

**COMMISSION REGULATION (EU) 2020/878****of 18 June 2020****amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)****(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 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 <sup>(1)</sup>, and in particular Article 131 thereof,

Whereas:

- (1) Annex II to Regulation (EC) No 1907/2006 lays down requirements for the compilation of safety data sheets, used to provide information on chemical substances and mixtures in the Union.
- (2) As of 1 January 2020, Commission Regulation (EU) 2018/1881 <sup>(2)</sup> amending Annexes I, III and VI to XII to Regulation (EC) No 1907/2006 shall apply. Regulation (EU) 2018/1881 introduces specific requirements for nanoforms of substances. As information related to those requirements is to be included in the safety data sheets, Annex II to Regulation (EC) No 1907/2006 should be modified accordingly.
- (3) The Globally Harmonised System of Classification and Labelling of Chemicals (GHS) developed in the framework of the United Nations, sets out internationally harmonised criteria for the classification and labelling of chemicals and rules on safety data sheets. The Union confirmed its intention to incorporate the GHS criteria into Union law.
- (4) The instruments foreseen by GHS to communicate the hazards of substances and mixtures are labels and safety data sheets. The GHS provisions on safety data sheets are included in Regulation (EC) No 1907/2006. Therefore, the requirements for safety data sheets laid down in Annex II to Regulation (EC) No 1907/2006 should be adapted to the rules for safety data sheets of the sixth and seventh revision of the GHS.
- (5) Annex VIII to Regulation (EC) No 1272/2008 of the European Parliament and of the Council <sup>(3)</sup> will allow, inter alia, the possibility that the unique formula identifier be indicated only in the safety data sheet as regards hazardous mixtures supplied for use at industrial sites. It will also require for certain mixtures which are not packaged that the unique formula identifier be indicated in the safety data sheet. For reasons of consistency, Annex II to Regulation (EC) No 1907/2006 should reflect those changes and indicate where the unique formula identifier should appear in the safety data sheet.
- (6) The Commission Communication of 7 November 2018 ‘Towards a comprehensive European Union framework on endocrine disruptors’ <sup>(4)</sup> indicates that the Commission is assessing how to improve the communication through the supply chain for endocrine disruptors under Regulation (EC) No 1907/2006 in the context of the work on safety data sheets. A number of specific requirements for safety data sheets have been identified as relevant for substances and mixtures with endocrine disrupting properties and Annex II of this Regulation should therefore be modified accordingly.

<sup>(1)</sup> OJ L 396, 30.12.2006, p. 1.

<sup>(2)</sup> Commission Regulation (EU) 2018/1881 of 3 December 2018 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annexes I, III, VI, VII, VIII, IX, X, XI, and XII to address nanoforms of substances (OJ L 308, 4.12.2018, p. 1).

<sup>(3)</sup> 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 (OJ L 353, 31.12.2008, p. 1).

<sup>(4)</sup> COM(2018)734

- (7) Specific concentration limits, multiplying factors and acute toxicity estimates set in accordance with Regulation (EC) No 1272/2008, are relevant for the safe use of substances and mixtures, and should therefore be provided in safety data sheets, if available.
- (8) Requiring economic operators who have already compiled safety data sheets, to update them immediately in accordance with the provisions of this Regulation would impose a disproportionate burden on them. Operators should rather be allowed to continue providing safety data sheets in accordance with Regulation (EC) No 1907/2006, as amended by Commission Regulation (EU) 2015/830<sup>(5)</sup> for a certain period. This is without prejudice to the obligation to update the safety data sheets in accordance with Article 31(9) of Regulation (EC) No 1907/2006, and to the cases where the unique formula identifier is added to safety data sheets as provided for in section 5 of Part A of Annex VIII to Regulation (EC) No 1272/2008.
- (9) The measures provided for in this Regulation are in accordance with the opinion of the Committee established under Article 133 of Regulation (EC) No 1907/2006,

HAS ADOPTED THIS REGULATION:

*Article 1*

Annex II to Regulation (EC) No 1907/2006 is replaced by the text in the Annex to this Regulation.

*Article 2*

By way of derogation from Article 3, safety data sheets not complying with the Annex to this Regulation may continue to be provided until 31 December 2022.

*Article 3*

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

It shall apply from 1 January 2021.

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

Done at Brussels, 18 June 2020.

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

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<sup>(5)</sup> Commission Regulation (EU) 2015/830 of 28 May 2015 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ L 132, 29.5.2015, p. 8).

## ANNEX

## ANNEX II

## REQUIREMENTS FOR THE COMPILATION OF SAFETY DATA SHEETS

## PART A

**0.1. Introduction**

- 0.1.1. This Annex sets out the requirements that the supplier shall fulfil for the compilation of a safety data sheet that is provided for a substance or a mixture in accordance with Article 31.
- 0.1.2. The information on substances provided in the safety data sheet shall be consistent with the information in the registration and in the chemical safety report, where required. Where a chemical safety report has been completed, the relevant exposure scenario(s) shall be placed in an annex to the safety data sheet.
- 0.1.3. The safety data sheet shall mention in each relevant section whether and which different nanoforms it covers and link the relevant safety information to each of those nanoforms. As provided for in Annex VI, the term “nanoform” in this Annex refers to a nanoform or a set of similar nanoforms.

