

# Dermatologists, Patients, Consumers, and Sunscreens

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The safety of sunscreens recently has been challenged by a variety of consumer watchdog groups concerned that absorption of filters may cause cancer and estrogenic effects on the body. Sunscreens are considered over-the-counter drugs and are regulated by the government because of safety issues regarding filters, including which filters can be used, their concentrations, and their combinations. To market sunscreens in the United States, manufacturers must follow the rules set forth in the sunscreen monograph, which are some of the most restrictive for approved filters.

At present, only a tentative monograph has been approved, but this past summer, the US Food and Drug Administration brought forth some ideas in a guidance to assist manufacturers and solicit comments on a variety of important issues.<sup>1</sup> This article examines the safety of sunscreens, as patients might read about the new sunscreen guidance and request additional information.

## Method of Risk Assessment for Sunscreens

Sunscreen safety is carefully studied through hazard identification, risk characterization, and dose-response assessment. Sunscreen risk assessment is performed by applying the product in the equivalent amount of 64,000 cm<sup>2</sup> every 2 hours over 1 day of UV exposure. The application of 2 mg/cm<sup>2</sup> every 2 hours is equivalent to approximately 1 bottle of sunscreen daily; this amount is required to demonstrate a product's safety.

The safety of sunscreen filters must be evaluated as well as other ingredients in the vehicle. It may surprise many consumers that the preservatives used in sunscreens are more problematic than the filters themselves. Most preservatives are antimicrobial and therefore possess some

intrinsic toxicities. All products containing preservatives, including sunscreens, possess some risks. To this end, sunscreens should not be ingested. Children who often put their hands in or near their mouths should wear protective clothing instead of sunscreen to avoid accidental ingestion. The use of sunscreens or sunscreen-containing moisturizers should be avoided at night, minimizing unnecessary sunscreen exposure. Sunscreens should be used sparingly and carefully only when required. Remember that sunscreens are over-the-counter drugs; this regulatory classification is deemed necessary by the government for the protection of the public.

The safety of the majority of UV filters was reviewed in 1978. There are now 16 active ingredients included in the monograph.<sup>1</sup> Only certain concentrations and combinations are allowed. For example, avobenzone cannot be used in combination with titanium dioxide,<sup>1</sup> even though this combination has been demonstrated to be safe by industry-marketed sunscreen products around the world. Concerns have been raised that avobenzone might be absorbed by titanium dioxide, making the avobenzone less effective. Nine filters comprise the majority of sunscreen products. The use of avobenzone has greatly increased with a decrease in octyl methoxycinnamate and an increase in octocrylene, which can be used to photostabilize avobenzone. These changes in the utilization of sunscreen filters certainly will change exposure patterns to the public and reports of resulting problems.

## Nanosized Titanium Dioxide and Zinc Oxide

One of the biggest controversies in sunscreen safety is the use of nanosized titanium dioxide and zinc oxide. Consumer watchdog groups have issued Internet warnings stating that nanoparticle zinc oxide can "damage organs when absorbed into the bloodstream after being absorbed by the skin, lungs, or gut," which begs the following question: Can nanoparticles that are topically applied to the skin actually be absorbed through the stratum corneum? Theoretically, the answer is yes, but in actuality, it is no.

First patented in the 1980s, nanoparticle titanium dioxide and zinc oxide are not new technologies. Nanoparticle sunscreen products have been on the market since the

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1990s; however, when the federal government expressed safety concerns, all large sunscreen manufacturers stopped production of these products because of legal concerns. Nanoparticles may be valuable components in sunscreens because their small size can make titanium dioxide and zinc oxide invisible due to particles that are smaller than a wavelength of light. When titanium dioxide and zinc oxide are used in this form, they behave more like organic sunscreens with less UV scattering and more absorption.

