

**COMMISSION DELEGATED REGULATION (EU) 2020/1677****of 31 August 2020****amending Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures in order to improve the workability of information requirements related to emergency health response****(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 <sup>(1)</sup>, and in particular Article 45(4) thereof,

Whereas:

- (1) Regulation (EC) No 1272/2008 was amended by Commission Regulation (EU) 2017/542 <sup>(2)</sup> to add certain requirements for the submission of information relating to emergency health response and for the inclusion of a 'unique formula identifier' in the supplemental information provided on the label of a hazardous mixture. The requirements were amended by Commission Delegated Regulation (EU) 2020/11 <sup>(3)</sup>. Importers and downstream users are required to start complying with the requirements in stages, according to a series of compliance dates depending on the use for which a mixture is placed on the market
- (2) Concerns have been raised by various industry sectors regarding the workability of the emergency health response information requirements in certain cases, notably with regard to the difficulty of knowing the exact composition of mixtures in cases where raw materials with a highly variable or unknown composition are used in the manufacture of the mixture, in cases where toxicologically very similar components supplied by multiple, different suppliers are used together in the same production line, or in cases involving complex supply chains. Concerns have also been raised, in the case of bespoke mixtures, about the impossibility of knowing in advance which exact bespoke mixtures are to be placed on the market.
- (3) It is necessary to address the situation where different but toxicologically very similar components are used in a mixture, and where it is unknown which component is present in a particular mixture placed on the market at a given time. To ensure that the emergency health response requirements can be complied with properly in practice, importers and downstream users should be allowed to group toxicologically similar components of a mixture together in an interchangeable component group and provide information on the total concentration of those components present in the mixture, without having to specify their separate concentrations. In order to allow poison centres to formulate a suitable emergency health response, components should only be grouped in an interchangeable component group if their classification for health and physical effects is identical and if the hazards identification and the additional hazard information are identical for all possible combinations of the resulting final mixture incorporating those components. For components classified for certain hazard classes, it should also be necessary for them to have the same technical function and the same toxicological properties in order to be grouped.

<sup>(1)</sup> OJ L 353, 31.12.2008, p. 1.

<sup>(2)</sup> Commission Regulation (EU) 2017/542 of 22 March 2017 amending Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures by adding an Annex on harmonised information relating to emergency health response (OJ L 78, 23.3.2017, p. 1).

<sup>(3)</sup> Commission Delegated Regulation (EU) 2020/11 of 29 October 2019 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 (OJ L 6, 10.1.2020, p. 8).

- (4) In order to address particular difficulties encountered by the gypsum, ready-mixed concrete and cement sectors and to allow them to comply with the emergency health response requirements without reducing the level of safety, it should be possible for emergency health response information relating to certain standardised mixtures within those three sectors to be submitted by reference to a standard composition. However, in order to allow poison centres to formulate a suitable emergency health response, this option should only be available in cases where the mixture classification does not change according to the mixture's composition within the concentration ranges specified in the standard formula, and where the information on composition is at least as detailed as the information contained in the mixture's safety data sheet, drawn up in accordance with Article 31 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council ('safety data sheet')<sup>(4)</sup>. In the event that the information contained in the safety data sheet is more detailed than the information on the composition in the standard formula, importers and downstream users should be required to notify the information in the safety data sheet instead.
- (5) In order to address particular difficulties anticipated for certain fuels, and taking into account the facts that fuels placed on the market normally conform to a technical standard and that poison centres have communicated a low number of poisoning incidents with fuels, it should be possible, until a more suitable solution is found, to submit emergency health response information by reference to the information contained in the safety data sheet, as well as any other known information on the products' chemical composition.
- (6) In order to satisfy customer demand for very specific paint shades, formulators are sometimes asked to formulate and supply paints on a bespoke basis at the point of sale. These bespoke paints could have an almost unlimited number of different compositions. Therefore, without any mitigating measures, compliance with the emergency health response requirements in Annex VIII to Regulation (EC) No 1272/2008 would require formulators of bespoke paints either to submit information and create unique formula identifiers (UFIs) in advance for an extremely large number of paints of all possible colour combinations, many of which might never be supplied in reality, or to postpone each supply until the information had been submitted and the UFI had been created. Either approach would place a disproportionate burden on the bespoke paints industry, in particular small and medium-sized enterprises, without improving the level of safety significantly.
- (7) Poison centres have not communicated a significant number of accidents related to paints. In light of the apparently lower risks compared to other mixtures, it is justified to allow a more flexible approach, as this would not be reducing the current level of safety.
- (8) It is therefore appropriate to provide for the possibility to exempt bespoke paints from the notification obligations in Annex VIII and from the requirement to create a UFI. However, in that case, in order to allow poison centres to formulate a suitable emergency health response, the individual mixtures contained in bespoke paints should remain subject to all the requirements of that Annex. Alongside this Regulation, Commission Delegated Regulation (EU) 2020/1676<sup>(5)</sup> amends Article 25 of Regulation (EC) No 1272/2008 to add a new rule, in the case of bespoke paints for which no submission in accordance with Annex VIII has been made and no corresponding UFI has been created, requiring the UFIs of all the individual mixtures contained in the bespoke paint to be indicated on the label of the bespoke paint, together with the specific concentration of each such mixture with a UFI that is present in a concentration exceeding 5 %.
- (9) Given the number of changes to Annex VIII to Regulation (EC) No 1272/2008, it is appropriate to replace the whole Annex for the sake of legal clarity.
- (10) Considering that the compliance date for mixtures for consumer and professional use of 1 January 2021 laid down in Annex VIII to Regulation (EC) No 1272/2008 is approaching, and that this Regulation enables all sectors to comply with that Annex, this Regulation should enter into force as early as possible.
- (11) Regulation (EC) No 1272/2008 should therefore be amended accordingly,

