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HARMONISED INFORMATION RELATING TO EMERGENCY HEALTH RESPONSE AND PREVENTATIVE MEASURES

PART A

GENERAL REQUIREMENTS

1. Application

- 1.1. Importers and downstream users placing on the market mixtures for consumer use, within the meaning of section 2.5 of Part A of this Annex, shall comply with this Annex from 1 July 2019.
- 1.2. Importers and downstream users placing on the market mixtures for professional use, within the meaning of section 2.5 of Part A of this Annex, shall comply with this Annex from 1 July 2020.
- 1.3. Importers and downstream users placing on the market mixtures for industrial use within the meaning of section 2.5 of Part A of this Annex, shall comply with this Annex from 1 July 2023.
- 1.4. Importers and downstream users having submitted information relating to hazardous mixtures to a body appointed in accordance with Article 45(1) of Regulation (EC) No 1272/2008 before the dates of applicability mentioned in sections 1.1, 1.2 and 1.3 and which are not in accordance with this Annex, shall not be required to comply with this Annex until 1 January 2025.
- 1.5. By way of derogation from section 1.4, if one of the changes described in section 4.1 of Part B of this Annex occurs before 1 January 2025, importers and downstream users shall comply with this Annex before placing that mixture, as changed, on the market.

2. Purpose, definitions and scope

- 2.1. This Annex sets out the requirements that importers and downstream users placing mixtures on the market, hereinafter 'submitters', shall fulfil in respect of the submission of information so that appointed bodies shall have at their disposal the information to carry out the tasks for which they are responsible under Article 45.
- 2.2. This Annex shall not apply to mixtures for scientific research and development and to mixtures for product and process oriented research and development as defined in Article 3(22) of Regulation (EC) No 1907/2006.

This Annex shall not apply to mixtures classified only for one or more of the following -hazards:

- (1) Gases under pressure;
- (2) Explosives (Unstable explosives and Divisions 1.1 to 1.6)

2.34. 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 5.3 of this Part and 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 Part B.

2.45. For the purposes of this Annex the following definitions shall apply:

- (1) 'Mixture for industrial use' means a mixture intended to be used at industrial sites [only](#);
- (2) 'Mixture for consumer use' means a mixture intended to be used by consumers;
- (3) 'Mixture for professional use' means a mixture intended to be used by professional users but not at industrial sites.

Where mixtures have more than one use, the following requirements for all [relevant](#) categories shall be met.

3. Submission requirements

3.1. Before placing mixtures on the market, submitters shall provide information relating to mixtures classified as hazardous on the basis of their health or physical effects to the bodies appointed under Article 45(1) (hereinafter 'appointed bodies'), in the Member State or Member States where the mixture is placed on the market.

The submission shall contain the information laid down in Part B. It shall be submitted by electronic means in a XML format provided by the Agency and made available free of charge.

3.2. ~~Where following receipt of a submission under 3.1 an appointed body makes a reasoned request to the submitter that additional information or clarification is necessary for that appointed body to carry out the tasks for which it is responsible under Article 45, the submitter shall provide the necessary information or clarification requested. Further to a reasoned request from an appointed body, submitters shall provide to the appointed bodies any additional information necessary for the appointed body to carry out its tasks.~~

3.3. The language used in the submission shall be the official language or languages of the Member State or Member States where the mixture is placed on the market, except where a Member State allows submission in another language as an alternative.

3.4. The intended use of the mixture shall be described in accordance with a harmonised product categorisation system provided by the Agency.

- 3.5. A submission update shall be made when the conditions laid down in section 4.1 of Part B are met.

4. Group submission

- 4.1. A single submission, hereinafter 'group submission', may be provided for more than one mixture where all ~~the mixtures in a grouped mixtures~~ have the same classification for health and physical hazards and the information in that submission covers all the composition variants of the ~~grouped mixtures~~ in a group in accordance with section 1.1.1 of Part B for each of those mixtures.
- 4.2. A group submission shall only be permitted when the concentration of a component (substance or mixture in mixture) present in the group of mixtures lies within the concentration range, as provided in section 3.4 of Part B.

5. Unique Formula Identifier (UFI)

- 5.1. The submitter shall create a Unique Formula Identifier, hereinafter UFI, by electronic means made available by the Agency. The UFI is a unique alphanumeric code that unambiguously links the submitted information on the composition of a mixture or a group of mixtures to a specific mixture or group of mixtures. The assignment of a UFI is free of charge and it shall be provided in the format set out in Part C.

A new UFI shall be created when a change in the composition of components in the mixture fulfils one or more of the conditions foreseen in points (a), (b) and (c) of the third indent of section 4.1. of Part B.

- 5.2. The submitter shall print or affix the UFI on the label or packaging of a hazardous mixture supplied for consumer and/or professional use. The UFI shall be preceded by the acronym "UFI" in capital letters and it shall be clearly visible, legible and indelibly marked.
- 5.3. In the case of a limited submission referred to in section 2.4, the UFI shall be indicated only in the Safety Data Sheet.

