



Council of the
European Union

Brussels, 13 July 2015
(OR. en)

10870/15

MI 488
ENT 160
CONSUM 129
SAN 230
ECO 90

COVER NOTE

From:	European Commission
date of receipt:	10 July 2015
To:	General Secretariat of the Council
No. Cion doc.:	D039780/02
Subject:	COMMISSION DIRECTIVE (EU) .../... of XXX amending, for the purpose of adopting specific limit values for chemicals used in toys, Appendix C to Annex II to Directive 2009/48/EC of the European Parliament and of the Council on the safety of toys, as regards chloromethylisothiazolinone and methylisothiazolinone, both individually and in a ratio of 3:1

Delegations will find attached document D039780/02.

Encl.: D039780/02



Brussels, **XXX**
[...] (2015) **XXX** draft

COMMISSION DIRECTIVE (EU) .../...

of **XXX**

amending, for the purpose of adopting specific limit values for chemicals used in toys, Appendix C to Annex II to Directive 2009/48/EC of the European Parliament and of the Council on the safety of toys, as regards chloromethylisothiazolinone and methylisothiazolinone, both individually and in a ratio of 3:1

(Text with EEA relevance)

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amending, for the purpose of adopting specific limit values for chemicals used in toys, Appendix C to Annex II to Directive 2009/48/EC of the European Parliament and of the Council on the safety of toys, as regards chloromethylisothiazolinone and methylisothiazolinone, both individually and in a ratio of 3:1

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys¹, and in particular Article 46(2) thereof,

Whereas:

- (1) In order to ensure a high level of protection of children against risks caused by chemical substances in toys, Directive 2009/48/EC establishes certain requirements with regard to chemical substances such as those classified as carcinogenic, mutagenic or toxic for reproduction (CMR) under Regulation (EC) No 1272/2008 of the European Parliament and of the Council², allergenic fragrances and certain elements. In addition, Directive 2009/48/EC empowers the Commission to adopt specific limit values for chemicals used in toys which are intended for children under 36 months and in other toys intended to be placed in the mouth in order to ensure adequate protection in the case of toys involving a high degree of exposure. The adoption of such limit values takes the form of an inclusion in Appendix C to Annex II to Directive 2009/48/EC.
- (2) For a number of chemicals, currently applicable limit values are either too high in the light of available scientific evidence or do not exist. Specific limit values should therefore be adopted for them, taking into account the packaging requirements for food as well as the differences between toys and food contact materials.
- (3) In order to advise the European Commission in the preparation of legislative proposals and policy initiatives in the area of toy safety, the Commission established the Expert Group on Toys Safety. The mission of its subgroup "Chemicals" is to provide such advice with regard to chemical substances which may be used in toys.

¹ OJ L 170, 30.6.2009, p. 1.

² Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

- (4) 5-Chloro-2-methylisothiazolin-3(2H)-one (CMI) and 2-methylisothiazolin-3(2H)-one (MI) in a ratio of 3:1 (CAS number 55965-84-9)³ as well as its individual components CMI (CAS number 26172-55-4) and MI (CAS number 2682-20-4) are used as preservatives in water-based toys⁴ including hobby paints, finger paints, window/glass paints, glues and soap bubbles⁵.
- (5) In its deliberations about CMI and MI in a ratio of 3:1 as well as the individual components CMI and MI the subgroup "Chemicals" took as a basis the related opinion of the Scientific Committee on Health and Environmental Risks (SCHER) noting that neither CMI and MI in a ratio of 3:1 nor the individual components CMI or MI are recommended for use in toys, due to contact allergic reactions observed with these substances in cosmetics⁶. The subgroup "Chemicals" also took account of the related SCCS opinion which considers CMI and MI in a ratio of 3:1 an extreme contact allergen in humans as demonstrated by available data⁷.
- (6) CMI and MI in a ratio of 3:1 is classified under Regulation (EC) No 1272/2008 as a skin sensitizer; CMI and MI individually are not classified under the Regulation. Directive 2009/48/EC has currently no specific limit value for CMI/MI 3:1, nor for CMI or MI individually, nor a general limit value for sensitizers.
- (7) In the light of the above the subgroup "Chemicals" recommended at its meeting of 15 February 2012 that CMI and MI in a ratio of 3:1 should not be used in toys.
- (8) According to the German Federal Institute for Risk Assessment (BfR, Bundesinstitut für Risikobewertung)⁸ limit values for CMI and MI, which are strongly allergenic, should be set at a concentration considered protective for individuals who are already sensitized. This is the strictest way to limit allergens, since already sensitized individuals suffer from an allergy outbreak at even lowest allergen concentrations. According to the abovementioned SCCS opinion such concentration is below 2 mg/kg⁹.
- (9) According to the BfR, market surveillance is able to routinely quantify CMI down to 0,75 mg/kg and MI down to 0,25 mg/kg¹⁰ (limits of quantification, LOQs).
- (10) In the light of the above, the Expert Group on Toys Safety recommended at its meeting of 23 May 2014 to also limit the uses of CMI and MI individually to their LOQs.

³ Trade names are Kathon, Acticide, Microcare, etc., according to the Scientific Committee on Consumer Safety (SCCS), Opinion on the mixture of 5-chloro-2-methylisothiazolin-3(2H)-one and 2-methylisothiazolin-3(2H)-one. Opinion adopted on 8 December 2009, p. 6.

⁴ Danish EPA (2014) Survey and health assessment of preservatives in toys. Survey of chemical substances in consumer products no. 124, 2014, table 24 on p. 56.

⁵ See footnote 4, pp. 38 – 39.

⁶ Scientific Committee on Health and Environmental Risks (SCHER), Opinion on "CEN's response to the opinion of the CSTEE on the assessment of CEN report on the risk assessment of organic chemicals in toys", adopted on 29 May 2007, p. 8 and table 1 on p. 9.

⁷ See the SCCS opinion in footnote 3, p. 35.

⁸ Position paper of the German Federal Institute for Risk Assessment (Bundesinstitut für Risikobewertung, BfR) of 24.9.2012, p. 4.

⁹ See the SCCS opinion in footnote 3, p. 33.

¹⁰ See footnote 8, p. 4.

- (11) While there is a specific migration limit for MI individually as an additive for use in certain food contact materials, the basic assumptions for deriving that migration limit are different from those for the content limit for MI in toys. The uses of CMI and MI in a ratio of 3:1 and of CMI individually are not regulated for food contact materials.
- (12) In view of the above, Appendix C of Annex II to Directive 2009/48/EC should be amended to include content limits for CMI and MI in a ratio of 3:1, as well as for CMI and MI individually, in toys.
- (13) The measures provided for in this Directive are in accordance with the opinion of the Committee established in Article 47 of Directive 2009/48/EC,

HAS ADOPTED THIS DIRECTIVE:

Article 1

In Appendix C of Annex II to Directive 2009/48/EC, the following entries shall be added:

"

Substance	CAS No	Limit value
reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1)	55965-84-9	1 mg/kg (content limit) in aqueous toy materials
5-Chloro-2-methyl-isothiazolin-3(2H)-one	26172-55-4	0,75 mg/kg (content limit) in aqueous toy materials
2-methylisothiazolin-3(2H)-one	2682-20-4	0,25 mg/kg (content limit) in aqueous toy materials

"

Article 2

- Member States shall adopt and publish, by [*Fill in date falling 24 months after publication in the OJ*] at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions.

They shall apply those provisions from [*Fill in same date as in previous subparagraph*].

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels,

*For the Commission
The President
Jean-Claude Juncker*