**0.2. General requirements for compiling a safety data sheet**

- 0.2.1. The safety data sheet shall enable users to take the necessary measures relating to protection of human health and safety at the workplace, and protection of the environment. The writer of the safety data sheet shall take into account that a safety data sheet must inform its audience of the hazards of a substance or a mixture and provide information on the safe storage, handling and disposal of the substance or the mixture.
- 0.2.2. The information provided by safety data sheets shall also meet the requirements set out in Directive 98/24/EC. In particular, the safety data sheet shall enable employers to determine whether any hazardous chemical agents are present in the workplace and to assess any risk to the health and safety of workers arising from their use.
- 0.2.3. The information in the safety data sheet shall be written in a clear and concise manner. The safety data sheet shall be prepared by a competent person who shall take into account the specific needs and knowledge of the user audience, as far as they are known. Suppliers of substances and mixtures shall ensure that such competent persons have received appropriate training, including refresher training.
- 0.2.4. The language used in the safety data sheet shall be simple, clear and precise, avoiding jargon, acronyms and abbreviations. Statements such as “may be dangerous”, “no health effects”, “safe under most conditions of use” or “harmless” or any other statements indicating that the substance or mixture is not hazardous or any other statements that are inconsistent with the classification of that substance or mixture shall not be used.
- 0.2.5. The date of compilation of the safety data sheet shall be given on the first page. When a safety data sheet has been revised and the new, revised version is provided to recipients, the changes shall be brought to the attention of the recipients in Section 16 of the safety data sheet, unless the changes have been indicated elsewhere. For the revised safety data sheets, the date of compilation, identified as “Revision: (date)”, shall appear on the first page, as well as one or more indications of which version is replaced, such as version number, revision number, or supersedes date.

**0.3. Safety data sheet format**

- 0.3.1. A safety data sheet is not a fixed length document. The length of the safety data sheet shall be commensurate with the hazard of the substance or mixture and the information available.
- 0.3.2. All pages of a safety data sheet, including any annexes, shall be numbered and shall bear either an indication of the length of the safety data sheet (such as “page 1 of 3”) or an indication whether there is a page following (such as “Continued on next page” or “End of safety data sheet”).

#### 0.4. **Safety data sheet content**

The information required by this Annex shall be included in the safety data sheet, where applicable and available, in the relevant subsections set out in Part B. The safety data sheet shall not contain blank subsections.

#### 0.5. **Other information requirements**

The inclusion of additional relevant and available information in the relevant subsections may be necessary in some cases in view of the wide range of properties of substances and mixtures.

Additional safety and environmental information is required to address the needs of seafarers and other transport workers in the bulk transport of dangerous goods in sea-going or inland navigation bulk carriers or tank-vessels subject to International Maritime Organisation (IMO) or national regulations. Subsection 14.7 recommends the inclusion of basic classification information when such cargoes are transported in bulk according to the relevant IMO instruments. In addition, ships carrying oil or oil fuel, as defined in Annex I of MARPOL <sup>(1)</sup>, in bulk or bunkering oil fuel are required, before loading, to be provided with a "material safety data sheet" in accordance with the IMO's Maritime Safety Committee (MSC) resolution "Recommendations for Material Safety Data Sheets (MSDS) for MARPOL Annex I Oil Cargo and Oil Fuel" (MSC.286(86)). Therefore, in order to have one harmonised safety data sheet for maritime and non-maritime use, the additional provisions of Resolution MSC.286(86) may be included in the safety data sheets, where appropriate, for marine transport of MARPOL Annex I cargoes and marine fuel oils.

#### 0.6. **Units**

The units of measurement as set out in Council Directive 80/181/EEC <sup>(2)</sup> shall be used.

#### 0.7. **Special cases**

Safety data sheets shall also be required for the special cases listed in paragraph 1.3 of Annex I to Regulation (EC) No 1272/2008 for which there are labelling derogations.

### 1. **SECTION 1: Identification of the substance/mixture and of the company/undertaking**

This section of the safety data sheet shall prescribe how the substance or mixture shall be identified and how the identified relevant uses, the name of the supplier of the substance or mixture and the contact detail information of the supplier of the substance or mixture, including an emergency contact, shall be provided in the safety data sheet.

#### 1.1. **Product identifier**

The product identifier shall be provided in accordance with Article 18(2) of Regulation (EC) No 1272/2008 in the case of a substance and in accordance with Article 18(3)(a) of Regulation (EC) No 1272/2008 in the case of a mixture, and as provided on the label in the official language(s) of the Member State(s) where the substance or mixture is placed on the market, unless the Member State(s) concerned provide(s) otherwise.

For substances subject to registration, the product identifier shall be consistent with that provided in the registration and the registration number assigned under Article 20(3) of this Regulation shall also be indicated. Additional identifiers may be provided even if they have not been used in the registration.

Without affecting the obligations of downstream users laid down in Article 39 of this Regulation, the part of the registration number referring to the individual registrant of a joint submission may be omitted by a supplier who is a distributor or a downstream user provided that:

- (a) this supplier assumes the responsibility to provide the full registration number upon request for enforcement purposes or, if the full registration number is not available to him, to forward the request to his supplier, in line with point (b); and

<sup>(1)</sup> Marpol – Consolidated edition 2006, London, IMO 2007, ISBN 978-92-801-4216-7.

<sup>(2)</sup> Council Directive 80/181/EEC of 20 December 1979 on the approximation of the laws of the Member States relating to units of measurement and on the repeal of Directive 71/354/EEC (OJ L 39, 15.2.1980, p. 40).

- (b) this supplier provides the full registration number to the Member State authority responsible for enforcement (the enforcement authority) within 7 days upon request, received either directly from the enforcement authority or forwarded by his recipient, or, if the full registration number is not available to him, this supplier shall forward the request to his supplier within 7 days upon request and at the same time inform the enforcement authority thereof.

A single safety data sheet may be provided to cover more than one substance or mixture where the information in that safety data sheet fulfils the requirements of this Annex for each of those substances or mixtures.

Where different forms of a substance are covered by one safety data sheet, relevant information shall be included, clearly indicating which information is related to which form. Alternatively, a separate safety data sheet may be prepared per form or group of forms.

If the safety data sheet pertains to one or more nanoforms, or substances that include nanoforms, this shall be indicated by using the word "nanoform".

