

COMMISSION DELEGATED REGULATION (EU) 2023/1435**of 2 May 2023****amending Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures as regards the modification of entries in Part 3 of Annex VI for 2-ethylhexanoic acid and its salts, boric acid, diboron trioxide, tetraboron disodium heptaoxide hydrate, disodium tetraborate anhydrous, orthoboric acid sodium salt, disodium tetraborate decahydrate, and disodium tetraborate pentahydrate****(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, Table 3, of Annex VI to Regulation (EC) No 1272/2008 contains a list of harmonised classification and labelling of hazardous substances based on the criteria set out in Parts 2 to 5 of Annex I to that Regulation.
- (2) Proposals to introduce harmonised classification and labelling of certain substances and to update or delete the harmonised classification and labelling of certain other substances have been submitted to the European Chemicals Agency (the 'Agency') pursuant to Article 37 of Regulation (EC) No 1272/2008. The Committee for Risk Assessment of the Agency (the 'RAC') adopted opinions on those proposals, after having taken account of the comments received from the parties concerned.
- (3) The RAC's opinion of 20 September 2019 concerning boric acid, diboron trioxide, tetraboron disodium heptaoxide hydrate, disodium tetraborate anhydrous, orthoboric acid sodium salt, disodium tetraborate decahydrate and disodium tetraborate pentahydrate ⁽²⁾, as well as the RAC's opinion of 11 June 2020 concerning 2-ethylhexanoic acid and its salts ⁽³⁾, described scientific evidence indicating that the reproductive toxicity of each of those substance groups is due to a molecular entity common to all members of a substance group. Member State experts consulted in the Commission expert group CARACAL (Competent Authorities for Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and Classification, Labelling and Packaging (CLP)) therefore requested the addition of notes to the entries related to the substance groups referred to in those RAC opinions of 2019 and 2020, in order to address the situation in which several substances belonging to one of those groups are present together in a mixture and to provide that the applicable concentration limit for classification of the mixture is to be compared with the sum of the concentrations of those substances. Those notes were added to Part 1, section 1.1.3.2, of Annex VI to Regulation (EC) No 1272/2008 by Commission Delegated Regulation (EU) 2023/1434 of 25 April 2023 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 as regards the addition of notes to Part 1, section 1.1.3, of Annex VI ⁽⁴⁾, as note 11 and note 12. It is therefore appropriate to add a reference to note 11 to the entries for boric acid, diboron trioxide, tetraboron disodium heptaoxide hydrate, disodium tetraborate anhydrous, orthoboric acid sodium salt, disodium tetraborate decahydrate and disodium tetraborate pentahydrate and a reference to note 12 to the entry for 2-ethylhexanoic acid and its salts.

⁽¹⁾ OJ L 353, 31.12.2008, p. 1.

⁽²⁾ <https://echa.europa.eu/documents/10162/584263da-199c-f86f-9b73-422a4f22f1c3>

⁽³⁾ <https://echa.europa.eu/documents/10162/8740de5b-368d-55a7-7955-094ef602d760>

⁽⁴⁾ See page 3 of this Official Journal.