6. Formats and technical support for submission of information

- 6.1. The Agency shall specify, maintain and update the UFI generator, the XML formats for submissions and a harmonised product categorisation system and make them available free of charge on its website.
- 6.2. The Agency shall provide technical and scientific guidance, technical support and tools facilitating the submission of information.

PART B

INFORMATION CONTAINED IN A SUBMISSION

1. Identification of the mixture and of the submitter

1.1. Product identifier of the mixture

The product identifier shall be provided in accordance with Article 17(2) and Article 18(3)(a).

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

In addition, the UFI(s) shall be included in the submission.

1.1.1. Group submission

In the case of a group submission, all product identifiers for the relevant mixtures shall be provided according to the criteria listed in section 1.1.

1.2. Details of the submitter

The name, full address, telephone number and e-mail address of the submitter shall be provided. This information shall be consistent with the data provided on the label in accordance with Article 17(1)(a).

1.3. Telephone number for rapid access to additional product information

In the case of a limited submission as laid down in section 2.4 of Part A, a telephone number for rapid access to additional detailed product information services shall be provided. It shall consist of a telephone number accessible 24 hours per day, 7 days per week at which rapid access to detailed additional product information in the language provided in section 3.3 of part A is available for appointed bodies during emergencies.

2. Hazards identification and additional information

This section sets out the health and physical hazards of the mixture and the appropriate warning information associated with those hazards, as well as the additional information to be included in a submission.

2.1. Classification of the mixture

The classification of the mixture for health and physical hazards (hazard class and category) shall be provided in accordance with the classification rules in Annex I.

2.2. Label elements

The following labelling elements required in accordance with Article 17 shall be provided, if applicable:

- hazard pictogram codes (Annex V);
- signal word;

- hazard statement codes (Annex III including supplemental hazard information);
- precautionary statements codes.

2.3. Toxicological information

The submission shall include the information on the toxicological effects of the mixture or its components contained in Section 11 of the Safety Data Sheet of the mixture, in accordance with Annex II to Regulation (EC) No 1907/2006.

2.4. Additional information

The following additional information shall be provided:

- the type(s) and size(s) of the packaging used to place the mixture on the market for consumer or professional use;
- the colours and the physical states of the mixture, as supplied;
- the pH of the mixture (where applicable the pH shall be indicated for an aqueous solution of the mixture; in that case the concentration shall be expressed in % w/w);
- product categorisation (see section 3.4 of Part A);
- use (consumer, professional, industrial).

3. Information on mixture components

3.1. General requirements

The chemical identity and the concentrations of the components contained in the mixture shall be indicated in the submission in accordance with sections 3.2, 3.3 and 3.4.

3.1.1. Requirements for mixtures for industrial use

In the case of a limited submission as laid down in section 2.4 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 components is rapidly available on request in emergencies in accordance with section 1.3.

3.2. Mixture components

3.2.1 Substances

The product identifier for the substances identified according to section 3.3 shall be provided in accordance with Article 17(2) and Article 18(2). However, an INCI name or a colour index name may be used, provided the chemical name unambiguously defines the substance identity.

~~By derogation from the first paragraph, the generic product identifiers ‘perfumes’, ‘fragrances’ or ‘colouring agents’ may be used for mixture components where applicable, where the following conditions are met:~~

~~— the mixture components are not classified for health hazards of major concern as defined in Section 3.4.1.;~~

~~to the extent that the concentration of mixture components identified with a given generic product identifier does not exceed 10 % for perfumes/fragrances of the mixture in total.~~ The chemical name of substances for which an alternative chemical name has been allowed in accordance with Article 24 shall be provided as well.

3.2.2. Mixture in mixture

When a mixture is used in the composition of a second mixture placed on the market, the first mixture is referred to as a mixture in mixture (hereinafter MIM).

Information on the composition of substances contained in a MIM shall be provided in accordance with the criteria of this Section, unless the submitter does not have access to information on its full composition. In the latter case, information in accordance with Section 3 on known mixture components shall be provided and the MIM shall be identified by means of its product identifier in accordance with Article 18(3)(a), together with its concentration and UFI, when available; the name, e-mail address and telephone number of the MIM supplier shall also be provided.

3.2.3. Generic product identifiers

~~By derogation from the sections 3.2.1. and 3.2.2., the generic product identifiers ‘perfumes’, ‘fragrances’ or ‘colouring agents’ may be used for mixture components where applicable, where the following conditions are met:~~

- ~~– the mixture components are not classified for health hazards of major concern as defined in Section 3.4.1.;~~
- ~~– 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 fragrances, and
 - b) 20% for colouring agents.~~

3.3. Mixture components subject to submission requirements

The following mixture components (substances and MIM) 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~~ ~~higher~~ than 0.1%;

- are identified, even if in concentrations lower than 0.1%;
- (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%.

3.4. Concentration and concentration ranges of the mixture components

Submitters shall provide the following information with regard to the concentration of the mixture components (substances and MIM), identified in accordance with section 3.3.

