

SHADOWS CAST ON SUNSCREENS

IN THIS COLUMN, I have been documenting the upheaval and unrest that continues to mar the sunscreen landscape. The lack of final regulations from the FDA and the absence of a proactive and effective response from the American Academy of Dermatology (AAD), the Personal Care Product Council (The Council) and cosmetic companies encouraged bloggers and environmental groups, most notably the Environmental Working Group (EWG), to cast doubts on the efficacy of sunscreens as a primary protocol to protect consumers from the ravages of the sun and skin cancers.

The EWG issued, on May 24, its fourth annual sunscreen report containing a stinging and misguided indictment of the current crop of sunscreen products on the US market.¹ The report provided sweeping premature conclusions, including the assertion that only 8% of sunscreen products are safe and effective. EWG called for a ban of retinyl palmitate (vitamin-A derivative) and oxybenzone (benzophenone-3) from all sunscreen products and questioned the use of spray and powder sunscreen products as well as products with an SPF higher than 50.

EWG's report casts a shadow of doubt on the use of sunscreens as an effective protocol for sun protection with insinuations that sunscreen products may be contributing to the epidemic rise of skin cancer. In fact, Jane Houlihan, vice president, EWG, called most of the best-selling sunscreens in the U.S. "the equivalent of modern-day snake oil."

A Controversial Report

The authors of the EWG sunscreen report claimed that their methodology is based on an in-house compilation of standard industry, government and academic data sources, and a thorough review of the technical literature (see EWG's *Flawed Methodology* on p. 46). As a result, only 39 of 500 sunscreen products (8%) were deemed safe and effective. None of the major brands were on this list with the exception of La Roche-Posay Anthelios 40 sunscreen cream, and even it ranked 34th! EWG's conclusions were in sharp contrast to the study released on May 26 by *Consumer Reports*.² Four spray sunscreen products topped the Consumer Reports (CR) list, namely Target Up&Up Sports Continuous Spray 30, Walgreens Sport Continuous Spray SPF 50, Banana Boat Performance Continuous Spray 30 and Aveeno Continuous Spray SPF 50. Yet, all four of them would rank very poorly and would not be recommended by the EWG.

The industry, The Council, and the AAD's response to this report has been swift albeit defensive. In his response, Dr. John Bailey of the PCPC countered that the EWG report made baseless assertions that "may lead consumers to abandon use of science and question their science."

He added that the "EWG calculation of SPF values has been proven to be inaccurate and unreliable by sunscreen experts" and that the report "lacks scientific credibility" and "represents a disservice to those working to decrease the incidence of skin cancer."

Dr. Henry Lim from the Ford Hospital in Detroit countered by reporting that studies

on retinyl palmitate are based on the testing of mice, which are more susceptible to skin cancer than humans. Regarding oxybenzone, he noted "animals were fed significantly greater amounts than commonly applied in sunscreen products."

Dr. Alan Cooney at Rutgers University remarked "epidemiological studies would be needed to determine whether humans are at risk."

Dr. Darrel Rigel from New York University noted that since "vitamin A is used in skin cancer treatment, then the EWG claim is a dubious one." He added that "there is little merit to the claims. They are arguing that because vitamin A thins the skin, it makes us more susceptible to skin cancer, but there is no evidence that even suggests that. Tens of millions of Americans use these sunscreens and we have not seen any problems."

The peer review study on retinyl palmitate is expected to be released by January 2011 by the Technical Report Review Subcommittee (TRRS). The FDA has said that it is too early to draw conclusions. Moreover, the cosmetics containing retinyl palmitate have not been tested with sunscreens. In fact, Dr. Joshua Zeichner, a New York dermatologist, insists that the absence of sunscreens in the initial study is a significant element. "We know that vitamin A and sun do not mix," he said.

A Response Is Needed

We need an adequate scientific and technical response to the EWG report, which ironically claims to be scientific and technical. It should be followed by an extensive campaign by the AAD, The Council, Skin Cancer Foundation, AMA and every major sunscreen marketer, especially Johnson & Johnson, Merck, Energizer, L'Oréal, BASF and others emphasizing the need for sunscreen products as a primary protocol for protection and presenting the science behind the design of sun care products and ingredients.



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EWG's Flawed Methodology

EWG RATED PRODUCTS for overall safety and efficacy in sun protection considering two major factors, namely the health hazard and the sunscreen efficacy (sun hazard). The final score (0 through 8, with 0 being the safest and most effective) is calculated by combining those two factors roughly equally.

The health hazard of the listed ingredients, according to EWG, is based on a review of nearly 60 standard industry, academic, and government regulatory and toxicity databases. The sun efficacy is calculated based upon four factors: 28% for the UVA protection, 28% for the UVB protection, 28% for the UVA/UVB balance and 16% for the stability (presumably the photostability).