<sup>(4)</sup> Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

<sup>(5)</sup> Commission Delegated Regulation (EU) 2020/1676 of 31 August 2020 amending Article 25 of Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures as regards bespoke paints (See page 1 of this Official Journal).

HAS ADOPTED THIS REGULATION:

*Article 1*

Annex VIII to Regulation (EC) No 1272/2008 is replaced by the text in the Annex to this Regulation.

*Article 2*

This Regulation shall enter into force on the day after 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, 31 August 2020.

*For the Commission*  
*The President*  
Ursula VON DER LEYEN

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## ANNEX

## 'ANNEX VIII

**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 2.4 of Part A of this Annex, shall comply with this Annex from 1 January 2021.
- 1.2. Importers and downstream users placing on the market mixtures for professional use, within the meaning of Section 2.4 of Part A of this Annex, shall comply with this Annex from 1 January 2021.
- 1.3. Importers and downstream users placing on the market mixtures for industrial use or mixtures with an end use not subject to notification within the meaning of Section 2.4 of Part A of this Annex, shall comply with this Annex from 1 January 2024.
- 1.4. Importers and downstream users having submitted information relating to hazardous mixtures to a body appointed in accordance with Article 45(1) 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 for those mixtures 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, SCOPE AND DEFINITIONS

- 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).
- 2.2a. In the case of bespoke paints, submitters may, without prejudice to Article 25(8), opt not to submit information and not to create a Unique Formula Identifier in accordance with this Annex.
  - 2.3. In the case of mixtures with an end use not subject to notification or 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 the second subparagraph of Section 3.1 of Part B, provided that a rapid access to additional detailed product information is available in accordance with Section 1.3 of that Part.
  - 2.4. For the purposes of this Annex, the following definitions shall apply:
    - (1) "mixture for consumer use" means a mixture intended to be used by consumers, either on its own or incorporated in another mixture that is intended to be used by consumers and is subject to the information requirements in Article 45;

- (2) “mixture for professional use” means a mixture intended to be used by professional users but not at industrial sites, either on its own or incorporated in another mixture that is intended to be used by professional users but not at industrial sites and is subject to the information requirements in Article 45;
- (3) “mixture for industrial use” means a mixture intended to be used at industrial sites only;
- (4) “mixture with an end use not subject to notification” means a mixture, incorporated in another mixture where the latter is intended to be used by consumers or professional users, but which is not subject to the information requirements in Article 45;
- (5) “bespoke paint” means a paint that is formulated in limited amounts on a tailor-made basis for an individual consumer or professional user at the point of sale by tinting or colour mixing.

Where mixtures have more than one use, the requirements for all relevant categories of use 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) (“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 an XML format provided by the Agency and made available free of charge.

- 3.2. Where following receipt of a submission under Section 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 without undue delay.
- 3.3. The submission shall be in the official language(s) of the Member State(s) where the mixture is placed on the market, unless the Member State(s) concerned provide(s) otherwise.
- 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 without undue delay when the conditions laid down in Section 4.1 of Part B are met.

