »

in-cosmetics® global Paris • 5-7 April 2022

in-cosmetics global - April 2022, 5-7 - Paris

We will be pleased to met you on our booth

HelioScreen
44, rue Léon Blum
60100 Creil - France
Phone: +33 (0)3 44 24 33 29
commercial@helioscreen.fr

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Author, Editor & Design:
S. MIKSA

In Vitro Sand Resistance

Beyond the static sun protection performance provided by sunscreen products against UV radiations, the photoprotection is challenged by consumers in real conditions of use (such as the Water Resistance) but none standardized nor harmonized in vivo or in vitro method are available today concerning the Sand Resistance assessment. For this purpose, a new relevant in vitro method has been published[1] allowing the evaluation of the Sand Resistance percentage of a sunscreen product by comparing the in vitro SPF before and after a specific agitation in a standardized sand.

INTRODUCTION

The photoprotection is challenged by consumers under real conditions of use such as the Water Resistance, the Rub Resistance, the Sweat Resistance, etc. In this way, one of the factors concerns the Sand Resistance as an important component linked to real condition of use on the beach, but none standardized nor harmonized in vivo or in vitro method are available today. In other terms, the sand resistance of a sunscreen product represents its capacity to retain the photoprotection performance after a contact with sand.

Few proposals have been recently published with in general, a totally different sand application with for example a too vigorous in vitro rub stress[2] (by means of an electric toothbrush) or without an in vivo rub stress[3] (sand was only poured). Moreover, in the vivo study[3], only 1 sunscreen product was tested by only 1 laboratory and according to only 1 method challenging the relevance of the method in terms of value and in terms of reproducibility between operators. Additionally, the sand grade impact was discussed but it seems difficult to reproduce the methodology at an international level without a standardization consideration of the sand.

As in vivo methods are expensive, time-consuming, technically limited and ethically discussed, this present study focused on the in vitro alternative only. Therefore, this new in vitro method allows the evaluation of the Sand Resistance percentage of a sunscreen product by comparing the ratio of the in vitro SPF (Sun Protection Factor) before and after an agitation time in a specific sand (two standardized sand have been tested with a fine grade and a medium grade). For this purpose, the product is spread on a textured substrate, the quantity per unit area being identical to the one used for SPF determination. Samples are placed in contact with a specific sand and agitated with an automatic agitator. Testing conditions such as the time, the speed and the movements of agitation in sand have been previously selected to obtain reliable results and to allow only a moderate sand rubbing.

[1] New in vitro method for sand resistance assessment of sunscreen products, S. MIKSA and C. VINCENT, H&PC Today, November/December 2021
[2] R. P. STOKES and D. L. DIFFEY, A novel ex vivo technique to assess the sand/rub resistance of sunscreen products, IJCS, 22 329-334 (2000)
[3] M. CASWELL, C. WOOD and A. MATINEZ, Sand resistance of sunscreens, J. Cosmet. Sci., 63, 255-258 (July/August 2012)

Method

Sunscreen products: 20 sunscreen products (emulsion, lipstick, oil, and alcoholic spray) with SPF 6 to 50+.

Substrate: Moulded polymethyl methacrylate (PMMA) plates HELIOPLATE HD6 (HelioScreen, Creil, France) in compliance with the ISO 24443 standard for in vitro UVA-PF determination.

Application: Rate of 1.3 mg/cm² with at least nine droplets.

Spreading: Automated spreading device HD-SPREADMASTER. After spreading, samples were allowed to dry and settle for 15 min (dark) before the first measurement (25°C ± 2.0°C).

Transmittance measurements: The spectrophotometer UV-2000S (Labsphere Inc., North Sutton - USA).

Agitator: The automated mini-shaker Multi Bio 3D (BioSan SIA, Rïga - Latvia). The movement conditions included 5 combined cycles of (i) a 3D orbital shaking with speed at 100 RPM (revolution per minute) with 7° pitch during 30 seconds followed with (ii) a 3D Reciprocal shaking with a turning angle of 360°, a speed at 100 RPM with 7° pitch during 30 seconds.

Sand: Two standardized sands have been used:
- Standard sand ASTM C778 (named “Fine Sand”)
- Standard sand CEN EN 196-1 (named “Medium Sand”)

Calcul: The in vitro SPF was calculated before and after sand rubbing to determine the individual percentage of sand resistance (%SAND) for each individual substrate and the average is considered (minus the 90% unilateral confidence interval for the mean %SAND).

Sand Resistance: First, the Sand Resistance is positive when the %SAND ≥ 50% (ratio before and after sand rubbing). Second, all tested products cannot be considered positive (or negative) based on a reasonable selectivity (to distinguish sand resistance performance). For this method, a 70–80% level of selectivity was considered which represents a “PASS” result for only 1/4 to 1/5 of tested products.

Results and Discussion

Therefore, the 20 sunscreen products were tested according to the present method with the two different sand (named "Fine Sand" and "Medium Sand") and results presented in **Table 1**.

