

Brussels, 12 December 2013

Recommendation

Cosmetics Europe, following discussions with the European Society of Contact Dermatitis (ESCD), recommends that the use of Methylisothiazolinone (MIT) in leave-on skin products including cosmetic wet wipes is discontinued. This action is recommended in the interests of consumer safety in relation to adverse skin reactions. It is recommended that companies do not wait for regulatory intervention under the Cosmetics Regulation but implement this recommendation as soon as feasible.

Background

Methylisothiazolinone (MIT) is an effective preservative for a wide range of cosmetics and personal care products. The Scientific Committee for Cosmetic Products and Non-food products intended for Consumers (SCCNFP)ⁱ conducted a safety review and published their opinion in 2004, following which MIT was authorised as a preservative in accordance with the European Cosmetic Products legislation (Directive 76/768/EEC, subsequently Regulation (EC) 1223/2009), for use in leave-on and rinse-off cosmetic products up to a maximum concentration of 0.01% (100ppm).

MIT was introduced to the market as a cosmetic preservative in 2006, and since then has been widely used due to its broad spectrum preservation properties.

Recent publications from the dermatology community report clinical evidence of a sharp increase in positive and relevant patch test reactions to MIT in patients suffering from dermatitis through cosmetic use. Cosmetics Europe took these concerns seriously and, with the support of experts from ingredient suppliers and cosmetic product manufacturers conducted a thorough review of the clinical, toxicological and cosmetovigilance data for MIT. In particular it also updated the risk assessment using a technique called Quantitative Risk Assessment for allergens (QRA), which had not been commonly used when MIT was first assessed by the SCCS in 2004.

Based on the careful assessment of available data, the industry experts concluded that there was evidence to suggest a relationship between the use of leave-on skin products, including cosmetic wet wipes containing MIT, and the induction of contact allergy and allergic contact dermatitis. Therefore the removal of MIT from leave-on

skin products including cosmetic wet wipes is expected to significantly decrease the incidence of induction of contact allergy to MIT.

ⁱ The SCCNFP is now called the Scientific Committee on Consumer Safety, the SCCS, and is the European Commission's independent committee of scientists which assesses ingredient safety.