### 4. GROUP SUBMISSION

- 4.1. A single 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. Such a submission shall be referred to as a “group submission”.
- 4.2. A group submission shall only be permitted when all mixtures in the group contain the same components (as identified in Section 3.2 of Part B), and for each of the components, the reported concentration range is the same for all mixtures (as provided in Section 3.4 of Part B).
- 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 %.
- 4.4. In the case of a group submission, the information required in Part B shall be provided for each of the mixtures contained in the group where applicable.

### 5. UNIQUE FORMULA IDENTIFIER (UFI)

- 5.1. The submitter shall create a Unique Formula Identifier (“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.

A new UFI shall be created when a change in the composition of the mixture or group of mixtures fulfils one or more of the conditions laid down in points (a), (b) and (c) of the fourth indent of the first subparagraph of Section 4.1 of Part B or, as the case may be, one or other of the conditions laid down in the second subparagraph of that Section.

By way of derogation from the second subparagraph of this Section, 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.

By way of derogation from the second subparagraph of this Section, a new UFI shall not be required where a change fulfilling the condition foreseen in point (a) of the fourth indent of the first subparagraph of Section 4.1 of Part B solely concerns one or more components grouped in an interchangeable component group already included in the submission in accordance with Section 3.5 of Part B.

- 5.2. 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.
- 5.3. 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.

In the case of packaged mixtures supplied for use at an industrial site, instead of including the UFI on the label or packaging, the submitter may opt to indicate it 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 18(3)(a).

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.

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

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

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

- 1.3. **Name, telephone number and email 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 email 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.

## 2. HAZARDS IDENTIFICATION AND ADDITIONAL INFORMATION

This Section sets out the information requirements related to 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, category and statement) shall be provided in accordance with the classification rules in Annex I.

### 2.2. Label elements

The following label 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 statement codes (Annex IV).

### 2.3. Toxicological information

The submission shall include the information on the toxicological effects of the mixture or its components that is required 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 colour(s) and the physical state(s) of the mixture, as supplied,
- the pH, if available, of the mixture as supplied, or where the product 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,
- product category (see Section 3.4 of Part A),
- use (consumer, professional, industrial, or a combination of any of the three).

## 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.

By way of derogation from the first subparagraph, 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 or a mixture with an end use not subject to notification 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 rapidly available on request in emergencies in accordance with Section 1.3.

Components which are not present in a mixture shall not be notified. However, if they are notified as part of an interchangeable component group in accordance with Section 3.5 or their concentration has been submitted as a range of percentages in accordance with Sections 3.6 or 3.7, they may be notified if they will certainly be present in the mixture at some point in time.

By way of derogation from the third 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.

### 3.2. Identification of mixture components

A mixture component is either a substance or a mixture in mixture.

#### 3.2.1. Substances

The product identifier for the substances identified according to Section 3.3 shall be provided in accordance with Article 18(2). However, an INCI name, a colour index name or another international chemical name may be used, provided the chemical name is well known and unambiguously defines the substance identity. 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 ("MIM").

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,

- (a) if a UFI has been created for the MIM and the appointed body has 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 UFI;
- (b) if a UFI has been created for the MIM, but 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 UFI and the compositional information contained in the Safety Data Sheet in accordance with Annex II to Regulation (EC) No 1907/2006 of the MIM and any other known components, as well as the name, email address and telephone number of the MIM supplier;
- (c) in absence of a UFI, 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 in accordance with Annex II to Regulation (EC) No 1907/2006 of the MIM and any other known components, as well as the name, email address and telephone number of the MIM supplier.

#### 3.2.3. Identification by generic component identifiers

By way of derogation from Sections 3.2.1 and 3.2.2, the generic component 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 component identifier does not exceed in total:
  - (a) 5 % for the sum of perfumes; and
  - (b) 25 % for the sum of colouring agents.

### 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 %.



### 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.

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

When mixture components are classified in accordance with this Regulation for at least one of the hazard categories listed below, their concentration in the mixture shall be expressed as exact percentages, 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.

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

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

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
$\geq 25 - < 100$	20 % units
$\geq 10 - < 25$	10 % units
$\geq 1 - < 10$	3 % units
$> 0 - < 1$	1 % units

By way of derogation from the first subparagraph, for perfume components in a group submission 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.

### 3.5. Grouping of components in an interchangeable component group

Components may be grouped in a submission in an interchangeable component group provided that:

- (a) for all components in the interchangeable component group:
  - the technical function(s) for which the components are used in the mixture for which the submission is made is (are) identical, and
  - the classification for health and physical hazards is identical (hazard class and category), and
  - the toxicological properties, including at least the type of toxicological effect(s) and the target organ(s), are the same; and
- (b) for all possible combinations of the resulting final mixture based on the components in the interchangeable component group, the hazards identification and additional information referred to in Section 2 of Part B are identical.

