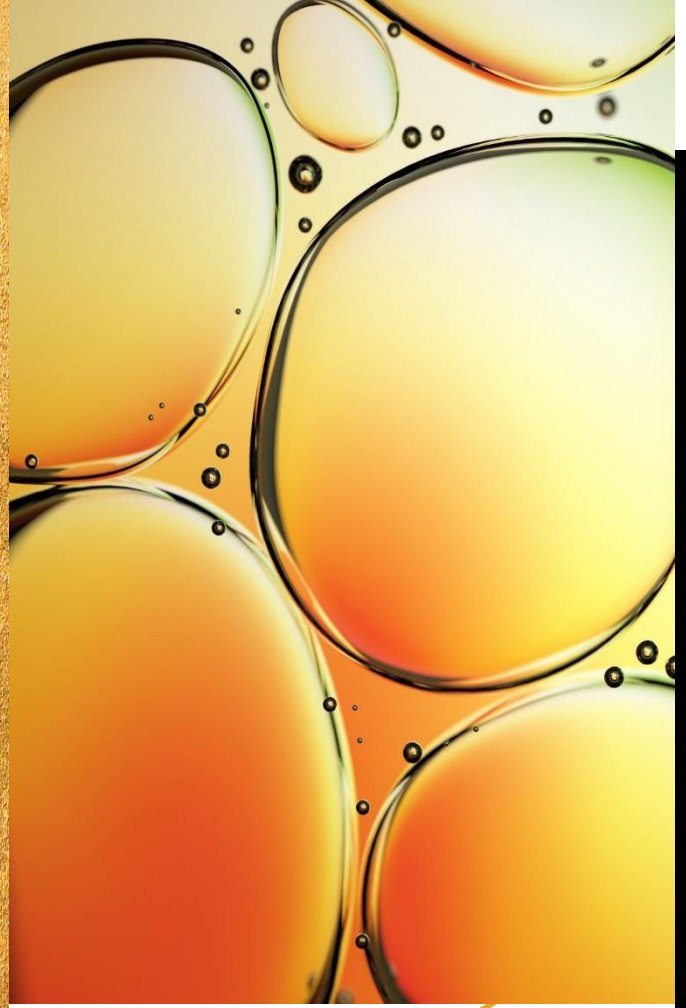
ISO 23675:2024

The Double-Plate *In Vitro* Sun Protection Method
History
Protocol

08/07/2025

We personally care

Cosmetics Europe
the personal care association



AGENDA

01

Background & Objective

SPF determination challenges

A journey to ISO publication

02

Methodology SPF in vitro

Design and validation

03

Implementation

Practical aspects

Advantages

04

Questions & Answers

To usual questions

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SPF VITRO: A TARGET SINCE LONG...

- Sunscreens : an important category within the Cosmetic field
  - Part of publich health policies (prevention of skin cancer)
  - Standard indices (Sun Protection Factor; UVA-Protection Factor)
  - Standardized testing methods (ISO24444 (SPF))

- Encouragement to developp **alternative methodologies** to evaluate the performance of solar products

Why?

ETHIC

Reduce in vivo tests, UV exposure ...

QUALITY

Overcome in vivo variability
Eliminate technical challenging procedures: application, MED reading...

TEST BETTER & FASTER

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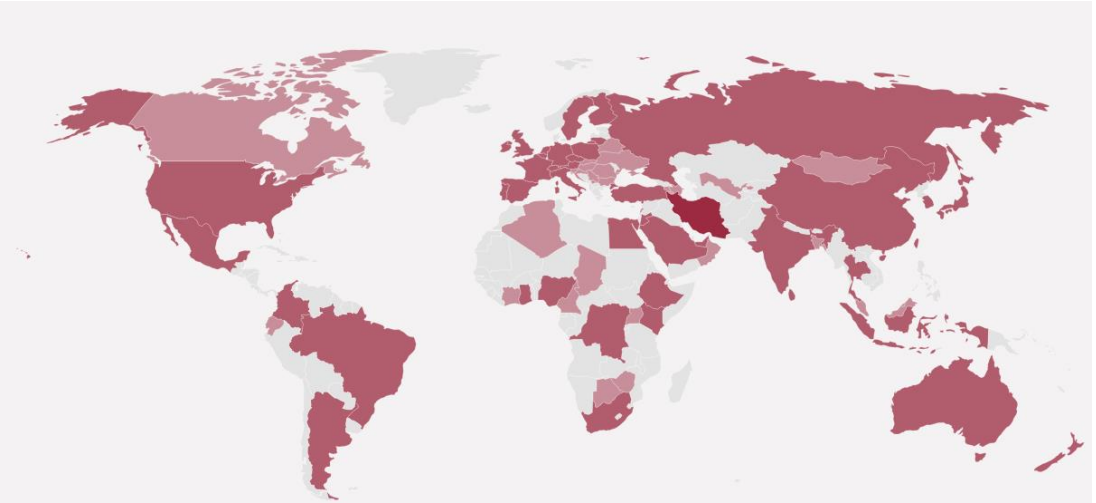
International Organization for Standardization
ISO TC217 - Cosmetics

- CAG: Chairman Advisory group
- WG1: Microbiological Standards & limits
- WG3: Analytical methods
- WG4: Terminology
- WG7: Sun protection test methods



49	3	45	29
Published ISO standards *	ISO standards under development *	Participating members	Observing members

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METHOD STANDARDIZATION

A JOURNEY TO ISO PUBLICATION

< 2000 Methods patchwork	2003-2006 1st harmonization	>2007 International Standard in ISO/TC217
		❑2006 Creation of Sun protection working group WG7 within the ISO/TC217 (Cosmetics)
❑ 1978 FDA USA ❑ 1984 German DIN 67501 ❑1991 JCIA ❑1994 COLIPA guidelines ❑1993/1998 Austr. Standard ❑1998 SABS method ❑1999 FDA USA	❑2003 International SPF test method (Colipa, JCIA, CTFA-SA) ❑2006 International test SPF method (Colipa, JCIA, CTFA-SA) supported by PCPC (USA)	❑2009 ISO/TR 26369:2009 ❑2010 ISO24444 first publication ❑2019 ISO24444 revision ❑2021 ISO24444 Amd1
		❑2011 ISO24442 first publication ❑2012 ISO24443 first publication ❑2022 ISO24442 revision ❑2021 ISO24443 revision

SPF

UVA-PF

INTERNATIONAL GOLD STANDARDS
of voluntary adoption

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+/- 5 years

TC may introduce into its work programme, by a simple majority vote of its P-members, PWI which are not yet sufficiently mature for processing to further stages and for which no target dates can be established.
All preliminary work items that have not progressed to the proposal stage in ISO within 3 years will be automatically cancelled.

This stage can be used for the elaboration of a new work item proposal and the development of an initial draft.

This first step is to confirm that a new International Standard in the subject area is really needed.
A new work item proposal (NWIP) is submitted to the committee for vote using *Form 4*.
The person being nominated as *project leader* is named on the Form.
If there are possible complications around copyright, patents or conformity assessment they should be raised at this early stage.
This stage can be skipped for revisions and amendments to ISO standards that are already published (as long as the scope does not change).

Usually a working group (WG) is set up by the parent committee to prepare the working draft (WD). The WG is made up of experts and a Convenor.
During this stage, experts continue to look out for issues around copyright, patents and conformity assessment.
Successive WDs can be circulated until the experts are satisfied that they have developed the best solution they can.

The draft is then forwarded to the WG's parent committee who will decide which stage to go to next (Committee stage or Enquiry stage).

This stage is optional.
During this stage the draft from the working group is shared with the members of the parent committee.

If the committee uses this stage, the committee draft (CD) is circulated to the members of the committee who then comment and vote using the Electronic Balloting Portal.

Successive CDs can be circulated until consensus is reached on the technical content.

The Draft International Standard (DIS) is submitted to ISO Central Secretariat by the committee secretary. It is then circulated to all ISO members who then have 12 weeks to vote and comment on it.
The DIS is approved if a two-thirds of the P-members of the TC are in favor and not more than one-quarter of the total number of votes cast are negative
If the DIS is approved and no technical changes are introduced in the draft, the project goes straight to publication.

If technical changes are introduced, FDIS stage is mandatory.

This stage will be automatically skipped if the DIS has been approved and no technical changes are introduced
However, if the draft incorporates technical changes following comments at the DIS stage the FDIS stage becomes mandatory. If this stage is used, the Final Draft International Standard (FDIS) is submitted to ISO/Central Secretariat (ISO/CS) by the committee secretary. The FDIS is then circulated to all ISO member for an 8 week vote, The standard is approved if a two-thirds majority of the P-members of the TC is in favor and not more than one-quarter of the total number of votes cast are negative.

At this stage the secretary submits the final document for publication through the Submission Interface. But if the standard has passed through the Approval stage, the secretary may submit the project leader's responses to member body comments on the FDIS.

Only editorial corrections are made to the final text.

It is published by the ISO Central Secretariat as an International Standard.

Experts

Countries

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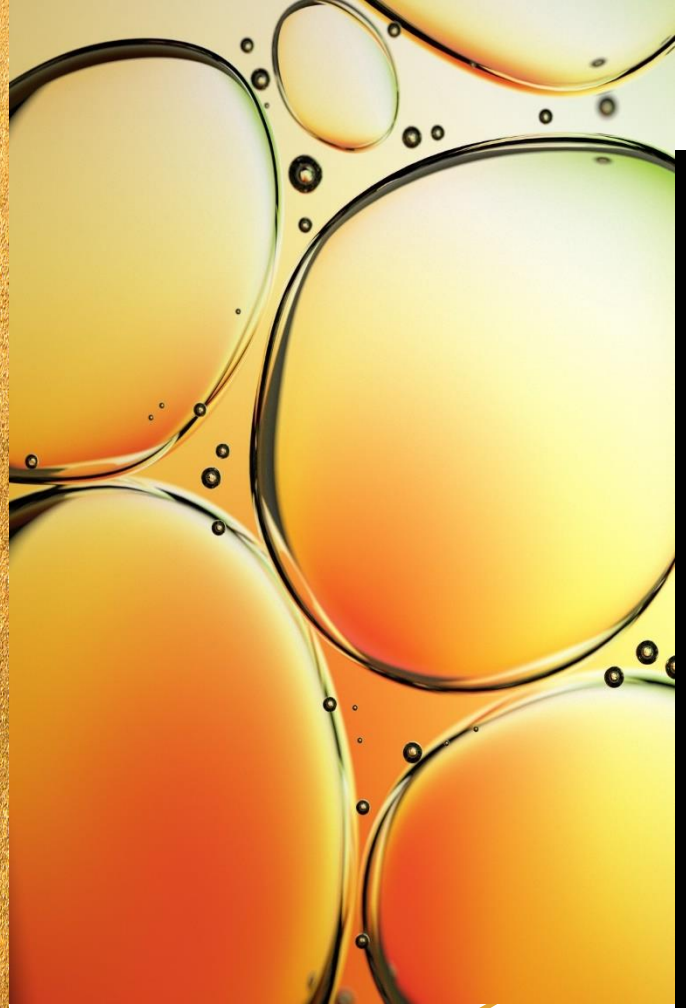
A NEW METHODOLOGICAL LANDSCAPE

