

## **ASCC POSITION STATEMENT –**

### **“Octocrylene – Safety and Environment”**

**Prepared by George Orban – ASCC Technical Committee, July 2023**

#### **Background**

Concerns have been raised regarding the safety and environmental impacts of Octocrylene, in particular the presence of Benzophenone, potential endocrine disruption and potential aquatic toxicity.

The US Food and Drug Administration (FDA) has classified Octocrylene as a Category III material. As the FDA is concerned about potential transdermal absorption and hormonal effects, it requires more information to fill “significant data gaps” in order to consider Octocrylene to be Generally Regarded as Safe and Effective (GRASE.)<sup>(1)</sup>

The Therapeutic Goods Administration (TGA) in Australia is currently maintaining a watching brief on FDA deliberations in the US.

#### **Overview**

Octocrylene (CAS No. 6197-30-4) is a cinnamate based compound that has been widely used in sunscreen products for several years. It is a UVB absorber with peak absorbance at 303 nm. It is also known to be an effective photostabiliser for photo unstable active ingredients such as Avobenzone. It is also an effective solvent for solid active ingredients such as Avobenzone and Diethylamino Hydroxybenzoyl Hexyl Benzoate.

It is commercially available globally under trade names such as Parsol 340, Neo Heliopan 303, Escalol 597, Eusolex OCR and Uvinul N-539.

#### **Regulatory Status**

Octocrylene is approved for use in sunscreen products at up to 10% w/w in most global markets.

In Australia, as at mid-July 2023, 564 products containing Octocrylene were listed on the Therapeutic Goods Administration’s (TGA) Register of Therapeutic Goods (ARTG.)<sup>(2)</sup>

The update to the European Union Annex VI List of UV Filters, dated 31/01/2023, limits Octocrylene to a maximum of 9% in propellant spray products, while a maximum of 10% is allowed for all other products.<sup>(3)</sup>

Products containing Octocrylene are now banned in Palau, Marshall Islands, US Virgin Islands, Maui and Hawaii Island, due to concerns about reef toxicity.

#### **Benzophenone**

Recently, concerns have been raised about the presence of Benzophenone in products containing Octocrylene. A recent study by Downs, C.A. et.al. suggests that Benzophenone, said to be a mutagen, carcinogen and endocrine disruptor, accumulates over time in sunscreen products containing Octocrylene<sup>(4)</sup>. A counter argument put forward by Wong, M. questions the methodology and conclusions of the Downs study.<sup>(5)</sup>

In Australia, the TGA is reviewing the safety of Benzophenone and has pledged to take action if unacceptable levels of Benzophenone are found in products.<sup>(6)</sup>

The European Commission's Scientific Committee on Consumer Safety (SCCS) considers Octocrylene to be safe at 10% in cosmetic products, while noting that "Benzophenone is a hazardous impurity and degradation product of Octocrylene and it should be monitored and kept at trace levels."<sup>(7)</sup>

Regulators appear to be investigating possible limits as well as test methodology.

Suppliers also monitor Benzophenone levels in Octocrylene. However, there is some variability with Benzophenone content between batches.

### **Endocrine Disruption**

The SCCS has noted that, while some in-vivo studies have suggested Octocrylene may have some endocrine effects, the evidence is inconclusive for Octocrylene to be considered an endocrine disruptor.<sup>(7)</sup>

### **Aquatic Toxicity**

Octocrylene is currently banned in a number of jurisdictions due to concerns around toxicity to coral reefs<sup>(8)</sup>. Bans are currently in place in Palau, Marshall Islands, US Virgin Islands and the islands of Maui and Hawaii in the state of Hawaii. In fact, Hawaii is considering a state-wide ban of all organic UV actives.<sup>(9)</sup>

Octocrylene is considered to be very toxic to aquatic organisms with long lasting effects.<sup>(10)</sup> Studies on coral reef toxicity have largely been conducted in laboratories where active ingredient concentrations are many times higher than in the environment and further studies are required.<sup>(11)</sup>

### **Conclusion**

Octocrylene continues to be widely used in sunscreen formulations. At this time, it is considered safe by authorities such as the EU's SCCS and Australia's TGA and there appears to be no movement by authorities to ban Octocrylene based on health concerns, even though the US FDA is seeking additional data. TGA is currently maintaining a watching brief on FDA deliberations and has already opened discussions with industry on how to manage this. However, bans are coming into effect in a number of jurisdictions as a result of concerns about potential damage to coral reefs. (Further information may be found in the ASCC's Position Statement on "Reef Safe" claims.)<sup>(12)</sup>

As it is an effective UVB absorber, photostabiliser and solvent for solid UV actives, Octocrylene remains an important ingredient in sunscreen formulations. However, users will need to be aware that further bans or restrictions may come into effect if further information comes to light.

1. <https://www.federalregister.gov/documents/2019/02/26/2019-03019/sunscreen-drug-products-for-over-the-counter-human-use> (Accessed 19/6/2023)
2. <https://www.tga.gov.au/search?keywords=octocrylene+ARTG&submit=Search> (Accessed 20/7/2023)

3. [https://ec.europa.eu/growth/tools-databases/cosing/pdf/COSING\\_Annex%20VI\\_v2.pdf](https://ec.europa.eu/growth/tools-databases/cosing/pdf/COSING_Annex%20VI_v2.pdf) (Accessed 19/6/2023)
4. <https://pubmed.ncbi.nlm.nih.gov/33682414/> (Accessed 20/7/2023)
5. <https://labmuffin.com/octocrylene-causes-cancer-and-im-propaganda-now-with-video/> (Accessed 20/7/2023)
6. <https://www.tga.gov.au/news/news/sunscreens-ensuring-products-are-effective-and-safe-2021-22-summer#benzophenone> (Accessed 20/7/2023)
7. [https://health.ec.europa.eu/system/files/2022-08/sccs\\_o\\_249.pdf](https://health.ec.europa.eu/system/files/2022-08/sccs_o_249.pdf)

(Accessed 19/6/2023)

8. <https://enveurope.springeropen.com/articles/10.1186/s12302-021-00515-w> (Accessed 19/6/2023)
9. [https://www.capitol.hawaii.gov/sessions/session2021/bills/HB102\\_.HTM](https://www.capitol.hawaii.gov/sessions/session2021/bills/HB102_.HTM) (Accessed 19/6/2023)
10. <https://echa.europa.eu/registration-dossier/-/registered-dossier/14858/6/2/1>

(Accessed 19/6/2023)

11. <https://www.consumerreports.org/health/sunscreens/the-truth-about-reef-safe-sunscreen-a3578637894/> (Accessed 19/6/2023)
12. <https://ascc.com.au/wp-content/uploads/2022/08/ASCC-Position-Statement-Reef-Safe-Sunscreens-Reviewed-August-2022.pdf> (Accessed 18/9/2023)

## Disclaimer

*While care has been taken in compiling this document, the information provided is general in nature. Any information, recommendation, opinion or conclusion in this document is not advice and should be carefully considered and tailored to meet your specific circumstances and requirements. It should also be reviewed by you on a regular basis to ensure it is current. To the extent permitted by law, the writer and The Australian Society of Cosmetic Chemists (ASCC) disclaim any liability for any loss or damage suffered by any party arising from any reliance on, or any action taken due to, any information, recommendation, opinion or conclusion provided in this document. Reference in this document to any product or service is not an endorsement by the writer or for the product or service. Regulatory and legislative requirements affecting the topics in this document may vary over jurisdictions and time. You should seek independent expert advice prior to any final decision on matters mentioned in this document.*