

NEWSLETTER

7 June 2023

FDA Safety Data Review Expected to Start September 2023

– May See Further Ban of UV Chemical Filters

Many popular and commonly used UV chemical filters were approved for use in Sunscreens in 1978, including, **Oxybenzone, Homosalate, Octisalate, Oxinoxate, Avobenzone, Cinoxate, Dioxybenzone and Sulisobenzene** [1].

In 2019, the chemical companies could not provide sufficient safety data for the FDA to classify these ingredients generally safe and effective (GRASE) despite these being used in sunscreens for over 40 years [2].

When safety data was provided for **Aminobenzoic Acid (PABA)**, first patented in 1943, and used in sunscreens, the FDA deemed this ingredient as unsafe and not GRASE in 2019 [3,4].

Over the past 14 years, scientific research papers have highlighted the dangers of these UV chemical filters including, entering blood streams affecting kidney disorders, nervous system disorders, reproduction disorders and generally harmful to babies and pregnant women as well as negatively impacting reef and marine life. As a result, a list of countries and states have banned the sale of chemical sunscreens and use of chemicals in sunscreens, including, Hawaii, Palau, Bonaire, Marshall Islands, Japan, Sweden, U.S. Virgin Islands, Aruba and Nature Reserves Mexico [5,6].

Please use this opportunity to discuss with all of your customers to start thinking about development alternatives, including zinc, for their products if the FDA ban some of these chemicals or deem them unsafe for use in sunscreens later this year.

For enquiries on Antaria's Non-Nano Zinc Based Products, please contact Jack at Wilfrid Smith, jwalkey@wilfrid-smith.co.uk or you can email me on geoff@antaria.com.

[1] Pantelic MN, Wong N, Kwa M, Lim HW. Ultraviolet filters in the United States and European Union: A review of safety and implications for the future of US sunscreens. J Am Acad Dermatol. 2023 Mar;88(3):632-646. doi: 10.1016/j.jaad.2022.11.039. Epub 2022 Nov 26. PMID: 36442641.

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- [3] Orville Wyss and Bernard J. Ludwig, B. N. (1943). *New York Patent No. 2,393,673* .
- [4] U.S. Food & Drug Administration . (2019 , February 21). *FDA advances new proposed regulation to make sure that sunscreens are safe and effective*. Retrieved from U.S. Food & Drug Administration : <https://www.fda.gov/news-events/press-announcements/fda-advances-new-proposed-regulation-make-sure-sunscreens-are-safe-and-effective>
- [5] Oral D, Yirun A, Erkekoglu P. Safety Concerns of Organic Ultraviolet Filters: Special Focus on Endocrine-Disrupting Properties. *J Environ Pathol Toxicol Oncol*. 2020;39(3):201-212. doi: 10.1615/JEnvironPatholToxicolOncol.2020033188. PMID: 32865912.
- [6] George, V. (2023, February 5). *Countries That Have Banned Chemical SPF's and Why*. Retrieved from SunsolveMD: <https://www.sunsolvemd.com/article/countries-that-have-banned-chemical-spfs-and-why>