

5-STAR RESEARCH; BELOW PAR RATINGS

CONFLICTING NEWS ON the benefits and dangers of sunscreen and skin cancer has saturated news both in print and online for the past few months. Several interesting reports on new ingredients as well as sun care formulations have surfaced. In addition, the last vestiges of regulations and testing protocols were recently reported. With all the contradictory available information, we need some clarity; it is time, once again, for THE SUNSCREEN FILTER.

Let me first review the recent developments on the controversial topic of the benefits and drawbacks of sun protection by the application of sunscreens to prevent skin cancers.

Retinyl Palmitate

Earlier last year, the Environmental Working Group (EWG) highlighted preliminary FDA observations on the potential negative impact of using retinyl palmitate (RP) in sunscreen formulations.¹ They advocated the omission of RP in sunscreens and, in fact, implemented a heavily skewed negative rating on any sunscreen product that

utilizes RP in its formulations. Dermatologists and the Skin Cancer Foundation defended the use of RP which contributed to the controversy surrounding the safe and effective use of this ingredient in sunscreen formulations.² Last month, the National Toxicology Program (NTP) published its final report on RP and concluded that its use in sunscreen formulations does contribute a negative impact on its safety and effectiveness.³ Obviously, this will not be the final word on banning RP in sunscreens, but for the time being, the controversy over its usage continues.

Does Sunscreen Prevent Skin Cancer?

Concerning whether sunscreens prevent melanomas, a number of credible reports have been published recently. In an interview with HAPPY (January 2011), Dr. Steve Wang, from the Memorial-Sloan Kettering Cancer Center in New York, stated that regular sunscreen use provides benefits in preventing squamous cell cancers (SCC), but the data on sunscreens preventing melanoma is inconclusive.⁴ A number of studies have been published recently including a report by Dr. Marianne Berwick from the University of New Mexico that appeared in the January 2011 issue of *Clinical Pharmacology and Therapeutics*. In her article, she concluded that sunscreens offer questionable protection from melanoma cancer.⁵

Fortunately, she also stated that "I would never tell anyone not to wear sunscreen. It's just that they feel like they're bulletproof if they've got it on." She added, "Death from skin cancer is advertised as being avoidable with the use of sunscreens. This position might actually be true, but



there is as yet absolutely no scientific evidence to support it."

An earlier Australian study, published in the *Journal of Clinical Oncology* in December 2010 involving 1,600 people in Queensland, showed for the first time that daily sunscreen application can prevent potentially deadly melanoma.⁶

Adding to the confusion, seven UK health organizations are urging the population to get sun. The Cancer Research UK and the National Osteoporosis Society in the UK have reversed decades of warnings about the presumed dangers of sun exposure. The seven groups now cooperatively agree that humans need regular vitamin D.⁷ Studies have found that about 70% of whites and 97% of blacks are deficient in vitamin D. A recent news poll in Australia has shown that 62% of Australians believe that it is safe to spend some time in the sun without sunscreen.⁸



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Ingredients

On the positive side, a number of ingredients for skin cancer protection were recently presented. They include:

1. A recent study spearheaded by Craig Elmets from the University of Alabama was published in the *Journal of National Cancer Institute*⁹ that showed that Celecoxib chemoprevention may reduce non-melanoma skin cancers. The efficacy and safety of Celecoxib (Celebrex, an arthritis pill by Pfizer) were evaluated as a chemopreventive agent for actinic keratoses and nonmelanoma skin cancers, including cutaneous squamous cell carcinomas (SCCs) and basal cell carcinomas (BCCs).

2. Scientists in the U.S. have tested broccoli extract on human volunteers and mice, and showed that their skin was protected against sunburn. Broccoli contains an antioxidant called sulforaphane, which reportedly reduces sunburn and tumor development. Scientists in New Zealand have also suggested that extracts from Totara and Manuka trees could act in a similar way to broccoli.¹⁰

3. A study published in the *British Journal of Dermatology* reviewed extracts from the *Cordyceps* fungus and found that they could help protect the skin from damage caused by UVB radiation.¹¹ The polysaccharides in the fungus may offer photoprotection and help lower the risk of basal cell carcinoma (BCC).

4. A study conducted at the Medical College of Georgia highlights how antioxidants can be used to pre-treat skin cells to reduce a protein, Kinase-D, which the researchers have identified as playing a key role in the proliferation of skin cancer cells.¹²

5. An extensive study was published in the *Journal of Cosmetic Sciences* (October 2010) on the influence of purple sweet potato extracts on the UV absorption properties of a cosmetic cream.¹³ Anthocyanins extracted from the purple sweet potato were added to a cosmetic cream to provide additional protection against UV radiation.

Regulations

One of our favorite topics, regulations, or

lack of them, includes the issuance of the FDA Final Monograph and the status of the TEA list of actives. No regulations were finalized last year. Meanwhile, the U.S. Department of Health and Human Services published, on December 20, 2010, its "Unified Agenda," which announced what regulations will soon be published.¹⁴ Conspicuously absent is a date for when the Final Monograph (the UVA/UVB Final Action) will be available. HHS does, however, state that the next step for the Time and Extent Application (TEA) will be in April 2011.