	SPF	UVA-PF	Water Resistancy
IN VIVO	**ISO 24444:2019 (Amd1)**	**ISO 24442:2022**	**ISO 16217:2020** Immersion procedure **ISO 18861:2020** WR% calculation
IN VITRO	NEW **ISO 23675:2024 "Double Plate"**	**ISO 24443:2021**	
HYBRID	NEW **ISO 23698:2024 "Hybrid Diffuse Reflectance Spectroscopy"**		



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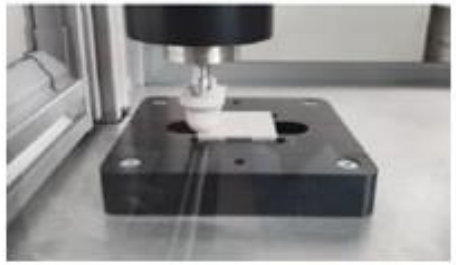
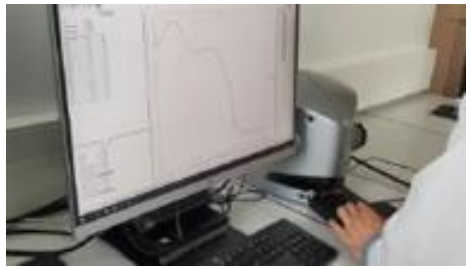
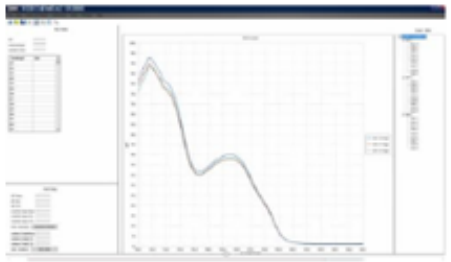
IN VITRO SPF DOUBLE PLATE METHOD

1. Test sample application



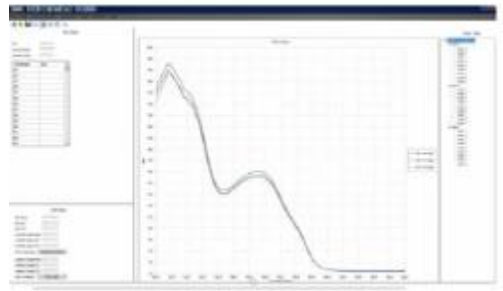
2. Initial SPF value test





3. UV irradiation

4. Final SPF value test



*Complementary “Double-substrates” approach => **Improve prediction level of vivo SPF**
*Robot application => **Improved reproducibility**
*UV irradiation step => **Integrated photostability impact seen in vivo case**

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Summary technical presentation for the *In Vitro* SPF method

18 years

- 1998: Latin working group -> initial thoughts on *in vitro* SPF - introduction of **PMMA plates**
- 2007: working group publication -> first ring test on 10 samples and 5 laboratories - determination of the **quantity** to be applied and first correlation
- 2007: SPF *in vitro* NWIP at ISO -> first international work – Working Draft **ISO24445**
- 2009: first ISO Ring test -> 7 products and 11 labs
- 2010: creation of an ISO Advisory group: improve the existing physical in vitro SPF transmission test method.

ISO 24445

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Summary technical presentation for the *In Vitro* SPF method

18 years

- 2012: RT1 ➔ Results show an obvious lack of reproducibility.
- 2013: RT2 ➔ 8 products - 4 substrates / spreading procedure HD6 - HD6 PT - SMS PT - Sandblasted SB – **Temperature**
- Workshop 2014: 12 products x 12 operators x 3 plate types x 5 protocols ➔ 6745 spectrum !!!

Robot – double plate – Irradiation – Temperature

➔ **The Double Plate method**

ISO 24445

ISO 23675

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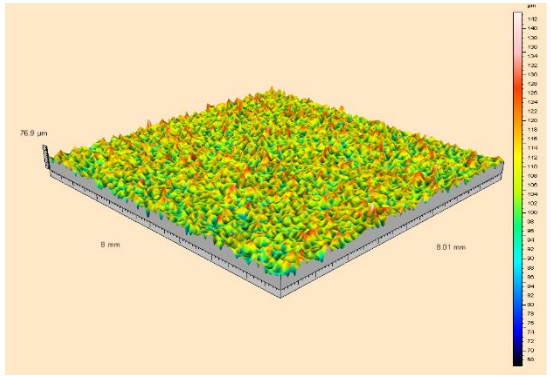
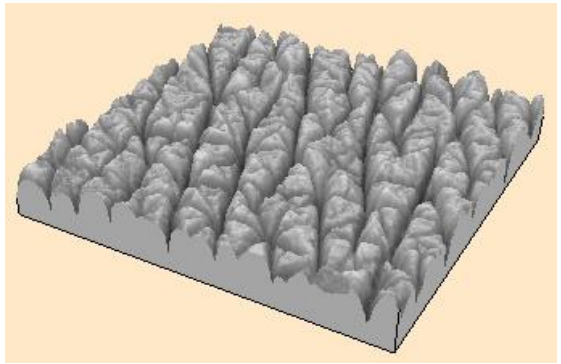
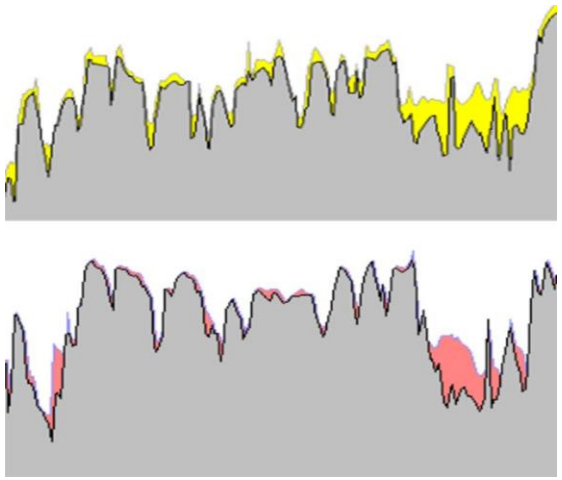
TEST SUBSTRATE CHARACTER
IMPORTANCE OF ROUGHNESS CONTROL

PMMA plate



Skin





0,1 mm

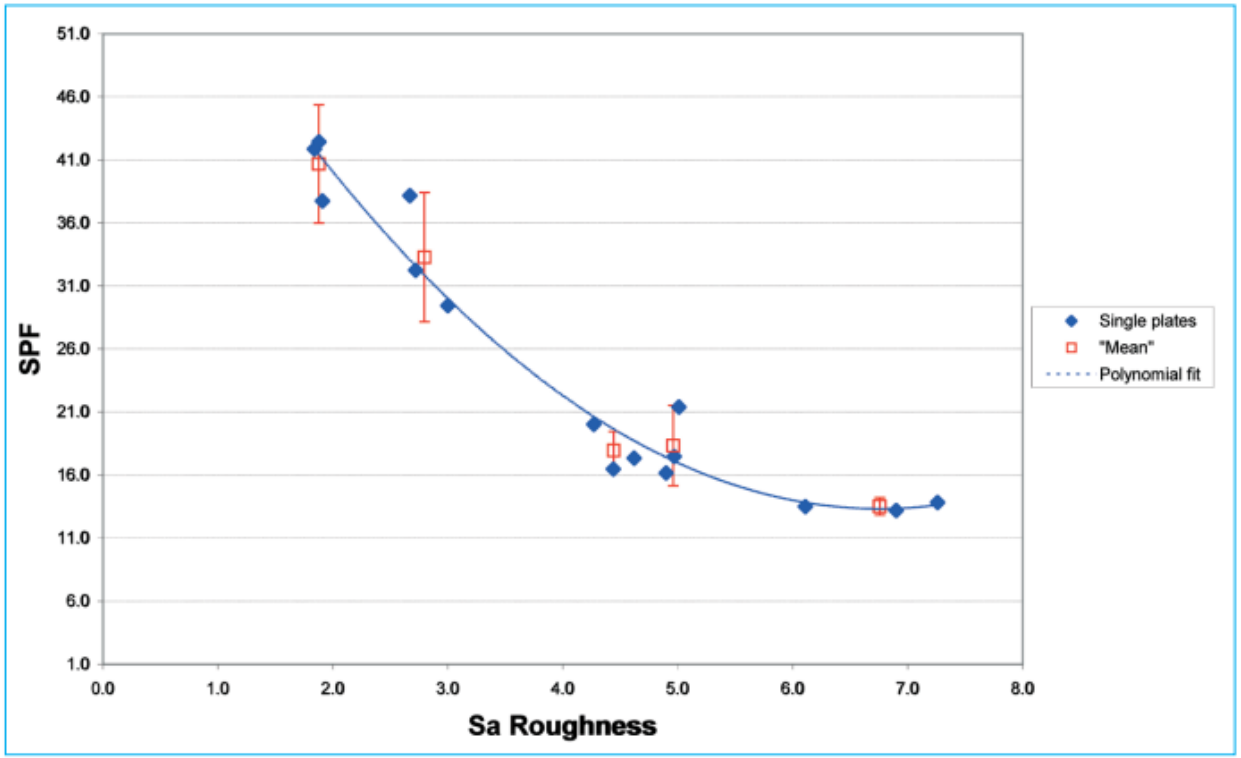


Figure 3: *In vitro SPF measured on PMMA plates of different roughness for the same amount of sunscreen applied at 1 mg cm^{-2}. Mean values and single plate values are reported.*

Importance of Substrate Roughness for In Vitro Sun Protection Assessment
IFSCC Magazine Vol9(2), Apr/Jun, 2006, L. Ferrero, M. Pissavini, A. Dehais, S. Marguerie, L. Zastrow

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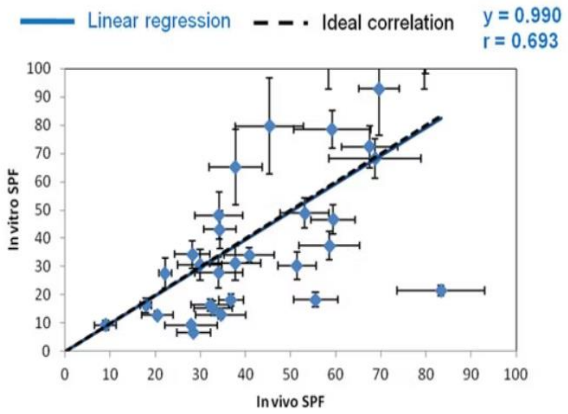
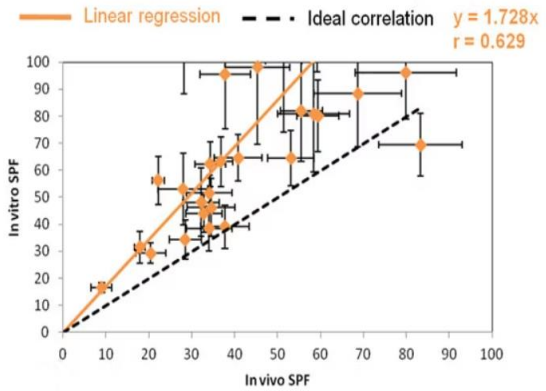
TEST SUBSTRATE CHARACTER

