EUROPEAN
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ANNEX

ANNEX

to the

Commission Delegated Regulation

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 information relating to emergency health response

ANNEX

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

(1) Part A is amended as follows:

(a) Section 1.1 is replaced by the following:

‘1.1 Importers and downstream users placing on the market mixtures for consumer use, within the meaning of Section 2.4 of Part A of this Annex, shall comply with this Annex from 1 January 2021.’;

(b) Section 2.3 is replaced by the following:

‘ 2.3. In the case of mixtures placed on the market for industrial use only, submitters may opt for a limited submission, as an alternative to general submission requirements, in accordance with Section 3.1.1 of Part B, provided that a rapid access to additional detailed product information is available in accordance with Section 1.3 of that Part.’;

(c) Section 4.1 is replaced by the following:

‘ 4.1 A single submission, hereinafter 'group submission', may be provided for more than one mixture where all the mixtures in a group have the same classification for health and physical hazards.’;

(d) Section 4.3. is replaced by the following:

‘ 4.3. By way of derogation from Section 4.2, a group submission shall also be allowed where the difference in the composition between different mixtures in the group only concerns perfumes, provided that the total concentration of the differing perfumes contained in each mixture does not exceed 5 %.’;

(e) in Section 5.1, the third subparagraph is replaced by the following:

‘ By way of derogation from the second subparagraph, a new UFI shall not be required for mixtures in a group submission containing perfumes provided that the change in the composition only concerns those perfumes or the addition of new perfumes.’;

(f) Section 5.2 is replaced by the following:

‘ 5.2. Instead of including the UFI in the supplemental information on the label, the submitter may opt to print or affix it on the inner packaging located with the other label elements.

Where the inner packaging is either in such a shape or so small that it is impossible to affix the UFI on it, the submitter may print or affix the UFI located with the other label elements on an outer packaging.

In the case of mixtures which are not packaged, the UFI shall be indicated in the Safety Data Sheet or be included in the copy of the label elements referred to in Article 29(3), as applicable.

The UFI shall be preceded by the acronym "UFI" in capital letters followed by a colon (“UFI:”) and it shall be clearly visible, legible and indelibly marked.’;

(g) Section 5.3 is replaced by the following:

‘ 5.3 By way of derogation from the first subparagraph of Section 5.2, in the case of mixtures supplied for use at industrial sites, the UFI may alternatively be indicated in the Safety Data Sheet.’;

(2) Part B is amended as follows:

(a) in Section 1.1, the second subparagraph is replaced by the following:

‘The complete trade name(s) of the mixture shall be provided, including, where relevant, brand name(s), name of the product and variant names as they appear on the label, without abbreviations and enabling its specific identification.’;

(b) Section 1.2 is replaced by the following:

‘ *1.2. Details of the submitter and contact point*

The name, full address, telephone number and e-mail address of the submitter shall be provided and, if different, the name, full address, telephone number and e-mail address of the point of contact to be used for obtaining further information relevant for emergency health response purposes.’;

(c) Section 1.3 is replaced by the following:

‘ *1.3. Name, telephone number and e-mail address for rapid access to additional product information*

In the case of a limited submission as laid down in Section 2.3 of Part A, a name, a telephone number and an e-mail address shall be provided at which rapid access to detailed additional product information relevant for emergency health response purposes is available in the language provided in Section 3.3 of Part A. The telephone number shall be accessible 24 hours per day, 7 days per week.’;

(d) in Section 2.4, the third indent is replaced by the following:

‘ – the pH, if available, of the mixture as supplied, or, where the mixture is a solid, the pH of an aqueous liquid or solution at a given concentration. The concentration of the test mixture in water shall be indicated. If the pH is not available, the reasons shall be given;’

(e) in Section 3.1, the third and fourth subparagraphs are replaced by the following:

‘ By way of derogation from the second subparagraph, in a group submission, perfume components in mixtures shall be present in at least one of the mixtures.

For group submissions where the perfumes vary between the mixtures contained in the group, a list shall be provided of the mixtures and the perfumes they contain, including their classification.’;

(f) Section 3.1.1 is replaced by the following:

‘ 3.1.1. Requirements for mixtures for industrial use

In the case of a limited submission as laid down in Section 2.3 of Part A, the information to be submitted on the composition of a mixture for industrial use may be limited to the information contained in the Safety Data Sheet in accordance with Annex II to Regulation (EC) No 1907/2006, provided that additional information on the composition is available on request for rapid access in accordance with Section 1.3.’;

(g) the heading to Section 3.2 is replaced by the following:

‘ *Identification of mixture components*’;

(h) in Section 3.2, the following paragraph is inserted before Section 3.2.1:

‘ A mixture component is either a substance or a mixture in mixture.’;

(i) in Section 3.2.2, the second subparagraph is replaced by the following:

