

## SCIENTIFIC COMMITTEE ON CONSUMER SAFETY (SCCS)

**Request for a scientific opinion:** Methylisothiazolinone (MI) CAS n. 2682-20-4 (P94)

### 1. Background

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

On the basis of those opinions Methylisothiazolinone (MI) was listed in Annex V/57 of Regulation (EC) No 1223/2009 to be used as preservative at maximum concentration of 0.01% (100ppm) in cosmetics products.

According to several Member States and some literature, the sensitization to MI is becoming an increasing problem all over Europe, particularly with sensitization in young children from moist toilet paper/hygiene moist tissues or cosmetics and, in light of this information, the Commission requested to the Scientific Committee (SCCS) a reassessment of the safety of the MI when it is used as preservative in cosmetics products at maximum concentration of 100ppm. The scientific opinion (SCCS/1521/13) on Methylisothiazolinone (P94) Submission II (Sensitisation only) was delivered in March 2014 with the following conclusion:

*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.*

The Commission received new data from Cosmetics Europe concerning safety of MI in rinse-off and hair leave on products in June 2014 and new cosmetovigilance data are expected for the end of 2014. Considering that the concentration limit of MI to 15ppm suggested by SCCS is based on the data related to the mixture MCI/MI (SCCS/1238/09) and according to Cosmetic Europe 15ppm would be insufficient for effective preservation in the majority of commercially available products, the Commission finds it appropriate to request the safety evaluation of MI in rinse-off and leave-on hair cosmetic products.

### 2. Terms of reference

- 1. On the basis of the data provided, does the SCCS consider Methylisothiazolinone (MI) to be safe for consumers, when used as a preservative in rinse-off products up to concentration limit of 100ppm from the view of induction of contact allergy?*
- 2. On the basis of the data provided, does the SCCS consider Methylisothiazolinone (MI) to be safe for consumers, when used as a preservative in leave-on hair*

*products up to concentration limit of 100ppm from the view of induction of contact allergy?*

3. *Does the SCCS have any further scientific concerns with regard to the use of Methylisothiazolinone (MI) in cosmetic products?*

**3. Deadline:**

**4. Supporting documents**

1. Cosmetics Europe Dossier on MI