MULTI PLATE APPROACH

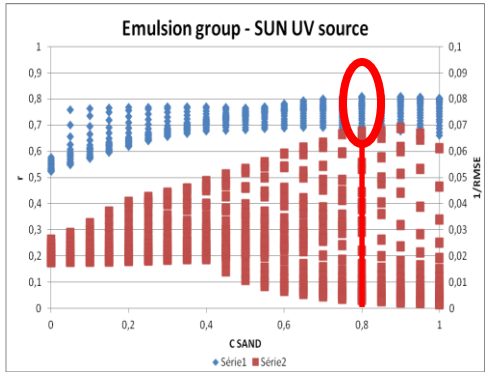
Molded PMMA Plate(MPP)

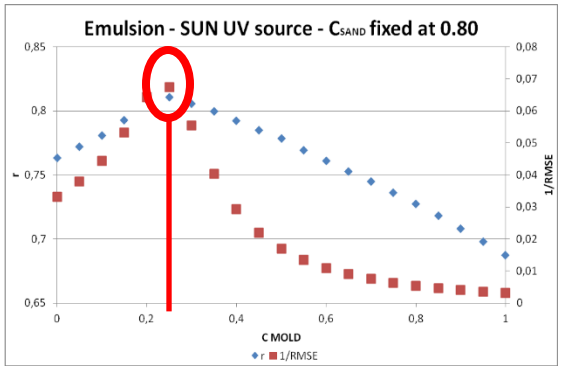


Sand-blasted PMMA Plate (SPP)



High impact
No ideal substrate
Multi-substrate approach





Determined contribution ratio(%) of Csand, Cmold to be
*Highest "r" for in vivo SPF result ,
*Minimal "RMSE(Root Mean Squared Error"

For Emulsions

- C_{SAND}= 0.800 (higher 1/RMSE and r)
- C_{MOLD}= 0.225 (higher 1/RMSE and r)

Fageon, L., et al (2009) "Importance of sunscreen products spreading protocol and substrate roughness for in vitro sun protection factor assessment". Int. J. Cosmet. Sci. 31, 405–418.
Miksa, S. et al (2013). "In vitro/vivo SPF Correlation and Repeatability According to Substrate", *Cosm & Toil.*
Pissavini, M., et al. (2016). "SPF tests reveal no ideal in vitro substrate exists." Cosm & Toil.

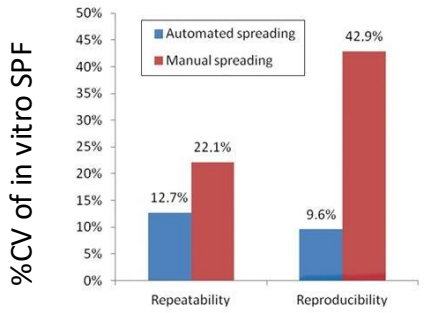
APPLICATION ROBOT

FOR BETTER REPEATABILITY & REPRODUCIBILITY

Conditions :

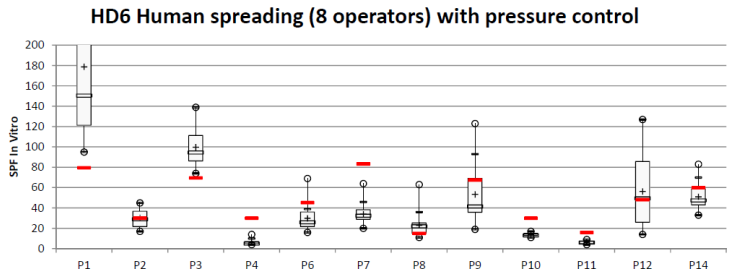
- 8
- 32

Repeatability and reproducibility comparison

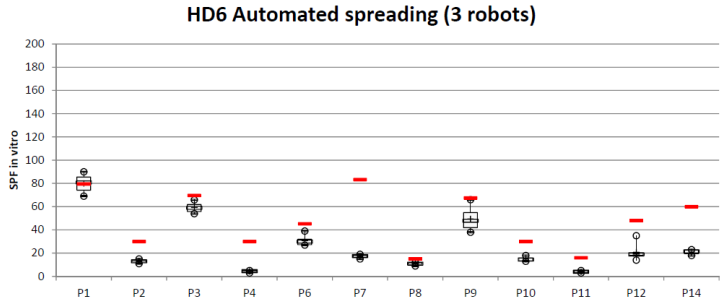


Part 1. Reproducibility - SPREADING

*SPF In Vivo in red

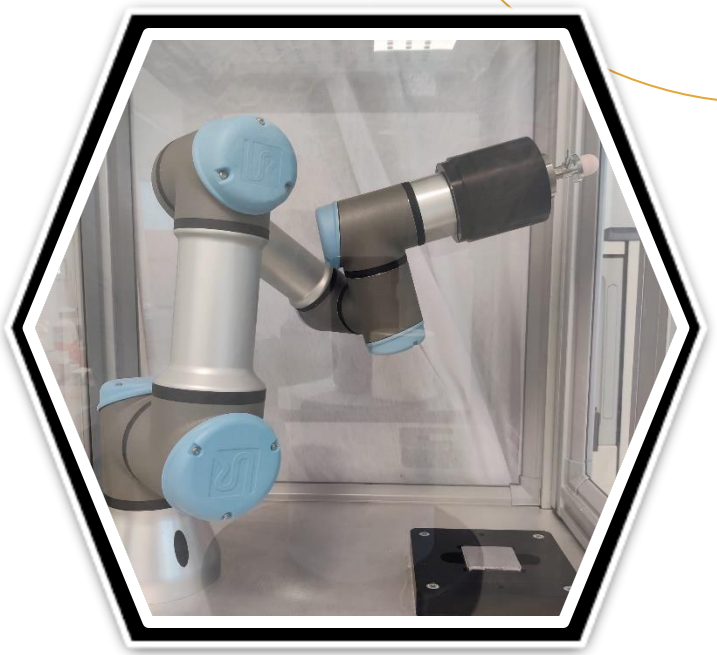


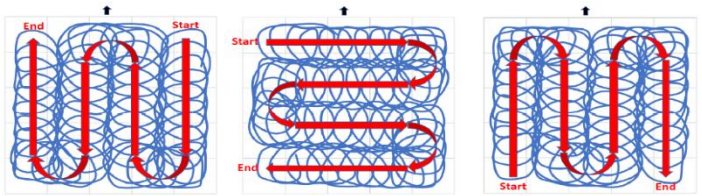
$\%CV_{mean}$ = 37.4



$\%CV_{mean}$ = 13.9

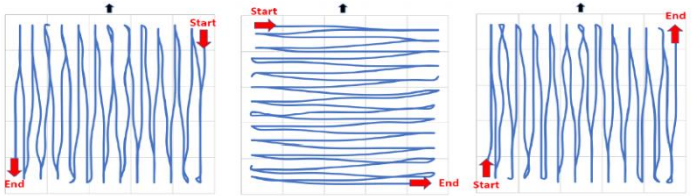
S. Miksa, D. Lutz and C. Guy, In vitro UV testing-robot vs. human spreading for repeatable, reproducible results. Cosmt. Toil. 128, 742-752 (2013)





Phase 1

Phase 2



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SPF IN-VITRO DOUBLE PLATE METHOD

18 years

INVESTIGATION OF IMPACT FACTORS AND OPTIMIZATION TO ACHIEVE GOOD REPEATABILITY, REPRODUCIBILITY AND CORRELATION TO VIVO SPF:

Substrates →	High impact No ideal substrate **Multi-substrate approach**
Spreading →	High impact **Robotic application**
Temperature →	Requires strict control **(27 ± 2°C)**
UV pre-irradiation →	Improves correlation **SSR spectrum** (idem ISO24444) Control T° and airflow Dose **D = 0.25 x initial SPFi**
Calculation (integral) →	**I(λ) of the Sun Spectrum** improves correlation
Spectrophotometer →	No influence *Horizontal positioning*

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SPF IN-VITRO DOUBLE PLATE METHOD

START OF NEW JOURNEY: ISO 23675

2016 – 2020: Cosmetics Europe Task Force

- 2 ring tests (8 labs – 100 products)
- 2 international publications

➔ A new work item proposal at ISO : **ISO 23675**

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SPF IN-VITRO DOUBLE PLATE METHOD

VALIDATION

International Journal of Cosmetic Science, 2018, **40**, 263–268 doi: 10.1111/ics.12459

Validation of an *in vitro* sun protection factor (SPF) method in blinded ring-testing

M. Pissavini*, C. Tricaud†, G. Wiener‡, A. Lauer§, M. Contier¶, L. Kolbe**, C. Trullás Cabanas††, F. Boyer‡‡, V. Nollent§§, E. Meredith¶¶, E. Dietrich*** and P. J. Matts†††

1rst study : 24 products

emulsion
23 O/W, + 1 W/O, organic or mixed UV filters
in-vivo ISO24444 testing in 3 different laboratories (n=5 subjects)
in-vitro Double Plate testing in 3 different laboratories

International Journal of Cosmetic Science, 2020, **42**, 421–428 doi: 10.1111/ics.12625

Validation of a new *in vitro* Sun Protection Factor method to include a wide range of sunscreen product emulsion types

M. Pissavini* C. Tricaud†, G. Wiener‡, A. Lauer§, M. Contier¶, L. Kolbe** C. Trullás Cabanas††, F. Boyer‡‡, E. Meredith§§, J de Lapuente¶¶, E. Dietrich*** and P.J. Matts†††

2nd study : 76 products

emulsion
73 W/O (17 orga; 44 mineral; 12 mixed UV filters)
3 O/W (mineral only)
in-vivo ISO24444 testing in 1 lab. (n=10 subjects)
in-vitro Double Plate testing in 1-2 laboratory(ies)

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Scope of the method: Sunscreen products with an emulsion chassis

- Results from previous blinded ring test for method validation
- 24 products :
  - 23 O/W
  - 1 W/O

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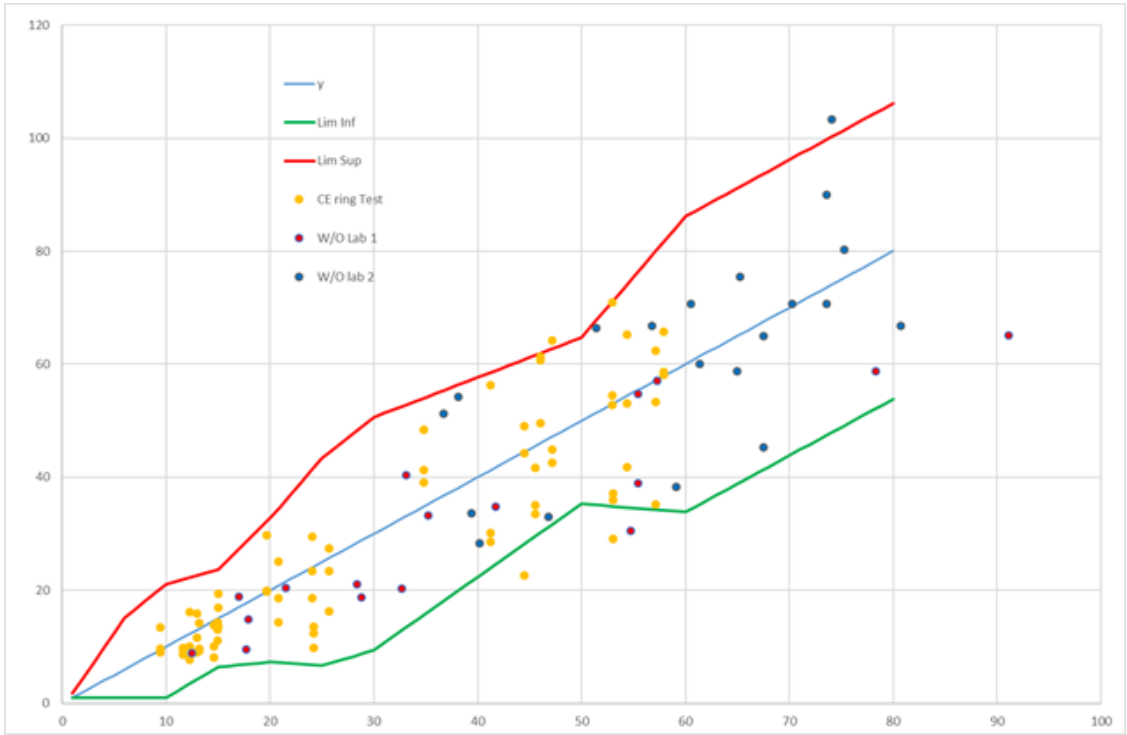
Scope of the method: Sunscreen products with an emulsion chassis