- (4) In its opinion of 11 June 2020 concerning 2-ethylhexanoic acid and its salts, the RAC recommended adding a note to this entry, in order to address the possibility that, while the entry for this group of substances is based on the toxic properties of a common part of those substances, another, substance-specific, part of the substances may warrant classification in a higher category or classification with a broader scope, e.g. including additional differentiation, target organs and/or hazard statements, for certain substances in the entry. Such note was added to Part 1, section 1.1.3.1, of Annex VI to Regulation (EC) No 1272/2008 by Delegated Regulation (EU) 2023/1434 as note X. It is therefore appropriate to add a reference to note X to the entry concerning 2-ethylhexanoic acid and its salts.
- (5) Member State experts consulted in the CARACAL expert group suggested that the current note A should be applicable to 2-ethylhexanoic acid and its salts. Note A prescribes that for substances covered by an entry with a general description, such as ‘...compounds’ or ‘...salts’, the supplier is required to state on the label the correct name. As the entry for 2-ethylhexanoic acid and its salts bears such a general description, a reference to note A should be added to the entry.
- (6) As Delegated Regulation (EU) 2023/1434 was adopted on 25 April 2023, the notes included in that Regulation could not be inserted in Table 3 of Annex VI at the time of the adoption of Commission Delegated Regulation (EU) 2021/849 ⁽⁵⁾ and Commission Delegated Regulation (EU) 2022/692 ⁽⁶⁾ which added the respective entries to Table 3 of Annex VI to Regulation (EC) No 1272/2008. It is therefore necessary to update the entries concerning boric acid; diboron trioxide; tetraboron disodium heptaoxide hydrate; disodium tetraborate anhydrous; orthoboric acid sodium salt; disodium tetraborate decahydrate; disodium tetraborate pentahydrate, by adding reference to note 11 to each of them. It is also necessary to update entry concerning 2-ethylhexanoic acid and its salts by adding a reference to note 12 and note X to that entry.
- (7) Regulation (EC) No 1272/2008 should therefore be amended accordingly.
- (8) Compliance with the revised harmonised classifications should not be required immediately as suppliers need some time to adapt the labelling and packaging of substances and mixtures to the revised harmonised classifications and to sell existing stocks of substances and mixtures. That period of time would also allow suppliers to take the actions required to ensure compliance with other requirements set out in Regulation (EC) No 1272/2008, as amended by this Regulation. Suppliers should, however, have the possibility to apply the revised harmonised classifications, and to adapt the labelling and packaging accordingly, on a voluntary basis as from the entry into force of this Regulation, to ensure a high level of protection of human health and of the environment and to provide sufficient flexibility to suppliers,

HAS ADOPTED THIS REGULATION:

Article 1

Amendments to Regulation (EC) No 1272/2008

Annex VI to Regulation (EC) No 1272/2008 is amended as set out in the Annex to this Regulation.

Article 2

Entry into force and application

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

Article 1 shall apply from 1 February 2025.

⁽⁵⁾ OJ L 188, 28.5.2021, p. 27.

⁽⁶⁾ OJ L 129, 3.5.2022, p. 1.

Suppliers may classify, label and package substances and mixtures listed in the Annex to this Regulation in accordance with Regulation (EC) No 1272/2008, as amended by this Regulation, as from 31 July 2023.

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

Done at Brussels, 2 May 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

In Part 3, Table 3, of Annex VI, the entries corresponding to index numbers 005-007-00-2, 005-008-00-8, 005-011-00-4 and 607-230-00-6 are replaced by the following entries respectively:

Index No	Chemical Name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	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)		
'005-007-00-2	boric acid; [1]	233-139-2 [1]	10043-35-3 [1]	Repr. 1B	H360FD	GHS08	H360FD			11'
	boric acid [2]	234-343-4 [2]	11113-50-1 [2]			Dgr				
'005-008-00-8	diboron trioxide	215-125-8	1303-86-2	Repr. 1B	H360FD	GHS08 Dgr	H360FD			11'
'005-011-00-4	tetraboron disodium heptaoxide, hydrate; [1]	235-541-3 [1]	12267-73-1 [1]	Repr. 1B	H360FD	GHS08	H360FD			11'
	disodium tetraborate, anhydrous; [2]	215-540-4 [2]	1330-43-4 [2]			Dgr				
	orthoboric acid, sodium salt; [3]	237-560-2 [3]	13840-56-7 [3]							
	disodium tetraborate decahydrate; [4]	215-540-4 [4]	1303-96-4 [4]							
	disodium tetraborate pentahydrate [5]	215-540-4 [5]	12179-04-3 [5]							
'607-230-00-6	2-ethylhexanoic acid and its salts, with the exception of those specified elsewhere in this Annex	-	-	Repr. 1B	H360D	GHS08 Dgr	H360D			A, X, 12'