Preface

People have protected themselves from solar radiation since time immemorial. Limiting time spent in the sun by seeking shade under trees or rocks was a matter of course. Pigments and plant extracts have also been used to prevent sun-induced skin damage or soothe irritated skin. Already in prehistoric times, inhabitants of the Arctic wore some sort of protective goggles with fine slits to protect from the glittering light during hunting. These concepts in sun protection are still valid but have been expanded and significantly refined over the past 100 years. In the 1940s, the first light-protecting sunscreen products became available. In the years that followed and until recently, a wide variety of sunscreen filters have been developed. They are incorporated into simple to advanced formulations to be easily and evenly distributed to ensure optimal protection of the sun-exposed skin. In addition to shade and clothing, the use of topical sunscreen products has become the third pillar of sun protection.

In recent years, a number of challenges have arisen in the development of topical sunscreen products that have captured the attention of research and development scientists, health care professionals, patients and consumers alike. The objective of the authors of this volume – entitled

Challenges in Sun Protection – was to compile selected topics on recent improvements, on controversies and obstacles and on new observations and developments.

Of great importance are (a) expectations towards task and performance of sunscreen products, (b) safety and (c) regulations.

Expectations towards Task and Performance of Sunscreen Products Influence Perception

Over the past 50–70 years, expectations towards the task of sunscreen products have been continuously changing. Initially, the focus was on protection against sun-induced erythema (tan without burn). Later, triggered by clinical and experimental observations linking sun exposure to the formation of skin cancers and skin ageing, the expectation arose that sunscreen products should prevent different types of skin cancer and premature skin ageing. Experimental research on effects of specific radiation ranges beyond ultraviolet light to identified additional hazards from blue, visible and infrared light. On the basis of these results, a new product range was created that was to offer additional protection with ex-

traordinary claims. In the context of ultraviolet light, degree of exposure and resulting health impact are clinically proven. Associations between blue, visible and infrared light and potential resulting hazards (e.g., reactive oxygen species and signs of skin ageing) have been identified experimentally in vitro and in vivo. However, the clinical relevance of this protection is still controversial.

Every expectation towards a task is closely linked to the expectation towards an associated performance. For the determination of the ultraviolet protection performance of sunscreen products, several, including standardized methods, have become available (e.g., $\text{SPF}_{\text{ISO24444}}$). They allow a categorization of product protection performance. However, recent observations have revealed two important limitations: (1) Despite a high degree of standardization, a large inter-laboratory variance in the determination of the sun protection factor ($\text{SPF}_{\text{ISO24444}}$) is observed. This raises questions concerning the reliability of the claimed SPF on the product packaging and the verdicts of the consumer protection organizations on unmatched SPFs, particularly when based on a single determination in only one laboratory. (2) The confined radiation spectrum used by the $\text{SPF}_{\text{ISO24444}}$ methods produces SPF values that are much higher than SPF values that would be obtained when using natural solar radiation. This reveals that the often-promoted method of calculating the protection time in the sun by multiplying the SPF value with the intrinsic protection time leads to erroneous conclusions. For the determination of protection performance against blue, visible and infrared light, several in vitro and in vivo methods have been proposed. None of these methods have been standardized, and performance categorization has not been established so far.

The changing expectations towards the task and the performance of sunscreen products have also shaped our perception. Originally, sunscreen products were intended to enable tanning with-

out sunburn and simply to open up the opportunity to stay in the sun longer. According to the spirit of the times, sunscreens were intended to support the preservation of health and beautification of the body. Later, when excessive sunlight exposure and sunburn were linked to the risks of skin cancer, photoageing sunscreen products became a way to prevent skin cancer and avert photoageing. Today, advertising, media and recommendations serve the perception of sunscreen products as tanning enabler, skin cancer preventative and an averter of skin ageing.

Safety: Percutaneous Absorption, Nanoparticulate Filters, Endocrine Activity and Environmental Issues

Requirements for the safety of sunscreen filters and sunscreen products are explicitly ruled in all three regulatory categories – medicinal products, medical devices and cosmetics. Recent US Food and Drug Administration (FDA) testing (2019/2020) has shown that some common filters from sunscreen products used as labelled are absorbed into the body and may linger in some cases for days or even weeks. The observed filter concentrations in the blood were beyond the FDA's threshold for determining if they need more study to consider the filter safe for use. More recently, the European Scientific Committee on Consumer Safety (SCCS) (2020/2021) has published opinions on three filters (benzophenone-3, homosalate and octocrylene) used in the FDA testing and concluded that the data are not entirely conclusive but that they were safe when used at the partially reduced maximum use concentrations. Such (seemingly) contradictions are comprehensible only to those who know the regulatory texts in the very last detail. For most people, the only thing that remains is a great uncertainty that weakens (in an unjustified way) the credibility of the authorities in the eyes of many. This uncertainty is reinforced by the media and may

account for the wide dissemination and popularity of decipher application, which gives consumers possibility to find alternative safety information on specific substances and products. At the same time, it is completely overlooked that this information has not been subjected to a broad in-depth review process by proven experts.

The size of nanoparticulate sunscreen filters leads many to suspect – affirmed and reinforced by the media – that the particles permeate the skin, are absorbed by the blood and are distributed throughout the body, causing illness. The idea that the small size of nanoparticles was responsible for their absorption through the skin frightened many but made them forget that all other approved filters are smaller by dimensions. Increasing the sunscreen filter size by creating a molecular glomerate is a proven way to decrease (bio)availability and increase safety. One may certainly conclude that nanoparticulate sunscreen filters are bigger than all non-nanoparticulate sunscreen filters.

The endocrine activity of substance after gastrointestinal, pulmonary or percutaneous absorption is known. It is intentionally used for contraception but can also be harmful. For some sunscreen filters, such activities have also been described and subsequently are no longer permitted as filters in sunscreen products. Requirements of various authorities demand a detailed assessment of this safety criterion for the approval of sunscreen filters. Similar to nanoparticulate sunscreen filters, the topic is extensively considered in the media and often presented in a distorted manner. Here, too, fear is omnipresent among the general population.

Medicines and cosmetics, sunscreen products included, that we use contain substances that sooner or later reach our waters. These substances can be detected in various bodies of water around the globe, including remote waters in the mountains or the Arctic. Reports on the harmful effects of sunscreen filters on corals have attracted particular attention. The issue is of great

relevance, but in essence, it concerns not only sunscreen filters but also all substances that we release into the environment. Algorithms to identify the most environmentally friendly and efficient sunscreen filters for use in sunscreen products are currently under development.

Sunscreen Regulation: Confusion with the Categories

Although sunscreen products have been around since the 1940s, they were not regulated until about 1980. Since then, a globally very heterogeneous regulation has developed. Most likely, on the basis of the understanding of opinion leaders in the legislative bodies of the given regions at that time, sunscreen products were allocated into three different regulatory categories: medicinal products, medical devices and cosmetics. Although the performance assessment and the safety requirements for sunscreen products and filters in all three categories are comparable, the situation has created confusion, insecurity and unequal access to effective sunscreen filters. Harmonization efforts are underway, but solutions seem remote.

Against this background, we compiled a series of selected papers written by experts covering (a) general aspects of sun protection, (b) sunscreen formulations and performance, (c) sunscreen filters/products and safety, (d) sunscreen products and regulatory aspects, (e) sun protection in everyday life and finally (f) controversies and challenges with sun protection and sunscreen products.

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