- New added results from new studies
- 24 products + 37 new products:
  - 23 O/W
  - 1 W/O + 37 W/O (including 8 minerals) ➔ from 2 different labs



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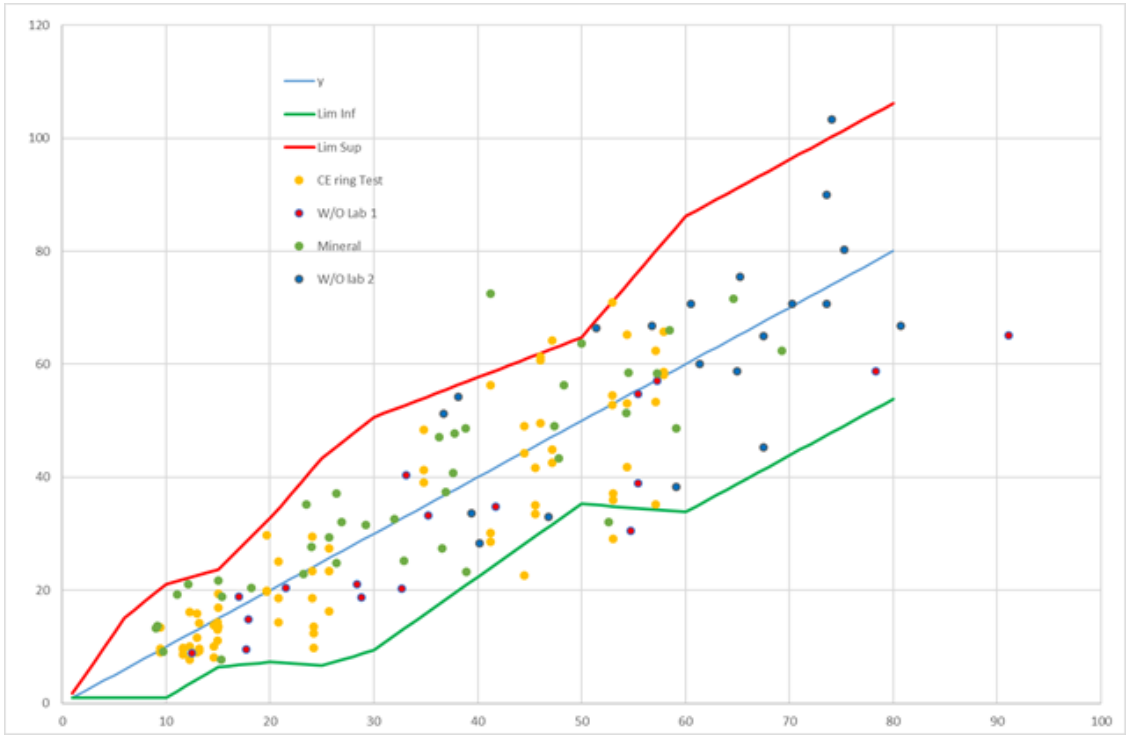
Scope of the method: Sunscreen products with an emulsion chassis

- New added results from new studies
- 24 products + 37 new product + 39 new products:
  - 23 O/W
  - 1 W/O + 37 W/O (including 8 minerals) ➔ from 2 different labs
  - 39 minerals (including 3 O/W and 36 W/O)



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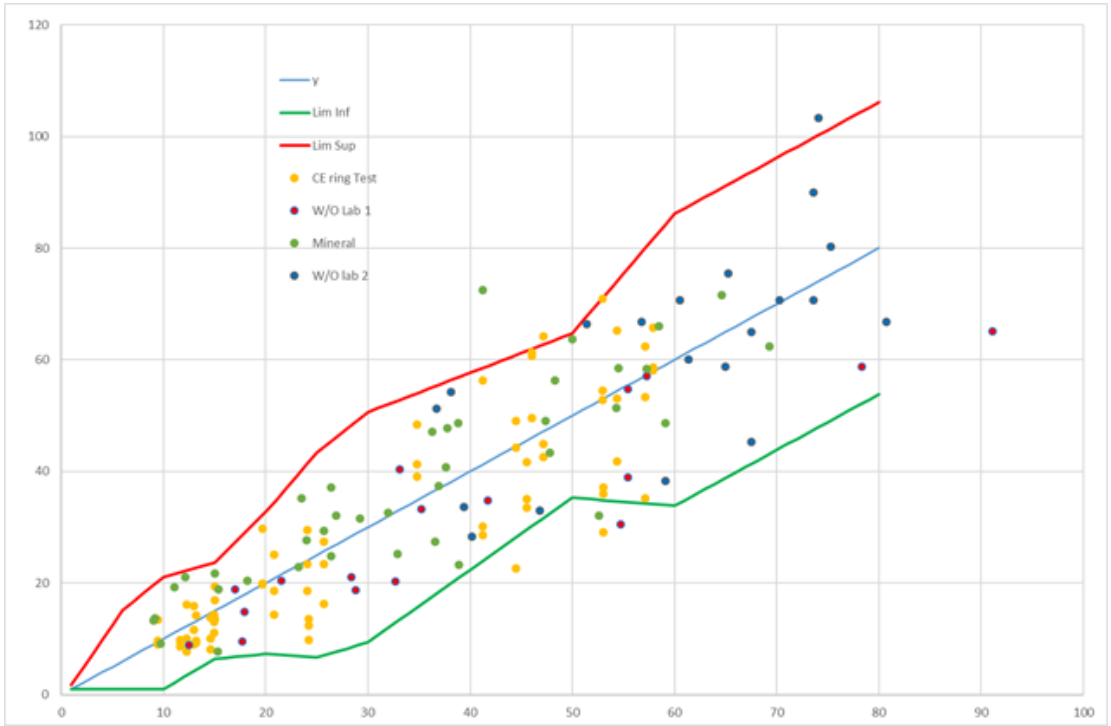
Scope of the method: Sunscreen products with an emulsion chassis

TOTAL

- 148 data
- 100 products:
  - 23 **O/W** ➔ 13 products 100% organic UV filters + 10 products organic/inorganic UV filters
  - 38 **W/O** ➔ 17 products 100% organic filters + 9 products 100% inorganic filters + 12 products organic/inorganic UV filters
  - 39 **mineral** ➔ from SPF 6 TO SPF 50+, including all category of filters

✓ At least 95% of the coupled data lies within the upper and lower confidence intervals of the "funnel" ➔ emulsion scope confirmed !



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ALT-SPF CONSORTIUM
PERFORMANCE CHARACTERIZATION

ALT-SPF CONSORTIUM

alt-spf

Purpose : to evaluate and characterize alternative SPF methods against ISO 24444:2019 regarding precision and degree of agreement

DESIGN:

Sample selection

The ALT-SPF consortium selected a set of 32 sunscreen samples that represent a reasonably large spectrum of product types and SPF levels found in the market and for which the alternative methods are applicable.

ISO 24444:2019 testing

SPF samples will be tested according to the SPF in vivo method ISO 24444:2019. Each sample will be tested by four labs in two independent set-ups.

Inter-lab variability

Intra-lab variability

OUTPUTS:

Characterization of the performance of the alternative method vs ISO24444:2019 in regards with :

- precision (reproducibility)
- trueness (bias)

RESULTS: To be published in peer-reviewed journal by mid year 2025

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ISO 23675 PERFORMANCE

ALT-SPF CONSORTIUM FIRST RESULTS

Initial performance assessment

Table 9-1: Overview of performance assessment for the Double-plate

Method	Product group	Criterion 1 [%]	Criterion 2 [%]	Criterion 3 [%]	Criterion 4 [%]	Criterion 5 [%]	All criteria
Double plate	1	117.2	30.2	222.0	209.7	256.5	
	2	58.8	13.2	172.7			
	3	45.3	23.6	64.3	158.8		
	4	108.9	59.6	168.3	179.9		
	5	60.3	44.9	60.3	17.2		
	6	60.2	42.6	132.8	79.8		
	7	41.3	0.0	41.3	22.7		
	8	91.8	39.2	128.1	122.9		

*Is the **reproducibility** of the alternative method better than those of the reference method?*

YES

*Are the results within the **prediction range** calculated from the reference method?*

MIXED

*Is the **bias** acceptable?*

MIXED

Correlation to in vivo is finetuned by a mathematical function

ISO 23675 PERFORMANCE

ALT-SPF FINAL RESULTS

Simulation of the performance assessment **post-adjustment**

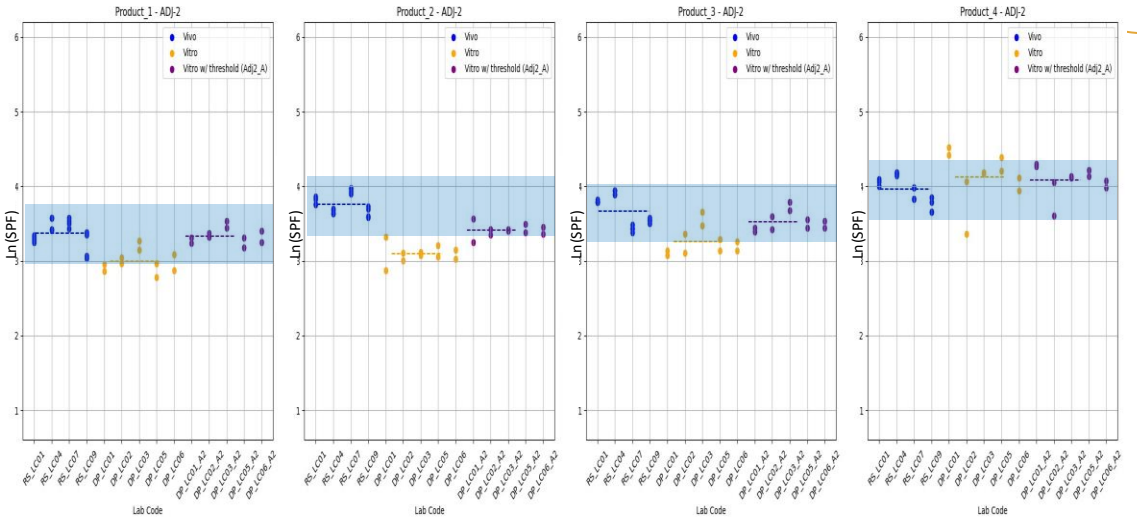
Method	Product Group	criterion1 sR_alt.sR_ref	criterion2 sLab_pers_alt.0.3	criterion3 sR_alt_augm.sR_ref	criterion4 abs.bias..DL	criterion5 Bias. CL	All criteria
DP	1	76%	20%	128%	70%		
DP	2	187%	25%	384%	59%		
DP	3	48%	26%	71%	74%		
DP	4	76%	42%	139%	77%		
DP	5	35%	28%	35%	12%		
DP	6	43%	30%	95%	10%		
DP	7	17%	6%	17%	21%		
DP	8	40%	17%	69%	8%		