#### *Other means of identification*

Other names or synonyms by which the substance or mixture is labelled or commonly known may be provided.

Where a mixture has a unique formula identifier (UFI) in accordance with section 5 of Part A of Annex VIII to Regulation (EC) No 1272/2008 and that UFI is indicated in the safety data sheet, then the UFI shall be provided in this subsection.

### 1.2. **Relevant identified uses of the substance or mixture and uses advised against**

At least a brief description of the identified uses (for example, floor cleaning, or industrial use in polymer production, or professional use in cleaning agents) relevant for the recipient(s) of the substance or mixture shall be indicated.

The uses which the supplier advises against and the reasons why shall, where applicable, be stated. This need not be an exhaustive list.

Where a chemical safety report is required, the information in this subsection of the safety data sheet shall be consistent with the identified uses in the chemical safety report and the exposure scenarios from the chemical safety report set out in the annex to the safety data sheet.

### 1.3. **Details of the supplier of the safety data sheet**

The supplier of the safety data sheet, whether it is the manufacturer, importer, only representative, downstream user or distributor, shall be identified. The full address and telephone number of the supplier shall be given as well as an email address for a competent person responsible for the safety data sheet.

In addition, if the supplier is not located in the Member State where the substance or mixture is placed on the market and he has nominated a responsible person for that Member State, a full address and telephone number for that responsible person shall be given.

Where an only representative has been appointed, details of the non-Union manufacturer or formulator may also be provided.

For registrants, the information on the supplier of the safety data sheet and, if provided, on the supplier of the substance or mixture, shall be consistent with the information on the identity of the manufacturer, importer or only representative provided in the registration.

### 1.4. **Emergency telephone number**

References to emergency information services shall be provided. If an official advisory body exists in the Member State where the substance or mixture is placed on the market (this may be the body responsible for receiving information relating to health referred to in Article 45 of Regulation (EC) No 1272/2008), its telephone number shall be given and can suffice. If availability of such services is limited for any reasons, such as hours of operation, or if there are limits on specific types of information provided, this shall be clearly stated.

## 2. **SECTION 2: Hazards identification**

This section of the safety data sheet shall describe the hazards of the substance or mixture and the appropriate warning information associated with those hazards.

## 2.1. Classification of the substance or mixture

The classification of the substance or the mixture which results from the application of the classification criteria in Regulation (EC) No 1272/2008 shall be given. Where the supplier has notified information regarding the substance to the classification and labelling inventory in accordance with Article 40 of Regulation (EC) No 1272/2008, or has provided that information as part of a registration pursuant to this Regulation, the classification given in the safety data sheet shall be the same as the classification provided in that notification or registration.

If the mixture does not meet the criteria for classification in accordance with Regulation (EC) No 1272/2008, this shall be clearly stated.

Information on the substances in the mixture is provided under subsection 3.2.

If the classification, including the hazard statements, is not written out in full, reference shall be made to section 16 where the full text of each classification, including each hazard statement, shall be given.

The most important adverse physical, human health and environmental effects shall be listed in accordance with sections 9 to 12 of the safety data sheet, in such a way as to allow non-experts to identify the hazards of the substance or mixture.

## 2.2. Label elements

Based on the classification, at least the following elements appearing on the label in accordance with Regulation (EC) No 1272/2008 shall be provided: hazard pictogram(s), signal word(s), hazard statement(s) and precautionary statement(s). A graphical reproduction of the full hazard pictogram in black and white or a graphical reproduction of the symbol only may be substituted for the colour pictogram provided in Regulation (EC) No 1272/2008.

The applicable label elements in accordance with Article 25(1) to (6) and Article 32(6) of Regulation (EC) No 1272/2008 shall be provided.

## 2.3. Other hazards

Information shall be provided on whether the substance meets the criteria for persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with Annex XIII, whether the substance was included in the list established in accordance with Article 59(1) for having endocrine disrupting properties, and whether the substance is a substance identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 <sup>(3)</sup> or Commission Regulation (EU) 2018/605 <sup>(4)</sup>. For a mixture, information shall be provided for each such substance that is present in the mixture at a concentration equal to or greater than 0,1 % by weight.

Information shall be provided on other hazards which do not result in classification but which may contribute to the overall hazards of the substance or mixture, such as formation of air contaminants during hardening or processing, dustiness, explosive properties which do not fulfil the classification criteria of part 2 Section 2.1 of Annex I to Regulation (EC) No 1272/2008, dust explosion hazards, cross-sensitisation, suffocation, freezing, high potency for odour or taste, or environmental effects like hazards to soil-dwelling organisms, or photochemical ozone creation potential. The statement "May form explosible dust-air mixture if dispersed" is appropriate in the case of a dust explosion hazard.

## 3. SECTION 3: Composition/information on ingredients

This section of the safety data sheet shall describe the chemical identity of the ingredient(s) of the substance or mixture, including impurities and stabilising additives as set out below. Appropriate and available safety information on surface chemistry shall be indicated.

### 3.1. Substances

The chemical identity of the main constituent of the substance shall be provided by providing at least the product identifier or one of the other means of identification given in subsection 1.1.

<sup>(3)</sup> Commission Delegated Regulation (EU) 2017/2100 of 4 September 2017 setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 of the European Parliament and Council (OJ L 301, 17.11.2017, p. 1).

<sup>(4)</sup> Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties (OJ L 101, 20.4.2018, p. 33).

The chemical identity of any impurity, stabilising additive, or individual constituent other than the main constituent, which is itself classified and which contributes to the classification of the substance shall be provided as follows:

- (a) the product identifier in accordance with Article 18(2) of Regulation (EC) No 1272/2008;
- (b) if the product identifier is not available, one of the other names (usual name, trade name, abbreviation) or identification numbers.

