

Public consultation on Methylchloroisothiazolinone and methylisothiazolinone

In the framework of Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products

1. Background

Methylchloroisothiazolinone and methylisothiazolinone with magnesium chloride and magnesium nitrate (INCI) is currently regulated as a preservative in the Cosmetics Regulation in Annex V, entry 39 with the maximum authorized concentration 0.0015% (15 ppm) of a mixture in the ratio 3:1 of 5-chloro-2-methylisothiazolin-3(2H)-one and 2-methylisothiazolin-3(2H)-one. Methylisothiazolinone is also allowed on its own in entry 57.

Following the submission of a fully updated dossier by the industry in 2006, the SCCS adopted an opinion in 2009¹, in which it concluded the following:

"On the basis of the data submitted, the SCCS is of the opinion that the mixture of 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-4-isothiazolin-3-one in a ratio of 3:1 does not pose a risk to the health of the consumer when used as a preservative up to a maximum authorised concentration of 0.0015 % in rinse-off cosmetic products, apart from its sensitising potential."

In light of the scientific opinion ([SCCS/1238/09](#)), the Commission proposes to restrict the use of this mixture to rinse-off products.

The issue of stabilizers for this mixture was addressed in opinion [SCCNFP/0670/03](#), final. The Committee stated that *"taking into account that the active ingredients and their ratio remain unchanged and that the concentration of the stabiliser system in the finished cosmetic products is negligible, the SCCNFP is of the opinion that: the replacement of magnesium chloride and magnesium nitrate by copper sulfate or any other authorised cosmetic ingredient as a stabiliser system in the mixture of 5-Chloro-2-methyl isothiazolin-3(2H)-one and 2-Methylisothiazolin-3(2H)-one does not alter the toxicological profile of this mixture."*

When requested by the Commission to clarify their interpretation of the word "authorised", the Committee replied in opinion [SCCP/0849/04](#) that *"the expression "authorised cosmetic ingredient" should be interpreted as "any ingredient which, in the light of the Cosmetics Directive, is allowed or not prohibited and may be used in cosmetic products, provided that any substance belonging to the classes of ingredients listed in the Annexes III-VI² of the Directive may be used only if it is included in the respective annex."*

¹ SCCS/1238/09.

² We assume that the SCCP wanted to refer to the substances functioning as colorants, preservatives or UV-filter, which need to be explicitly authorized by being listed in Annexes IV, VI and VII. These three Annexes should therefore be mentioned, and not "Annexes III-VII".

In addition, the conclusion of the most recent opinion on "Mixture of 5-chloro-2-methyl-isothiazolin-3(2H)-one and 2-methyl-isothiazolin-3(2H)-one", SCCS/1238/09, assesses the safety of the above-mentioned mixture and makes no reference to the stabilizers taken into consideration.

In light of the 2003 opinion (SCCNFP/0670/03), and of the fact that stabilizers added in a raw material should be treated like any substance added in a cosmetic product, we conclude that any substance "allowed and not prohibited" by the Cosmetics Directive/Regulation could be used as a stabilizer in the mixture under discussion.

2. Action proposed by the Commission

The Commission envisages amending Annex V of the [Cosmetics Regulation \(EC\) No. 1223/2009](#) to restrict the use of methylchloroisothiazolinone and methylisothiazolinone to rinse-off products, as suggested by the SCCS.

Undertakings should be granted six months to place on the market compliant products, and twelve months to withdraw from the market non-compliant products after the entry into force of this Regulation.

The Commission will therefore propose that entries 39 and 57 of Annex V to Regulation (EC) No 1223/2009 on cosmetic products are amended as follows:

Reference number	Substance Identification				Conditions			Wording of conditions of use and warnings
	Chemical name/INN	Name of Common Ingredients Glossary	CAS number	EC number	Product type, Body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i
39	Mixture of 5-Chloro-2-methylisothiazol-3(2H)-one and 2-methylisothiazol-3(2H)-one	Methylchloroisothiazolinone and Methylisothiazolinone ³	26172-55-4, 2682-20-4, 55965-84-9	247-500-7, 220-239-6	Rinse-off products	0,0015 % (of a mixture in the ratio 3:1 of 5-chloro-2-methylisothiazol 3(2H)-one and 2-methylisothiazol-3 (2H)-one		
57	2-Methyl-2H-isothiazol-3-one	Methylisothiazolinone ⁴	2682-20-4	220-239-6		0,01 %		

³ Methylisothiazolinone is also regulated in entry 57. The two entries are mutually exclusive.

⁴ Methylisothiazolinone is also regulated in entry 39 in a mixture with methylchloroisothiazolinone. The two entries are mutually exclusive.

3. Public consultation

DG Health & Consumers would like to invite any interested parties to submit their comments on the considered measure and on its possible economic impact.

With relation to the economic impact the information/comments should refer, *inter alia*, to the following topics:

- competitiveness, markets and trade,
- direct and indirect costs imposed on business, including SMEs,
- innovation and research,
- specific regions, sectors or workers,
- third countries and international relations,
- macroeconomic environment.

4. Who can submit comments

Any interested parties, including:

- Authorities of the Member States,
- manufacturers of cosmetic products,
- producers of these substances,
- relevant industry and consumers associations

are welcome to submit their comments on the considered measure and on its possible impact.

5. How to submit your contribution

Any comments should be sent with the reference:

"Methylchloroisothiazolinone and methylisothiazolinone - Public Consultation"

by mail or e-mail by **8 October 2013** at the latest to:

European Commission
Directorate General Health and Consumers
Unit B/2, Health Technology and Cosmetics,
Office DM24 02/082
B-1049 Brussels,
Belgium

E-mail: sanco-cosmetics-and-medical-devices@ec.europa.eu

6. Languages

A summary of this public consultation is available in all EU languages at the following links:

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