According to these results, only 5 products (P11, P14, P15, P18 and P19) demonstrated a Sand Resistance efficacy for the Fine Sand, and only 6 products (P8, P11, P14, P15, P17 and P19) demonstrated a Sand Resistance efficacy for the Medium Sand. In other terms, the Fine Sand allows a slightly stronger selectivity (75%) compared to selectivity with the Medium Sand (70%) and that most products maintain their sand resistance conclusion performance with two different sands.

In a second step, the percentage of variability between the results for the same product is expressed via the %COV (Coefficient of Variation) in the **Table 1**. From these results, the average of variability (Mean %COV) is equal to 16.9% for the Fine Sand and 23.0% for the Medium Sand.

Table 1. Results obtained for %SAND with two different sands

Product		Fine Sand (ASTM C778)			Medium Sand (CEN EN 196-1)		
		%SAND	%COV	Conclusion	%SAND	%COV	Conclusion
P1	STICK	25,8	54,7	FAIL	45,0	4,6	FAIL
P2	STICK	32,9	18,1	FAIL	38,0	9,1	FAIL
P3	ALCOHOL	24,7	14,3	FAIL	15,1	43,7	FAIL
P4	OIL	26,9	18,1	FAIL	29,6	20,0	FAIL
P5	STICK	25,7	15,1	FAIL	35,2	35,3	FAIL
P6	EMULSION	18,3	28,1	FAIL	12,0	41,6	FAIL
P7	EMULSION	13,1	14,8	FAIL	10,6	26,7	FAIL
P8	OIL	17,1	11,6	FAIL	66,4	11,2	PASS
P9	EMULSION	32,8	15,7	FAIL	44,0	8,8	FAIL
P10	EMULSION	46,6	9,5	FAIL	39,9	11,2	FAIL
P11	EMULSION	95,7	26,3	PASS	68,8	56,3	PASS
P12	EMULSION	13,4	15,9	FAIL	15,1	48,3	FAIL
P13	EMULSION	25,0	12,2	FAIL	29,1	5,0	FAIL
P14	EMULSION	91,3	6,4	PASS	≥100.0	3,8	PASS
P15	EMULSION	63,2	20,9	PASS	≥100.0	17,9	PASS
P16	EMULSION	30,8	18,8	FAIL	30,4	25,0	FAIL
P17	EMULSION	45,9	12,9	FAIL	71,3	10,6	PASS
P18	STICK	69,3	6,1	PASS	37,4	24,8	FAIL
P19	EMULSION	≥100.0	12,5	PASS	≥100.0	14,2	PASS
P20	ALCOHOL	49,2	5,3	FAIL	28,7	43,0	FAIL

Conclusion

The aim of this study was to propose an in vitro method to determine the Sand Resistance performance of sunscreen products.

Based on the results, the Fine Sand (ASTM C778) was preferred for this in vitro method allowing a selectivity level of 75% (only 5 products on the 20 tested received a positive result) and the lower variability compared to the Medium Sand (CEN EN 196-1).

Even if it should be preferred to have a correlation between the in vitro and the clinical in vivo way, none standardized (national and international) in vivo sand resistance method is currently available. Therefore, as a basic point, as no official method is proposed, it should be difficult to select one in vivo method knowing the potential variability between different methodologies.

Moreover, the repeatability and reproducibility of the method were tested, and the conclusion obtained for the sand resistance percentage was similar. It was therefore concluded that this method is reproducible and repeatable.

In conclusion, until an in vivo sand resistance method is worldwide standardized to check the correlation, the reliability of a new in vitro test to assess the Sand Resistance of sunscreen products has been demonstrated in this study.

Limits of Blue Light protection claim for uncolored sunscreen products

Introduction

Beyond a previous publication[4] dedicated to the development of an in vitro method for Blue Light protection assessment afforded by sunscreen products including some limits proposal for claiming based on all tested products (25 products), in this complementary synthesis, we divided tested products to focus only on the uncolored sunscreen products (representing 20 products). To remind, for the colored sunscreen products, the limits remain at **%BL ≥ 35%** and **BL-CW ≥ 385 nm.**

Therefore, the aim of this complementary analysis is to avoid a potential overestimation of the Blue Light protection limits mainly provided by pigments coloration representing secondary sunscreen product (as having a primary function other than sun protection whilst providing some protection of the skin from ultraviolet radiation such as Skin care, Colour/Lip, etc.) and which commonly not representing primary sunscreen products (a product that is represented as being primarily to protect the skin from ultraviolet radiation such as a beach product).

