Commission Regulation (EU) 2016/1179 of 19 July 2016 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (Text with EEA relevance)

COMMISSION REGULATION (EU) 2016/1179

of 19 July 2016

amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to 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[(1)], and in particular Article 37(5) thereof,

Whereas:

(1) Part 3 of Annex VI to Regulation (EC) No 1272/2008 contains two lists of harmonised classification and labelling of hazardous substances. Table 3.1 lists the harmonised classification and labelling of hazardous substances based on the criteria set out in Parts 2 to 5 of Annex I to Regulation (EC) No 1272/2008. Table 3.2 lists the harmonised classification and labelling of hazardous substances based on the criteria set out in Annex VI to Council Directive 67/548/EEC[(2)].

(2) Since Directive 67/548/EEC has been repealed with effect from 1 June 2015, Table 3.2 in Part 3 of Annex VI should be deleted. However, in order to ease the transition to full applicability of Regulation (EC) No 1272/2008, that deletion should not take effect until 1 June 2017.

(3) Proposals for new, updated or deleted harmonised classification and labelling of certain substances have been submitted to the European Chemicals Agency (ECHA) pursuant to Article 37 of Regulation (EC) No 1272/2008. Based on the opinions on those proposals issued by the Committee for Risk Assessment of ECHA (RAC), as well as on the comments received from the parties concerned, it is appropriate to introduce, update or delete harmonised classification and labelling of certain substances.

(4) With regard to the substance lead, RAC proposes in its scientific opinion of 5 December 2013 to classify it as toxic for reproduction category 1A. However, in view of the lack of certainty regarding the bioavailability of lead in the massive form, a distinction needs to be made between the massive form (particle size more than or equal to 1 mm) and the

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powder form (particle size of less than 1 mm). It is therefore appropriate to introduce a specific concentration limit (SCL) of ≥ 0,03 % for the powder form and a generic concentration limit (GCL) of ≥ 0,3 % for the massive form.

(5) With regard to the copper substances, the environmental classification recommended in the RAC opinions of 4 December 2014 should be included in Annex VI to Regulation (EC) No 1272/2008 since sufficient scientific evidence is available justifying this new classification. However, the proposed M-factors for long-term aquatic hazard should not be included since they require further assessment by RAC in view of scientific data on aquatic toxicity presented by industry after the RAC opinion was forwarded to the Commission.

(6) Regulation (EC) No 1272/2008 should be amended accordingly.

(7) Compliance with the new harmonised classifications should not be required immediately, as a certain period of time will be necessary to allow suppliers to adapt the labelling and packaging of substances and mixtures to the new classifications and to sell existing stocks. This period of time will also be necessary to allow suppliers to adapt to and to comply with other legislative obligations resulting from the new harmonised classifications for substances such as those provided for in Article 22(f) or Article 23 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council[(3)], those provided for in Article 50 of Regulation (EU) No 528/2012 of the European Parliament and of the Council[(4)] or those in Article 44 of Regulation (EC) No 1107/2009 of the European Parliament and of the Council[(5)].

(8) In line with the transitional provisions of Regulation (EC) No 1272/2008 which allow the application of the new provisions at an earlier stage on a voluntary basis, suppliers should have the possibility of applying the new harmonised classifications and of adapting the labelling and packaging accordingly on a voluntary basis before the deadline for compliance.

(9) The measures provided for in this Regulation are in accordance with the opinion of the Committee established by Article 133 of Regulation (EC) No 1907/2006,

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 1272/2008 is amended as follows:

(1) Annex VI is amended in accordance with the Annex to this Regulation;

(2) in Annex VI, Table 3.2 is deleted.

Article 2

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

2 This Regulation shall apply from 1 March 2018.

Article 1(2) shall apply from 1 June 2017.

3 By way of derogation from paragraph 2, substances and mixtures may, before 1 March 2018, be classified, labelled and packaged in accordance with Regulation (EC) No 1272/2008 as amended by this Regulation.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 19 July 2016.

For the Commission

The President

Jean-Claude JUNCKER

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2016/1179. (See end of Document for details)*

ANNEX

Table 3.1 of Part 3 of Annex VI to Regulation (EC) No 1272/2008 is amended as follows:

(a) the entries corresponding to index numbers 607-331-00-5 and 609-066-00-0 are deleted;

(b) the entries corresponding to index numbers, 006-035-00-8, 029-002-00-X, 602-020-00-0, 602-033-00-1, 603-055-00-4, 604-030-00-0, 604-092-00-9, 605-013-00-0, 605-022-00-X, 606-014-00-9, 606-021-00-7, 607-056-00-0, 607-059-00-7, 607-157-00-X, 607-172-00-1, 607-375-00-5, 607-623-00-2, 613-166-00-X, 613-121-00-4, 616-011-00-4, 616-037-00-6 and 616-207-00-X are replaced by the following entries respectively:

Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
‘006-035-00-8	pirimicarb (ISO); 2-(dimethylamino)-5,6-dimethylpyrimidin-4-yl dimethylcarbamate	245-430-3	23103-98-2	Carc. 2 Acute Tox. 3 Acute Tox. 3 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H351 H331 H301 H317 H400 H410	GHS08 GHS06 GHS09 Dgr	H351 H331 H301 H317 H410		M = 10 M = 100’	
‘029-002-00-X	dicopper oxide; copper (I) oxide	215-270-7	1317-39-1	Acute Tox. 4 Acute Tox. 4 Eye Dam. 1 Aquatic Acute 1 Aquatic Chronic 1	H332 H302 H318 H400 H410	GHS07 GHS05 GHS09 Dgr	H332 H302 H318 H410		M = 100’	

‘602-020-00-8	1,2-dichloropropane; propylene dichloride	201-152-2	78-87-5	Flam. Liq. 2 Carc. 1B Acute Tox. 4* Acute Tox. 4*	H225 H350 H332 H302	GHS02 GHS08 GHS07 Dgr	H225 H350 H332 H302’			
‘602-038-00-1	1-chloro-2-nitrobenzene	202-809-6	88-73-3	Flam. Liq. 3 Acute Tox. 4 Skin Irrit. 2 Aquatic Chronic 2	H226 H332 H315 H411	GHS02 GHS07 GHS09 Wng	H226 H332 H315 H411’			
‘603-055-00-4	propylene oxide; 1,2-epoxypropane; methyloxirane	200-879-2	75-56-9	Flam. Liq. 1 Carc. 1B Muta. 1B Acute Tox. 3 Acute Tox. 3 Acute Tox. 4 STOT SE 3 Eye Irrit. 2	H224 H350 H340 H331 H311 H302 H335 H319	GHS02 GHS08 GHS06 Dgr	H224 H350 H340 H331 H311 H302 H335 H319’			
‘604-030-00-0	bisphenol A; 4,4′-isopropylidenediphenol	201-245-8	80-05-7	Repr. 1B STOT SE 3 Eye Dam. 1 Skin Sens. 1	H360F H335 H318 H317	GHS08 GHS05 GHS07 Dgr	H360F H335 H318 H317’			