3.4.1. Hazardous components of major concern for emergency health response and preventive measures

When mixture components are classified in accordance with this Regulation for at least one of the hazard categories listed below, their concentration in a mixture shall be expressed as exact percentage, in descending order by mass or volume:

- Acute toxicity, Category 1, 2 or 3;
- Specific target organ toxicity - Single exposure, Category 1 or 2;
- Specific target organ toxicity - Repeated exposure, Category 1 or 2;
- Skin corrosion, category 1, 1A, 1B or 1C;
- Serious eye damage, Category 1;
- Aspiration toxicity, Category 1;
- Skin sensitisation, Category 1, 1A or 1B
- Respiratory Sensitisation, Category 1, 1A or 1B;
- Carcinogen, Category 1A or 1B;
- Germ cell mutagen, Category 1A or 1B;
- Reproductive toxicant, Category 1A or 1B.

As an alternative to providing concentrations as exact percentages, a range of percentages may be submitted in accordance with Table 1.

Table 1

Concentration ranges applicable to hazardous components of major concern for emergency health response (substances or MIM)

Concentration range of the hazardous component contained in the mixture (%)	Maximum width of the concentration range to be used in the submission
≥ 25 - < 100	5 % units
≥ 10 - < 25	3 % units

$\geq 1 - < 10$	1 % units
$\geq 0.1 - < 1$	0.3 % units
$>0 - < 0.1$	0.1 % units

3.4.2. Other hazardous components and components not classified as hazardous

The concentration of the hazardous components in a mixture not included in section 3.4.1. and of the identified components not classified as hazardous present at 1 % or above 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.

Table 2

Concentration ranges applicable to other hazardous components and components not classified as hazardous (substances or mixtures in mixture MIM)

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

3.5. Classification of mixture components (substances and MIM)

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 Sheet. Alternatively, in the case of a MIM, only its classification for health and physical hazards may be provided.

4. Submission update

4.1. Where one of the following changes applies to a mixture, submitters shall provide a submission update before placing that mixture, as changed, on the market:

- when the mixture product identifier (including the UFI) has ~~been~~ changed;
- when the mixture classification for health and physical hazards has changed;

- when relevant new toxicological information contained in Section 11 of the Safety Data Sheet becomes available on the hazardous properties of the mixture or its components;
- if a change in the composition of components in the mixture fulfils one of the following conditions:
 - (a) addition, substitution, or deletion of one or more components in the mixture that shall be indicated in accordance with Section 3.3;
 - (b) change in the concentration of a component in the mixture beyond the concentration range provided in the original submission;
 - (c) ~~when~~ the exact concentration of a component was provided, in accordance with section 3.4.1., and a change occurs to that concentration beyond the limits identified in Table 3.

Table 3

Variations of the concentration of components requiring a submission update

Exact concentration of the component contained in the mixture (%)	Variations (\pm) of the initial component concentration requiring a submission update
> 25 - \leq 100	5 %
> 10 - \leq 25	10 %
> 2.5 - \leq 10	20 %
\leq 2.5	30 %

4.2. Content of the submission update

The submission update shall ~~consist-comprise~~ a revised version of the previous submission containing the new information available as described in Section 4.1

PART C
SUBMISSION FORMAT

1.1. Submission Format

The submission of information to appointed bodies in accordance with Article 45 shall be in a format to be provided by the Agency. The submission format shall include the following headings:

1.2. Identification of the mixture and of the submitter

Product identifier

- Complete trade name of the product (in case of group submission, all product identifiers shall be listed)
- Other names, synonyms
- Unique Formula Identifiers (UFI)
- Others identifiers (registration number, authorisation number, company product codes)

Contact details of the submitter

- Name
- Address (street, city, postal code, country)
- Telephone number
- E-mail

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

- Name
- Telephone number (24 hours per day, 7 days per week)

1.3. Classification of the mixture, label elements and toxicology

Classification of the mixture and label elements

- Hazard class and category
- Hazard pictograms codes (Annex V)
- Signal word
- Hazard statement codes (Annex III including supplemental hazard information)
- Precautionary statement codes (Annex IV)

Toxicological information

- Description of the toxicity of the mixture or its components (as specified in Section 11 of the Safety Data Sheet in accordance with Annex II to Regulation No 1907/2006)

Additional Information on the mixture

- Colour
- pH (where applicable)
- Physical state
- Packaging (type and size)
- Intended use (Product categorisation Code)
- Uses identification (indicate all uses: consumer, professional or industrial)

1.4 Product identifiers of the mixture components

Product identifiers of the mixture components (substances and mixtures in mixtures where applicable)

- Chemical/trade name of the components
- CAS number (where applicable)
- EC number (where applicable)
- UFI (where applicable)

Concentration and concentration ranges of the mixture components

- Exact concentration or concentration range

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Classification of mixture components (substances and MIM)

- Hazard classification (where applicable)
- Additional identifiers (where applicable and relevant for health response)