



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 BHT (Butylated Hydroxytoluene) (CAS No 128-37-0, EC No 204-881-4)

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. BHT (Butylated hydroxytoluene) (CAS No 128-37-0, EC No 204-881-4) is one of the above-mentioned 14 substances for which the call for data took place.

2. Background on BHT (Butylated hydroxytoluene)

BHT is a lipophilic organic compound. More specifically, it is a synthetic antioxidant widely used in multiple sectors, including food additives, cosmetics and personal care products, pharmaceuticals, plastics/rubbers and other petroleum products. Butylated hydroxytoluene is reducing the free-radical induced damage and spoilage; therefore, it helps maintain the properties

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

and performance of products when exposed to air (i.e. preventing change in odour, colour, texture, etc.). BHT is reported to be used as an antioxidant at a range of concentrations (0.0002 - 0.8%) across a wide spectrum of cosmetic product types, dermally applied and sprayable products.

The ingredient BHT (Butylated hydroxytoluene) (CAS No 128-37-0, EC No 204-881-4) with the chemical name '2,6-Di-Tert-Butyl-4-Methylphenol' is not currently regulated under the Cosmetic Regulation (EC) No. 1223/2009, however it is included in the European database for information on cosmetic substances and ingredients (CosIng) with the reported functions of 'antioxidant' and 'fragrance'.

During the call for data, stakeholders submitted scientific evidence to demonstrate the safety of BHT (Butylated hydroxytoluene) in cosmetic products. The Commission requests the SCCS to carry out a safety assessment on BHT (Butylated hydroxytoluene) 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 BHT (Butylated hydroxytoluene), does the SCCS consider BHT safe:*
 - (a) *when used in mouthwash up to the maximum concentration of 0.001% and in toothpaste up to the maximum concentration of 0.1% ?*
 - (b) *when used in other leave on and rinse-off products up to a maximum concentration of 0.8 % ?*
- (2) *Alternatively, what is according to the SCCS the maximum concentration considered safe for use of BHT (Butylated hydroxytoluene) in cosmetic products?*
- (3) *Does the SCCS have any further scientific concerns with regard to the use of BHT (Butylated hydroxytoluene) in cosmetic products?*

4. Deadline

9 months.

5. Supporting documents

Input from the call for data on the safety of BHT (Butylated hydroxytoluene) in Cosmetic Products.

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