Alternatively, components that are classified only for skin corrosion, skin irritation, eye damage, eye irritation, aspiration toxicity, or respiratory or skin sensitisation, or a combination thereof, may be grouped in an interchangeable component group provided that:

- (a) the classification for health and physical hazards (hazard class and category) is identical for all components; and
- (b) the pH, where applicable, of all components classified for skin corrosion, skin irritation, eye damage, or eye irritation is either acidic, neutral or alkaline; and
- (c) the interchangeable component group does not contain more than five components; and
- (d) for all possible combinations of the resulting final mixture based on the components grouped in the interchangeable component group, the hazards identification and additional information referred to in Section 2 of Part B are identical.

#### 3.5.1. *Name of interchangeable component group and identification of grouped components*

An interchangeable component group shall be given a name which corresponds to the technical function(s) of the grouped components for which they were incorporated in the mixture.

Each component in an interchangeable component group shall be identified in accordance with Section 3.2.1 or 3.2.2, as applicable.

#### 3.5.2. *Concentration and concentration ranges of grouped components*

By way of derogation from the first subparagraph of Section 3.4, for components grouped in an interchangeable component group, submitters shall provide the information laid down in Sections 3.4.1 and 3.4.2 with regard to the total concentration of all components present in the mixture and grouped in the interchangeable component group.

When mixture components grouped in an interchangeable component group are classified in accordance with this Regulation for at least one of the hazard categories listed in Section 3.4.1, the total concentration of the components present in the mixture and grouped in the interchangeable component group shall be expressed as exact percentages, in descending order by mass or volume. As an alternative, a range of percentages may be submitted in accordance with Table 1 of that Section.

The total concentration of the hazardous components present in the mixture and grouped in an interchangeable component group that are not classified for any of the hazard categories listed in Section 3.4.1, and the total concentration of the identified components present in the mixture and grouped in an interchangeable component group not classified as hazardous, shall be expressed, in accordance with Table 2 of Section 3.4.2, as ranges of percentages in descending order by mass or volume. As an alternative, exact percentages may be provided.

### 3.6. Mixtures complying with standard formulas

By way of derogation from Sections 3.2, 3.3 and 3.4, for a mixture with a composition conforming with a standard formula specified in Part D, where the mixture classification does not change depending on the components' concentration within the ranges of percentages specified in the corresponding standard formula:

- if the information on composition in the standard formula, together with information as specified in Sections 3.2 to 3.4 on the identity and concentration of the components not specified in the standard formula, is not less detailed than that contained in the Safety Data Sheet in accordance with Annex II to Regulation (EC) No 1907/2006, the identity and concentration of one or more of the mixture's components may be submitted as specified in the standard formula for the components mentioned in that formula and as specified in Sections 3.2 to 3.4 for the other components,
- if the information referred to in the previous indent is less detailed than that contained in the Safety Data Sheet in accordance with Annex II to Regulation (EC) No 1907/2006, the information on the identity and concentration of all the mixture's components contained in the Safety Data Sheet in accordance with Annex II to Regulation (EC) No 1907/2006 shall be given.

### 3.7. Fuels

By way of derogation from Sections 3.2, 3.3 and 3.4, for those fuels listed in Table 3, the identity and concentration of the mixture's components listed in the Safety Data Sheet in accordance with Annex II to Regulation (EC) No 1907/2006 may be submitted. The identity and concentration of any other *known component shall also be submitted*.

Table 3

#### List of fuels

Fuel	Product description
Gasoline EN228	Automotive fuels – Unleaded petrol
Gasoline E85	Automotive fuels – Ethanol (E85) automotive fuel
Gasoline alkylate	Motor fuels – special petrol for powered implements
LPG	Liquefied Petroleum Gas used as fuel
LNG	Liquefied Natural Gas used as fuel
Diesel fuel	Automotive fuels – diesel engine fuels with/without biofuel
Paraffinic diesel fuels (e.g GTL, BTL or HVO)	Automotive fuels – Paraffinic diesel fuel from synthesis or hydrotreatment
Heating oil	Liquid mineral fuels with the characteristics of domestic fuel oil
MK 1 diesel	Automotive fuels – Diesel fuel oil of environmental class 1 and 2 for high-speed diesel engines
Aviation fuels	Aviation turbine engine and piston engine fuels
Kerosene – Illuminating paraffin	Illuminating paraffin lampoil Type B and C
Heavy fuel oil	All grades of heavy fuel oil
Marine fuel	Marine fuels, containing or not biodiesel
Fatty acid methyl esters (FAME) – Diesel B100	Fatty acid methyl esters (FAME) for use in diesel engines and heating applications

