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## Commentary

## Opinion of the scientific committee on consumer safety (SCCS) – Final version of the opinion on Ethylzingerone - ‘Hydroxyethoxyphenyl Butanone’ (HEPB) - Cosmetics Europe No P98 - in cosmetic products

Scientific Committee of Consumer Safety - SCCS<sup>a, \*</sup>, Ulrike Bernauer<sup>b, 1</sup><sup>a</sup> SCCS Secretariat at the European Commission, Directorate General for Health and Food Safety, 11, rue E. Ruppert, L-2920 Luxembourg, Luxembourg<sup>b</sup> Federal Institute for Risk Assessment (BfR), Berlin, Germany

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Regulation 1223/2009

CAS 569646-79-3

Ethylzingerone with INCI name ‘Hydroxyethoxyphenyl Butanone’ (HEPB) Cosmetics Europe No P98 - CAS No 569646-79-3 is a cosmetic ingredient not regulated under Cosmetic Regulation No 1223/2009 with the function as skin conditioning agent.

In September 2015, the Commission’s services received a dossier from industry to support the safe use of Hydroxyethoxyphenyl Butanone (HEPB) when used as preservative in rinse-off, oral care and leave-on cosmetic products.

According to the above-mentioned dossier the safety profile of HEPB has been studied in preclinical studies conducted according to Good Laboratory Practices and following OECD guidelines whenever available. They were conducted using HEPB from batches which were well characterised analytically with a minimum purity of 95.9%.

In light of the data provided by the applicant, the use of Hydroxyethoxyphenyl Butanone (HEPB) as a cosmetic preservative in rinse-off, oral care and leave-on cosmetic products with a maximum concentration of 2.0% under an aggregate exposure scenario for cosmetics is not considered safe by the SCCS.

It is of note that a maximum concentration of 2.0% under an aggregate exposure scenario for cosmetics could be considered safe if more reliable and supporting data on in vitro dermal penetration was provided.

In light of the data provided by the applicant, a maximum concentration of 0.7% of Hydroxyethoxyphenyl Butanone (HEPB) as a cosmetic preservative in rinse-off, oral care and leave-on cosmetic products can be considered safe.

The SCCS is aware that Hydroxyethoxyphenyl Butanone (HEPB) is also used as skin conditioning agent. According to the Cosmetics Regulation 1223/2009 a substance authorised as preservative at specific conditions of use (e.g. maximum concentration) can only be used for other purposes at the same conditions of use set up for the preservative function. In the specific case of Ethylzingerone, this substance cannot be used as conditioning agent at concentrations higher than that one authorised for the preservative function.

More evidence would be needed to exclude eye irritation.

## Opinion to be cited as

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## Authors of the Opinion

**SCCS members:** Dr. U. Bernauer (rapporteur), Dr. L. Bodin, Prof. Q. Chaudhry, Prof. P.J. Coenraads (Chair), Prof. M. Dusinska, Dr. E. Ezendam, Prof. C. L. Galli, Dr. B. Granum, Dr. E. Panteri, Prof. V. Rogiers, Dr. Ch. Rousselle, Dr. M. Stepnik, Prof. T. Vanhaecke, Dr. S. Wijnhoven

**Former SCCS members:** Prof. G. H. Degen, Prof. J. Duus-

\* Corresponding author.

E-mail address: [SANTE-C2-SCCS@ec.europa.eu](mailto:SANTE-C2-SCCS@ec.europa.eu) (SCCS).

<sup>1</sup> Rapporteur of the Opinion.

Johansen, Dr. J. van Benthem

### Transparency document

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### Reference

Final version of the opinion on Ethylzingerone - 'Hydroxyethoxyphenyl Butanone' (HEPB) - Cosmetics Europe No P98 - in cosmetic products: [https://ec.europa.eu/health/sites/health/files/scientific\\_committees/consumer\\_safety/docs/sccs\\_o\\_203.pdf](https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_203.pdf).