These are the seven ingredients under consideration for adoption in the U.S. Without them, it is not possible to achieve a 4-star UVA rating for a product. In a recent study by Dr. Olga Dueva and myself, eight SPF 100+ products on the U.S. market were evaluated and we found that no products could claim a 4-star rating.¹⁵

The FDA revealed the Final Phase of its Transparency Initiative in January 2011.¹⁶ This initiative is intended to improve the transparency of its rule making process within the industries it regulates. FDA commissioner Margaret Hamburg said, "Clarity and consistency are pillars of an effective regulatory system that efficiently regulates products essential to health. In order to succeed, the FDA must clearly communicate standards and expectations to the industries it regulates." Let's hope that this

clarity is communicated effectively, and soon, with the publication of the Final Monograph and the TEA ingredients.

In New Zealand, the cosmetic regulations were updated allowing companies until Oct. 31, 2011 to comply with all the changes. In the U.S., the Cosmetic Regulations and the Safe Cosmetics Act of 2010 are still under review. Regulations, skin cancer and ingredients will be reviewed at the Florida Sunscreen Symposium, Sept. 15-17. The Society of Cosmetic Chemists Annual Scientific meeting, held Dec. 9-10, 2010 in New York City, had a scientific session on sun protection. Unfortunately, regulations were not discussed; instead, three papers were presented on nanoparticles, inorganic UV filters and an antioxidant ingredient useful in sunscreens.¹⁷

Point of Contact: Consumers

The application of scientific analysis comes at the point of contact, where the consumer uses the carefully designed sun care product. Are consumers receiving the product and the information they need? Two interesting scientific reports on consumer products appeared recently. The first, by Wang, Goulart and Lim, was published in the *Archives of Dermatology*.¹⁸ They evaluated 29 products with ultraviolet ingredients and found that at least six products contained no active ingredients for UVA1 protection. Of the remaining 23 products, only three



In one study, researchers found many products lacked the proper UV protection factor.

contained zinc oxide concentrations of 5% or more, and another three had photostabilized avobenzone in their formulations. The study concluded that many day creams do not offer long-wave UVA protection. The second study, conducted by Dueva-Koganov and Shaath,¹⁵ evaluated eight SPF 100+ commercial products for their in-vitro UVA protection. We found that none of them qualified for four stars, the “highest UVA protection” criterion. Measurements of the contact angle of water to the surface modifying effects of test products on skin-substitute substrate, suggested similarities in sensorial profiles for certain SPF 100+ products.

How do these studies relate to the sales of sun care products to the consumer? Most consumers are not delving into scientific journals and yet they are concerned and seek information. How does this information reach the consumer? A joint report by an online information network “BlogHer” and DeVries, a public relations firm, found that blogs are more than twice as likely to inspire cosmetic and beauty purchases as magazines.¹⁹ Cosmetic companies should focus their efforts on what bloggers are writing about their products. Filling the void in the absence of officially sanctioned regulations, blogger posts, their conclusions and their interpretation of the scientific literature on the safety of products, regulations, photoprotection and skin cancers, all impact consumer decision-making. ●

References

1. www.ewg.org/2010sunscreens
2. www.aad.org/media/backgroundnews, “Analysis Finds Sunscreens Containing Retinyl Palmitate do not Cause Skin Cancer,” Aug. 10, 2010.
3. <http://ntp.niehs.nih.gov>
4. Wang, S., HAPPI, January 2011, “Uncovering the Controversies Which Cloud Sunscreens.”
5. Berwick, M. et al., *Clinical Pharmacology and Therapeutics*, January 2011.
6. Green, A. et al., *Journal of Clinical Oncology*, Dec. 6, 2010
7. <http://truthonmedicine.wordpress.com/2011/01/13>
8. <http://www/sls.com.au> (News poll conducted online in November 2010 among n=1,209 adults aged 18-64).
9. Elmetts, C., et al., *J. Natl. Cancer Institute* 2010; 102:1-10.
10. <http://www.zeenews.com>
11. Wong, W., et al., *British Journal of Dermatology*, December, 2010.
12. <http://www.cosmeticsdesign.com/content/view/print/346329>
13. Chan, C., et al., *J. Cosmetic Sci.*, 61, 331-341 (October, 2010)
14. Department of Health and Human Services, Dec. 20, 2010, Unified Agenda, www.Regulations.gov
15. Dueva-Koganov, O. and Shaath, N., HAPPI, December 2010, “Comparative Evaluation of Commercial SPF 100+ Sunscreen Products.”
16. www.HHS.gov, January 2011.
17. Soc. of Cosmetic Chemists Annual Scientific Meeting, Dec. 9, 2010, New York.
18. Wang, S., Goulart, J. and Lim, H., *Arch. Dermatol.*, Jan. 17, 2011.
19. <http://www.cosmeticsdesign.com/content/view/print/352839>