### 3.8. Classification of mixture components

The classification for health and physical effects (hazard classes, hazard categories and hazard statements) of substances identified in accordance with Section 3.3 and contained in the mixture shall be provided. This includes the classification for at least all substances, indicated pursuant to Point 3.2.1 of Annex II to Regulation (EC) No 1907/2006 in the Safety Data Sheet of the mixture and in the Safety Data Sheet of any MIM contained in the mixture. For MIMs identified in accordance with Section 3.3 where the submitter does not have access to the full composition of the MIM, the classification for health and physical effects of the MIM shall be provided in addition.

## 4. SUBMISSION UPDATE

### 4.1. Conditions for submission update

Where one of the following changes applies to a mixture in an individual or group submission, submitters shall provide a submission update before placing that mixture, as changed, on the market:

- when the mixture product identifier or the UFI has changed,
- when the mixture classification for health or physical hazards has changed,
- when relevant new toxicological information that is required 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 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) the exact concentration of a component was provided in accordance with Sections 3.4.1 or 3.4.2, and a change occurs to that concentration beyond the limits identified in Table 4.

By way of derogation from the fourth indent of the first subparagraph, the following shall apply:

- (a) a submission update for mixtures with a composition conforming with any of the standard formulas specified in Part D is required only when the composition of the mixture changes in such a manner that the mixture's composition no longer conforms with the standard formula;
- (b) for mixtures where the information on composition is provided based on the Safety Data sheet in accordance with Section 3.6 or 3.7 a submission update is required when Section 3 of the Safety Data Sheet is updated.

Table 4

#### 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 %

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

### 4.2. Content of the submission update

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

## PART C

**SUBMISSION FORMAT**

## 1. 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 address the following elements:

1.2. **Identification of the mixture, submitter and contact point***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 contact point*

- Name
- Full address
- Telephone number
- Email 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)
- Email address

1.3. **Classification of the mixture, label elements and toxicology***Classification of the mixture and label elements*

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

*Toxicological information*

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

*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)

#### 1.4. Information on the mixture components and interchangeable component groups

##### *Identification of the mixture components*

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

##### *Name of interchangeable component groups (where applicable)*

##### *Concentration and concentration ranges of the mixture components*

- Exact concentration or concentration range

##### *Classification of mixture components*

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

##### *List according to Part B, Section 3.1, fifth subparagraph (where applicable)*

### PART D

#### STANDARD FORMULAS

For standard formulas 1-17 the following conditions apply:

- Heavy metal, trace elements: As, Ba, Cd, Cr, Co, Cu, Hg, Mo, Ni, Pb, Sb, Sn, Te, Tl, V are below 0,1 w/w % and Mn, Sr, Zn are below 1 w/w %
- PAHs are not present

Note applying to standard formulas 1-17:

- <sup>(1)</sup> UVCB substance consists of variable amounts of calcite, tricalcium silicate, dicalcium silicate, calcium oxide, quartz, potassium chloride, potassium sulfate, calcium sulfate, sodium aluminium silicate, magnesium aluminium silicate, muscovite, ...

#### 1. CEMENT

Cement Standard Formula – 1		
Product description	Portland cement with one main constituent: clinker	
Component name	EC No	Concentration (w/w%)
Portland cement clinker	266-043-4	86,5 – 100
Calcium sulfate	231-900-3	0 – 8
Flue dust <sup>(1)</sup>	270-659-9	0 – 5
Inorganic natural mineral materials	310-127-6	
Iron(II) sulfate	231-753-5	0 – 1
Tin(II) sulfate	231-302-2	0 – 0,1

**Cement Standard Formula – 2**

Product description	Portland-slag cement and Blast furnace cement <i>with two main constituents: clinker and slag</i>	
Component name	EC No	Concentration (w/w %)
Portland cement clinker	266-043-4	4,6 – 94
Granulated blast furnace slag	266-002-0	5,5 – 95
Calcium sulfate	231-900-3	0 – 8
Flue dust <sup>(1)</sup>	270-659-9	0 – 5
Inorganic natural mineral materials	310-127-6	
Iron(II) sulfate	231-753-5	0 – 1
Tin(II) sulfate	231-302-2	0 – 0,1

