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TO: emlsecretariat@who.int

The Secretary

WHO Expert Committee on Selection and Use of Essential Medicines

Essential Medicines Team

Department of Health Products Policy and Standards

World Health Organization, Geneva

Application to add SPF50+ broad-spectrum sunscreen to the WHO Model List of Essential Medicines and Model List of Essential Medicines for Persons and Children with Albinism

Dear WHO Expert Committee Members,

As experts in the field of sun protection and skin cancer prevention from academia, industry, and standardization organizations, we wholeheartedly support the application to add UV-filters to the WHO Model List of Essential Medicines for Persons and Children with Albinism.

We would like to present some observations and remarks to substantiate our support:

Sematic Note

We would like to add a semantic note to the text. Often, no clear distinction is made between “UV filters” and “sun protection products”. The two are frequently grouped together under the general term “sunscreen”, which can lead to misunderstandings. We make a clear distinction between “UV filters” and “sun protection products”.

Unfortunately, a distinction is often made between “chemical” and “physical” filters. This distinction can be misleading, as all filters are chemical substances and the mechanism of action of filters is a physical phenomenon. Although the distinction between organic and inorganic filters is correct, it offers little added value for the application of filters. A simpler and clearer distinction is between “soluble” and “insoluble” (particulate) filters.

Reinstatement of UV-Filters in the Essential Medicines List After its Removal in 2005

UV-filters were initially included in the WHO Essential Medicines List (EML) but were removed in 2005 due to accessibility challenges rather than concerns about efficacy. Over the past two decades, UV-filters have become increasingly effective, and the market has expanded to offer more affordable options. This raises the important question of how to evaluate and choose UV-filters that are most beneficial for persons and children with albinism.

Meeting the SPF 50+ Requirement: Challenges in Performance Assessment of Sunscreen Products

Since 2010, the determination of Sun Protection Factor (SPF) has been standardized under ISO 24444. Assessing SPF in sunscreens can be expensive due to concerns over reproducibility between laboratories, which can vary by as much as ± 30% (see Reference Samples, ISO 24444, Annex C). In contrast, repeatability within a single laboratory is relatively consistent, with a deviation of ± 17% as outlined in ISO 24444.

Tools for Rapid Assessment of Sunscreen Product Performance and Cost Reduction in Testing

Currently, two simulation tools are available to assess the character and performance of sunscreen products: the Sunscreen Simulator from BASF (www.sunscreensimulator.basf.com) and the Sunscreen Optimizer from DSM-Firmenich (www.sunscreen-optimizer.com). By providing the composition of UV-filters, these tools can evaluate the character and performance of potential sunscreen products at no cost.

For further information on the scientific basis of these in silico methods, please refer to the following references:

1. Herzog B, Sohn M. The Formula for Best Sunscreen Performance: Beer-Lambert's Law Under the Microscope. Curr Probl Dermatol. 2021;55:133-143. doi: 10.1159/000517663.
2. Herzog B, Osterwalder U. Simulation of sunscreen performance. Pure Appl Chem. 2015;87:937–51. doi: 10.1515/pac-2015-0401

As sun protection experts, we are pleased to offer our expertise in evaluating and selecting the appropriate UV-filters for persons, including children, with albinism.

Thank you for your consideration.

Yours sincerely,

Uli Osterwalder I SPF GmbH I Chair ISO/TC 217 - COSMETICS

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Christian Surber, Ph.D., is Professor of Dermatopharmacology and Hospital Pharmacy at the University of Basel, and visiting Professor at the Departments of Dermatology in Basel and Zürich, Switzerland.
His research interest and expertise are

a) The in vivo assessment and optimization of drug delivery from topical formulations,
b) Topical delivery vehicle design,
c) Topical bioavailability /bioequivalence testing,
d) Topical pharmacotherapy of barrier function impairment (dry skin, atopic dermatitis, psoriasis) and solar damage (skin cancer),
e) Development of sun protective means
f) Patient and consumer adherence to topical pharmacotherapy and to topical protection and care products.

Christian Surber supervises doctoral students and teaches as a lecturer in Dermatology and Pharmacy at the University of Basel and Zürich and at the Swiss Federal Institute of Technology Zürich.

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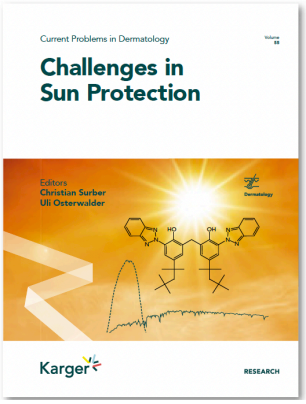
Uli Osterwalder studied chemical engineering at ETH Zurich, Switzerland, and at the University of Houston, Texas. He joined Ciba-Geigy in Basel in 1979, where he first developed a phosgene generator as part of core process development. He subsequently developed his skills in project management and process analysis. At Ciba Specialty Chemicals, Uli Osterwalder contributed to the development of new activities in the fabric care and personal care sectors. After the acquisition by BASF SE, he became Senior Marketing Manager and Scientific Adviser in Sun Care in Ludwigshafen and Duesseldorf.
In 2016, he returned to Basel and worked for DSM for two years as Senior Scientific Adviser for Sun Care products. In 2018, he set up his own company, Sun Protection Facilitator GmbH, and is committed to helping improve sun protection. Uli Osterwalder works for ISO on the development of new methods for assessing UV protection, and currently chairs ISO technical committee TC/217 (Cosmetics).
He is the author and co-author of numerous scientific articles and book chapters on sun protection.



Challenges in Sun Protection

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