‘Information on the substances contained in a MIM shall be provided in accordance with the criteria of Section 3.2.1, unless the submitter does not have access to information on the full composition of the MIM. In the latter case, the MIM shall be identified by means of its product identifier in accordance with Article 18(3)(a), together with its concentration and UFI, if available and if the appointed body has received the information on the MIM in a prior submission. In absence of a UFI or if the appointed body has not received the information on the MIM in a prior submission, the MIM shall be identified by means of its product identifier in accordance with Article 18(3)(a), together with its concentration and the compositional information contained in the Safety Data Sheet of the MIM and any other known components, as well as the name, e-mail address and telephone number of the MIM supplier.’;

(j) Section 3.2.3 is replaced by the following:

‘ 3.2.3. Generic product identifiers

By way of derogation from Sections 3.2.1 and 3.2.2, the generic product identifiers “perfumes” or “colouring agents” may be used for mixture components used exclusively to add perfume or colour, where the following conditions are met:

– the mixture components are not classified for any health hazard,

– the concentration of mixture components identified with a given generic product identifier does not exceed in total:

(a) 5 % for the sum of perfumes; and

(b) 25 % for the sum of colouring agents.’;

(k) Section 3.3 is replaced by the following:

‘ *3.3. Mixture components subject to submission requirements*

The following mixture components shall be indicated:

(1) mixture components classified as hazardous on the basis of their health or physical effects which:

– are present in concentrations equal to or greater than 0.1 %;

– are identified, even if in concentrations lower than 0.1 %, unless the submitter can demonstrate that those components are irrelevant for the purposes of emergency health response and preventative measures;

(2) mixture components not classified as hazardous on the basis of their health or physical effects which are identified and present in concentrations equal to or greater than 1 %.’;

(l) Section 3.4 is replaced by the following:

‘ *3.4. Concentration and concentration ranges of the mixture components*

Submitters shall provide the information laid down in Sections 3.4.1 and 3.4.2 with regard to the concentration of the mixture components, identified in accordance with Section 3.3.';

(m) in Section 3.4.1, the title of Table 1 is replaced by the following:

'**Concentration ranges applicable to hazardous components of major concern for emergency health response**';

(n) Section 3.4.2 is replaced by the following:

' 3.4.2. Other hazardous components and components not classified as hazardous

The concentration of the hazardous components in a mixture that are not classified for any of the hazard categories listed in Section 3.4.1 and of the identified components not classified as hazardous shall be expressed, in accordance with Table 2, as ranges of percentages in descending order by mass or volume. As an alternative, exact percentages may be provided.

By way of derogation from the first subparagraph, for perfume components that are not classified or only classified for skin sensitisation Category 1, 1A or 1B or aspiration toxicity, submitters shall not be required to provide information on their concentration, provided that their total concentration does not exceed 5 %.

Table 2

Concentration ranges applicable to other hazardous components and components not classified as hazardous

Concentration range of the component contained in the mixture (%)	Maximum width of the concentration range to be used in the submission
≥ 25 - < 100	20 % units
≥ 10 - < 25	10 % units
≥ 1 - < 10	3 % units
>0 - < 1	1 % units';

(o) Section 3.5 is replaced by the following:

' *3.5. Classification of mixture components*

The classification of mixture components for health and physical hazards (hazard classes, hazard categories and hazard statements) shall be provided. This includes the classification for at least all substances referred to in Point 3.2.1 of Annex II to Regulation (EC) No 1907/2006 on requirements for the compilation of Safety Data Sheets. In the case of a MIM identified by means of its product identifier and its UFI in accordance with Section 3.2.2. of Part B, only the classification for health and physical hazards of the MIM shall be provided.';

(p) in Section 4.1, the title of Table 3 is replaced by the following:

‘**Variations of the concentration of components requiring a submission update**’;

(q) in Section 4.1, the final subparagraph is replaced by the following:

‘When the perfumes in a group submission change, the list of mixtures and the perfumes they contain as required in Section 3.1. shall be updated.’;

(3) Part C is amended as follows:

(a) Section 1.2 is replaced by the following:

‘**1.2. Identification of the mixture and of the submitter**

Product identifier

– Complete trade name(s) of the product (in case of group submission, all product identifiers shall be listed)

– Other names, synonyms

– Unique Formula Identifier(s) (UFI)

– Other identifiers (authorisation number, company product codes)

Contact details of the submitter and, where applicable, contact point

– Name

– Full address

– Telephone number

– E-mail address

Contact details for rapid access to additional product information (24 hours/7 days). Only for limited submission.

– Name

– Telephone number (accessible 24 hours per day, 7 days per week)

– E-mail address’

(b) in Section 1.3, the list of “Additional information on the mixture” is replaced by the following:

‘ *Additional information on the mixture*

– Colour(s)

– The pH, if available, of the mixture as supplied, or, where the mixture is a solid, the pH of an aqueous liquid or solution at a given concentration. The concentration of the test mixture in water shall be indicated. If the pH is not available, the reasons shall be given;

– Physical state(s)

– Packaging (type(s) and size(s))

– Intended use (product category)

– Uses (consumer, professional, industrial)’.