



EUROPEAN COMMISSION

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

Resources Based, Manufacturing and Consumer Goods Industries

Consumer Industry

SCIENTIFIC COMMITTEE ON CONSUMER SAFETY (SCCS)

Request for a scientific Opinion on Kojic acid (CAS No 501-30-4, EC No 207-922-4)

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 the review¹ of Regulation (EC) No 1223/2009 on cosmetic products ('Cosmetics Regulation') regarding substances with endocrine disrupting (ED) 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 carried out a public call for data² in 2019 on 14³ of the 28 substances (to be treated with higher priority-Group A substances) in preparation of the safety assessment of these substances. Kojic acid (CAS No 501-30-4, EC No 207-922-4) is one of the above-mentioned 14 substances for which the call for data took place.

2. Background on Kojic acid

Kojic acid is a secondary metabolite commonly produced by many species of filamentous fungi including *Aspergillus* and *Penicillium*. Due to its inhibitory effect on tyrosinase activity and melanogenesis Kojic acid has been widely used as a skin lightening/whitening or depigmenting agent in cosmetic products. In addition, the ingredient Kojic acid (CAS No 501-30-4, EC No

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

²https://ec.europa.eu/growth/content/call-data-ingredients-potential-endocrine-disrupting-properties-used-cosmetic-products_en

³Benzophenone-3, kojic acid, 4-methylbenzylidene camphor, propylparaben, triclosan, Homosalate, octocrylene, triclocarban, butylated hydroxytoluene (BHT), benzophenone, homosalate, benzyl salicylate, genistein and daidzein

207-922-4) with the chemical name '5-Hydroxy-2-(hydroxymethyl)-4H-pyran-4-one', is also included in the European database for information on cosmetic substances and ingredients (CosIng) with the reported functions of 'bleaching' and 'antioxidant'.

Kojic acid has been subject to safety evaluations by the SCCP in 2008⁴ and 2012⁵. In particular, the SCCP Opinion from 2012 (SCCP/1481/12) concluded that '*...a concentration of 1.0% in leave-on creams, which are generally applied to the face and/or hands leads to the conclusion that it [Kojic acid] is safe for the consumers*'. Currently, Kojic acid is not regulated under the Cosmetic Regulation (EC) No. 1223/2009.

Kojic acid has been reported to interfere with either iodine organification or iodine uptake by the thyroid, resulting in altered thyroid functions, hence it was included in the priority list for safety assessment. During the call for data, stakeholders submitted scientific evidence to demonstrate the safety of Kojic acid in cosmetic products. The Commission requests the SCCS to carry out a safety assessment on Kojic acid in view of the information provided.

3. Terms of reference

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

4. Deadline

9 months.

5. Supporting documents

Input from the call for data on the safety of Kojic acid in Cosmetic Products.

The SCCS approved this mandate by written procedure on 8 March 2021.

⁴ https://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_148.pdf

⁵ https://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_098.pdf