The specific concentration limit, the M-factor and the acute toxicity estimate for substances included in Part 3 of Annex VI to Regulation (EC) No 1272/2008 or determined in accordance with Annex I to that Regulation shall be indicated, if available.

If the substance is registered and it covers a nanoform, the particle characteristics that specify the nanoform, as described in Annex VI, shall be indicated.

If the substance is not registered, but the safety data sheet covers nanoforms, the particle characteristics of which have impact on the safety of the substance, those characteristics shall be indicated.

Suppliers of substances may choose to list in addition all constituents including non-classified ones.

This subsection may also be used to provide information on multi-constituent substances.

### 3.2. Mixtures

The product identifier, the concentration or concentration ranges and the classifications shall be provided for at least all substances referred to in points 3.2.1 or 3.2.2. Suppliers of mixtures may choose to list in addition all substances in the mixture, including substances not meeting the criteria for classification. This information shall enable the recipient to identify readily the hazards of the substances in the mixture. The hazards of the mixture itself shall be given in section 2.

The concentrations of the substances in a mixture shall be described as either of the following:

- (a) exact percentages in descending order by mass or volume, if technically possible;
- (b) ranges of percentages in descending order by mass or volume, if technically possible.

When using a range of percentages, if the effects of the mixture as a whole are not available, the health and environmental hazards shall describe the effects of the highest concentration of each ingredient.

If the effects of the mixture as a whole are available, the classification determined from this information shall be included under section 2.

Where the use of an alternative chemical name is permitted in accordance with Article 24 of Regulation (EC) No 1272/2008, that name can be used.

3.2.1. For a mixture meeting the criteria for classification in accordance with Regulation (EC) No 1272/2008, the following substances (see also Table 1.1) shall be indicated, together with their concentration or concentration range in the mixture:

- (a) substances presenting a health or environmental hazard within the meaning of Regulation (EC) No 1272/2008, if those substances are present in concentrations equal to or greater than the lowest of any of the following:
  - (i) the generic cut-off values set out in Table 1.1 of Annex I to Regulation (EC) No 1272/2008;
  - (ii) the generic concentration limits given in parts 3 to 5 of Annex I to Regulation (EC) No 1272/2008, taking into account the concentrations specified in the notes to certain tables in part 3 in relation to the obligation to make available a safety data sheet for the mixture upon request, and for aspiration hazard (Section 3.10 of Annex I to Regulation (EC) No 1272/2008)  $\geq 1\%$ ;
  - (iii) the specific concentration limits given in Part 3 of Annex VI to Regulation (EC) No 1272/2008;

- (iv) if a M-factor has been given in Part 3 of Annex VI to Regulation (EC) No 1272/2008, the generic cut-off value in Table 1.1 of Annex I to that Regulation, adjusted using the calculation set out in Section 4.1 of Annex I to that Regulation;
  - (v) the specific concentration limits provided to the classification and labelling inventory established under Regulation (EC) No 1272/2008;
  - (vi) one tenth of the specific concentration limit for a substance classified as skin sensitiser or respiratory sensitiser with a specific concentration limit;
  - (vii) the concentration limits set out in Annex II to Regulation (EC) No 1272/2008;
  - (viii) if an M-factor has been provided to the classification and labelling inventory established under Regulation (EC) No 1272/2008, the generic cut-off value in Table 1.1 of Annex I to that Regulation, adjusted using the calculation set out in Section 4.1 of Annex I to that Regulation;
- (b) substances for which there are Union workplace exposure limits which are not already included under point (a);
- (c) provided that the concentration of an individual substance is equal to or greater than 0,1 %, substances that meet any of the following criteria:
- substances that are persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII,
  - substances included in the list established in accordance with Article 59(1) for reasons other than the hazards referred to in point (a) of this subsection such as endocrine disrupting properties,
  - substances identified as having endocrine disrupting properties in accordance with the criteria set out in Delegated Regulation (EU) 2017/2100 or Regulation (EU) 2018/605.

Table 1.1

**List of hazard classes, hazard categories and concentration limits for which a substance shall be listed as a substance in a mixture in subsection 3.2.1**

| Hazard class and category  | Concentration limit (%) |
|--|-------------------------|
| Acute toxicity, category 1, 2 and 3  | ≥ 0,1                   |
| Acute toxicity, category 4   | ≥ 1                     |
| Skin corrosion/irritation, category 1, categories 1A, 1B, 1C and category 2  | ≥ 1                     |
| Serious damage to eyes/eye irritation, category 1 and 2                      | ≥ 1                     |
| Respiratory sensitiser category 1 or category 1B                             | ≥ 0,1                   |
| Respiratory sensitiser category 1A   | ≥ 0,01                  |
| Skin sensitiser category 1 or category 1B                                    | ≥ 0,1                   |
| Skin sensitiser category 1A  | ≥ 0,01                  |
| Germ cell mutagenicity category 1A and 1B                                    | ≥ 0,1                   |
| Germ cell mutagenicity category 2  | ≥ 1                     |
| Carcinogenicity category 1A, 1B and 2  | ≥ 0,1                   |
| Reproductive toxicity, category 1A, 1B, 2 and effects on or via lactation    | ≥ 0,1                   |
| Specific target organ toxicity (STOT) – single exposure, category 1, 2 and 3 | ≥ 1                     |
| Specific target organ toxicity (STOT) – repeated exposure, category 1 and 2  | ≥ 1                     |



| Hazard class and category   | Concentration limit (%) |
|---|-------------------------|
| Aspiration toxicity   | ≥ 1                     |
| Hazardous to the aquatic environment – Acute, category 1            | ≥ 0,1                   |
| Hazardous to the aquatic environment – Chronic, category 1          | ≥ 0,1                   |
| Hazardous to the aquatic environment – Chronic, category 2, 3 and 4 | ≥ 1                     |
| Hazardous for the ozone layer                                       | ≥ 0,1                   |

