eurofins | Cosmetics & Personal Care

Sunscreen E-Summit
SPF Global Updates

May 15, 2022

About us: Nicki Kauffman

is currently the Lab Manager at Eurofins CRL Cosmetics, Inc. NC where she oversees the clinical testing of both of R&D sun protecting products and cosmetic toiletry products. She has 13 years of experience in the SPF industry which began when she started as SPF In-Vitro Intern Technician, then worked her way up to Photobiology Management when she took on the role of site technical leadership. Nicki has worked to refine and streamline the CRL SPF testing process, developed an In-Vitro HEV testing method, navigated recent regulation updates, and aiding in the adoption and harmonization efforts of Eurofins sites for ISO24444:2019.

About us: Chelcie Mejia

is currently the Photobiology Manager at Eurofins CRL Cosmetics, Inc. NC where she oversees the daily clinical testing operations of R&D sun protecting products. She has 5 years of experience in the SPF industry which began when she started as SPF In-Vivo Research Technician. Chelcie has worked to build strong lab/sponsor relationships and aided implementation of ISO24444:2019 and ISO16217/18861 regulation changes to the testing site.

Nicki Kauffman, Mike Anthonavage (Vice President of Operations & Technology), and Chelcie Mejia (Photobiology Manager) all collectively sit on the 5 sub committees of the PCPC Sunscreen Task Force and are up to date and aligned on the latest monograph/method changes.

FDA Monograph: Current FDA Regulations FDA FR:2011

In-Vivo (Testing on humans)

- Static
- Water Resistance
- Static/WR combo

SPF Claim Requirements:

- Minimum of 10, Maximum of 20 VALID subjects on the panel
- Maximum of 3 invalid subjects
- Standard Sunscreen Label SPF is within allowable range
- Label SPF = Claim SPF

FDA is used for samples intended to be marketed in the US and Canada

In-Vitro (Testing on substrate test plates)

- FDACW (Broad Spectrum)

In-Vitro Claim Requirements:

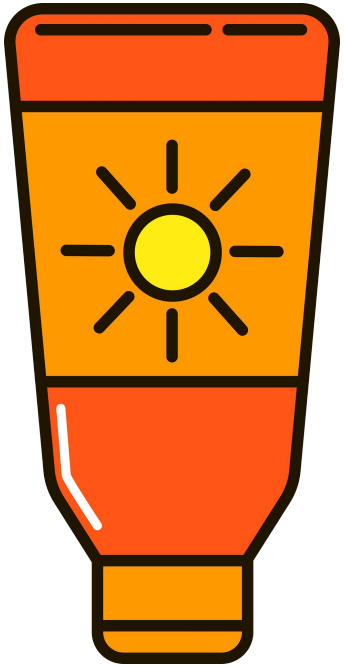
- Test product has an SPF of at least 15
- Obtains a critical wavelength (CW) of 370 after irradiation
- There must be protection over all of UVB and just over half of UVA

FDA 2021 Proposal

The FDA has ended their comment period and should be working on releasing a new monograph in 2022, per the timeline set forth in the CARES Act. Any procedural changes proposed are not definite and have no impact on the current testing procedures. No release date has been announced.

Items mentioned in the proposal:

- **Sunscreen active ingredients**
- **Maximum SPF levels**
- **Broad Spectrum requirements (UVA1 to UV ratio)**
- **Dosage forms**



FDA Ingredient Ban

Ingredients used for sunscreen formulation

Currently a ban and a request for additional safety information in certain sunscreen ingredients, such as but not limited to: avobenzone, oxybenzone and octinoxate is in effect. According to the FDA, studies show sunscreens containing these ingredients are harmful or could be harmful to human health, coral reefs, and marine life.

Due to this, we have seen an influx in mineral-based sunscreen formulations from all clients, in the US and internationally. The main two ingredients being used for new formulations are zinc oxide and titanium dioxide. Unfortunately, these are not consumer preferred ingredients

ISO Monograph:

Current ISO Regulations
ISO24444:2019 (Static)
ISO16217/18861:2020 (WR)
ISO24443:2012 (In-vitro)

In-Vivo (Testing on humans)

- Static
- Static/Water Resistance

SPF Claim Requirements:

- Minimum of 10, Maximum of 20 VALID subjects on the panel
- Maximum of 5 invalid subjects
- Standard Sunscreen Label SPF is within allowable range
- Mean SPF = Claim SPF by 5's

ISO is used for samples intended to be marketed internationally

In-Vitro (Testing on substrate test plates)

- ISO24443:2012

In-Vitro Claim Requirements:

- Obtains a critical wavelength (CW) of 370 after irradiation
- 95% Confidence interval is within 17% of the mean UVAPF value
- S2 Standard falls within acceptable range
- There must be protection over all of UVB and just over half of UVA

Where is ISO accepted?