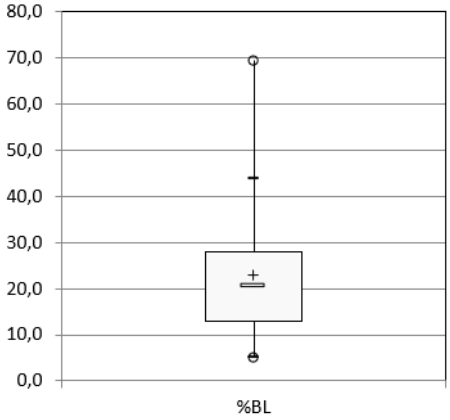
Results and Discussion

As previously, as no reference or guidance is provided regarding a minimum level of Blue Light protection for consumers, the proposed limits are determined to obtain a selectivity level of 70-80% of Pass-Fail conclusion (i.e. only 4 to 6 products should pass the limits based on the 20 uncolored tested products) and showing a significant protection level compared to other products.

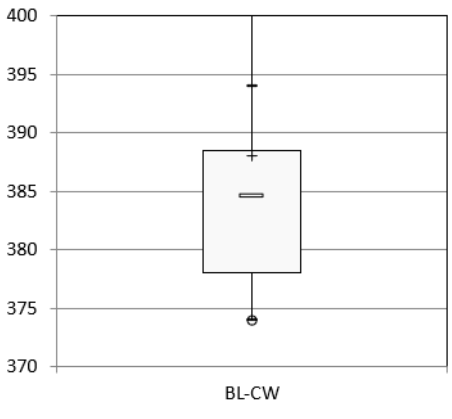
Therefore, to reach this selectivity level for the uncolored sunscreen products and to be around the 3rd quartile, new limits are proposed:

%BL ≥ 30%
BL-CW ≥ 385 nm

Here below, box plots used to have a visual representation of results and proposed limits.



Name	%BL
q1	13,1
min	5,2
moust. inf.	5,2
median	20,3
average	23,1
moust. sup.	43,8
max	69,4
q3	27,9
n	20



Name	BL-CW
q1	378
min	374
moust. inf.	374
mediane	384,5
average	388,1
moust. sup.	394
max	452
q3	388,5
n	20

[4]E. Delamour, S. Miksa and D. Lutz. Are you ready to protect yourself from Blue Light? New In Vitro method allowing the Blue Light Protection assessment of sunscreens, Euro Cosmetics October 2017

The results for the uncolored sunscreen products are collected in the Table 2 here below.

Table 2. Blue Light protection obtained for uncolored sunscreen products

Product	Aspect	Labelled SPF	%BL	BL-CW (nm)	Conclusion
P1	Cream	30	25,5	388	
P2	Milk	30	26,4	387	
P3	Alcoholic Spray	50	13,6	380	
P4	Cream	20	23,2	386	
P5	Stick	50+	43,8	420	Pass
P6	Cream	50+	32,7	390	Pass
P8	Cream	50+	33,6	391	Pass
P10	Stick	30	8,5	374	
P11	Milk	30	24,4	388	
P12	Oil	6	5,2	375	
P13	Cream	20	11,4	378	
P14	Cream	50+	13,7	378	
P15	Alcoholic spray	50	11,5	378	
P18	Milk	30	14,2	378	
P19	Milk	50	69,4	452	Pass
P20	Cream	50+	36,1	394	Pass
P21	Oil	30	10,5	378	
P23	Cream	50	16,3	378	
P24	Cream	15	17,3	383	
P25	Cream	50	25,7	386	
				Total pass	**5**
				Total product	**20**
				% Selectivity	**75**

CONCLUSION

To conclude, this complementary analysis is interesting to highlight that limits for Blue Light protection claim should be adapted for uncolored products to be able to have a standard baseline to compare products having similar function (primary sunscreen products) and characteristic (no coloration). In this new analysis for uncolored sunscreen products, new limits are proposed to respect a selectivity of 75% (i.e. only 5 products among the 20 test products pass the criteria) with %BL ≥ 30% and BL-CW ≥ 385 nm, both required to ensure a global Blue Light protection claim.

The ALT-SPF partnership will evaluate alternative sunscreen testing methods

A consortium of users and developers of sun protection factor (SPF) tests will identify, characterise, and evaluate alternative sunscreen testing methods. The partnership, which was kicked off in July 2021, will test a set of 32 sunscreen samples covering a large spectrum of product types by using the current gold standard - ISO 24444 - and five alternative methods that include in vitro, in silico and non-invasive in vivo testing in the next 12 months. Moreover, the consortium (project managed by Cosmetics Europe - the European trade association for the cosmetics and perconal care industry) brings together 28 partners in 10 countries, representing both personal care companies as well as laboratories developing alternative SPF tests.

As the international laboratory involved in sunscreen testing since 1999, **HelioScreen** joined the **ALT-SPF Consortium** as an in-kind contributor to evaluate, characterize and compare alternative testing methods to current gold standard in vivo testing method ISO 24444:2019 for sun protection factors. For this purpose, HelioScreen will participate in the Ring Test dedicated to the In Vitro SPF Double plate method (ISO Draft 23675).

For more information about the initiative, please visit www.alt-spf.com