



# SCIENTIFIC ADVISORY GROUP ON CHEMICAL SAFETY OF NON-FOOD AND NON-MEDICINAL CONSUMER PRODUCTS (SAG-CS)

## Opinion on Salicylic Acid Restrictions in Cosmetic Products.

### 1. Summary

- 1.1. 2-hydroxy-benzoic acid (INCI name: Salicylic Acid) (CAS 69-72-7) is currently regulated under entry 98 of Annex III and entry 3 of Annex V of the UK Cosmetic Regulation No 1223/2009 (as amended)<sup>1</sup>. These restrictions can be seen in Table 1 below.
- 1.2. In October 2018, as part of the 13<sup>th</sup> Adaptation to Technical Progress (ATP), salicylic acid under [Commission Delegated Regulation \(EU\) 2018/1480](#) was classified as a Category 2 reproductive toxicant under [EC Regulation No 1272/2008 - classification, labelling and packaging of substances and mixtures](#) (CLP).
- 1.3. Following the Category 2 classification of salicylic acid, industry submitted a derogation to support the use of salicylic acid in cosmetic products in accordance with the second sentence of Article 15(I) of the EC Cosmetics Regulation.
- 1.4. At this stage, prior to the CMR classification, salicylic acid and its salts were listed as an allowed preservative in cosmetic products in entry 3 of Annex V to EC Regulation No 1223/2009, up to a concentration of 0.5% (as acid equivalent). In addition to this it was also listed in entry 98 of Annex III to EC Regulation No 1223/2009, as a restricted substance that was only allowed

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<sup>1</sup> The UK Regulation currently consists of the Regulation UK No 1223/2009 as amended by [SI 696/2019 Product Safety and Metrology \(EU Exit\) Regulations](#). The full consolidated UK text will be available soon.



when used for purposes other than preservative, up to a concentration of 3% in rinse off hair products and a concentration of 2% in other products.

- 1.5. Based on the proposed derogation from industry, and in accordance with the second sentence of Article 15(l) of EC Regulation No 1223/2009 (as amended), the Scientific Committee on Consumer Safety (SCCS) was mandated to form an opinion on the safe use of salicylic acid. In December 2018, the [SCCS](#) adopted an opinion on the use of salicylic acid and concluded that salicylic acid is safe for consumer use when used as a preservative in cosmetic products at a concentration of up to 0.5%, considering the current restrictions already in place for salicylic acid.
- 1.6. [Commission Regulation 2019/1966](#) introduced changes to entry 98 of Annex III to Regulation No (EC) 1223/2009, however this change did not fully align with the conclusion the SCCS made in their opinion of salicylic acid in December 2018. In this regulation, salicylic acid was authorised for use for purposes other than that of a preservative in rinse-off hair products in a concentration of up to 3% and in other products in a concentration of up to 2% with the exception of body lotion, eye shadow, mascara, eyeliner, lipstick, and roll-on deodorant applications. The SCCS however did conclude that in body lotion, eye shadow, mascara, eyeliner, lipstick, and roll-on deodorant applications, salicylic acid is safe to use up to a concentration of 0.5%.
- 1.7. The SAG-CS were asked to consider if the safety data available support the use of salicylic acid for purposes other than a preservative function in body lotion, eye shadow, mascara, eyeliner, lipstick, and roll-on deodorant applications at a concentration of up to 0.5%.



Table 1: Current salicylic acid restrictions.

<u>Annex</u>	<u>Entry</u>	<u>Product Type and uses</u>	<u>Maximum Concentration</u>	<u>Other conditions</u>	<u>Product Labelling</u>
III	98	Only allowed, when used for purposes other than preservative in: 1. Rinse off hair-products. 2. Other products with the exception of body lotion, eye shadow, mascara, eyeliner, lipstick and roll-on deodorant.	1. 3% 2. 2%	<ul style="list-style-type: none"><li>• Not to be used in applications that may lead to exposure of the end-user's lungs by inhalation.</li><li>• Not to be used in products for children under 3 years of age.</li><li>• Not to be used in oral products.</li><li>• For purposes other than inhibiting the development of micro-organisms in the product.</li></ul>	Must contain the warning: <ul style="list-style-type: none"><li>• Not to be used in products for children under 3 years of age.</li></ul>
V	3	Cosmetic products, considering its current restrictions.	0.5 % (as acid)	<ul style="list-style-type: none"><li>• Not to be used in applications that may lead to exposure of the</li></ul>	<ul style="list-style-type: none"><li>• Not to be used in products for children under 3 years of age-</li></ul>



