



Commentary

Opinion of the Scientific Committee on Consumer safety (SCCS) – Opinion on the safety of cosmetic ingredient salicylic acid (CAS 69-72-7)

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Salicylic acid (CAS 69-72-7) and its salts, as Calcium salicylate, Magnesium salicylate, MEA- salicylate, Sodium salicylate, Potassium salicylate and TEA- salicylate (CAS 824-35-1/ 18917-89-0/ 59866- 70-5/ 54-21-7/ 578- 36-9/ 2174-16-5) are currently listed in Annex V (entry 3) of the Regulation (EC) No. 1223/20091 (Cosmetics

Regulation) as preservative to be used in all cosmetic products up to a maximum concentration of 0.5% (acid). The following restriction applies: Not to be used for children under 3 years old, except for shampoos.

Salicylic acid (CAS 69-72-7) is also listed in Annex III (entry 98) of

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the Cosmetics Regulation to be used up to a maximum concentration of 3.0 % for the cosmetic rinse-off hair products and of 2.0 % for other products.

The following restrictions apply:

Not to be used for children under 3 years old, except for shampoos. For purposes other than inhibiting the development of micro-organisms in the products.

This purpose has to be apparent from the presentation of the product.

The SCCNFP published an opinion on the safety of Salicylic acid (CAS 69-72-7) in June 2002 (SCCNFP/0522/01)2.

ECHA's Risk Assessment Committee (RAC) adopted its opinion on the harmonised classification for Salicylic acid (CAS 69-72-7) on 10 March 2016, with a proposed classification as CMR2 3 under Regulation (EC) No. 1272/2008. This proposed classification does not cover the salts of Salicylic acid.4

Art. 15 (1) of the Cosmetics Regulation states that '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. To these ends the Commission shall adopt the necessary measures in accordance with the regulatory procedure with scrutiny referred to in Article 32(3) of this Regulation'.

In December 2017, Cosmetics Europe transmitted a safety dossier on Salicylic acid (CAS 69-72-7) intended to demonstrate the safety of the ingredient for its current uses and restrictions.

Based on the data provided in the dossier, the SCCS considers salicylic acid (CAS 69-72-7) safe when used as preservative at a concentration of 0.5 % in cosmetic products considering its current restrictions in place.

This Opinion is not applicable to any oral product (such as toothpaste and mouthwash) with the exception of lipsticks. Sprayable products that could lead to exposure of the consumer's lung by inhalation are also excluded. The provided information shows that salicylic acid is an eye irritant with the potential to cause serious damage to the eye.

Based on the data provided and available literature, the SCCS considers salicylic acid (CAS 69-72-7) safe when used for purposes other than preservative at a concentration up to 3.0 % for the cosmetic rinse-off hair products and up to 2.0 % for other products, considering its

current restrictions in place. However, in body lotion, eye shadow, mascara, eyeliner, lipstick and roll on deodorant applications, salicylic acid is considered safe up to 0.5 %. The SCCS position is that these levels are inclusive of any use of salicylic acid, i.e. should not exceed the stated levels with additional use as a preservative.

This Opinion is not applicable to any oral product (such as toothpaste and mouthwash) with the exception of lipsticks. Sprayable products that could lead to exposure of the consumer's lung by inhalation are also excluded.

Salicylic acid is also used as a preservative in food and as a biocide in some consumer products (see section 3.2.3) or in various pharmaceutical formulations such as anti-acne products. As no specific exposure data were made available to SCCS to assess exposure following these non-cosmetic uses, it was not possible to include them in the aggregated exposure scenarios. Therefore, the actual total exposure of the consumer may be higher than exposure from cosmetic products alone.

The conclusions of this Opinion refer only to Salicylic Acid and should not be applied to other salicylates or salicylic acid salts.

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Declaration of interests

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.

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Reference

https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_223.pdf.