



## EUROPEAN COMMISSION

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

Consumer, Environmental and Health Technologies  
**Health Technology and Cosmetics**

### SCIENTIFIC COMMITTEE ON CONSUMER SAFETY (SCCS)

#### **Request for a scientific opinion on Octocrylene (CAS No 6197-30-4, EC No 228-250-8)**

**Commission Department requesting the Opinion:** Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

#### **1. Background on substances with endocrine disrupting properties**

On 7 November 2018, the Commission adopted a review<sup>1</sup> of Regulation (EC) No 1223/2009 on cosmetic products ('Cosmetics Regulation') regarding substances with endocrine disrupting properties. The review concluded that the Cosmetics Regulation provides the adequate tools to regulate the use of cosmetic substances that present a potential risk for human health, including when displaying ED properties.

The Cosmetics Regulation does not have specific provisions on EDs. However, it provides a regulatory framework with a view to ensuring a high level of protection of human health. Environmental concerns that substances used in cosmetic products may raise are considered through the application of Regulation (EC) No 1907/2006 ('REACH Regulation').

In the review, the Commission commits to establishing a priority list of potential EDs not already covered by bans or restrictions in the Cosmetics Regulation for their subsequent safety assessment. A priority list of 28 potential EDs in cosmetics was consolidated in early 2019 based on input provided through a stakeholder consultation. The Commission then organised a public call for data<sup>2</sup> from 16 May 2019 – 15 October 2019 on 14<sup>3</sup> of the 28 substances (to be treated with higher priority) in order to be able to prepare the safety assessment of these substances. Octocrylene is one of the above-mentioned 14 substances for which the call for data took place.

#### **2. Existing information on Octocrylene**

In cosmetic products, the ingredient Octocrylene (CAS No 6197-30-4, EC No 228-250-8) with the chemical name 2-Cyano-3,3-diphenyl acrylic acid, 2-ethylhexyl ester is currently regulated as a UV-filter in sunscreen products in a concentration up to 10 % (as acid) (Annex VI/10).

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<sup>1</sup> <https://ec.europa.eu/transparency/regdoc/rep/1/2018/EN/COM-2018-739-F1-EN-MAIN-PART-1.PDF>

<sup>2</sup> [https://ec.europa.eu/growth/content/call-data-ingredients-potential-endocrine-disrupting-properties-used-cosmetic-products\\_en](https://ec.europa.eu/growth/content/call-data-ingredients-potential-endocrine-disrupting-properties-used-cosmetic-products_en)

<sup>3</sup> Octocrylene, kojic acid, 4-methylbenzylidene camphor, propylparaben, triclosan, resorcinol, octocrylene, triclocarban, butylated hydroxytoluene (BHT), benzophenone, homosalate, benzyl salicylate, genistein and daidzein

Octocrylene has been subject to a safety evaluation from SCCP in 1994, where the SCCP concluded that Octocrylene was not toxic, non-irritant and non-sensitizer. In addition, the SCCP noted that *'no carcinogenicity study was conducted'*.

During the call for data in 2019, stakeholders submitted scientific evidence to demonstrate the safety of Octocrylene as a UV-filter in cosmetic products. The Commission requests the SCCS to carry out a safety assessment on Octocrylene in view of the information provided.

## **2. Terms of reference**

- (1) *In light of the data provided and taking under consideration the concerns related to potential endocrine disrupting properties of Octocrylene, does the SCCS consider Octocrylene safe when used as a UV-filter in cosmetic products up to a maximum concentration of 10 % (as acid)?*
- (2) *(2) Alternatively, what is according to the SCCS the maximum concentration considered safe for use of Octocrylene as a UV-filter in cosmetic products?*
- (3) *Does the SCCS have any further scientific concerns with regard to the use of Octocrylene in cosmetic products?*

**3. Deadline:** 9 months, extended until January 2021.

**4. Supporting documents:**

Input from the call for data in 2019 on the safety of Octocrylene in Cosmetic Products.

The SCCS approved this mandate by written procedure on 4 February 2020. The extension of deadline was agreed by DG GROW on 10 September 2020.