**Cement Standard Formula – 3**

Product description	Portland-silica fume cement <i>Portland cements with two main constituents: clinker and silica fume</i>	
Component name	EC No	Concentration (w/w%)
Portland cement clinker	266-043-4	82 – 94
Silica fume	273-761-1	5,5 – 10
Calcium sulfate	231-900-3	0 – 8
Flue dust <sup>(1)</sup>	270-659-9	0 – 5
Inorganic natural mineral materials	310-127-6	
Iron(II) sulfate	231-753-5	0 – 1
Tin(II) sulfate	231-302-2	0 – 0,1

**Cement Standard Formula – 4**

Product description	Portland-pozzolana cement, Pozzolanic cement <i>Portland cements with two main constituents: clinker and pozzolan (natural or natural calcined pozzolan)</i>	
Component name	EC No	Concentration (w/w %)
Portland cement clinker	266-043-4	41 – 94
Natural (calcined) pozzolana	310-127-6	5,5 – 55
Calcium sulfate	231-900-3	0 – 8
Flue dust <sup>(1)</sup>	270-659-9	0 – 5
Inorganic natural mineral materials	310-127-6	
Iron(II) sulfate	231-753-5	0 – 1
Tin(II) sulfate	231-303-2	0 – 0,1

**Cement Standard Formula – 5**

Product description	Portland-fly ash cement, Pozzolanic cement <i>Portland cements with two main constituents: clinker and fly ash (siliceous and calcareous fly ash)</i>	
Component name	EC No	Concentration (w/w %)
Portland cement clinker	266-043-4	41 – 94
Fly ash	931-322-8	5,5 – 55
Calcium sulfate	231-900-3	0 – 8
Flue dust <sup>(1)</sup>	270-659-9	0 – 5
Inorganic natural mineral materials	310-127-6	
Iron(II) sulfate	231-753-5	0 – 1
Tin(II) sulfate	231-302-2	0 – 0,1

**Cement Standard Formula – 6**

Product description	Portland-burnt shale cement <i>Portland cements with two main constituents: clinker and burnt shale</i>	
Component name	EC No	Concentration (w/w %)
Portland cement clinker	266-043-4	59 – 94
Burnt shale	297-648-1	5,5 – 35
Calcium sulfate	231-900-3	0 – 8
Flue dust <sup>(1)</sup>	270-659-9	0 – 5
Inorganic natural mineral materials	310-127-6	
Iron(II) sulfate	231-753-5	0 – 1
Tin(II) sulfate	231-302-2	0 – 0,1

**Cement Standard Formula – 7**

Product description	Portland-limestone cement <i>Portland cements with two main constituents: clinker and limestone</i>	
Component name	EC No	Concentration (w/w %)
Portland cement clinker	266-043-4	59 – 94
Limestone	215-279-6	5,5 – 35
Calcium sulfate	231-900-3	0 – 8
Flue dust <sup>(1)</sup>	270-659-9	0 – 5
Inorganic natural mineral materials	310-127-6	
Iron(II) sulfate	231-753-5	0 – 1
Tin(II) sulfate	231-302-2	0 – 0,1



**Cement Standard Formula – 8**

Product description	Portland-composite cement, Composite cement (slag – limestone) <i>Portland cements with three main constituents: clinker, slag and limestone</i>	
Component name	EC No	Concentration (w/w %)
Portland cement clinker	266-043-4	31,9 – 88
Granulated blast furnace slag	266-002-0	5,5 – 59
Limestone	215-279-6	5,5 – 29
Calcium sulfate	231-900-3	0 – 8
Flue dust <sup>(1)</sup>	270-659-9	0 – 5
Inorganic natural mineral materials	310-127-6	
Iron(II) sulfate	231-753-5	0 – 1
Tin(II) sulfate	231-302-2	0 – 0,1

**Cement Standard Formula – 9**

Product description	Portland-composite cement, Composite Cement (slag – fly ash) <i>Portland cements with three main constituents: clinker, blast-furnace slag, siliceous and calcareous fly ash</i>	
Component name	EC No	Concentration (w/w %)
Portland cement clinker	266-043-4	18,2 – 88
Granulated blast furnace slag	266-002-0	5,5 – 59
Fly ash	931-322-8	5,5 – 49
Calcium sulfate	231-900-3	0 – 8
Flue dust <sup>(1)</sup>	270-659-9	0 – 5
Inorganic natural mineral materials	310-127-6	
Iron(II) sulfate	231-753-5	0 – 1
Tin(II) sulfate	231-302-2	0 – 0,1

