



## Commentary

## Opinion of the Scientific Committee on Consumer safety (SCCS) – Opinion on the safety of the use of Methylisothiazolinone (MI) (P94), in cosmetic products (sensitisation only)



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## ABSTRACT

**Conclusion of the opinion:** The information provided does not support the safe use of MI as a preservative in rinse-off cosmetic products up to a concentration limit of 100 ppm from the view of induction of contact allergy.

For rinse-off cosmetic products, a concentration of 15 ppm (0.0015%) MI is considered safe for the consumer from the point of view of induction of contact allergy.

The information provided does not support the safe use of MI as a preservative in leave-on hair cosmetic products up to a concentration limit of 100 ppm from the point of view of induction of contact allergy. The concerns and opinions raised in SCCS Opinion SCCS/1521/13 (12 December 2013 with revision 27 March 2014) remain. The results of the recent Scandinavian study do not support safety of MI in rinse-off products at either 100 ppm or at 50 ppm for elicitation or induction.

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[http://ec.europa.eu/health/scientific\\_committees/consumer\\_safety/docs/sccs\\_o\\_178.pdf](http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_178.pdf)

[http://ec.europa.eu/health/scientific\\_committees/consumer\\_safety/docs/sccs\\_o\\_178.pdf](http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_178.pdf)

The Scientific Committee on Cosmetic Products and Non-Food Products (SCCNFP) adopted two opinions on “Methylisothiazolinone” respectively in March 2003 (SCCNFP/0625/02) and in April 2004 (SCCNFP/0805/04).

The SCCNFP (March 2003 – SCCNFP/0625/02) concluded that the information submitted was insufficient at that time to allow an adequate risk assessment of Methylisothiazolinone to be carried out. The SCCNFP required: more detailed information concerning the physico-chemical properties of Methylisothiazolinone (e.g. LCMS analysis, pH, stability and degradation products); information on the material used in the tests (batch numbers, purity and impurities); an in vitro percutaneous absorption study and relevant and adequate genotoxicity/mutagenicity studies.

In response to the opinion of the SCCNFP concerning Methylisothiazolinone, adopted during the 23rd plenary meeting of 18 March 2003 (doc. n° SCCNFP/0625/02), additional information on the physico-chemical properties of the substance, an in vitro percutaneous absorption study and two studies on mutagenicity/genotoxicity were submitted to the SCCNFP for evaluation. In April 2004 the SCCNFP (SCCNFP/0805/04) concluded that the requested data were complete. Methylisothiazolinone was considered non genotoxic/mutagenic.

Methylisothiazolinone (MI) was listed in Annex V/57 of

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Regulation (EC) No 1223/2009 to be used as preservative at maximum concentration of 0.01% (100 ppm) in cosmetics products.

According to several Member States and a good number of published papers, the sensitisation to MI is becoming an increasing problem all over Europe. In light of this information, the Commission requested to the Scientific Committee (SCCS) a reassessment of the safety of MI when it is used as preservative in cosmetics products at maximum concentration of 100 ppm. The scientific opinion of the SCCS (SCCS/1521/13) on Methylisothiazolinone (P94) Submission II (Sensitisation only) was delivered in March 2014 with the following conclusions:

Current clinical data indicate that 100 ppm MI in cosmetic products is not safe for the consumer. For leave-on cosmetic products (including 'wet wipes'), no safe concentrations of MI for induction of contact allergy or elicitation have been adequately demonstrated. For rinse-off cosmetic products, a concentration of 15 ppm (0.0015%) MI is considered safe for the consumer from the view of induction of contact allergy. However, no information is available on elicitation.

Recently, the SCCS received a new mandate in order to assess safety of 100 ppm of MI included in rinse off and hair leave on products. Data from Cosmetics Europe concerning the safety of MI in rinse-off and hair leave on products were received in June 2014, new cosmetovigilance data in February 2015 and data on aggregate exposures to rinse-off products in May 2015. The concentration limit of MI to 15 ppm proposed by the SCCS for rinse off products is based on the data available related to the mixture MCI/MI (SCCS/1238/09). New data are submitted trying to demonstrate that

100 ppm included in rinse-off and in leave-on hair cosmetics products is safe for the consumers. The SCCS was requested to give an opinion about the safety of MI at 100 ppm in rinse-off and leave-on hair cosmetic products.

The information provided does not support the safe use of MI as a preservative in rinse-off cosmetic products up to a concentration limit of 100 ppm from the view of induction of contact allergy.

For rinse-off cosmetic products, a concentration of 15 ppm (0.0015%) MI is considered safe for the consumer from the point of view of induction of contact allergy.

The information provided does not support the safe use of MI as a preservative in leave-on hair cosmetic products up to a concentration limit of 100 ppm from the point of view of induction of contact allergy.

The concerns and opinions raised in SCCS Opinion SCCS/1521/13 (12 December 2013 with revision 27 March 2014) remain. The results of the recent Scandinavian study do not support safety of MI in rinse-off products at either 100 ppm or at 50 ppm for elicitation or induction.

**Reference:**

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**Transparency document**

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