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SCCS scientific opinion on Butylated hydroxytoluene (BHT) - SCCS/1636/21

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Comprehensive Review

SCCS scientific opinion on Butylated hydroxytoluene (BHT) - SCCS/1636/21



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Regulation 1223/2009

ABSTRACT

Opinion to be cited as: SCCS (Scientific Committee on Consumer Safety), scientific opinion on Butylated hydroxytoluene (BHT), preliminary version of September 27, 2021, final version of December 2, 2021, SCCS/1636/21.

On November 7, 2018, the Commission adopted the review 1 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

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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 data 2 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.

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 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.

The SCCS concludes the following:

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%?

On the basis of a safety assessment, and considering the concerns related to potential endocrine disrupting properties of BHT, the SCCS is of the opinion that BHT is safe as an ingredient up to a maximum concentration of 0.001% in mouthwash and 0.1% in toothpaste.

(b) when used in other leave on and rinse-off products up to a maximum concentration of 0.8%?

On the basis of a safety assessment, and considering the concerns related to potential endocrine disrupting properties of BHT, the SCCS is of the opinion that BHT is safe as an ingredient up to a maximum concentration of 0.8% in other leave-on and rinse-off products. BHT is also considered safe for a combined use of mouthwash at a concentration of 0.001%, toothpaste at a concentration of 0.1% and other leave-on and rinse-off products at the 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?

The SCCS mandates do not address environmental aspects. Therefore, this assessment did not cover the safety of BHT for the environment.

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CRediT authorship contribution statement

Berit Granum (rapporteur): Writing – original draft, Writing – review & editing, SCCS member, rapporteur. **Ulrike Bernauer:** Writing – original draft, Writing – review & editing, SCCS member. **Laurent Bodin:** Writing – original draft, Writing – review & editing, SCCS member. **Qasim Chaudhry:** credit author, Writing – original draft, Writing – review & editing, SCCS member. **Coenraads Pieter Jan:** Writing – original draft, Writing – review & editing, SCCS member. **Maria Dusinska:** Writing – original draft, Writing – review & editing, SCCS member. **Janine Ezendam:** Writing – original draft, Writing – review & editing, SCCS member. **Eric Gaffet:** Writing – original draft, Writing – review & editing, SCCS member. **Corrado L. Galli:** Writing – original draft, Writing – review & editing, SCCS member. **Vera Rogiers:** Writing – original draft, Writing – review & editing, SCCS member. **Christophe Rousselle:** Writing – original draft, Writing – review & editing, SCCS member. **Maciej Stepnik:** Writing – original draft, Writing – review & editing, SCCS member. **Tamara Vanhaecke:** Writing – original draft, Writing – review & editing, SCCS member. **Susan Wijnhoven:** Writing – original draft, Writing – review & editing, SCCS member. **Aglaia Koutsodimou:** Writing – original draft, Writing – review & editing, SCCS member. **Wolfgang Uter:** Writing – original draft, Writing – review & editing, SCCS external expert. **Natalie von Goetz:** Writing – original draft, Writing – review & editing, SCCS external expert.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

The data that has been used is confidential.

Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.yrtph.2022.105312>.