



EUROPEAN COMMISSION

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

Dir F: Ecosystems I: Chemicals, food, Retail

Unit F2: Bioeconomy, Chemicals & Cosmetics

SCIENTIFIC COMMITTEE ON CONSUMER SAFETY (SCCS)

Request for a scientific opinion on Biphenyl-2-ol and Sodium 2-biphenylolate (CAS/EC No. 90-43-7/201-993-5 and 132-27-4/205-055-6)

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

1. Background

‘Biphenyl-2-ol’ and ‘Sodium 2-biphenylolate’ (CAS/EC No. 90-43-7/201-993-5 and 132-27-4/205-055-6) are known with the INCI names ‘o-Phenylphenol’ and Sodium ‘o-Phenylphenate’, respectively, as cosmetic ingredients.

The use of o-Phenylphenol as a preservative is currently authorised in entry 7 of Annex V to the Cosmetics Regulation (EC) No.1223/2009, with a maximum concentration of 0.15 % (as phenol) in leave-on and 0.2 % (as phenol) in rinse-off cosmetic products.

The Scientific Committee on Consumer Safety (SCCS) adopted an opinion on o-Phenylphenol (OPP), Sodium o-Phenylphenate (SOPP), and Potassium o-Phenylphenate (POPP) (SCCS/1555/15)¹ in June 2015, later revised on 15 December 2015, with the following conclusion: ‘*Based on the information provided, no conclusions of safe use can be drawn for Sodium o-Phenylphenate and Potassium o-Phenylphenate*’. In 2018, the SCCS released an addendum² to the above scientific opinion, specifically addressing Sodium o-Phenylphenate, Potassium o-Phenylphenate, and MEA o-Phenylphenate. The SCCS concluded that ‘*Due to the lack of relevant information, the SCCS is unable to answer the question regarding the safe use level of sodium-OPP, potassium-OPP, and MEA-OPP. In the SCCS's view, a direct comparison between the safety of o-Phenylphenate (OPP) and its three compounds cannot be made*’. The conclusions of this opinion resulted in amending entry 7 of Annex V to the Cosmetics Regulation, removing from the list the previously authorised OPP salts.

It should be noted that o-Phenylphenol, Sodium and Potassium o-Phenylphenate are active ingredients in broad-spectrum fungicides surface biocides. Under EU biocidal Regulation (EU) 528/2012, o-Phenylphenol has been evaluated for the different product types (PTs) such as PT 1, PT 2, PT4, PT 6 as a preservative ranging from 0.1 to 0.5 % w/w.

The European Risk Assessment Committee (RAC) of ECHA issued in December 2022 an opinion recommending among others a classification for o-Phenylphenol³ as ‘Carcinogen of

¹ https://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_177.pdf

² <https://op.europa.eu/en/publication-detail/-/publication/acb1d4ba-38cc-11e9-8d04-01aa75ed71a1/language-en>

³ <https://echa.europa.eu/documents/10162/0ca2507c-20b8-9cf7-cbbb-9b654457faa9>

Category 2'. Following the RAC opinion, the European Commission may propose a classification for o-Phenylphenol as a 'Carc.2' (CLP Regulation Annex VI entry).

According to Article 15(1) of the Cosmetics Regulation '*the use in cosmetic products of substances classified as CMR substances, of category 2, under Part 3 of Annex VI to Regulation (EC) No 1272/2008 shall be prohibited. However, a substance classified in category 2 may be used in cosmetic products where the substance has been evaluated by the SCCS and found safe for use in cosmetic products*'. In view of these provisions, regulatory measures must be adopted by the Commission services within 15 months of the classification as CMR 1A or 1B of the substance(s) concerned in Part 3 of Annex VI to Regulation (EC) No 1272/2008.

In December 2023, the Commission services received a dossier to defend the safe use of o-Phenylphenol, as well as its sodium salt (CAS/EC No. 90-43-7/201-993-5 and 132-27-4/205-055-6) as preservatives in cosmetic products according to Article 15(1) of the Cosmetics Regulation 1223/2009. The Commission, therefore, requests the SCCS to carry out a safety assessment on these ingredients in view of the information provided.

2. Terms of reference

- (1) *In light of the data provided and taking under consideration the classification as 'Carcinogen Cat. 2', does the SCCS consider o-Phenylphenol safe when used as preservative up to a maximum concentration of 0.2 % in rinse-off and 0.15 % in leave-on cosmetic products?*
- (2) *Alternatively, what is according to the SCCS, the maximum concentration considered safe for use of o-Phenylphenol in cosmetic products?*
- (3) *In light of the data provided and taking under consideration the classification as 'Carcinogen Cat. 2' of o-Phenylphenol, does the SCCS consider Sodium o-Phenylphenate safe when used as preservative up to a maximum concentration of 0.2 % in rinse-off and 0.15 % in leave-on cosmetic products?*
- (4) *Alternatively, what is according to the SCCS, the maximum concentration considered safe for use of Sodium o-Phenylphenate in cosmetic products?*
- (5) *Does the SCCS have any further scientific concerns with regard to the use of o-Phenylphenol and Sodium o-Phenylphenate in cosmetic products?*

3. Deadline

6 months.

4. Supporting documents

OPP & SOPP dossier

→ The SCCS approved this mandate by written procedure on 28 February 2024.