				<p>end-user's lungs by inhalation.</p> <ul style="list-style-type: none"><li>• Not to be used in products for children under 3 years of age.</li><li>• Not to be used in oral products.</li><li>• Not to be used in products for children under 3 years of age, except for shampoos.</li></ul>	<p>solely for products which might be used for children under 3 years of age.</p> <ul style="list-style-type: none"><li>• Not to be used in products for children under 3 years of age-solely for products which might be used for children under 3 years of age, and which remain in prolonged contact with the skin.</li></ul>
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## 2. Presentation and Discussion by The Scientific Advisory Group on Chemical Safety of Non-Food and Non-Medicinal Consumer Products (SAG-CS)

- 2.1. At the meeting held 21<sup>st</sup> July 2021, the SAG-CS discussed a paper which focussed on safety data available to support the use of salicylic acid for purposes other than a preservative function in body lotion, eye shadow, mascara, eyeliner, lipstick, and roll-on deodorant applications at a concentration of up to 0.5%.
- 2.2. Members considered the exposure of individuals to salicylic acid by different routes over time and questioned if there was a risk from aggregate exposure with pharmaceutical products and ingestion. Members agreed that a value of 0.5% was sensible for addressing aggregate exposure taking a conservative approach. Members also discussed the applicability of salicylic acid limits to leave on and rinse off cosmetics.
- 2.3. Members discussed in detail the use of read-across data from studies using acetyl salicylate, sodium salicylate, and methyl salicylate presented within the paper and the European Chemicals Agency (ECHA) registration dossier for salicylic acid.
- 2.4. Members discussed the data presented relating to genotoxicity of salicylic acid in-depth. Members noted that the opinion of both ECHA and the SCCS was that, based on the results provided, salicylic acid did not pose a genotoxic hazard. Members noted that some positive genotoxicity results both *in vitro* (e.g. Stitch *et al*, 1981) and *in vivo* (e.g. Giri *et al*, 1996) had been dismissed by the SCCS. They considered that without access to further information, it was not possible to comment further.
- 2.5. Members agreed that analytical methods for salicylic acid are well known and that it should be methodologically straightforward to enforce a 0.5% standard. Members further discussed difficulties with extraction of salicylic acid from formulations and suggested that interpretation of any regulation may be difficult for enforcers and that provision of guidance may be useful.



### 3. Conclusions

*Members were satisfied that there was sufficient evidence to form an opinion at this stage.*

*Members agreed that there would be no appreciable increase in health risk following the addition of salicylic acid for purposes other than preservative function in body lotion, eye shadow, mascara, eyeliner, lipstick, and roll-on deodorant applications in a concentration of up to 0.5%.*

*Members stated that salicylic acid use in products may need to be further reviewed with respect to body burden and aggregate exposure from other routes.*

*Members noted that there may be a need to further consider the genotoxicity data in the future including going back to the original papers to assess the results and methodologies in more detail.*

### Scientific Advisory Group on Chemical Safety of Non-Food and Non-Medicinal Consumer Products

January 2022

### References

European Chemicals Agency (ECHA) [registration dossier on salicylic acid](#).

Giri AK, Adhikari N, Khan KA (1996) [Comparative genotoxicity of six salicylic acid derivatives in bone marrow cells of mice](#). Mutat Res 370:1-9.

Scientific Committee on Consumer Safety (SCCS) Opinion on Salicylic Acid, Final opinion 21 December 2018, SCCS/1601/18  
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Stich H.F., Rosin M.P. Wu C.H. and Powrie W.D. [The action of transition metals on the genotoxicity of simple phenols, phenolic acids and cinnamic acids](#). Cancer Lett., 1981, 14: 251-260