3.2.2. For a mixture not meeting the criteria for classification in accordance with Regulation (EC) No 1272/2008, substances present in an individual concentration equal to or greater than the following concentrations shall be indicated, together with their concentration or concentration range:

- (a) 1 % by weight in non-gaseous mixtures and 0,2 % by volume in gaseous mixtures for:
  - (i) substances which present a health or environmental hazard within the meaning of Regulation (EC) No 1272/2008; or
  - (ii) substances for which Union workplace exposure limits have been assigned;
- (b) 0,1 % by weight for substances that meet any of the following criteria:
  - substances that are persistent, bioaccumulative and toxic in accordance with the criteria set out in Annex XIII,
  - substances that are very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII,
  - substances included in the list established in accordance with Article 59(1) for reasons other than the hazards referred to in point (a) of this subsection such as endocrine disrupting properties;
  - identified as having endocrine disrupting properties in accordance with the criteria set out in Delegated Regulation (EU) 2017/2100 or Regulation (EU) 2018/605;
- (c) 0,1 % of a substance classified as skin sensitiser category 1 or 1B, respiratory sensitiser category 1 or 1B, or carcinogenic category 2;
- (d) 0,01 % of a substance classified as skin sensitiser category 1A or respiratory sensitiser category 1A;
- (e) one tenth of the specific concentration limit for a substance classified as skin sensitiser or respiratory sensitiser with a specific concentration limit;
- (f) 0,1 % of a substance classified as toxic to reproduction categories 1A, 1B or 2, or with effects on or via lactation.

3.2.3. For the substances indicated in subsection 3.2:

- the classification of the substance according to Regulation (EC) No 1272/2008, including the hazard class (es) and category code(s) as provided in Table 1.1 of Annex VI to that Regulation as well as the hazard statements and supplemental hazard statements, shall be provided. The hazard statements and the supplemental hazard statements do not need to be written out in full in this subsection; their codes shall be sufficient. In cases where they are not written out in full, reference shall be made to section 16, where the full text of each relevant hazard statement shall be listed. If the substance does not meet the classification criteria, the reason for indicating the substance in subsection 3.2 shall be described, such as “non-classified vPvB substance” or “substance with a Union workplace exposure limit”.
- the specific concentration limit, the M-factor and the acute toxicity estimate for the substance in Part 3 of Annex VI to Regulation (EC) No 1272/2008 or as determined in accordance with Annex I to that Regulation shall be indicated, if available.
- if the substance as used in the mixture is in nanoform and is as such registered or addressed by the downstream user chemical safety report, the particle characteristics that specify the nanoform, as described in Annex VI, shall be indicated. If the substance as used in the mixture is in nanoform but is not registered or addressed by the downstream user chemical safety report, the particle characteristics which have impact on the safety of the mixture, shall be provided.

- 3.2.4. For the substances indicated in subsection 3.2 the name and, if available, the registration number, as assigned under Article 20(3) of this Regulation, shall be given.

Without affecting the obligations of downstream users laid down in Article 39 of this Regulation, the part of the registration number referring to the individual registrant of a joint submission may be omitted by the supplier of the mixture provided that:

- (a) this supplier assumes the responsibility to provide the full registration number upon request for enforcement purposes or, if the full registration number is not available to him, to forward the request to his supplier, in line with point (b); and
- (b) this supplier provides the full registration number to the Member State authority responsible for enforcement (hereinafter referred to as the enforcement authority) within seven days upon request, received either directly from the enforcement authority or forwarded by his recipient, or, if the full registration number is not available to him, this supplier shall forward the request to his supplier within seven days upon request and at the same time inform the enforcement authority thereof.

The EC number, if available, shall be given in accordance with Regulation (EC) No 1272/2008. The CAS number, if available, and the IUPAC name, if available, may also be given.

For substances indicated in this subsection by means of an alternative chemical name in accordance with Article 24 of Regulation (EC) No 1272/2008, the registration number, EC number and other precise chemical identifiers are not necessary.

#### 4. **SECTION 4: First aid measures**

This section of the safety data sheet shall describe the initial care in such a way that an untrained responder can understand and provide it without the use of sophisticated equipment and without the availability of a wide selection of medications. If medical attention is required, the instructions shall state this, including its urgency.

##### 4.1. **Description of first aid measures**

- 4.1.1. First aid instructions shall be provided by relevant routes of exposure. Subdivisions shall be used to indicate the procedure for each route, such as inhalation, skin, eye and ingestion.

- 4.1.2. Advice shall be provided as to whether:

- (a) immediate medical attention is required and if delayed effects can be expected after exposure;
- (b) movement of the exposed individual from the area to fresh air is recommended;
- (c) removal and handling of clothing and shoes from the individual is recommended; and
- (d) personal protective equipment for first aid responders is recommended.

##### 4.2. **Most important symptoms and effects, both acute and delayed**

Briefly summarised information shall be provided on the most important symptoms and effects, both acute and delayed, from exposure.

##### 4.3. **Indication of any immediate medical attention and special treatment needed**

Where appropriate, information shall be provided on clinical testing and medical monitoring for delayed effects, specific details on antidotes (where they are known) and contraindications.

For some substances or mixtures, it may be important to emphasise that special means to provide specific and immediate treatment shall be available at the workplace.

#### 5. **SECTION 5: Firefighting measures**

This section of the safety data sheet shall describe the requirements for fighting a fire caused by the substance or mixture, or arising in its vicinity.

##### 5.1. **Extinguishing media**

Suitable extinguishing media:

Information shall be provided on the appropriate extinguishing media.

Unsuitable extinguishing media:

Indications shall be given whether any extinguishing media are inappropriate for a particular situation involving the substance or mixture (e.g. avoid high pressure media which could cause the formation of a potentially explosible dust-air mixture).

