

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****(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 53(1) thereof,

Whereas:

- (1) Part 1, section 1.1.3, of Annex VI to Regulation (EC) No 1272/2008 contains the list of notes which may be assigned to one or more harmonised classification and labelling entries and relate to the identification, classification and labelling of substances as well as the classification and labelling of mixtures.
- (2) In its opinion of 11 June 2020 concerning 2-ethylhexanoic acid and its salts ⁽²⁾, the Committee for Risk Assessment (RAC) under the European Chemicals Agency recommended to add a new note to Part 1, section 1.1.3.1, of Annex VI to Regulation (EC) No 1272/2008, to clarify that the classification covering a group of substances in the same entry is only based on the hazardous properties of that part of the substance which is common to all substances in that entry. According to RAC, for the non-common parts of a substance, it is necessary to assess if their hazardous properties may warrant a more severe classification (higher category) or a broader classification (including additional differentiation, target organs and/or hazard statements) for the same hazard class. A new note X should therefore be added to Part 1, section 1.1.3.1, of Annex VI to Regulation (EC) No 1272/2008. As that note is likely to be assigned to other substances with the same properties in the future, it should be worded in such way that it is not limited to that specific entry.
- (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 ⁽³⁾ as well as the RAC's opinion of 11 June 2020 concerning 2-ethylhexanoic acid and its salts, described scientific evidence that the reproductive toxicity of each of these substance groups is due to a molecular entity common to all members of the respective group. When considering proposals for harmonised classification of certain boron compounds and of 2-ethylhexanoic acid and its salts, Member State experts consulted in the CARACAL expert group (Competent Authorities for Registration, Evaluation, Authorisation and Restriction of

⁽¹⁾ OJ L 353, 31.12.2008, p. 1.

⁽²⁾ <https://echa.europa.eu/documents/10162/8740de5b-368d-55a7-7955-094ef602d760>

⁽³⁾ <https://echa.europa.eu/documents/10162/584263da-199c-f86f-9b73-422a4f22f1c3>

Chemicals (REACH) and Classification, Labelling and Packaging (CLP)) requested to add new notes in Part 1, section 1.1.3.2, of Annex VI to Regulation (EC) No 1272/2008. According to the discussion in the CARACAL expert group, these notes are necessary to allow a more accurate identification of the hazard of mixtures, which contain several substances belonging to the same 'group entry'. The principle of additivity should apply to substances whose hazard is due to the presence or formation of a common molecular entity. As a consequence, it is necessary to take account of the contribution of these substances to the overall hazardous property of the mixture in proportion to their concentration, by comparing the applicable generic or specific concentration limit with the sum of the concentrations of the substances present. Therefore, two new notes, note 11 and 12, should be added to Part 1, section 1.1.3.2, of Annex VI to Regulation (EC) No 1272/2008. As note 11 should be assigned to boric acid and its salts, and other boric compounds releasing boric acid/borate, in view of the specificity of the concerned entries, it should be worded in such way that it is specific for those entries. As note 12 is likely to be assigned in the future to substances other than 2-ethylhexanoic acid and its salts, it should be worded in such way that it is not limited to that specific entry.

- (4) Regulation (EC) No 1272/2008 should therefore be amended accordingly,

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

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

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

Done at Brussels, 25 April 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Part 1 of Annex VI to Regulation (EC) No 1272/2008 is amended as follows:

(1) in section 1.1.3.1, the following note X is added:

Note X:

The classification for the hazard class(es) in this entry is based only on the hazardous properties of the part of the substance which is common to all substances in the entry. The hazardous properties of any substances in the entry also depend on the properties of the part of the substance which is not common to all substances in the group. The latter must be evaluated to assess whether more severe classification(s) (i.e. a higher category) or a broader scope of the same classification (additional differentiation, target organs and/or hazard statements) might apply for the hazard class(es) in the entry;

(2) in section 1.1.3.2, the following notes 11 and 12 are added:

Note 11:

The classification of mixtures as reproductive toxicant is necessary if the sum of the concentrations of individual boron compounds that are classified as reproductive toxicant in the mixture as placed on the market is $\geq 0,3\%$.

Note 12:

The classification of mixtures as reproductive toxicant is necessary if the sum of the concentrations of individual substances covered by this entry in the mixture as placed on the market is equal to, or above, the applicable generic concentration limit for the assigned category, or a specific concentration limit given in this entry'.
