DRAFT

FDA Citizen Petition

Reclassification of the Sunscreen Actives Oxybenzone, Octinoxate and Octocrylene from Category III (More Data Needed) to Category II (Not Safe for Human Use)

&

Removal of Products Containing Oxybenzone, Octinoxate and Octocrylene from the Marketplace Based on their Dangers to Public Health and Negative Ecological Impact to US Virgin Islands, Hawaii, California, Florida and other Coastal Areas and Waterways

The undersigned submits this petition under CFR 10.30 of the Federal Food Drug and Cosmetic Act for which authority has been delegated to the Commissioner of Food and Drugs to request the Commissioner of Food and Drugs to enforce the reclassification of oxybenzone, octinoxate and octocrylene from the over-the-counter (OTC) sunscreen monograph drug status of Category III "insufficient data for use in sunscreens" to Category II "Not Generally Recognized as Safe & Effective" (GRASE, Category I) for human use. AND to remove all sunscreen products containing oxybenzone, octinoxate and octocrylene from the marketplace based on these chemicals' health risks and negative impact to waterways and coastlines including those in the US Virgin Islands, Hawaii, California, Florida and other Coastal Areas and Waterways.

A. Action Requested

On behalf of the undersigned representatives and environmental groups from the US Virgin Islands, Hawaii, California and Florida we request that the FDA ban the use of the "Toxic 3 Os," namely oxybenzone, octinoxate and octocrylene, in OTC sunscreen drugs and re-designate them as Category II "Not Recognized as Safe & Effective (GRASE) for use in sunscreens" from their current status of Category III "Insufficient Data for Use in Sunscreens." This includes the recall of all such products from the marketplace. Only active ingredients deemed Generally Recognized as Safe & Effective (GRASE, Category 1), which include zinc oxide and titanium dioxide (mineral sunscreens), should be permitted.

B. Statement of Grounds

Extensive published research demonstrates that oxybenzone, octinoxate and octocrylene, active ingredients present in more than 2/3 of all sunscreens, pose a threat to public health, marine life and coral reefs[1,2]. This includes the latest studies earlier this year showing that octocrylene in sun protection products degrades into benzophenone, a carcinogen that also can interfere with key hormones and reproductive organs[3]. Additionally, a major manufacturer of sunscreens has voluntarily decided to discontinue sales of the active octocrylene to its customers[4].

Although in February 2019, the FDA published a notice in the Federal Register removing 14 organic sun screen actives from the GRASE Category I list "because the public record does not currently contain sufficient data to support positive GRASE determinations," it is now time to once and for all ensure that all sunscreen products are safe for both people and the environment and

remove those that are not. Sunscreens, along with ultraviolet protective clothing (UPF), hats, sunglasses and avoiding direct sun during peak hours, are critical in protecting people against the harmful effects of UV radiation. But if the public cannot have confidence that their sunscreens are safe, the FDA has not done its job. Currently only the mineral barriers zinc and titanium dioxide are considered GRASE but thousands of sunscreen products containing the "Toxic 3 Os" are on the market and widely used.

The "Toxic 3 Os" have been shown to destroy coral and cause health risks to people and marine life [2, 5-14]. They cause human cell damage that has been linked to cancer, disrupt hormones, have been found in breast milk, blood and urine and are known allergens. Likewise, these chemicals are devastating to coral reefs and marine life. They wash off people's bodies when they swim and contaminate through waste water runoff and cause 'zombie' coral which looks healthy but is unable to reproduce, coral bleaching as well as other issues. Coral reefs take up less than one percent of the ocean floor but are home to more than twenty-five percent of marine life. They are vital to protecting coastlines and supporting life in oceans and have the highest biodiversity of any of the planet's ecosystems. Oxybenzone is particularly toxic to corals at concentrations as low as a few parts per trillion — the equivalent of three drops in an Olympic-size swimming pool may be enough to severely damage or kill coral. The "Toxic 3 Os" can also infiltrate to humans when there is fishing in contaminated waters.

The Personal Care Product Industry has had over 40 years to demonstrate the safety and efficacy of the "Toxic 3 Os" and the other Soluble Organic UV Filters (SOUVF) listed in the Agency's docket on the 2019 proposed rule "Sunscreen Drug Products for Over-the-Counter Human Use." Instead, the FDA affirmed that after decades of peer reviewed published literature on the safety and efficacy of the SOUVF group, there is still insufficient data in the public record to support a positive designation of GRASE.

Meanwhile, the weight of evidence, built over at least the last twenty years of research and hundreds of peer-reviewed scientific articles, demonstrates that oxybenzone, octinoxate, octocrylene and other SOUVF in Category III are toxic to humans, corals and other animals[15,16].

The SOUVF are structural and functional analogues to human estrogen, pesticides like DDT, BPA (Bisphenol A), phthalates, atrazine and glyphosate (Roundup), parabens, and other known hormone disruptors. They will never be found to be GRASE or environmentally safe because they aren't. No amount of further research can change their chemical nature. We therefore urge the FDA to apply the Precautionary Principle that the burden of proof for potentially harmful actions by industry or government rests on the assurance of safety and that when there are threats of serious damage, scientific uncertainty must be resolved in favor of prevention.

C. Environmental Impact

Although no formal environmental impact studies are being submitted with this petition, there have been multiple studies demonstrating that oxybenzone, octinoxate and octocrylene adversely impact the environment, particularly the coastlines and waterways of USVI, Hawaii, California, Florida and throughout the United States. This impacts both marine life and coral.