#### 5.2. **Special hazards arising from the substance or mixture**

Information shall be provided on hazards that may arise from the substance or mixture, like hazardous combustion products that form when the substance or mixture burns, such as “may produce toxic fumes of carbon monoxide if burning” or “produces oxides of sulphur and nitrogen on combustion”.

#### 5.3. **Advice for firefighters**

Advice shall be provided on any protective actions to be taken during firefighting, such as “keep containers cool with water spray”, and on special protective equipment for firefighters, such as boots, overalls, gloves, eye and face protection and breathing apparatus.

### 6. **SECTION 6: Accidental release measures**

This section of the safety data sheet shall recommend the appropriate response to spills, leaks, or releases, to prevent or minimise the adverse effects on persons, property and the environment. It shall distinguish between responses to large and small spills, in cases where the spill volume has a significant impact on the hazard. If the procedures for containment and recovery indicate that different practices are required, these shall be indicated in the safety data sheet.

#### 6.1. **Personal precautions, protective equipment and emergency procedures**

##### 6.1.1. *For non-emergency personnel*

Advice shall be provided related to accidental spills and release of the substance or mixture such as:

- (a) the wearing of suitable protective equipment (including personal protective equipment referred to under section 8 of the safety data sheet) to prevent any contamination of skin, eyes and personal clothing;
- (b) removal of ignition sources, provision of sufficient ventilation, control of dust; and
- (c) emergency procedures such as the need to evacuate the danger area or to consult an expert.

##### 6.1.2. *For emergency responders*

Advice shall be provided related to suitable fabric for personal protective clothing (such as “appropriate: butylene”; “not appropriate: PVC”).

#### 6.2. **Environmental precautions**

Advice shall be provided on any environmental precautions to be taken related to accidental spills and release of the substance or mixture, such as keeping away from drains, surface and ground water.

#### 6.3. **Methods and material for containment and cleaning up**

6.3.1. Appropriate advice shall be provided on how to contain a spill. Appropriate containment techniques may include any of the following:

- (a) bunding, covering of drains;
- (b) capping procedures.

6.3.2. Appropriate advice shall be provided on how to clean-up a spill. Appropriate clean-up procedures may include any of the following:

- (a) neutralisation techniques;
- (b) decontamination techniques;

- (c) adsorbent materials;
- (d) cleaning techniques;
- (e) vacuuming techniques;
- (f) equipment required for containment/clean-up (include the use of non-sparking tools and equipment where applicable).

6.3.3. Any other information shall be provided relating to spills and releases, including advice on inappropriate containment or clean-up techniques, such as by indications like “never use ...”.

#### 6.4. **Reference to other sections**

If appropriate sections 8 and 13 shall be referred to.

### 7. **SECTION 7: Handling and storage**

This section of the safety data sheet shall provide advice on safe handling practices. It shall emphasise precautions that are appropriate to the identified uses referred to under subsection 1.2 and to the unique properties of the substance or mixture.

Information in this section of the safety data sheet shall relate to the protection of human health, safety and the environment. It shall assist the employer in devising suitable working procedures and organisational measures according to Article 5 of Directive 98/24/EC and Article 5 of Directive 2004/37/EC.

Where a chemical safety report is required, the information in this section of the safety data sheet shall be consistent with the information given for the identified uses in the chemical safety report and the exposure scenarios showing control of risk from the chemical safety report set out in the annex to the safety data sheet.

In addition to information given in this section, relevant information may also be found in section 8.

#### 7.1. **Precautions for safe handling**

7.1.1. Recommendations shall be specified to:

- (a) allow safe handling of the substance or mixture, such as containment and measures to prevent fire as well as aerosol and dust generation;
- (b) prevent handling of incompatible substances or mixtures;
- (c) draw attention to operations and conditions which create new risks by altering the properties of the substance or mixture, and to appropriate countermeasures; and
- (d) reduce the release of the substance or mixture to the environment, such as avoiding spills or keeping away from drains.

7.1.2. Advice on general occupational hygiene shall be provided, such as:

- (a) not to eat, drink and smoke in work areas;
- (b) to wash hands after use; and
- (c) to remove contaminated clothing and protective equipment before entering eating areas.

#### 7.2. **Conditions for safe storage, including any incompatibilities**

The advice provided shall be consistent with the physical and chemical properties described in section 9 of the safety data sheet. If relevant, advice shall be provided on specific storage requirements including:

- (a) how to manage risks associated with:
  - (i) explosive atmospheres;
  - (ii) corrosive conditions;
  - (iii) flammability hazards;
  - (iv) incompatible substances or mixtures;

- (v) evaporative conditions; and
- (vi) potential ignition sources (including electrical equipment);
- (b) how to control the effects of:
  - (i) weather conditions;
  - (ii) ambient pressure;
  - (iii) temperature;
  - (iv) sunlight;
  - (v) humidity; and
  - (vi) vibration;
- (c) how to maintain the integrity of the substance or mixture by the use of:
  - (i) stabilisers; and
  - (ii) antioxidants;
- (d) other advice including:
  - (i) ventilation requirements;
  - (ii) specific designs for storage rooms or vessels (including retention walls and ventilation);
  - (iii) quantity limits under storage conditions (if relevant); and
  - (iv) packaging compatibilities.

### 7.3. **Specific end use(s)**

For substances and mixtures designed for specific end use(s), recommendations shall relate to the identified use (s) referred to in subsection 1.2 and be detailed and operational. If an exposure scenario is attached, reference to it may be made or the information as required in subsections 7.1 and 7.2 shall be provided. If an actor in the supply chain has carried out a chemical safety assessment for the mixture, it is sufficient that the safety data sheet and the exposure scenarios are consistent with the chemical safety report for the mixture, rather than with the chemical safety reports for each substance in the mixture. If industry or sector specific guidance is available, detailed reference to it (including source and issuing date) may be made.

