



EUROPEAN COMMISSION

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

Consumer, Environmental and Health Technologies
Health Technology and Cosmetics

SCIENTIFIC COMMITTEE ON CONSUMER SAFETY (SCCS)

Request for a scientific advice on Methyl-N-methylantranilate (CAS No. 85-91-6, EC No. 201-642-6)

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

1. Background

Methyl-N-methylantranilate (CAS No. 85-91-6, EC No. 201-642-6) is a fragrance ingredient used in various cosmetics, including fine fragrances, shampoos, soaps and other toiletries as well as in non-cosmetic products such as household cleaners and detergents.

Methyl-N-methylantranilate is a restricted substance according to the IFRA (International Fragrance Association) standards (concentration restriction of 0.10% in certain product categories)¹. It has also been subject to evaluation by the SCCNFP² in the opinion SCCNFP/0392/00 entitled "*An Initial List of Perfumery Materials which must not form part of Cosmetic Products except subject to the restrictions and conditions laid down*". SCCNFP recommended that the substances mentioned in this opinion may be used as ingredients in cosmetic products only under the conditions and restrictions specified in the table attached in its opinion. In that table, Methyl-N-methylantranilate was mentioned under entry No. 21 with the restriction: '*For applications on areas of the skin exposed to sunlight, excluding bath preparations, soaps and other wash-off products, limit to 10 % in the finished cosmetic product*'.

After the first submission, an updated IFRA recommendation led to submission II for this substance. It led to an SCCP³ opinion (SCCP/1068/06) on photo-toxicity being adopted in 2006 with the following conclusion: '*Methyl-N-methylantranilate is phototoxic as demonstrated by both in vivo and in vitro experiments. Although the action spectrum of the phototoxicity has not been provided, phototoxicity is normally within the UVA spectrum. The NOAEL in humans was at 0.5% with 16 J UVA/cm² (with 0.75 MED UVB) (ref 34768). However, an in vitro test indicated that it was phototoxic at 0.05%, the lowest dilution tested. Phototoxicity is related to the product of dose and UV exposure. Because of the phototoxicity, methyl-N-methylantranilate should not be deliberately added to leave-on cosmetic products, as there is always the potential for light exposure. Until appropriate toxicity data on the substance are available, including information on the possible nitrosamine formation by this secondary amine, up to 0.1% can be used in rinse-off finished*

¹ Amendment 49, published in 2020

² Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers

³ Scientific Committee on Consumer Products

cosmetic products. The above opinion applies also to the presence of methyl-N-methylantranilate in essential oils, including Petitgrain Mandarin’.

In 2008, EFFA⁴ submitted a compilation of studies based on a complete literature search in order to allow the substance to be use in concentration up 0.1% in leave-on products and up to 0.2% in rinse-off products. In 2011, the SCCS⁵ (SCCS/1455/11) concluded that there are no safety concerns on the use of methyl-N-methylantranilate at up to 0.2% in rinse-off products. Nevertheless, the SCCS stated that *‘Methyl-N-methylantranilate is phototoxic and this is the toxicological endpoint of concern. Whilst up to 0.1% methyl-N-methylantranilate may be safe for use in many leave-on cosmetic products, including deodorants and antiperspirants, the SCCS considers that for the use in sunscreen/sun care products or products (including fragrances) intended for use on areas exposed to light (especially face and neck), a risk cannot be excluded’.*

In our view, the health risk of methyl-N-methylantranilate is linked to its photosensitivity. In particular, such risk could be envisaged when body parts are exposed to intensive sunlight (natural UV light) or any artificial sources of UV light, after the application of cosmetics containing methyl-N-methylantranilate. In our understanding, products which pose risks of such exposure are sunscreens, as well as other products marketed for exposure to natural or artificial UV light (i.e. products marketed for sunbeds). Therefore, we would like to search advice from the SCCS on how these elements can be more precisely reflected in the conclusions. Notably, we would like to ask for a scientific advice on whether the clarification suggested below would be scientifically valid.

Provided that our suggested clarification is valid, we would consider that for leave-on products containing methyl-N-methylantranilate other than sunscreens and products marketed for exposure to natural or artificial UV light, this substance should be restricted to 0.1%.

2. Terms of reference

- *We would like to request scientific advice on whether the sentence from the SCCS opinion (SCCS/1455/11) "...the SCCS considers that for the use in sunscreen/sun care products or products (including fragrances) intended for use on areas exposed to light (especially face and neck), a risk cannot be excluded" would mean that methyl-N-methylantranilate should not to be used in sunscreen products and products marketed for exposure to natural/artificial UV light, but is considered safe to be used up to 0.1% for leave on and 0.2% for rinse off products".*

3. Deadline: October 2020

4. Supporting documents: /

The SCCS approved this mandate by written procedure on 16 September 2020.

⁴ European Flavour & Fragrance Association

⁵ Scientific Committee on Consumer Safety