Preservatives Regulatory

February 2017 update

Methylisothiazolinone (MIT)

From 12th of February 2017, cosmetic products must comply with EU legislation prohibiting the use of methylisothiazolinone (MI or MIT) in leave-on products (including wet wipes and hair products).

In December 2013, following allergy concerns, Cosmetics Europe issued a recommendation to discontinue the use of MIT in leave-on skin products. A SCCS (Scientific Committee on Consumer Safety) Opinion was also first published in December 2013 concluding no safe levels demonstrated for leave-on and suggesting 15 ppm safe for rinse-off. A further SCCS Opinion finalised in December 2015 concluded that MIT is only safe in rinse-off cosmetic products up to a maximum of 15 ppm.

European Member States are expected to vote in February 2017 to reduce the maximum allowed concentration of MIT from 100 ppm to 15 ppm in rinse-off products. A "contains methylisothiazolinone" labelling designation which was previously discussed in a Commission Consultation is no longer included in the current regulatory proposal. The proposed transition period is six months for placing on the market and nine months for final supply to the consumer meaning a potential final supply date in early 2018. These proposals are not finalized until a Regulation is published in the Official Journal.

Methylchloroisothiazolinone & Methylisothiazolinone (CMIT/MIT)

Since July 2015, the preservative mixture CMIT/MIT is only approved for rinse-off products at a maximum concentration of 15 ppm. Companies had until April 2016 to withdraw non-compliant products from the market.

Phenoxyethanol

Following a report and recommendations issued by the French authorities, the European Commission mandated the SCCS in April 2014 to consider whether the current maximum concentration of 1% phenoxyethanol in cosmetic products is safe and to take into account specific age groups.

The SCCS adopted its opinion on phenoxyethanol on the 6th of October 2016. The conclusions of the final opinion were the same as that of the draft opinion. The SCCS considers phenoxyethanol safe at the current use concentration of up to 1% in cosmetics and that the calculated Margin of Safety (MoS) also covers children three years of age and under.

ALTERNATIVE PRESERVATIVE SYSTEMS

The Ashland team can assist you in finding suitable preservative systems and our microbiological laboratories are able to perform challenge tests to support your reformulation work. Please find some suggested alternatives such as our Optiphen™, Suttocide™, LiquaPar™ and Rokonsal™ preservatives with use details below:

- Products with pH up to 6 can be protected with modern preservatives such as Optiphen DP and Optiphen DLP, Rokonsal/ Optiphen ND, Optiphen Plus and Optiphen BD.
- Systems that need broader pH ranges can be preserved with Optiphen, Optiphen 200 and 300, Germaben II and Suttocide A or an alternative aromatic ingredient, Conarom P-2.
- Short-chain Paraben-based formulations, including LiquaPar ME and Rokonsal/ LiquaPar MEP, are available.

If you have any additional questions, please do not hesitate to contact your Ashland sales or technical contact directly.

Formaldehyde and Formaldehyde Donors

The 6th ATP of the Classification, Labelling and Packaging (CLP) Regulation, published in June 2014, changed the harmonised classification for formaldehyde from carcinogen category 2 to carcinogen category 1B and mutagen category 2. This classification applied from 1st January 2016 and is based on nasopharyngeal cancer, a rare form of cancer in Europe which is relevant to the inhalation route of exposure.

Ashland's formaldehyde donor preservatives have not been reclassified as free formaldehyde and its equivalent (methylene glycol) are below the 0.1% CMR classification threshold. They each have their own entry in Annex V (approved preservatives) of the Cosmetics Regulation ((EC) No 1223/2009).

The European Chemical Agency (ECHA) is currently assessing whether formaldehyde releasers should be part of future potential restrictions formaldehyde. In July 2016, as part of this activity, it published a call for evidence on the use of formaldehyde releasers on their own, in mixtures or in articles by workers, professionals and consumers.

Ashland responded to the call for evidence as an individual company as well as contributing to trade association responses. The submissions all advocated the continued safe use of formaldehyde donors in cosmetic products and emphasized the importance of these preservatives to the personal care industry.

Salicylic Acid

The European Commission's Risk Assessment Committee (RAC) has proposed salicylic acid to be classified as a reprotoxic category 2 for developmental effects under the CLP (Classification, Labelling and Packaging) Regulation.

Salicylic acid is currently regulated in Annexes III and V of the Cosmetics Regulation.

Cosmetics Europe is forming an industry consortium for the defense of this ingredient.

PHMB

Polyaminopropyl biguanide (PHMB) was classified as a carcinogen category 2 in the 5th ATP of the Classification, Labelling and Packaging (CLP) Regulation and this classification applied from 1st of January 2015.

An SCCS Opinion in June 2014 concluded that current maximum concentration of 0.3% is not safe but the safe use of PHMB could be based on a lower use concentration.

A Cosmetics Europe Consortium submitted a dossier supporting the use of PHMB up to 0.1% as a preservative except in propellant driven aerosol sprays. A further SCCS Opinion adopted by written procedure in December 2016 and published in January 2017 concludes that "Based on the data provided, the SCCS is of the opinion that the use of Polyaminopropyl Biguanide (PHMB) as a preservative in all cosmetic products up to 0.1% is safe" and "As no new safety data on inhalation is available on PHMB, its use in sprayable formulations is not advised".

North America — Bridgewater, NJ
Tel: +1 800 505 8984

Latin America — Sao Paulo, Brazil
Tel: +55 11 3649 0455
+55 11 3649 0468

Europe — Cologne, Germany
Tel: +49 (0) 2236 9649 264
+49 (0) 2236 9649 266

Asia Pacific — Singapore
Tel: +65 6775 5366

Shanghai, P.R. China
Tel: +86 21 6090 6688

Middle East and Africa — Dubai, U.A.E.
Tel: +971 47 017 131

ashland.com/contact

Ashland™
always solving