

December 3, 2018

The Honorable Jimmy Weekley
City Commissioner, District 1
1300 White St.
Key West, FL 33040

The Honorable Mary Lou Hoover
City Commissioner, District V
1300 White St.
Key West, FL 33040

RE: Opposition to proposed ordinance banning the sale and distribution of any sunscreen products containing oxybenzone and/or octinoxate

Dear Commissioners Weekley and Hoover,

On behalf of the Consumer Healthcare Products Association (CHPA), the 137-year-old national trade association representing the leading manufacturers of over-the-counter (OTC) medicines, I am writing to express opposition to a proposal being considered by the Key West City Commission which seeks to prohibit the sale and distribution of SPF sunscreen containing oxybenzone and octinoxate. While we applaud attempts to limit coral decline and protect Florida sea life, we have strong reservations with attempts to do so by limiting access to ingredients (oxybenzone/octinoxate) which have proven benefits in the prevention of deadly skin cancers. CHPA is staunchly opposed to this proposal and asks for a more thorough examination of the unintended consequences of this potential policy shift before moving forward.

What Is Oxybenzone?

Oxybenzone is a safe, and effective ingredient approved by the Food and Drug Administration (FDA) in 1966 and found in nearly 2000 personal care products on the market today including some of the most popular sunscreens, lip balms, shampoos, make-up, aftershave and other lotions designed to guard against sun damage. It is found in an overwhelming majority of the most popular sunscreens due to its ability to offer broad-spectrum protection against both ultraviolet A (UVA) and ultraviolet B (UVB) rays that are the greatest contributors to skin cancer.

Sunscreen Saves Lives

Sunscreens quite literally saves lives and contribute greatly to public health. Every year there are more cases of skin cancer in the United States than the combined incidents of breast cancer, prostate cancer, lung cancer, and colon cancer combined. In fact, over the last 30 years, more people have experienced skin cancer than all other cancers combined.

Rather than limiting access to sunscreens, governments at all levels should be encouraging greater use of sunscreen. This is especially the case in Key West where the ultraviolet index averages 11 in the summer months and 6 in the winter months.¹ According to the United States Environmental Protection

¹ <https://www.weather-us.com/en/florida-usa/key-west-weather-july>

Agency (EPA), a UV Index reading of 11 (the highest index rating on the scale) or more means extreme risk of harm from unprotected sun exposure and suggests all precautions be sought because unprotected skin and eyes can burn in minutes. The EPA recommends individuals in areas with extreme UV radiation “generously apply broad spectrum sun protection factor (SPF) 30+ sunscreen every 2 hours, even on cloudy days, and after swimming or sweating.”²

In order to get ultra-high SPF, oxybenzone is required to serve as a stabilizer for other sunscreen ingredients in sunscreen. Without it, high SPF may not be achieved. One out of five Americans will develop skin cancer in their lifetime, and one person dies of melanoma (the deadliest form of skin cancer) every hour. The vast majority of melanomas are caused by the sun, and a person’s risk of melanoma doubles if he or she has had more than five sunburns. When used as directed, sunscreens containing oxybenzone on the market today are proven to be very effective in protecting skin against the sun’s harmful rays.

Studies Blaming Sunscreen for Coral Decline are Flawed

Only two studies – and both of them conducted in highly controlled lab environments rather than in natural settings – are provided as weak support for banning oxybenzone and octinoxate. Each of these studies utilized conditions where coral was continuously exposed to static concentrations of oxybenzone much higher than those found in the environment and should not be accepted as proof that the chemical would behave similarly in native environments. Indeed, one of the studies (Downs *et al.*) notes a number of “*quantitative uncertainty factors*” in the research including “...*calibration, sample matrix, environmental conditions, sample handling and equipment maintenance and operation*”.³ And in fact, much lower oxybenzone concentrations have been reported in the marine environment by other peer reviewed research (ng/L rather than high mg/L).

Additional concerns associated with the Downs *et al.* study include: (1) sampling at only one depth; (2) a failure to collect replicate environmental samples for analysis; (3) large variations in oxybenzone concentrations detected between adjacent sampling sites which would have been expected to be similar; (4) failure to employ a reference compound(s) to demonstrate that the test system was valid; and (5) a failure to control for researcher contamination. The authors also tested oxybenzone dissolved into DMSO, which is known to enhance penetration of chemicals.⁴ Sunscreen formulations, on the other hand, are polymer-based or water in oil emulsions; the active ingredients stay in formulation and typically become suspended at the surface dispersing in the water or penetrating into living tissue. In the environment, the formula will eventually disperse and break down.