reproducibility **YES**

Prediction interval **IMPROVED**

bias **YES**

PG1 – ALT-SPF STUDY



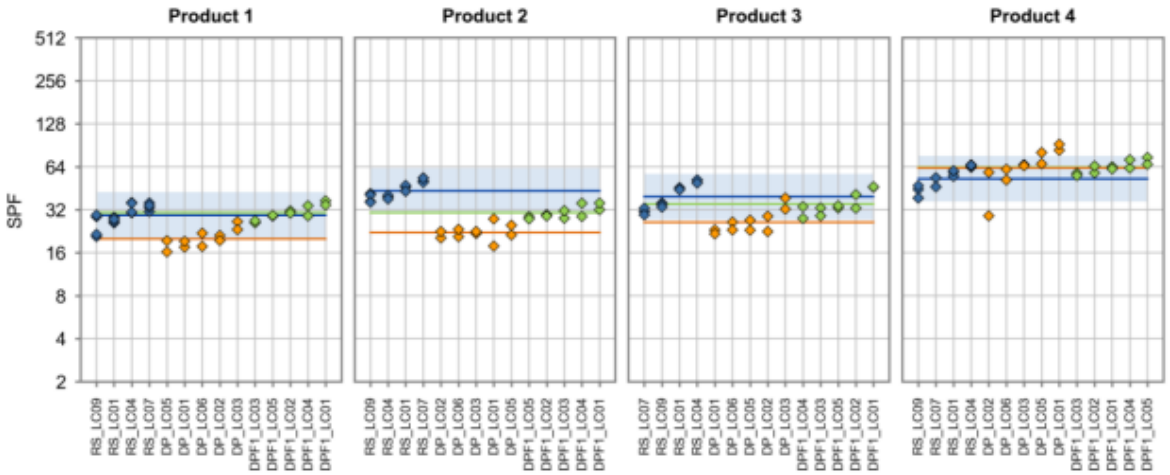
Updated performance assessment

Table 4-2: Product group 1 – overview of performance assessment for the double plate.

Study	Criterion 1 [%]	Criterion 2 [%]	Criterion 3 [%]	Criterion 4 [%]
ALT-SPF	117.2	30.2	222.0	209.7
Follow-up	69.7	23.6	137.3	37.4

CONFIRMED

PG1 – FOLLOW-UP STUDY

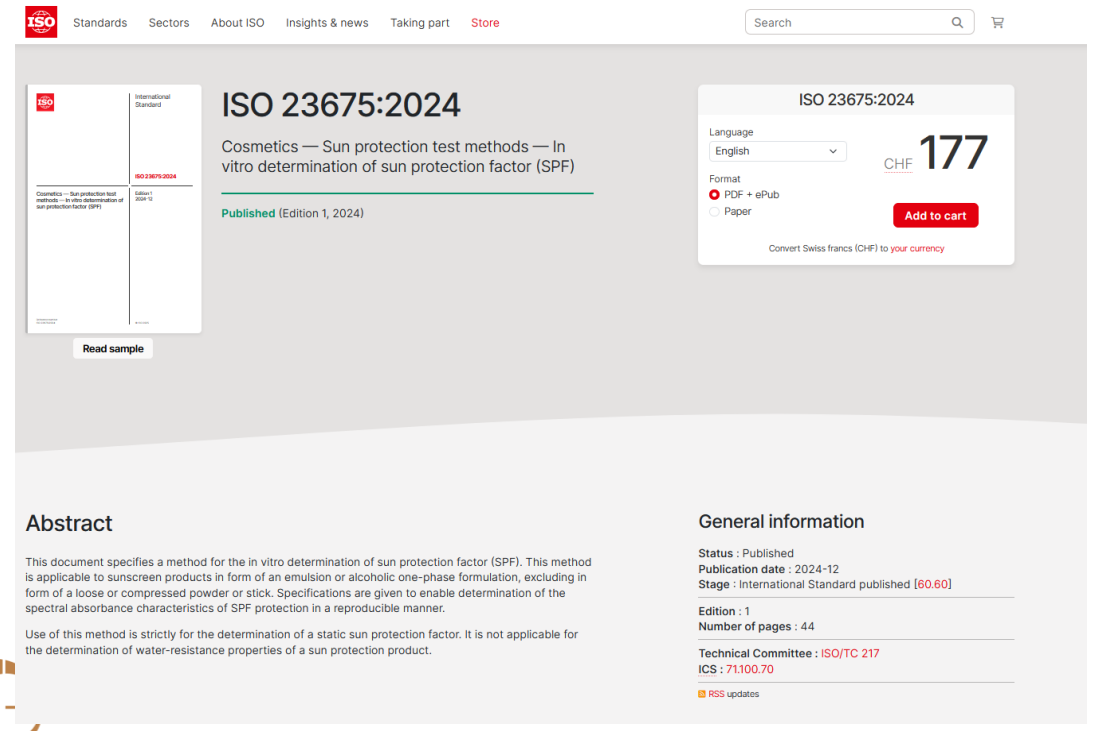


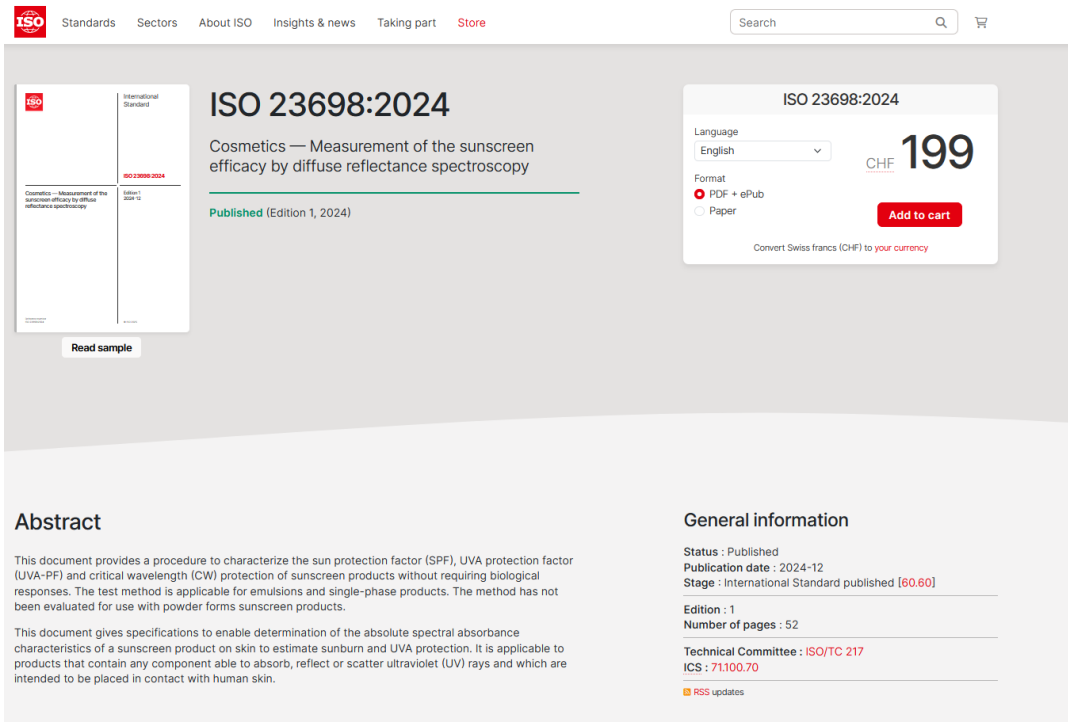
METHOD STANDARDIZATION

A JOURNEY TO ISO PUBLICATION

26 years

The methods ISO 23675 and ISO 23698 have been published by the ISO / TC 217 in December 2024.





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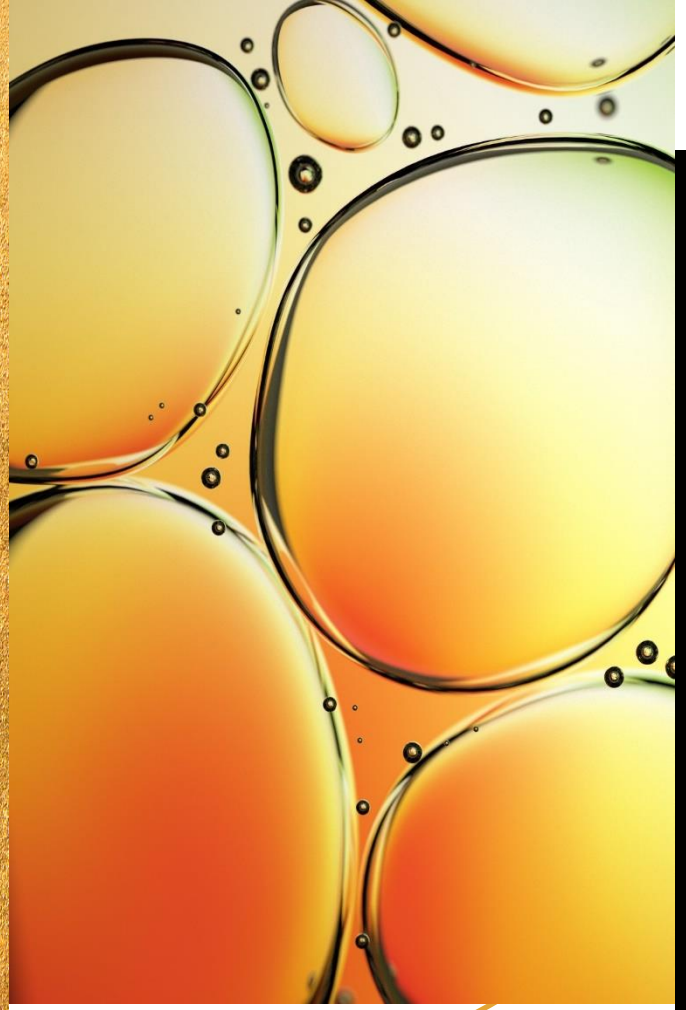

AGENDA

01

Background & Objective

SPF determination challenges

A journey to ISO publication

02

Methodology SPF in vitro

Design and validation

03

Implementation

Practical aspects

Advantages

04

Questions & Answers

To usual questions

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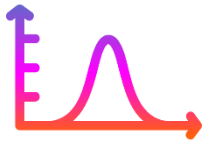
Presentation of the protocol

Preparation of reagents and materials

Product weighing

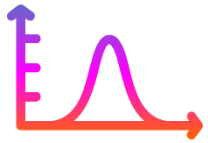
Product spreading

Calculation of final in vitro SPF



Measurement of absorbance

Irradiation



Measurement of absorbance

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https://www.iso.org/obp/ui#iso:std:iso:23675:dis:ed-1:v1:en

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PRESENTATION OF THE PROTOCOL