EWG does not conduct any actual efficacy/photostability tests on the sunscreen products. The information is taken from the product label regarding SPF, individual sunscreen actives and their concentrations, computing the transmission spectrum for the combination of actives, and using this spectrum for further calculations and ratings.

This methodology leads to the following inconsistencies:

1. EWG's analysis of sunscreen effectiveness that is based in part on the absorbance spectrum of each active ingredient is ignoring the role of the delivery system, SPF/PFA boosting and photostabilizing technologies, which can significantly increase the overall UVA/UVB efficacy and photostability parameters of the formulations.

2. EWG is evaluating the products' balance for UVA/UVB protection and assigning arbitrarily a score based on the ratio of UVA-PF to the labeled SPF, which is similar to COLIPA 2009 parameter, but without utilizing the specific pre-irradiation step/conditions recommended by COLIPA 2009.⁴ EWG is also completely ignoring UVAI/UV Ratio after

pre-irradiation—a comprehensive efficacy parameter proposed by the FDA in 2007.⁵

3. EWG is utilizing in its stability scoring/classification the extent of photodegradation after two hours of peak intensity exposure (10 MEDs); this pre-irradiation dose of 10 MEDs can be sufficient for SPF 15 sunscreen formulation, but is definitely not sufficient for the SPF 30 to 50 formulations. Apparently EWG is not considering the SPF value of the formulation—while suggesting the 10 MED as “universal” pre-irradiation dose as sufficient for all sunscreen products. This completely ignores the FDA 2007 proposed rules and COLIPA 2009 recommendations regarding required pre-irradiation doses for photostability testing.

As a result, many effective formulations that were extensively tested in vitro/in vivo for their safety/efficacy did not get EWG's approval. Despite their elaborate methodology, which was summarized in 31 pages of their report, the final rating in the end practically depended on four factors:

1. The presence or absence of retinyl palmitate;
2. The presence or absence of oxybenzone;
3. If the SPF of the product was higher than 50; and
4. If the sunscreen was either an aerosol or powder.

Products that contained one of the above four factors had a final score of not less than 3 (borderline) whereas products that contained two or more of the above four factors cannot score better than a 7 (dangerous!).

Thus the health hazard as defined by EWG dictated the overall rating of products regardless of their sunscreen efficacy. That is misleading the consumer and as NYU's Dr. Darrel Rigel concluded recently “Cancer-fear mongering would lead people to not using sunscreens. That is what the real danger is.”

More importantly, the FDA should issue the Final Monograph and the TEA of the new UVA ingredients to restore immediate confidence to the consumer. In May, a group of about 100 scientists and practitioners in the field petitioned the FDA to release the Final Monograph and the TEA.³ The FDA has since separated the finalization of these two issues and, presumably, will issue the report on the TEA ingredients this month and the Final Monograph in October. Amen!

Sunscreen manufacturers should pay closer attention to the barrage of criticism that is circulating in the press, on the internet, and among consumer advocacy groups. This includes paying specific attention to the manufacturing of sunscreen products that are truly broad-spectrum, photostable and offer adequate UVA and

UVB protection. They should also abandon the race for higher and higher SPF factors and provide sound reasoning and justification for the need for SPF products of 50+. Finally, they should investigate the safety of nanoparticles, oxybenzone, retinyl plamate and any other ingredient that is currently under scrutiny.

While segments of the EWG report have merit, the rating system needs a major overhaul. EWG's sweeping conclusion that sunscreens are “modern-day snake oil” is unwarranted sensationalism and a headline-grabbing tactic. Recommending that consumers use only hats, shade and protective clothing as the primary methods of protection is impractical and, perhaps, unwise. Wild claims about such serious subjects can only lead to chaos. ●

References

1. <http://www.ewg.org/2010Sunscreen/>
2. <http://www.consumerreports.org/>
3. The Sunscreen Filter, May 2010, *Happi*
4. Matts, P.J. et al. “The COLIPA invitro UVA method: A standard and reproducible measure of sunscreen UVA protection. *J. Cosm. Sci.*, 2010, 32, 35-46. COLIPA (2009) recommends pre-irradiation dose D equal to $UVAPF_0 \times D_0 \text{ J/cm}^2$; D_0 is unit UVA dose per unit $UVAPF_0$, to be applied with the UV source spectrum, experimentally determined to achieve a fair correlation between in vitro $UVAPF$ and in vivo PPD values; D_0 value is $1.2 \text{ J/cm}^2 \text{ UVA}$.
5. Fed Reg 49070-49182, August 27, 2007. FDA recommends pre-irradiation dose equal to SPF of sunscreen product multiplied by $200 \text{ J/m}^2\text{-eff}$ (an equivalent of 1 MED) multiplied by 2/3; according to the FDA, SPF 30 sunscreen would require pre-irradiation dose of 20 MEDs.

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