Another in vitro study (Danovaro *et al.*⁵) included experiments to examine the effects of individual sunscreen ingredients (including oxybenzone and octinoxate) as well as some finished sunscreen

² <https://www.epa.gov/sunsafety/uv-index-scale-0>

³ Downs CA et al., 2016 Toxicopathological Effects of the Sunscreen UV Filter, Oxybenzone (Benzophenone-3), on Coral Planulae and Cultured Primary Cells and Its Environmental Contamination in Hawaii and the U.S. Virgin Islands. *Arch Environ Contam Toxicol* 70(2):265-288.

⁴ Williams AC and Barry BW, 2012 Penetration enhancers, *Adv Drug Deliv Rev* 64(Suppl. 1):128-137; originally published in 2004, *Adv Drug Deliv Rev* 56(5):603-618.

⁵ Danovaro R et al., 2008 Sunscreens cause coral bleaching by promoting viral infections. *Environ Health Perspec* 116(4):441-7.

products on coral obtained from 4 separate areas (Atlantic, Indian, and Pacific Oceans, and the Red Sea). This study is flawed on multiple levels, and as such is not ecologically relevant. The tests were performed by enclosing the organisms in plastics bags, a situation which clearly does not approximate real world exposure. Tests were performed with compound concentrations (10, 33, 50, and 100 µL/L seawater) that are several magnitudes greater than observed under native conditions.

The authors also attempted to quantify the amount of UV filter ingredients released into seawater from formulated products. They subsequently used this calculated value to estimate the amount of sunscreen released into areas populated with coral. Unfortunately, this has led to widespread dissemination of unsubstantiated information regarding how much sunscreen is released onto coral reefs each year. Claiming that this amounts to “a potential release of 4,000-6,000 tons/year in reef areas,” the authors simultaneously note that “10,000 tons of UV filters are produced annually for the global market,” implying that 40-60% of all sunscreen produced ends up in reef areas. The Downs *et al.* study put the amount at “between 6000 and 14,000 tons of sunscreen lotion” without providing a citation.

Other stronger and higher quality evidence overwhelmingly points to climate change as the principal and perhaps singular cause of bleaching in Hawaii and worldwide – a multitude of studies in Hawaii and in other locations throughout the world demonstrates this. For example, one recent study⁶ found that water quality had no effect on coral bleaching. The major contributor to coral bleaching was found to be rising sea temperatures as a result of climate change. Further, this is something that has been known for decades – Hawaii had large scale bleaching events in 1996, 2002 and 2004 which prominent Hawaiian researchers described as being due to a warming of sea temperature.

While multiple causes of coral bleaching have been identified – pollution from runoff and sewage, climate change, and overfishing – a recent detailed analysis of the effects of local population density on coral reef health concluded that only actions to reduce ocean temperature would reverse coral reef decline and that there was no correlation to population density.⁷

Sound science requires extensive research and the performance of confirmatory studies utilizing tightly controlled conditions, including studies designed to demonstrate relevance in a native setting. None of that has been done regarding the effect of sunscreen ingredients on coral reef health. Researchers, including those who have conducted lab studies on oxybenzone, agree the major causes for coral bleaching are climate change, pollution, and overfishing. No sunscreen active ingredients, including oxybenzone and octinoxate, have been proven to cause bleaching of native coral reef populations.

Conclusion

Only the state of Hawaii has taken the drastic action of banning the sale of oxybenzone and octinoxate containing sunscreens. The law, however, does not go into effect until 2021 so no analysis has been done to measure the effectiveness of the new law on sea-life or the unintended health consequences on residents or tourists exposed to the sun. Additionally, no studies have been published to date that

⁶ Hughes TP *et al.*, 2017 Global warming and recurrent mass bleaching of corals, *Nature* 543(7645):373–377. doi:10.1038/nature2170

⁷ Bruno JF and Valdivia A 2016. Coral reef degradation is not correlated with local human population density. *Scientific Reports* doi: 10.1038/srep29778.

scientifically prove any sunscreen active ingredient is a primary reason for coral reef or sealife decline – including research by Dr. Craig Downs. Therefore, CHPA respectfully requests the Key West City Commission oppose this proposal. A greater standard of evidence must be considered before such a valuable contributor to public health is banned from sale or distribution.

We welcome continued dialogue as you attempt to formulate public policy on this issue. If you will allow, we would be glad to provide more detailed analysis and testimony from scientists and other sunscreen experts at your upcoming January 2nd commission meeting.

Should you have any questions for CHPA please contact me directly at 202.429.3521 or at cgutierrez@chpa.org.

Respectfully submitted,



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cc: Members of the Key West City Commission
Mayor Teri Johnston
Cheri Smith, City Clerk
Shawn Smith, City Attorney
Jim Scholl, City Manager