VIDEO

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THE NECESSARY EQUIPMENT

	INVESTMENT	SPECIFIC POINTS OF ATTENTION
SUBSTRATE	★☆☆	1.Moulded PMMA plates 2.Sandblasted PMMA plates
SURFACE TEMPERATURE CONTROLLER OF PLATES	★☆☆	To store plates and product at 27 (± 2)°C in the dark
ANALYTICAL BALANCE	★☆☆	with an accuracy of at least 10^{-4} g
AUTOMATIC PIPETTE	★☆☆	capable of delivering accurate and reproducible aliquots of approximately 1.6 mg to 1.8 mg of a sunscreen product
FINGERCOT	★☆☆	Latex, non-textured, powder-free, medium size
AUTOMATED SPREADING ROBOT	★★★	The spreading of the robot is defined in gesture and time to reproduce the gesture in vivo. The vertical force (z-axis), measured at the centre of the plate (without movement of the x and y axes), shall be 6.0 ± 0.5 N. Repeatable positioning at least ± 0.1 mm in the x, y and z axes.
TRANSMISSION UV SPECTROPHOTOMETER	★★☆	As described in ISO24443. Precise and reproducible positioning (before / after exposure) from 1 to 9 measuring points (≥16cm²) on the plate, which remains in a horizontal plane. Measures between 290nm and 400nm in steps of 1nm.
SOLAR SIMULATOR	★★★	A xenon arc solar simulator with the appropriate filters to deliver the right spectrum. It must be able to maintain a stable temperature at the sample level and be able to irradiate at least 2 plates at the same time with: - The spectrum used for UV vivo exposure of the ISO24444 method - No airflow on the plate - Good temperature stability at 27 ± 2°C - Good homogeneity of UV irradiation - The ability to place the plates without interrupting the UV flux
RADIOMETER / SPECTRORADIOMETER	★☆☆	Use a radiometer capable of providing flux measurement in MED/H Or use a spectroradiometer and perform the correct calculation (considering for example, 1 MED = 210 J/m²).

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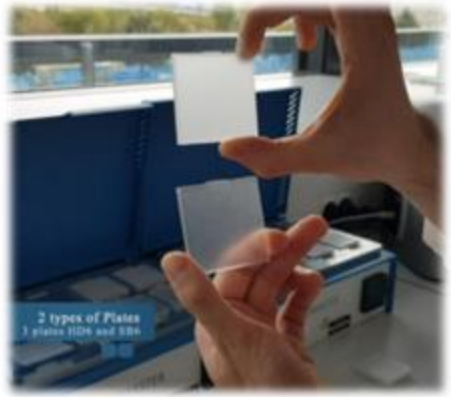
Step 1: Preparation

Oven of products and substrate

- *12h before*
- *27 ± 2 °C*

Note: no need to store the pipette nor the fingercots at 27± 2 °C

Note : no maximum duration



By product, plan

≥ 3 molded PMMA plates

≥ 3 sandblasted PMMA plates

+ plates for blank and saturation

Control parameters roughness

No pre-treatment

Wipe lightly sandblasted plates
(this helps to stop the fingercot from creasing)

Installation and saturation of the fingercot

Control absence of fold or crack

Repeated control after each application

Repeat of the step if necessary during the study

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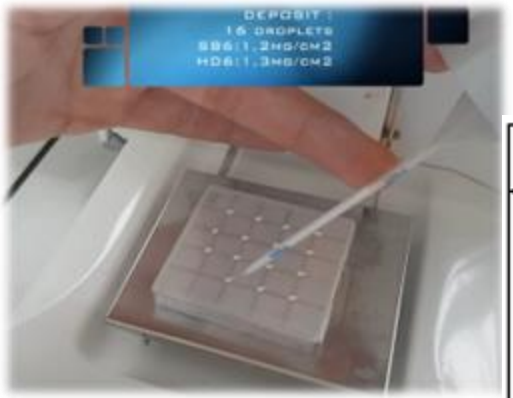
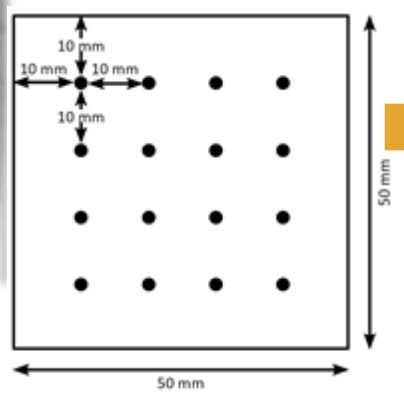
Step 2: Product application





Deposit of the product on the plate

1.3 mg/cm² on moulded plate

1.2 mg/cm² on sandblasted plate

16 drops evenly distributed

Note1 : Specific procedure for alcohols

Note2: Consider the spread area of the plate (4,7x4,7cm²)

Robotic automated spread

From deposit to beginning of spreading: < 30 s

Fingercot integrity check after each spread

Drying the plate

For 30min-60min

At 27 ± 2°C, in the dark

Repeat steps for all plates

Note1 : More convenient to do all the moulded then all the sandblasted plates.
Identify them to pair molded_1 w/ sand_1…

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Steps 3 – 4: measurement, initial SPF calculation

Measurement of initial absorbance

Between 290nm and 400nm

Cover ≥ 16 cm² in 1 or 9 measuring points, evenly distributed

Accurate and repeatable positioning

Calculation of the Initial Absorbance

Pairing of molded and sandblasted plates

$$A_{Initial}(\lambda) = C_{Moulded} * \min\left\{2{,}2; A_{Moulded}^{pre-irradiation}(\lambda)\right\} + C_{Sandblasted} * \min\left\{2{,}2; A_{Sandblasted}^{pre-irradiation}(\lambda)\right\}$$

where:

$A_{Moulded\text{-}pre\text{-}irradiation}$ = *absorbance of the molded plate before exposure to Uvs*

$A_{Sandlasted\text{-}pre\text{-}irradiation}$ = *absorbance of the sandblasted plate before exposure to UVs;*

$C_{Moulded}$ *and* $C_{Sandblasted}$ = *Correction factors Factors defined by product type (example for emulsions* $C_{moulded} = 0{,}225$ and $C_{Sandblasted} = 0{,}800$*)*

Calculation of the initial SPF

$$Initial\ in\ vitro\ SPF_i = \frac{\int_{290}^{400} E(\lambda)\ I(\lambda)\ d\lambda}{\int_{290}^{400} E(\lambda)\ I(\lambda)\ 10^{-A_{initial}(\lambda)}\ d\lambda}$$

$E(\lambda)$ = *Erythemal action Spectrum* CIE;

$I(\lambda)$ = *Irradiance spectrum* global;

$A_{Initial}(\lambda)$ = *monochromatic absorbance* of the product in test before UV exposure for each pair of plates

$d\lambda$ = *wavelength steps* (1 nm).

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Steps 5 – 6: dose calculation and irradiation

Calculation of exposure dose

$$Dx\ (MED) = 0{,}25 \times Initial\ in\ vitro\ SPF_i$$

For each pair of plates

Radiometer calibrated in MED/Hr

Exposure time T (Hr) = Dx (MED) / Flux (MED / Hr)

UV exposure

Exposure of 1 to 4 pairs of plates (depending on the size of the irradiation area)

Spectrum identical to ISO24444

No airflow

Stable plate temperature at 27 ± 2 °C

Good homogeneity of UV irradiation

Possibility to place / remove the plates without interrupting the UV flux

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Steps 7 – 8 : measurement, SPF calculation

Measurement of final absorbance

Between 290nm and 400nm

Cover ≥ 16 cm² in 1 or 9 measuring points, evenly distributed

Accurate and repeatable positioning

Calculation of final absorbance (per plate pair)

Pairing of molded and sandblasted plates

$$A_{\text{Final}}(\lambda) = C_{\text{Moulded}} * \min\left\{2{,}2; A^{\textit{post-irradiation}}_{\textit{Moulded}}(\lambda)\right\} + C_{\text{Sandblasted}} * \min\left\{2{,}2; A^{\textit{post-irradiation}}_{\textit{Sandblasted}}(\lambda)\right\}$$

where:

$A_{\text{Mold-post-irradiation}}$ = *absorbance of the molded plate after exposure to UVs;*

$A_{\text{Sand-post-irradiation}}$ = *absorbance of the sandblasted plate after exposure to UVs;*

C_{Mold} *et* C_{Sand} = *Correction factors Factors defined by product type (example for emulsions* $C_{\text{mold}} = 0{,}225$ *et* $C_{\text{Sand}} = 0{,}800$*)*

Calculation of the SPF post-irradiation (per plate pair)

$$\textbf{Post irradiation InVitro SPF}_i = \frac{\int_{290}^{400} E(\lambda)\, I(\lambda)\, d\lambda}{\int_{290}^{400} E(\lambda)\, I(\lambda)\, 10^{-A_{final}(\lambda)}\, d\lambda}$$

E(λ) = *Spectrum of action* erythemal CIE;

I(λ) = *Irradiance spectrum* global;

$A_{Final}(\lambda)$ = *averaged monochromatic absorbance* of the product after UV exposure for each pair of plates

dλ = *wavelength* step (1 nm).

! New !

Calculation of the final SPF* (per plate pair)

* Only for SPF ≥ 3,5 to avoid mathematical artifact

$$Final\ InVitro\ SPF_i = \frac{\sqrt{Post\ irradiation\ InVitroSPF_i} - 1.457}{0.107}$$

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Steps 9 – 10: validation, standards

Calculation of the final SPF

$$\text{Final In Vitro SPF} = (\Sigma \text{ Final } \textit{In Vitro} \text{ SPF}_i) \,/\, n$$

with n ≥ 3

Statistical criterion

CI95% ≤ 17% of the average final SPF

Same as ISO 24444

Possibility to add additional plates within the limit of 10 pairs in total

Test validation

P2 or P3, P5 or P6, and P8 validated once a month

Reference sunscreen formulation	Mean SPF	Acceptance limits	
		Lower limit	Upper limit
P2	16,1	13,7	18,5
P3	15,7	13,7	17,7
P5	30,6	23,7	37,4
P6	43,0	31,0	54,9
P8	63,1	43,9	82,3

Note1 : No need to check the CI95% for the reference sunscreen formulation, only the acceptance range.

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TACKLING THE CHALLENGES OF SPF DETERMINATION

#1 – Non-human model

More ethic

More standardized

No skin color no seasonal limitation

Why?

ETHIC

Reduce in vivo tests, UV exposure …

QUALITY

Overcome in vivo variability
Eliminate technical challenging procedures: application, MED reading…

TEST BETTER & FASTER

#2 – Improved repeatability and reproducibility

A robust determination of the SPF in **one and only testing**.

#3 – Fully blind testing

No need to submit target SPF values.