According to the National Oceanic and Atmospheric Administration (NOAA)[16], there is scientific evidence indicating that oxybenzone and chemicals like it are deadly to coral and threaten overall reef health. They cause coral bleaching, harm – and eventually kill - coral larvae by damaging DNA, and act as endocrine disruptors. We have already lost 50% of coral reefs worldwide (80% in the Caribbean) due to pollution and a variety of other issues. We can't afford to lose more. NOAA Scientist Cheryl Woodley cautions: "While additional research may incrementally add to our understanding of its impacts to additional coral reef species, additional research on the impacts of oxybenzone should not be a prerequisite to management action."

Downs identifies the environmental impact that oxybenzone and octinoxate have on navigable water ways whose biological/ecological receptors and structures can be impacted by sunscreens as a result of waste-water discharge (point and non-point sources), swimmer contamination, and/or from aerosol spray discharges from boaters and inflatable and rigid personal crafts (e.g., inflatable tubes, canoes, kayaks, paddle boards), all from the use of over-the-counter sunscreen SPF products. Contamination of these 851 bodies of waters in 21 States threaten subsistence fishers and USDA and National Marine Fisheries Service recognized fisheries in all the states listed below[2].

State of California (59 rivers and lakes); State of Colorado (9 rivers); State of Connecticut (36 rivers and lakes); State of Delaware 22 rivers and creeks); State of Hawaii (13 rivers and streams); State of Illinois (58 rivers and lakes); State of Indiana (37 rivers and lakes); State of Maine (30 rivers); State of Maryland (33 rivers and lakes); State of Massachusetts (35 rivers); State of Michigan (30 rivers); State of Montana (30 rivers); State of New Mexico (9 rivers); State of New York (37 rivers and lakes); State of Ohio (50 rivers and lakes); State of Oregon (124 rivers and lakes); State of Rhode Island (39 rivers);State of South Carolina (30 rivers); State of Virginia (40 rivers); State of Washington (100 rivers and lakes); State of Wisconsin (30 rivers).

Additionally, Downs also identifies the following 235 protected species at risk in the U.S.: marine mammals (10); reptiles (8); birds (16); Bivalves (26); crustaceans (28); fish (140) and coral (7).

D. Economic Impact

No formal economic impact studies are being submitted with this petition; however, it should be noted that the financial cost associated with treating the impact to both human health and the environment will be significant. Additionally, negative impacts to the tourism industry, the economic lifeblood of many coastal regions, could be significant if there isn't a focus on

sustainable, ecologically sound practices such as safe sunscreen. Likewise, the fishing industry could be decimated if toxins are allowed to continue pouring into our waterways unchecked.

E. Certification

The undersigned certifies that to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies and that it includes representative data and information known to the petition which are unfavorable to the petition.

Harith Wickrema (**Signing for ALL signatories - attached**)

Harith Wickrema (Name of petitioner)
President Island Green Living Association

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References:
1) DiNardo CDER Comments: Sunscreen Drug Products for OTC Use – Submitted to FDA on April 3, 2019.
2) Downs Environmental Impact Study: Oxybenzone and Octinoxate - Submitted to FDA July 14, 2021
3) Downs et al. Benzophenone Accumulates over Time from the Degradation of Octocrylene in Commercial Sunscreen Products. Chem Res Toxicol. 2021 Apr 19;34(4):1046-1054.
4) BASF Discontinuation of Uvinul® N 539T (Octocrylene) - Letter Dated 06/25/2021
5) Zhong et al. Comparison of toxicological effects of oxybenzone avobenzone octocrylene and octinoxate on cucumber plants (Cucumis sativus L.). Sci Total Environ. 2020 Apr 20;714:136879.
6) Thorel et al. Effect of 10 UV filters on the brine shrimp Artemia salina and the marine microalga Tetraselmis sp. Toxics. 2020 Apr 10;8(2):29.
7) Yan et al. Reproductive toxicity and estrogen activity in Japanese medaka exposed to environmentally relevant concentrations of octocrylene. Environ Pollut. 2020 Jun;261:114104.
8) Boyd et al. The effect of organic UV exposure avobenzone on the behavior and physiology of Daphnia magna. Sci Total Environ. 2021 Jan 1;750:141707.
9) Stien et al. A unique approach to monitor stress in coral exposed to emerging pollutants. Sci Rep. 2020 Jun 15;10(1):9601
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11) Gimeno-Monforte et al. Multiresidue Analysis of Organic UV Filters and UV Stabilizers in Fish of Common Consumption. Foods. 2020 Dec 9;9(12):1827.
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13) Muñiz-González and Martínez-Guitarte. Unveiling complex responses at the molecular level: Transcriptional alterations by mixtures of bisphenol A, octocrylene, and 2'-ethylhexyl 4-(dimethylamino)benzoate on Chironomus riparius. Ecotoxicol Environ Saf. 2020 Dec 15;206:111199.
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15) Downs et al. Oxybenzone contamination from sunscreen pollution and its ecological threat to Hanauma Bay, Oahu, Hawaii, U.S.A. Chemosphere - in peer review.
16) National Oceanic and Atmospheric Administration (NOAA). Skincare Chemicals and Coral Reefs. Available at https://oceanservice.noaa.gov/news/sunscreen-corals.html

Signatories

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