Solar Protection Via Space; SPF Testing Discrepancy

Most of my recent columns have dealt with sunscreen regulations or the lack thereof. Regulation proceedings are at a standstill due to the change in Administration and the COVID-19 epidemic, so this column is focused on other sunscreen developments and issues. This column details a novel development in the industry, as well as sunscreen SPF testing and why many sunscreens do not meet the SPF claims on their products.

FROM SPACE AND BACK

A novel new development in solar radiation protection that originated from space research was announced by Liberty Biosecurity, regarding a unique biological isolate obtained from a national government space exploration agency that affords significant UV shielding properties.[1] This new ingredient, registered in 2020 as Bacillus lysate, has shown the ability to absorb broad spectrum UV insults spanning the UVC, UVB, UVA, HEV and the near IR range. A safe, environmentally friendly, natural biological technology that affords protection from radiation emitted throughout the solar spectrum, it may provide both industry and clinicians with a breakout capability. The timing of this invention is excellent, as it coincides with an expanding body of research examining the human health implications of chronic exposure to these wavelengths in terms of hyper-pigmentation, erythema, inflammation and stimulation of reactive oxygen species that may produce conditions in tissues more favorable to causing disease and skin cancer.

The latest innovation in sun care has its origins in space.

Bacillus lysate is currently produced at a European pharmaceutical facility and will debut this year as an SPF booster in skin care products for the protection from the harmful solar radiation (UV, HEV, IR). This research has the potential to create drug candidates to replace and/or complement the current UV absorbing ingredients that have come under increasing pressure by consumers, environmentalists, regulators and healthcare professionals. The most fascinating aspect of this research was the observation that the bacteria managed to survive on the exterior of the Earth-orbiting satellite by being resistant to chronic UV radiation, especially UVC! Working with organisms that are discovered at the "extreme" boundaries of nature—high temperature, high pressure, high radiation and other environments that are hostile to most life forms enabled Liberty Biosecurity to bring this innovation to consumers.

Another biological development in this field that has not yet seen the light as a UV protectant has been the research conducted on the use of biocompatible mycosporine-like amino acids (MAA), which occur naturally in a wide range of marine species.[2] Their potential for human protection has been understudied. Those developments in biological research that may lead to ingredients with significant UV and other solar radiation potential are exciting and promise to produce safe, natural and truly effective sun care protection products in the future.

SPF TESTING DISCREPANCY

The currently approved SPF test affords a "relative" number, not an "absolute" number. Individuals may vary significantly from one another. However, the SPF number affixed on the label of a sunscreen product should be consistent for the same formulation throughout the product's shelf life. The SPF test has performed reasonably well and has provided adequate sun protection guidance for years. The ultimate answer for why SPF tests show discrepancies, and are not as reliable as we would all hope for, is the fact that this test is not performed using accurate scientific machinery or tested by actual sunlight exposure. Rather, it relies on human subjects and is evaluated by human technicians and, most importantly, relies on artificial solar simulators that do not entirely replicate the sun's actual fluctuating daily and seasonally variable solar radiation.

The test is performed in-vivo by applying the sunscreen product on the backs of volunteers with skin types I, II and III (as defined by Fitzpatrick). The volunteers are usually screened for any dermatological or system disorders, free from acute or chronic disease, with no uneven tones, pigmentation, scars, hair or other irregularities that interfere with the SPF study. Nevertheless, even in a perfect world, variants exist. The technicians will "visually" grade the erythema on a scale of 0 to 5; hence, variations from one technician to the other, even one laboratory to another, will undoubtedly reveal differences. More importantly, the amount applied and evenly spread by the technician on the backs of volunteers may be non-uniform, with varying

Nadim Shaath
Alpha Research & Development Ltd
alpharnd@aol.com

Dr. Nadim Shaath is the president of Alpha Research & Development, Ltd. in White Plains, NY. He has over 30 years of experience as chairman of the chemistry department at SUNY-Purchase and the CEO of Kato Worldwide. Recently he published his new book entitled "Healing Civilizations: The Search for Therapeutic Essential Oils and Nutrients" Cameron Books, Petaluma, CA.

film thickness, that will undoubtedly affect the SPF determinations. The artificial light source is a 150-watt Xenon Arc solar simulator with a continuous emission spectrum from 290 to 400nm. This requires filters to ensure that no radiation below 290nm and above 400nm is emitted. Obviously, machinery varies slightly from one another and, in fact, other light sources are used in SPF protocols in other countries outside the US. Consider the Australian/New Zealand standard write up for the evaluation of sunscreen products.[3] On page 19, Appendix D, they admirably address the experimental and statistical considerations that deal with the inherent uncertainties in determining SPF values. Most testing facilities are aware of those uncertainties and have their own internal procedures to adequately address them.

Another major factor that contributes to the potential inconsistencies of SPF test results, from one laboratory to the other, is obviously the sunscreen cosmetic formulation itself. I am not addressing here the errors in production of the product or the use of expired products, but rather the type of formulation and the ingredients present in the product. Is it a sunscreen that is made with inorganic particulates (mineral sunscreens), or is it made with UV absorbing organic molecules? Generally, mineral sunscreens have more variations in their SPF claims than those made with traditional UV absorbing organic filters. Does the rheology of the formulation and its ease of "spreadability" on the volunteer differ from one product to the other? Does the sunscreen cosmetic product contain any anti-inflammatory ingredients that can affect the SPF value? Are there any photostable ingredients? Are they photo stabilized adequately?

These statements are not meant to declare that our current protocols for SPF determination are lacking or generally unreliable, but rather to be aware of and understand those discrepancies and to inform the consumer that variations are possible in this "relative" test. The consumer should be aware of this fact and not rely solely on a sunscreen product to prevent a sunburn or skin damage while "baking" in the hot sun for hours without adequate clothing, umbrellas, hats, glasses or not avoiding intense exposure during the peak hours of 10 AM–3 PM. These other precautions must be adhered to and should be the clear message that is consistently delivered to consumers. ■

References:

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