**Cement Standard Formula – 10**

Product description	Portland-composite cement, Composite cement (slag – pozzolana) <i>Portland cements with three main constituents: clinker, blast-furnace slag, natural or natural calcined pozzolan</i>	
Component name	EC No	Concentration (w/w %)
Portland cement clinker	266-043-4	18,2 – 88
Granulated blast furnace slag	266-002-0	5,5 – 49
Natural (calcined) pozzolana	310-127-6	5,5 – 49
Calcium sulfate	231-900-3	0 – 8
Flue dust <sup>(1)</sup>	270-659-9	0 – 5
Inorganic natural mineral materials	310-127-6	
Iron(II) sulfate	231-753-5	0 – 1
Tin(II) sulfate	231-302-2	0 – 0,1

**Cement Standard Formula – 11**

Product description	Portland-composite cement (slag – burnt shale) <i>Portland cements with three main constituents: clinker, blast-furnace slag, burnt shale</i>	
Component name	EC No	Concentration (w/w %)
Portland cement clinker	266-043-4	59 – 94
Granulated blast furnace slag	266-002-0	5,5 – 29
Burnt shale	297-648-1	5,5 – 29
Calcium sulfate	231-900-3	0 – 8
Flue dust <sup>(1)</sup>	270-659-9	0 – 5
Inorganic natural mineral materials	310-127-6	
Iron(II) sulfate	231-753-5	0 – 1
Tin(II) sulfate	231-302-2	0 – 0,1

**Cement Standard Formula – 12**

Product description	Portland-composite cement (limestone – fly ash) <i>Portland cements with three main constituents: clinker, limestone, siliceous and calcareous fly ash</i>	
Component name	EC No	Concentration (w/w %)
Portland cement clinker	266-043-4	46 – 94
Limestone	215-279-6	5,5 – 29
Fly ash	931-322-8	5,5 – 44
Calcium sulfate	231-900-3	0 – 8
Flue dust <sup>(1)</sup>	270-659-9	0 – 5
Inorganic natural mineral materials	310-127-6	
Iron(II) sulfate	231-753-5	0 – 1
Tin(II) sulfate	231-302-2	0 – 0,1

**Cement Standard Formula – 13**

Product description	Portland-composite cement (limestone – pozzolana) <i>Portland cements with three main constituents: clinker, limestone, natural or natural calcined pozzolan</i>	
Component name	EC No	Concentration (w/w %)
Portland cement clinker	266-043-4	46 – 94
Limestone	215-279-6	5,5 – 29
Natural (calcined) pozzolana	310-127-6	5,5 – 44
Calcium sulfate	231-900-3	0 – 8
Flue dust <sup>(1)</sup>	270-659-9	0 – 5
Inorganic natural mineral materials	310-127-6	
Iron(II) sulfate	231-753-5	0 – 1
Tin(II) sulfate	231-302-2	0 – 0,1

**Cement Standard Formula – 14**

Product description	Portland-composite cement (limestone – burnt shale) <i>Portland cements with three main constituents: clinker, limestone and burnt shale</i>	
Component name	EC No	Concentration (w/w %)
Portland cement clinker	266-043-4	59 – 94
Limestone	215-279-6	5,5 – 29
Burnt shale	297-648-1	5,5 – 29
Calcium sulfate	231-900-3	0 – 8
Flue dust <sup>(1)</sup>	270-659-9	0 – 5
Inorganic natural mineral materials	310-127-6	
Iron(II) sulfate	231-753-5	0 – 1
Tin(II) sulfate	231-302-2	0 – 0,1

**Cement Standard Formula – 15**

Product description	Portland-composite cement, Pozzolanic cement (fly ash – pozzolana) <i>Portland cements with three main constituents: clinker, siliceous and calcareous fly ash, natural or natural calcined pozzolan</i>	
Component name	EC No	Concentration (w/w %)
Portland cement clinker	266-043-4	41 – 94
Natural (calcined) pozzolana	310-127-6	5,5 – 55
Fly ash	931-322-8	5,5 – 55
Calcium sulfate	231-900-3	0 – 8
Flue dust <sup>(1)</sup>	270-659-9	0 – 5
Inorganic natural mineral materials	310-127-6	
Iron(II) sulfate	231-753-5	0 – 1
Tin(II) sulfate	231-302-2	0 – 0,1