## 8. **SECTION 8: Exposure controls/personal protection**

This section of the safety data sheet shall describe the applicable occupational exposure limits and necessary risk management measures.

Where a chemical safety report is required, the information in this section of the safety data sheet shall be consistent with the information given for the identified uses in the chemical safety report and the exposure scenarios showing control of risk from the chemical safety report set out in the annex to the safety data sheet.

### 8.1. **Control parameters**

- 8.1.1. Where available, the following national limit values, including the legal basis of each of them, which are currently applicable in the Member State in which the safety data sheet is being provided shall be listed for the substance or for each of the substances in the mixture. When listing occupational exposure limit values, the chemical identity as specified in section 3 shall be used.
  - 8.1.1.1. the national occupational exposure limit values that correspond to Union occupational exposure limit values in accordance with Directive 98/24/EC, including any notations as referred to in Article 2(3) of Commission Decision 2014/113/EU <sup>(<sup>5</sup>)</sup>;
  - 8.1.1.2. the national occupational exposure limit values that correspond to Union limit values in accordance with Directive 2004/37/EC, including any notations as referred to in Article 2(3) of Decision 2014/113/EU;

<sup>(5)</sup> Commission Decision 2014/113/EU of 3 March 2014 on setting up a Scientific Committee on Occupational Exposure Limits for Chemical Agents and repealing Decision 95/320/EC (OJ L 62, 4.3.2014, p. 18).

- 8.1.1.3. any other national occupational exposure limit values;
- 8.1.1.4. the national biological limit values that correspond to Union biological limit values in accordance with Directive 98/24/EC, including any notations as referred to in Article 2(3) of Decision 2014/113/EU;
- 8.1.1.5. any other national biological limit values.
- 8.1.2. Information on currently recommended monitoring procedures shall be provided at least for the most relevant substances.
- 8.1.3. If air contaminants are formed when using the substance or mixture as intended, applicable occupational exposure limit values and/or biological limit values for these shall also be listed.
- 8.1.4. Where a chemical safety report is required or where a DNEL as referred to in Section 1.4 of Annex I or a PNEC as referred to in Section 3.3 of Annex I is available, the relevant DNELs and PNECs for the substance shall be given for the exposure scenarios from the chemical safety report set out in the annex to the safety data sheet.
- 8.1.5. Where a control banding approach is used to decide on risk management measures in relation to specific uses, sufficient detail shall be given to enable effective management of the risk. The context and limitations of the specific control banding recommendation shall be made clear.

## 8.2. **Exposure controls**

The information required in this subsection shall be provided, unless an exposure scenario containing that information is attached to the safety data sheet.

Where the supplier has waived a test under Section 3 of Annex XI, he shall indicate the specific conditions of use relied on to justify the waiving.

Where a substance has been registered as an isolated intermediate (on-site or transported), the supplier shall indicate that this safety data sheet is consistent with the specific conditions relied on to justify the registration in accordance with Article 17 or 18.

### 8.2.1. *Appropriate engineering controls*

The description of appropriate exposure control measures shall relate to the identified use(s) of the substance or mixture as referred to in subsection 1.2. This information shall be sufficient to enable the employer to carry out an assessment of risk to the safety and health of workers arising from the presence of the substance or mixture in accordance with Articles 4 to 6 of Directive 98/24/EC and Articles 3 to 5 of Directive 2004/37/EC, where appropriate.

This information shall complement that already given under section 7.

### 8.2.2. *Individual protection measures, such as personal protective equipment*

- 8.2.2.1. The information on use of personal protective equipment shall be consistent with good occupational hygiene practices and in conjunction with other control measures, including engineering controls, ventilation and isolation. Where appropriate, section 5 shall be referred to for specific fire/chemical personal protective equipment advice.

8.2.2.2. Taking into account Regulation (EU) 2016/425 of the European Parliament and of the Council <sup>(6)</sup> and referring to the appropriate CEN standards, detailed specifications shall be given on which equipment will provide adequate and suitable protection, including:

(a) Eye/face protection

The type of eye/face protection equipment required shall be specified based on the hazard of the substance or mixture and potential for contact, such as safety glasses, safety goggles, face-shield.

(b) Skin protection

(i) *Hand protection*

The type of gloves to be worn when handling the substance or mixture shall be clearly specified based on the hazard of the substance or mixture and potential for contact and with regard to the amount and duration of dermal exposure, including:

- the type of material and its thickness,
- the typical or minimum breakthrough times of the glove material,

If necessary, any additional hand protection measures shall be indicated.

(ii) *Other*

If it is necessary to protect a part of the body other than the hands, the type and quality of protection equipment required shall be specified, such as gauntlets, boots, bodysuit based on the hazards associated with the substance or mixture and the potential for contact.

If necessary, any additional skin protection measures and specific hygiene measures shall be indicated.

(c) Respiratory protection

For gases, vapours, mist or dust, the type of protective equipment to be used shall be specified based on the hazard and potential for exposure, including air-purifying respirators, specifying the proper purifying element (cartridge or canister), the adequate particulate filters and the adequate masks, or self-contained breathing apparatus.

(d) Thermal hazards

When specifying protective equipment to be worn for materials that represent a thermal hazard, special consideration shall be given to the construction of the personal protective equipment.

8.2.3. *Environmental exposure controls*

The information required by the employer to fulfil his commitments under Union environmental protection legislation shall be specified.

Where a chemical safety report is required, a summary of the risk management measures that adequately control exposure of the environment to the substance shall be given for the exposure scenarios set out in the annex to the safety data sheet.

9. **SECTION 9: Physical and chemical properties**

This section of the safety data sheet shall describe the empirical data relating to the substance or mixture, if relevant. Article 8(2) of Regulation (EC) No 1272/2008 shall apply.