Nanoparticles aggregate through chemical bonds and then agglomerate due to van der Waals forces. Despite their small particle size, aggregation and agglomeration of nanoparticles form clumps that are larger than the individual nanoparticles, thereby obviating penetration concerns. Studies on nanoparticle penetration demonstrated no dermal penetration in sunburned skin and skin afflicted with psoriasis. Although there may be safety issues related to their crystalline structure, new technology that coats the titanium dioxide or zinc oxide with nylon prevents structural issue concerns.

### **Oxybenzone**

Benzophenone-3 is reported to be an endocrine disruptor in vitro. After topical application, benzophenone-3 is bioavailable, which is confused with toxicity. The Environmental Working Group raised concerns about its safety in sunscreens used on children.<sup>2</sup> Sixty percent of beachwear products contain oxybenzone. It can be recovered from the urine and the serum, but it has never been shown to be toxic. Benzophenone-3 has been linked to binding sites for estradiol. Rodent endocrine effects are hard to extrapolate to humans, as it would take years to develop an equivalent cumulative dose. A concentration of up to 6% can be used in sunscreens, which is considered to allow for a large margin of safety.

### **Carcinogenicity and Sunscreen Products Containing Retinyl Palmitate**

Another controversial topic is the photocarcinogenic activity of retinyl palmitate in sunscreens. Some watchdog groups have stated that retinyl palmitate enhances the photocarcinogenic activity of simulated solar radiation. Retinyl palmitate is reversibly formed in human skin and serves as an endogenous storage form of retinol. Retinyl palmitate is not a synthetic retinoid but commonly is found in cosmetics as an antioxidant in concentrations less than 0.05%. The carcinogenicity of retinyl palmitate was studied in SKH1 hairless albino mice that possessed thin skin and no melanin. Although this model may be useful, it may not represent human skin behavior.

Photocarcinogenicity testing is not required for individual sunscreen ingredients, and retinyl palmitate is not an approved sunscreen filter.

### **Sunscreens and Children**

Everything in life has a risk-benefit ratio, including the use of sunscreen. I liken sunscreen use to placing a child in an automobile. No child would ever be involved in a car accident if he/she never rode in a car, but the risk of a car accident is low if the driver is well-trained and cautious. This same advice holds true for parents who apply sunscreen to their children. If a parent is well-trained and cautious, sunscreen is safe to use on children. The parent must apply an adequate and even coating to all sun-exposed areas and then realize that the child should wear clothing, seek shade, and avoid hours of peak sun exposure. As with everything in life, proper training and caution are key to avoid problems.

### **Sunscreens and Elderly Patients**

The same training and caution are necessary for safe sunscreen use in elderly patients. Since thermoregulation and the ability to perspire decrease with age, older individuals should not stay in the sun for prolonged periods of time to avoid heatstroke. Concern also has been raised that the use of sunscreens causes vitamin D deficiency among older patients; however, I do not believe this concern is valid. The skin's ability to produce vitamin D naturally decreases with age, while an individual's need for vitamin D increases as he/she gets older. Therefore, sunscreen should be used by elderly patients in combination with an oral vitamin D supplement.

### **Summary**

Sunscreens are the most effective products currently available for photoprotection, but safety issues cannot be ignored. For optimum sunscreen safety, I recommend the following tips:

- Only wear sunscreen-containing products during the day when sun exposure may occur. Do not use sunscreen-containing moisturizers at night; instead, buy a separate product for nighttime application, cutting sunscreen exposure in half.
- Do not use sunscreens on infants younger than 6 months whose ratio of body surface to body mass is high. It is recommended to keep infants out of the sun.
- Only apply sunscreen on areas of the skin that will be exposed to sun and not under clothing. Remember that clothing provides the best and safest photoprotection.

# COSMETIC CONSULTATION

- Avoid ingesting sunscreen when possible. Use specialized sunscreen-containing lip balms that minimize oral ingestion on the lips instead of regular sunscreens. Wash the palms of the hands after applying sunscreen to avoid accidental ingestion when handling food.

## References

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