

Public consultation on Methylisothiazolinone (MI) in the framework of Regulation (EC) No. 1223/2009 of the European Parliament and of the Council on cosmetic products - rinse-off cosmetic products

Background

Methylisothiazolinone (MI) is currently authorized as a preservative in cosmetics products through Annex V, entry 57, of Regulation (EC) No 1223/2009 ("Cosmetics Regulation") at a maximum concentration of 0.01% (100ppm).

However, a measure to ban the use of MI as a preservative in leave-on cosmetic products is to be adopted in 2016.

The Cosmetics Regulation also authorizes the mixture of Methylchloroisothiazolinone (MCI) and Methylisothiazolinone (MI) as a preservative in rinse-off cosmetic products at a maximum concentration of 0.0015% (15ppm) in a ratio 3:1 of the two substances (since 16 July 2015).

The first opinion related to MI was adopted by the Scientific Committee on Cosmetic Products and Non-Food Products (SCCNFP) in March 2003¹. The Committee adopted a second opinion on MI in April 2004², where it concluded that the use of MI as a preservative at a maximum concentration of 0.01% (100 ppm) in the finished cosmetic product did not pose a risk to the health of the consumer.

According to literature and clinical data³, sensitisation to MI is becoming an increasing problem all over Europe, particularly with sensitisation in young children from moist toilet tissue/hygiene moist tissues (wet wipes) or cosmetics. Several Member States asked the Commission to request the Scientific Committee for Consumer Safety (SCCS) to re-assess the safety of MI when used as a preservative in cosmetics products at a maximum concentration of 100ppm.

A third SCCS opinion was adopted on 12 December 2013 (later revised in March 2014⁴), concluding that:

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.

[...]

MI should not be used as an addition to a cosmetic product already containing MCI/MI.

¹ SCCNFP/0625/02.

² SCCNFP/0805/04.

³ See for example Urwin, R. & Wilkinson, M. (2013) Methylchloroisothiazolinone and methylisothiazolinone contact allergy: a new "epidemic". Contact dermatitis 68: 253–5.

⁴ SCCS/1521/13 Revision of 27 March 2014.

Labelling is only helpful to a consumer who has a known (established by diagnostic patch test investigations) allergy. It is unknown what proportion of the general population is now sensitized to MI and has not been confirmed as sensitized."

The maximum concentration of 15 ppm as concluded by the SCCS for rinse-off cosmetic products was calculated based on the data provided for Methylchloroisothiazolinone (and) Methylisothiazolinone, a mixture where the principal component is Methylchloroisothiazolinone. There are, however, differences both in terms of sensitization potential and efficacy between this mixture and Methylisothiazolinone alone.

Following this third opinion, Cosmetics Europe, the European cosmetics industry association, submitted additional data requesting a new risk assessment by the SCCS of the safety of Methylisothiazolinone in rinse-off and hair leave-on products (hair leave-on products to be exempted from the forthcoming ban of MI in leave-on products). The Commission sent a new mandate to the SCCS requesting them to establish a level of exposure that would prevent the induction of allergies.

The fourth SCCS opinion related to MI (rinse off/hair leave-on cosmetic products) was published on 15 December 2015⁵ confirming the following:

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.

⁵ SCCS/1557/15 (submission III, sensitisation only).