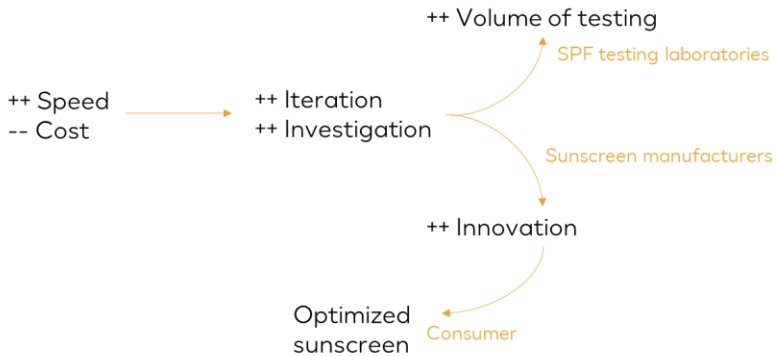
#4 – Elimination of technically challenging procedure

Easily develop the proper proficiency when developping capacity

#5 – Significant improvement in speed and cost

Benefit for innovation and business

Benefit for the consumer



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CURRENT EVOLUTIONS OF THE METHOD

UVA-PF

SPF	UVA-PF
ISO 24444:2019 (Amd1) Characteristics : in vivo Parameters : SPF	**ISO 24442:2022** Characteristics : in vivo Parameters : UVA-PF
ISO 23675:2024 “Double Plate” Characteristics : in vitro Parameters : SPF **Futur development**: UVA-PF, CWL	**ISO 24443:2021** Characteristics : in vitro Parameters : UVA-PF, critical wavelength
ISO 23698:2024 “Hybrid Diffuse Reflectance Spectroscopy” Characteristics : hybrid = in vivo (UVA) x in vitro (UVB) Parameters : SPF; UVA-PF, critical wavelength	

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CURRENT EVOLUTIONS OF THE METHOD

WATER RESISTANCY

	SPF	UVA-PF	Water Resistancy
IN VIVO	**ISO 24444:2019 (Amd1)** Characteristics : in vivo	**ISO 24442:2022** Characteristics : in vivo	**ISO 16217:2020** Characteristics : in vivo **ISO 18861:2020** Characteristics : in vivo
IN VITRO	**ISO 23675:2024 "Double Plate"** Characteristics : in vitro	**ISO 24443:2021** Characteristics : in vitro	**Futur development**: WR vitro Pissavini et al, 2025. doi: 10.1111/ics.13074 WIP
HYBRID	**ISO 23698:2024 "Hybrid Diffuse Reflectance Spectroscopy"** Characteristics : hybride = in vivo (UVA) x in vitro (UVB)		

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CURRENT EVOLUTIONS OF THE METHOD

NEW PRODUCT FORMS

SPF

ISO 23675:2024 “Double Plate”

Characteristics : in vitro

Parameters : SPF

Scope : Emulsions, monophase alcoholic

Futur development: Sticks – Oils;

Biphase?

/!\ WARNING in application :

the product shall be in emulsion form when applied and spread

- Shake well before apply
- New pipetting at each plate
- Respect the limited timing between application and spreading

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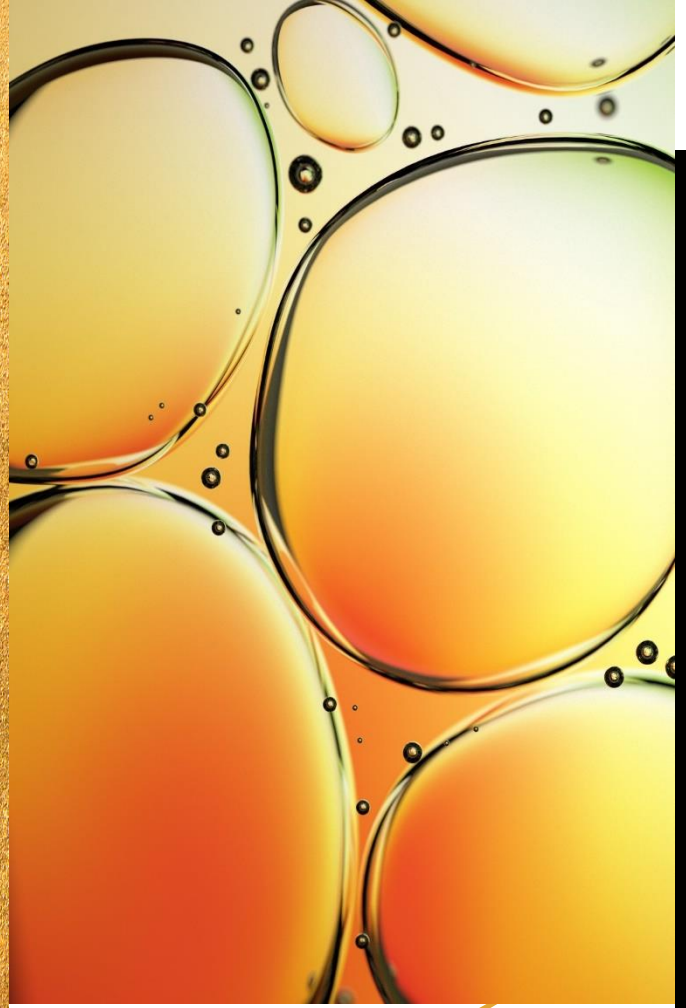

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Questions & Answers

To usual questions

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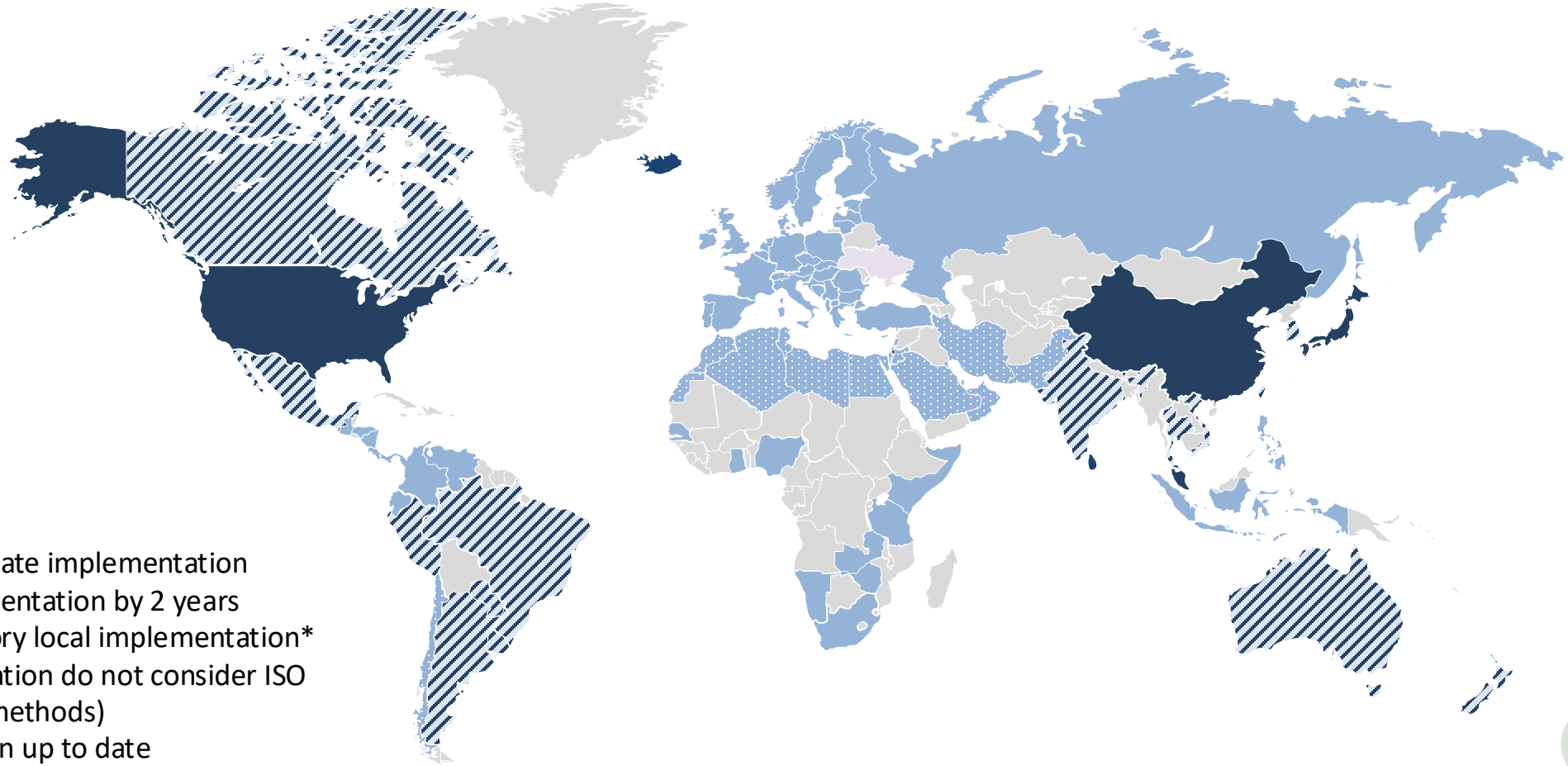
Q1 –Regulatory status ?

Worldwide deployment of new ISO methods



- Direct immediate implementation
- Direct implementation by 2 years
- Need regulatory local implementation*
- Current regulation do not consider ISO (or only vivo methods)
- No information up to date

* The current regulation needs to be updated for the new methodologies to be accepted

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Q2 – How to choose the method for SPF testing?

IMPORTANCE OF CHOOSING THE RIGHT TESTING METHOD

1. Standardized
2. Repeatable and Reproducible
3. Ethical and Inclusive
4. Cost-effective and Fast

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IMPORTANCE OF CHOOSING THE RIGHT TESTING METHOD

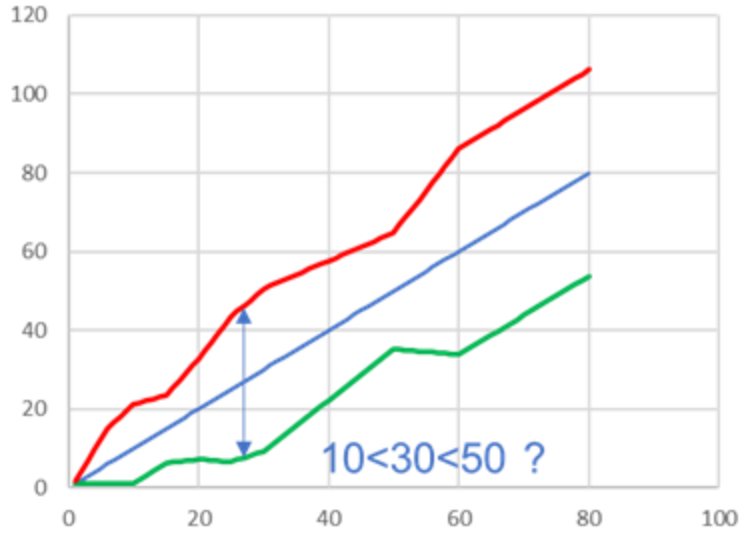
ISO 24444: SPF *in vivo*

1 Standardized

ISO standardized for consistency across the industry.

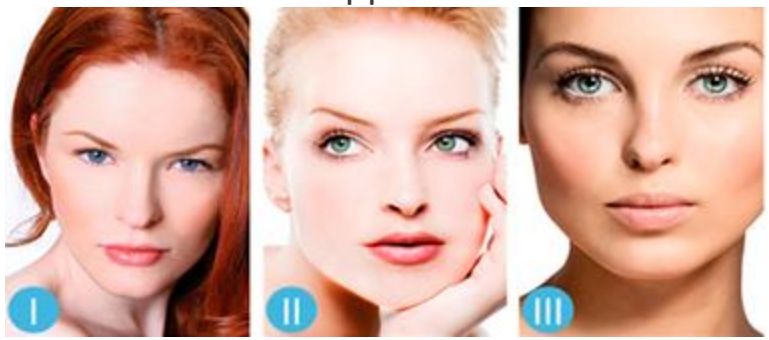
2 Repeatable and Reproducible

Repeatable with CI<17% but reproducible across different labs ?



