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 first opinion in March 2003 on “Methylisothiazolinone” (SCCNFP/0625/02).

The SCCNFP adopted the second opinion on “Methylisothiazolinone” on April 2004 (SCCNFP/0805/04) with the following conclusion:

The SCCNFP is of the opinion that the proposed use of Methylisothiazolinone as a preservative at a maximum concentration of 0.01% (100 ppm) in the finished cosmetic product does not pose a risk to the health of the consumer.

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.

The mixture of Methylchloroisothiazolinone(MCI) and Methylisothiazolinone (MI) is also currently allowed as a preservative in all cosmetic products at a maximum concentration of 0.0015% (15ppm) of a mixture in the ratio 3:1 of the two substances.

Several Member States raised concern on the use of Methylisothiazolinone (MI), as data demonstrates that MI is a sensitizer in animals and a contact allergen in human. The Commission received information on the issue of sensitizing potential of MI starting from 2011. According to this information both MCI/MI and MI alone are used in cosmetics as well as in household products and industrial products.

According to some 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 would like to request a reassessment of the safety of the MI when it is used as preservative in cosmetics products at maximum concentration of 100ppm.

2. Terms of reference

1. On the basis of the new clinical and epidemiological evidence in relation to contact allergy, does the SCCS consider Methylisothiazolinone (MI) to be safe for consumers, when used as a preservative in cosmetic products up to concentration limit of 100ppm? If no, what concentration limits in leave-on and rinse-off cosmetic products does the SCCS consider to be safe on the basis of information provided.

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

4. **Supporting documents**


2. Whilst Rome Burns: The Epidemic of Contact Allergy to Methylisothiazolinone- Contact Dermatitis • Editorial

3. Results of patch testing with fragrance mix 1, fragrance mix 2, and their ingredients, and Myroxylon pereirae and colophonium, over a 21-year period- Contact Dermatitis • Original Article

4. Methylchloroisothiazolinone/methylisothiazolinone contact sensitization: diverging trends in subgroups of IVDK patients in a period of 19 years- Uter et al - Contact Dermatitis 2012

5. Recent increase in allergic reactions to methylchloroisothiazolinone/methylisothiazolinone: is methylisothiazolinone the culprit- J. Geier et al- Contact Dermatitis 2012


7. Contact sensitization to methylisothiazolinone in Finland – a multicentre study – L. Ackermann et al. - Contact Dermatitis 2010

8. Contact allergy to methylchloroisothiazolinone/methylisothiazolinone (MCI/MI): findings from a Contact Dermatitis Unit- P. Maio et al- Cutaneous and Ocular Toxicology, 2011, 1–3

9. Methylisothiazolinone- Mari Paz Castanedo-Tardana et al- Contact Allergen of the Year 2013

10. Airborne and systemic dermatitis, mimicking atopic dermatitis, caused by methylisothiazolinone in a young child –O. Aerts et al- Contact Dermatitis, 68, 250–256

11. Airborne exposure to methylchloroisothiazolinone and methylisothiazolinone from a toilet cleaner- M. D. Lundov et al.- Contact Dermatitis, 68, 250–256


14. Two cases of airborne allergic contact dermatitis caused by methylisothiazolinone in paint - Michael D. Lundov et al. - John Wiley & Sons A/S • Contact Dermatitis, 65, 175–185

15. Recent increase in allergic reactions to MCI/MI: is MI the culprit? - Johannes Geier et al - Contact Dermatitis - Manuscript ID: COD-OM-06-12-1380.R1
