



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

Final Opinion on Methyl-*N*-methylantranilate in Cosmetic Products.

1. Summary

- 1.1. Methyl-*N*-methylantranilate (CAS 85-91-6) is currently not regulated under the Cosmetic Products Regulation UK No 1223/2009 (as amended).¹ Methyl-*N*-methylantranilate has a harmonised classification as an eye irritant under the [GB Classification, Labelling and Packaging \(CLP\) regulation](#) No 1272/2008 (as amended).²
- 1.2. Methyl-*N*-methylantranilate is a fragrance ingredient used in decorative cosmetics, fine fragrances, shampoos, toilet soaps, and other toiletries. Various toxicological studies have supported the potential for methyl-*N*-methylantranilate to exhibit a phototoxic effect.
- 1.3. As methyl-*N*-methylantranilate is a secondary amine, it may be prone to nitrosation, resulting in the formation of the corresponding nitrosamine. Nitrosamines are considered to be strong carcinogens that may produce cancer in diverse organs and tissues. Currently, no evidence exists for the carcinogenic effect of methyl-*N*-methylantranilate following dermal exposure, although its potential for nitrosation has been recognised.

¹ 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](#).

² The GB CLP Regulation No 1272/2008 as amended by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019.



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 their February 2022 meeting, the SAG-CS discussed a paper which focussed on risks posed to health by methyl-*N*-methylantranilate when used in sunscreen products and products marketed for exposure to natural/artificial UV light.
- 2.2. Methyl-*N*-methylantranilate was considered by the SAG-CS to have a clear phototoxic effect based upon the data supplied.
- 2.3. Members agreed that the mutagenicity data available were limited and were not considered sufficient to draw conclusions on the mutagenicity of methyl-*N*-methylantranilate.
- 2.4. Members discussed the risk posed by potential nitrosation of methyl-*N*-methylantranilate. Members agreed that nitrosamine formation depends on both the pH value of the surrounding medium and presence of nitrosating compounds.
- 2.5. Members agreed that the analytical methods available for determination of methyl-*N*-methylantranilate are adequate.
- 2.6. Members discussed the metabolism of methyl-*N*-methylantranilate in the skin and potential capacity for hydrolysis to the associated acid form.
- 2.7. Members discussed the distinction between oral food studies and dermal cosmetic studies for use in risk assessment.

3. Conclusions

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

*Members agreed that methyl-*N*-methylantranilate presented a potential risk from phototoxic effects if used in sunscreen products and products marketed for exposure to natural/artificial UV light.*

*The members have only been able to evaluate limited genotoxicity data for methyl-*N*-methylantranilate. Considering the limited available data and evidence of low dermal absorption, methyl-*N*-methylantranilate does not appear to present a cause for concern.*

*Members considered methyl-*N*-methylantranilate to be safe for use up to 0.1% for leave-on and 0.2% for rinse-off cosmetic products.*



**Office for Product
Safety & Standards**

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

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