3 Ethical and Inclusive

Not adhere to ethical standards and are not inclusive in its approach.



4 Cost-effective and Fast

No

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IMPORTANCE OF CHOOSING THE RIGHT TESTING METHOD

ISO 23675: SPF *in vitro*

1 Standardized

ISO standardized for consistency across the industry.

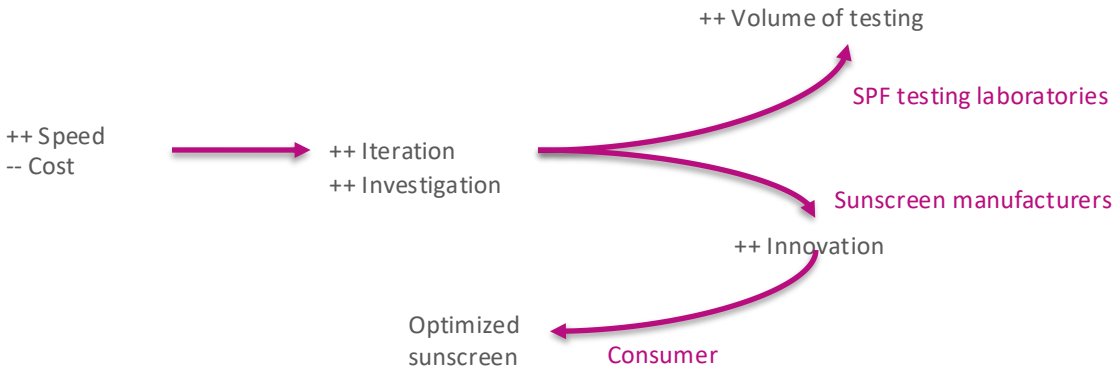
2 Repeatable and Reproducible

Repeatable with CI<17% and reproducible across different labs

3 Ethical and Inclusive

The method adhere to ethical standards and are inclusive in its approach.

4 Cost-effective and Fast



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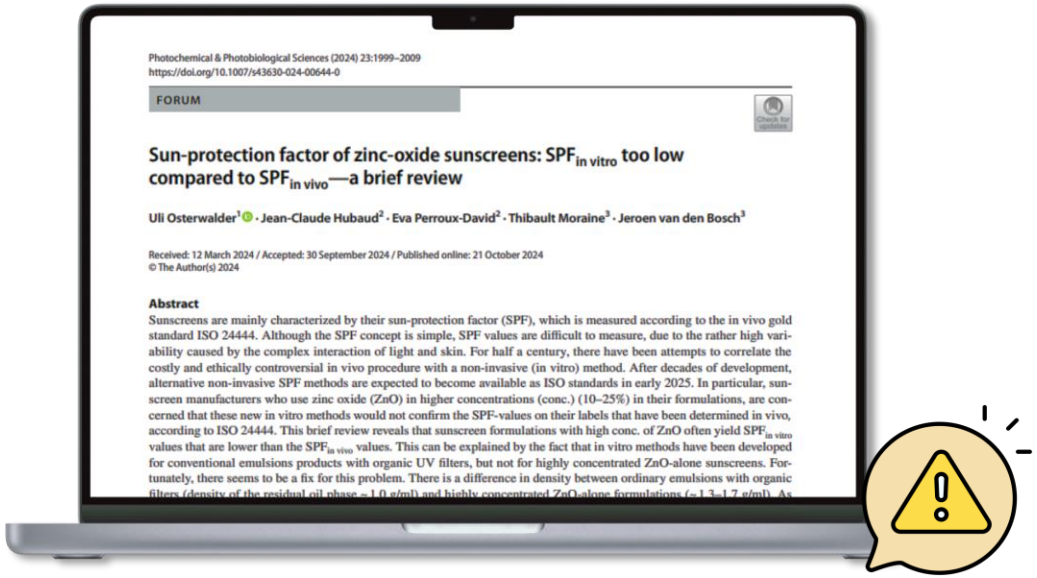
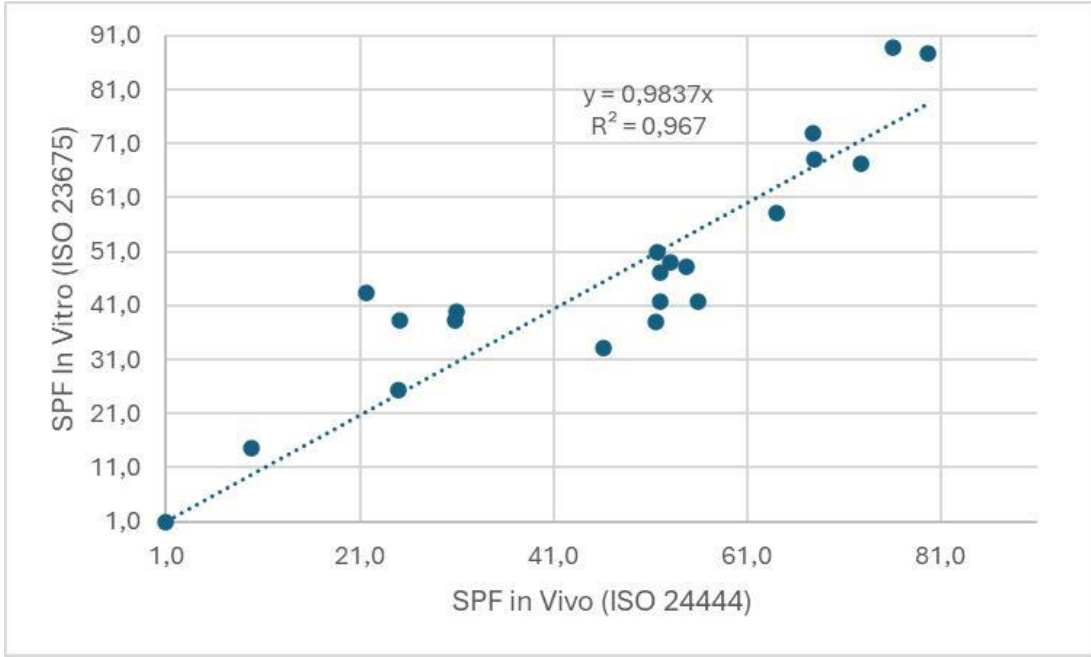
Q3 – Does it work for products with high inorganic UV filters concentration? #ZnO



An in-house *in vitro* method derived from ISO 24443 (UVA Protection Factor) was employed in this study. However, **this method lacks validation for Sun Protection Factor** (SPF) measurement according to ISO 24444. Consequently, the observed discrepancies compared to the ISO 24444 standard are not unexpected.

ISO 23675: the only validated *in vitro* alternative

EXTRAPOLATION FROM ANOTHER METHOD IS INAPPROPRIATE



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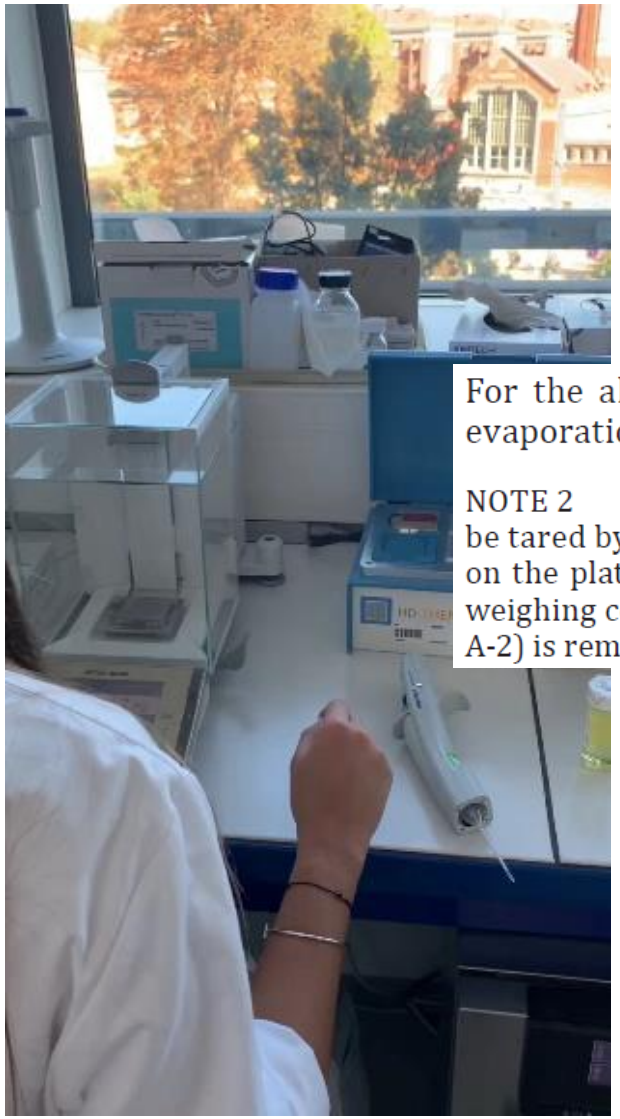
Q4 – Specific procedure for alcohol based products?



For the alcoholic one phase formulations, the application dose shall be determined while reducing the evaporation lost during application.

NOTE 2 For application of the alcoholic one phase formulations, when the type of plates allows it, the plates can be tared by superimposing 2 plates on top of each other (plate A-2 on the top of the plate A-1). The product is applied on the plate below (plate A-1), then immediately covered by the one above (plate A-2) to limit evaporation during weighing control. The 2 plates (plate A-1 and plate A-2) are then placed on the robot platform and the top plate (plate A-2) is removed just as the spreading process begins.

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Additionnal questions

- **Does a laboratory need to be ISO certified for its results to be acceptable?** – no certification but quality control (certification of the plates – reference formula – training – maintenance of the equipment - …)

- **Is it normal to have a high COV on an individual plate – as the spreader is not delivering a totally uniform spread, with striations on the plate?** – yes, the spreader is delivering a reproducible spread, not perfectly homogeneous depending on the product. That's why it's important to cover a large part when measuring, and to have a precise repositioning which is the same whatever the plate and product.

- **Can you reject plates if they really don't look as if they have spread? The ISO23675 talks about a minimum of three valid plates of each type is required. What makes a valid plate (ie. are there SD and COV criteria that each plate needs to be achieve)** – valid plate is when all the steps went properly (the right quantity – no issue with the spreading / fingercot creasing – the right temperature – irradiation time…). No criteria to reject a plate from intra-plate parameter. If you suspect an issue, better to reject.

Additionnal questions

- **When does a study start and finish? For example, if I have performed a test that didn't work at 3 paired plates and went on to do a further 3 paired plates do I need to report all 3 or just once the CI confidence is in specification. For example if plate 4 brings the CI in spec do I conclude the study (even if plates 5 and 6 then take CI out of spec)** – Consider all your data but have a critical view on it. If you are borderline and inconsistently reaching the CI criteria, it could mean that there is a technical issue. Just stop, reflect, analyze, , redo everything if needed. Question your practice and equipment but also the product.

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THANK YOU FOR YOUR ATTENTION

08/07/2025

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