



# Australian Society of Cosmetic Chemists (ASCC)

## POSITION STATEMENT

regarding

### **Sunscreen Issues from the Media December 2019-January 2020 – FDA Study on the Blood Plasma Absorption of Common Sunscreen Actives.**

Ric Williams February 2020

#### **Introduction**

Recent reporting on a study conducted in USA has caused concern that sunscreens may be harmful when used. This is based on a report; "Effect of Sunscreen Application Under Maximal Use Conditions on Plasma Concentration of Sunscreen Active Ingredients. A Randomized Clinical Trial" *conducted by the Center for Drug Evaluation and Research authorised by the American FDA and reported in the Journal of the American Medical Association (JAMA)* ( <https://jamanetwork.com/journals/jama/fullarticle/2733085>)

#### **Position Statement**

1. All sunscreens actives available in Australia have been approved by the Australian Therapeutic Goods Administration (TGA) as effective and safe for use. Government agencies from all countries, Non-Government Organisations (NGO's) such as the Cancer Council and health professionals worldwide stress the important health benefits sunscreens provide as part of a safe sun regimen to help prevent sunburn and reduce skin cancer risk.
2. The Journal of the American Medical Association (JAMA) report states that the presence of these ingredients, in plasma, does not suggest a safety issue and there were no serious drug-related adverse events reported in the trial, consistent with the excellent safety record associated with sunscreen active ingredients over decades of real-world use. The US Food and Drug Administration (FDA) makes it clear that the results of this study should not cause anyone to stop using sunscreen, just that more information should be sought. Sunscreen is a crucial step in the fight against skin cancer and premature skin aging.
3. The ASCC agrees with ACCORD and supports the use of the following statement as a response to any enquiries;

*"Sunscreen products available in Australia are actively regulated for safety and effectiveness by the Therapeutic Goods Administration (TGA). Sunscreens are vitally important for protection against harmful UV-radiation. The TGA is already aware of ongoing work by the US FDA looking at some sunscreen ingredients (see <https://www.tga.gov.au/blogs/tga-topics/everything-you-ever-wanted-know-about-sunscreens-were-afraid-ask>).*

*The local regulator will undoubtedly review this latest report, which needs to be put into proper perspective as it relied on a sunscreen use regime far in excess of normal consumer usage. Scientists from the US industry body have responded with the following statement - <https://www.personalcarecouncil.org/statement/statement-by-the-personal-care-products-council-and-the-consumer-healthcare-products-association-in-response-to-part-two-of-fdas-sunscreen-ingredient-maximal-usage-trial/>. And Professor Bruce Armstrong from the University of Western Australia has stated that 'what [the FDA] did was to test a regime, which is more extensive than usual, and that was four times a day for several days after a single application on the first day'. Australia remains a global hotspot for skin cancer and it is important for public health protection here that routine use of sunscreens is maintained."*

## **Concerns over the study**

This **pilot study** reported in JAMA (6 persons per formulation had two milligrams of sunscreen per 1 cm<sup>2</sup> was applied to 75% of body surface area over 4 days) found that several common sunscreen ingredients enter the bloodstream at levels high enough to trigger a government safety investigation. These levels are based on the US Food and Drug Administration (FDA) guidance that sunscreen active ingredients with systemic absorption Greater than 0.5ng/ml or with safety concerns should undergo non-clinical toxicology assessment including systemic carcinogenicity and additional development and reproductive studies. These ingredients continued to rise as daily use continued and then remained in the body for at least 24 hours after sunscreen use ended.

Further studies will now be conducted on sunscreens containing avobenzone, oxybenzone, octocrylene, homosalate, octisalate, and octinoxate to assess the systemic absorption and pharmacokinetics of the six active ingredients sunscreen products under single- and maximal-use conditions.

1. The study was conducted under maximised challenge conditions - 2mg/sq cm, repeated every 2 hrs and to 75% off the body. This level of use over 24 hrs would not normally reflect typical in use levels of product application. Additionally, reapplication is intended to compensate for loss due to friction, water interaction or towelling. It is not intended to be additive to applied amount.

2. **Limitations** (as stated in the JAMA Report).

*"This study has several limitations.*

*First, (as Study participants remained in the clinic for up to 7 days they were not exposed to direct sunlight during the study) the study was conducted in indoor conditions without exposure to heat, sunlight, and humidity, which may alter or modify the rate of absorption of sunscreen active ingredients. While this is a limitation, the study was designed to collect informative data in a standardized manner to design subsequent studies.*

*Second, the study was not designed to assess differences in absorption by formulation type, Fitzpatrick skin type, or participant age. However, as shown in the individual participant absorption profiles (Figure 2 and Figure 3), there was consistent absorption of multiple sunscreen active ingredients across the different formulation types, Fitzpatrick skin types, and ages in the study.*

*Third, the study was conducted with multiple applications of sunscreen products as per the labeled dosage regimen and not evaluated on single-dose application, so maximum plasma concentration and additional pharmacokinetic characteristics after a single application were not determined in this study."*

## References

1. "Effect of Sunscreen Application Under Maximal Use Conditions on Plasma Concentration of Sunscreen Active Ingredients. A Randomized Clinical Trial" *conducted by the Center for Drug Evaluation and Research authorised by the American FDA and reported in the Journal of the American Medical Association* ( <https://jamanetwork.com/journals/jama/fullarticle/2733085>)
2. **[Don't stop using sunscreen, even though chemicals `may seep into the bloodstream'](https://www.cosmeticsdesign-asia.com/article/2020/02/18/don-t-stop-using-sunscreen-even-though-chemicals-may-seep-into-the-bloodstream)**  
18-Feb-2020 By Richard Whitehead  
"Experts in Australia have been urging the public to carry on using sunscreen even though a widely publicised study has shown chemicals can be absorbed from some products into the bloodstream."  
**[HTTPS://WWW.COSMETICSDESIGN-ASIA.COM/ARTICLE/2020/02/18/DON-T-STOP-USING-SUNSCREEN-EVEN-THOUGH-CHEMICALS-MAY-SEEP-INTO-THE-BLOODSTREAM](https://www.cosmeticsdesign-asia.com/article/2020/02/18/don-t-stop-using-sunscreen-even-though-chemicals-may-seep-into-the-bloodstream)**