**Cement Standard Formula – 16**

Product description	Portland-composite <i>Portland cements with four main constituents: clinker and three of these constituents: blast-furnace slag, silica fume, fly ash, pozzolan, burnt shale, limestone</i>	
Component name	EC No	Concentration (w/w %)
Portland cement clinker	266-043-4	59 – 94
Granulated blast furnace slag	266-002-0	5,5 – 23
Natural (calcined) pozzolana	310-127-6	
Fly ashes	931-322-8	
Burnt shale	297-648-1	
Limestone	215-279-6	
Silica fume	273-761-1	
Calcium sulfate	231-900-3	0 – 8
Flue dust <sup>(1)</sup>	270-659-9	0 – 5
Inorganic natural mineral materials	310-127-6	
Iron(II) sulfate	231-753-5	0 – 1
Tin(II) sulfate	231-302-2	0 – 0,1

**Cement Standard Formula – 17**

Product description	Composite cement <i>Portland cements with four main constituents: clinker, slag, siliceous fly ash and natural or natural calcined pozzolan</i>	
Constituent	EC No	Concentration (w/w%)
Portland cement clinker	266-043-4	18,3 – 64
Granulated blast furnace slag	266-002-0	16,5 – 49
Natural (calcined) pozzolana	310-127-6	5,5 – 43
Fly ash	931-322-8	5,5 – 43
Calcium sulfate	231-900-3	0 – 8
Flue dust <sup>(1)</sup>	270-659-9	0 – 5
Inorganic natural mineral materials	310-127-6	
Iron(II) sulfate	231-753-5	0 – 1
Tin(II) sulfate	231-302-2	0 – 0,1

**Cement Standard Formula – 18**

Product description	Calcium aluminate cement	
Constituent	EC No	Concentration (w/w %)
Calcium aluminate cement clinker	266-045-5	86,5 – 100
Grinding aid	-	0 – 0,2

**Cement Standard Formula – 19**

Product description	Masonry cements – with clinker and lime – MC 5, MC 12,5, MC 22,5	
Component name	EC No	Concentration (w/w %)
Portland cement clinker	266-043-4	25 – 60
Building lime acc. to EN 459	215-138-9,	1 – 75
Hydrated lime acc. to EN 459	215-137-3	
Other, non-hazardous inorganic constituent	310-127-6	0 – 74
Inorganic pigments acc. to EN 12878	-	0 – 1

**Cement Standard Formula – 20**

Product description	Masonry cements – with clinker and without lime – MC 5, MC 12,5, MC 22,5	
Component name	EC No	Concentration (w/w %)
Portland cement clinker	266-043-4	25 – 60
Other, non-hazardous inorganic constituent	310-127-6	40 – 75
Inorganic pigments acc. to EN 12878	-	0 – 1

## 2. GYPSUM BINDER

<b>Gypsum binder Standard Formula</b>		
Component name	EC No	Concentration (w/w %)
Calcium sulphate	231-900-3	≥ 50 and < 100
Calcium dihydroxide	215-137-3	> 0 and ≤ 5

## 3. READY MIXED CONCRETE

<b>Ready mixed concrete Standard Formula 1</b> Concrete strength classes C8/10, C12/15, C16/20, C20/25, C25/30, C28/35, C32/40, C35/45, C40/50, C45/55, C50/60 LC8/9, LC12/13, LC16/18, LC20/22, LC25/28, LC30/33, LC35/38, LC40/44, LC45/50, LC50/55, LC55/60		
Component name	EC No	Concentration (w/w %)
Cement	270-659-9	3 – 18
Water	231-791-2	5 – 8
Aggregates	273-727-6	70 – 80
Air entrainers (admixture)	-	0 – 0,08
Plasticisers/superplasticisers (admixture)	-	0 – 0,15
Retarders (admixture)	-	0 – 0,4
Accelerators (admixture)	-	0 – 0,2
Water resisting (admixture)	-	0 – 0,25
Fly ash	931-322-8	0 – 8
Silica fume	273-761-1	0 – 3
GGBS	266-002-0	0 – 6

<b>Ready mixed concrete Standard Formula 2</b> Concrete strength classes C55/67, C60/75, C70/85, C80/95, C90/105, C100/105, LC 60/66, LC70/77, LC80/88		
Component name	EC No	Concentration (w/w %)
Cement	270-659-9	12 – 25
Water	231-791-2	5 – 8
Aggregates	273-727-6	70 – 80
Air entrainers (admixture)	-	0,04 – 0,08
Plasticisers/superplasticisers (admixture)	-	0 – 0,15
Retarders (admixture)	-	0 – 0,4
Accelerators (admixture)	-	0 – 0,2
Water resisting (admixture)	-	0 – 0,25
Fly ash	931-322-8	0 – 8
Silica fume	273-761-1	0 – 3
GGBS	266-002-0-	0 – 6'