ISO Accepted Regions

- Canada
- European Union
- ASEAN 10 Countries
- South Africa
- Mexico
- Chile
- Russia
- Israel
- Australia
- New Zealand
- India
- China
- Japan
- Taiwan
- Korea
- MERCOSUR 6 Countries

ISO24444:2019

Updates from newest monograph

- The definition of a MED was updated
- The mean ITA of the test panel must be within the range of 41 ° - 55° with a minimum of 3 subjects in 2 out of the 3 ITA band ranges
- Beam uniformity testing of solar simulators needing to be ≥ 90%
- Clearer application procedures for:
  - Viscous liquids and semi-solids
  - Powders
  - Foaming formulations
- New Standard Sunscreens for new testing SPF ranges were introduced:
  - P2,P3- SPF ≤ 24
  - P5, P6- SPF ≥ 25 but less than 50
  - P8- SPF ≥ 50
- Harmonization of reporting tables

ISO24444 Mar 2022 Amendment

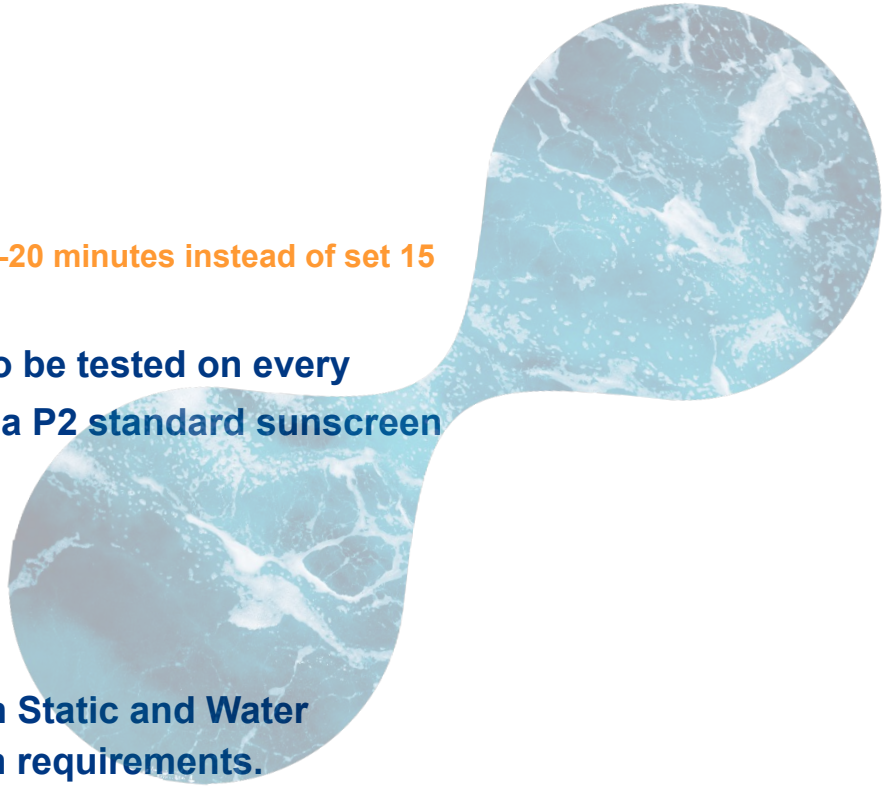
- The use of any standard sunscreen for test products with SPFs ≤ 24
- Removed the statistical test for reference standard sunscreens
- The uniformity testing for multiple beam solar simulators

ISO16217/18861:2020 WR

Updates from these monographs compared to Colipa 2005 WR

- **Water conditions:**
  - Increased temperature range
  - Electroconductivity minimum level determined
  - Flow rate of the water
  - Dry time during immersion cycles now range from 5-20 minutes instead of set 15 minutes
- **P2 Standard sunscreen is no longer required to be tested on every subject. Water Resistance Method validation via P2 standard sunscreen completed:**
  - Every 200 subjects

  Or
  - Every 2 months
- **% Water Resistance (Retention of SPF between Static and Water Resistance) is now based on local claim region requirements.**



ISO24443:2021

Implementation: Labs have until June 2022

- **Acceptance of sandblasted PMMA plates**
- **Introduction of new high UVA PF standard P8 (monthly calibration)**
- **Introduction of critical wavelength calculation**
- **Coefficient “C” accepted from the in-vivo screening or full panel SPF and new range set to 0.6-1.6**

Suncare Innovation Challenges

#1 Regulations

- UV filters (active ingredients) are regionally regulated
- Dosages and combinations

#2 Formulation

- SPF Performance
- Stability
- Application (feel on skin, spreadability)

Thank you for your time.

Contact us both at:

Nicki Kauffman
Lab Manager

Eurofins CRL Cosmetics, Inc.
Winston-Salem, NC
Tel.: +1 336-725-6501 ext 1202
nsimmons@suncarelab.com

Chelcie Mejia
Photobiology Manager

Eurofins CRL Cosmetics, Inc.
Winston-Salem, NC
Tel.: +1 336-725-6501 ext 1203
cmejia@suncarelab.com

Questions?