Sunscreen Safety: 2024 Updates

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Sunscreen is a cornerstone of skin cancer prevention. The first commercial sunscreen was developed nearly 100 years ago,[1] yet questions and concerns about the safety of these essential topical photoprotective agents continue to occupy our minds. This article serves as an update on some of the big sunscreen questions, as informed by the available evidence.

Are sunscreens safe?

The story of sunscreen regulation in the United States is long and dry. The major pain point is that sunscreens are regulated by the US Food and Drug Administration (FDA) as over-the-counter drugs rather than cosmetics (as in Europe).[2] Regulatory hurdles created a situation wherein no new active sunscreen ingredient has been approved by the FDA since 1999, except ecamsule for use in one product line. There is hope that changes enacted under the CARES Act will streamline and expedite the sunscreen approval process in the future.[3]

Amid the ongoing regulatory slog, the FDA became interested in learning more about sunscreen safety. Specifically, they sought to determine the GRASE (generally regarded as safe and effective) status of the active ingredients in sunscreens. In 2019, only the inorganic (physical/mineral) UV filters zinc oxide and titanium dioxide were considered GRASE.[4] Trolamine salicylate and para-aminobenzoic acid were not GRASE, but they currently are not used in sunscreens in the United States. For all the remaining organic (chemical) filters, additional safety data were required to establish GRASE status.[4] In 2024, the situation remains largely unchanged. Industry is working with the FDA on testing requirements.[5]

Why the focus on safety? After all, sunscreens have been used widely for decades without any major safety signals; their only well-established adverse effects are contact dermatitis and staining of clothing.[6] Although preclinical studies raised concerns that chemical sunscreens could be associated with endocrine, reproductive, and neurologic toxicities, to date there are no high-quality human studies demonstrating negative effects.[7,8]

However, exposure patterns have evolved. Sunscreen is recommended to be applied (and reapplied) daily. Also, chemical UV filters are used in many nonsunscreen products such as cosmetics, shampoos, fragrances, and plastics. In the United States, exposure to chemical sunscreens is ubiquitous; according to data from the National Health and Nutrition Examination Survey 2003-2004, oxybenzone was detected in 97% of more than 2500 urine samples, implying systemic absorption but not harm.[9]

The FDA confirmed the implication of systemic absorption via 2 maximal usage trials published in 2019 and 2020.[10,11] In both studies, several chemical sunscreens were applied at the recommended density of 2 mg/cm^2 to 75% of the body surface area multiple times over 4 days. For all tested organic UV filters, blood levels exceeded the predetermined FDA cutoff (0.5 ng/mL), even after one application.[10,11] What's the takeaway? Simply that the FDA now requires additional safety data for chemical sunscreen filters[5]; the findings in no way imply any associated harm. Two potential mitigating factors are that no one applies sunscreen at 2 mg/cm^2, and the FDA's blood level cutoff was a general estimate not specific to sunscreens.[4,12]

Nevertheless, a good long-term safety record for sunscreens does not negate the need for enhanced safety data when there is clear evidence of systemic absorption. In the meantime, concerned patients should be counseled that the physical/mineral sunscreens containing zinc oxide and titanium dioxide are considered GRASE by the FDA; even in nanoparticle form, they generally have not been found to penetrate beneath the stratum corneum.[7,13]

Does sunscreen cause frontal fibrosing alopecia?

Dermatologists are confronting the conundrum of rising cases of frontal fibrosing alopecia (FFA). Several theories on the pathogenesis of this idiopathic scarring alopecia have been raised, one of which involves increased use of sunscreen. Proposed explanations for sunscreen's role in FFA include a lichenoid reaction inducing hair follicle autoimmunity through an unclear mechanism; a T cell–mediated allergic reaction, which is unlikely according to contact dermatitis experts[14]; reactive oxygen species production by titanium nanoparticles, yet titanium has been detected in hair follicles of both patients with FFA and controls[15]; and endocrine disruption following systemic

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absorption, which has not been supported by any high-quality human studies.[7]

An association between facial sunscreen use and FFA has been reported in case-control studies[16]; however, they have been criticized due to methodologic issues and biases, and they provide no evidence of causality.[17,18] The jury remains out on the controversial association between sunscreen and FFA, with a need for more convincing data.

Does sunscreen impact coral reef health?

Coral reefs—crucial sources of aquatic biodiversity—are under attack from several different directions including climate change and pollution. As much as 14,000 tons of sunscreen enter coral reefs each year, and chemical sunscreen filters are detectable in waterways throughout the world—even in the Arctic.[19,20] Thus, sunscreen has come under scrutiny as a potential environmental threat, particularly with coral bleaching.

Bleaching is a process in which corals exposed to an environmental stressor expel their symbiotic photosynthetic algae and turn white; if conditions fail to improve, the corals are vulnerable to death. In a highly cited 2016 study, coral larvae exposed to oxybenzone in artificial laboratory conditions displayed concentration-dependent mortality and decreased chlorophyll fluorescence, which suggested bleaching.[19] These findings influenced legislation in Hawaii and other localities banning sunscreens containing oxybenzone. Problematically, the study has been criticized for acutely exposing the most susceptible coral life-forms to unrealistic oxybenzone concentrations; more broadly, there is no standardized approach to coral toxicity testing.[21]

The bigger picture (and elephant in the room) is that the primary cause of coral bleaching is undoubtedly climate change/ocean warming.[7] More recent studies suggest that oxybenzone probably adds insult to injury for corals already debilitated by ocean warming.[22,23]

It has been posited that a narrow focus on sunscreens detracts attention from the climate issue.[24] Individuals can take a number of actions to reduce their carbon footprint in an effort to preserve our environment, specifically coral reefs.[25] Concerned patients should be counseled to use sunscreens containing the physical/mineral UV filters zinc oxide and titanium dioxide, which are unlikely to contribute to coral bleaching as commercially formulated.[7]

Ongoing Questions

A lot of unknowns about sunscreen safety remain, and much hubbub has been made over studies that often are preliminary at best. At the time of this writing, absent a crystal ball, this author continues to wear chemical sunscreens; spends a lot more time worrying about their carbon footprint than what type of sunscreen to use at the beach; and believes the association of FFA with sunscreen is unlikely to be causal. Hopefully much-needed rigorous evidence will guide our future approach to sunscreen formulation and use.

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