To enable proper control measures to be taken, all relevant information on the substance or mixture shall be provided. The information in this section shall be consistent with the information provided in the registration or in the chemical safety report, where required, and with the classification of the substance or mixture.

In the case of a mixture, where information does not apply to the mixture as a whole, the entries shall clearly indicate to which substance in the mixture the data apply.

<sup>(6)</sup> Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (OJ L 81, 31.3.2016, p. 51).

Reported properties shall be clearly identified and reported in the appropriate measurement units. The method of determination shall be provided, including measurement and reference conditions, if relevant for the interpretation of the numerical value. Unless specified otherwise, standard conditions of temperature and pressure are 20 °C and 101,3 kPa, respectively.

The properties listed in subsections 9.1 and 9.2 may be presented in a form of a list. Within the subsections, the order of listing the properties may be different if deemed appropriate.

#### 9.1. **Information on basic physical and chemical properties**

Each safety data sheet shall include the properties mentioned below. If it is stated that a particular property does not apply or if information on a particular property is not available, this shall be clearly indicated, giving the reasons where possible.

(a) *Physical state*

The physical state (gas, liquid or solid) shall generally be indicated at standard conditions of temperature and pressure.

The definitions of the terms gas, liquid and solid, as provided in Section 1.0 of Annex I to Regulation (EC) No 1272/2008, shall apply.

(b) *Colour*

The colour of the substance or mixture as supplied shall be indicated.

In cases where one safety data sheet is used to cover variants of a mixture which may have different colours, the term "various" can be used to describe the colour.

(c) *Odour*

A qualitative description of the odour shall be given if it is well-known or described in the literature.

If available, the odour threshold shall be indicated (qualitatively or quantitatively).

(d) *Melting point/freezing point*

Does not apply to gases.

Melting point and freezing point shall be indicated at standard pressure.

In case the melting point is above the measuring range of the method, it shall be indicated up to which temperature no melting point was observed.

If decomposition or sublimation occur prior to or during melting, it shall be indicated.

As regards waxes and pastes, the softening point/range may be indicated instead of the melting point and freezing point.

As regards mixtures, if it is technically not possible to determine the melting point/freezing point, this shall be indicated.

(e) *Boiling point or initial boiling point and boiling range*

These properties shall be indicated at standard pressure. A boiling point at lower pressure might however be indicated, in case the boiling point is very high or in case decomposition occurs before boiling at standard pressure.

If the boiling point is above the measuring range of the method, the temperature up to which no boiling point was observed shall be indicated.

If decomposition occurs prior to or during boiling, this shall be indicated.

As regards mixtures, if it is technically not possible to determine their boiling point or range, this shall be indicated; in that case, the boiling point of the lowest boiling ingredient shall also be indicated.

(f) *Flammability*

Applies to gases, liquids and solids.

It shall be indicated whether the substance or mixture is ignitable, i.e. capable of catching fire or being set on fire, even if not classified for flammability.



If available and appropriate, further information may be indicated, such as whether the effect of ignition is other than a normal combustion (e.g. an explosion) and the ignitability under non-standard conditions.

More specific information on the flammability may be indicated based on the respective hazard classification. The information provided in subsection 9.2.1 shall not be provided in this point.

(g) *Lower and upper explosion limit* (?)

Do not apply to solids.

As regards flammable liquids, at least the lower explosion limit shall be indicated. If the flash point is approximately  $-25\text{ }^{\circ}\text{C}$  or higher, it may not be possible to determine the upper explosion limit at standard temperature; in that case, it is recommended to indicate the upper explosion limit at a higher temperature. If the flash point is higher than  $20\text{ }^{\circ}\text{C}$ , it may not be possible to determine the lower or the upper explosion limit at standard temperature; in that case, it is recommended to indicate both the lower and the upper explosion limits at a higher temperature.

(h) *Flash point*

Does not apply to gases, aerosols and solids.

For mixtures, a value for the mixture shall be indicated, if available. Otherwise, the flash point(s) of the substance(s) with the lowest flash point(s) shall be indicated.

(i) *Auto-ignition temperature*

Only applies to gases and liquids.

As regards mixtures the auto-ignition temperature for the mixture shall be indicated, if available. If the value for the mixture is not available, the auto-ignition temperature(s) of the ingredients with the lowest auto-ignition temperature(s) shall be indicated.

(j) *Decomposition temperature*

Only applies to self-reactive substances and mixtures, organic peroxides, and other substances and mixtures that may decompose.

The self-accelerating decomposition temperature (SADT) and the volume to which it applies, or the decomposition onset temperature shall be indicated.

It shall be indicated whether the temperature given is the SADT or the decomposition onset temperature.

If no decomposition was observed, it shall be indicated up to which temperature no decomposition was observed, e.g. "no decomposition observed up to  $x\text{ }^{\circ}\text{C}$ ".

(k) *pH*

Does not apply to gases.

The pH of the substance or mixture as supplied, or where the product is a solid, the pH of an aqueous liquid or solution at a given concentration, shall be indicated.

The concentration of the test substance or mixture in water shall be indicated.

(l) *Kinematic viscosity*

Only applies to liquids.

The measurement unit shall be  $\text{mm}^2/\text{s}$ .

For non-Newtonian liquids, the thixotropic or rheopexic behaviour shall be indicated.

(m) *Solubility*

Solubility shall generally be indicated at standard temperature.

The solubility in water shall be indicated.

The solubility in other polar and non-polar solvents may also be included.

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(?) *Note:* The term 'explosion limit' is synonymous to 'flammability limit', used outside the Union.

As regards mixtures, it shall be indicated if the mixture is fully or only partially soluble in or miscible with water or other solvent.

As regards nanoforms, the dissolution rate in water or in other relevant biological or environmental media shall be indicated in addition to the water solubility.

(n) *Partition coefficient n-octanol/water (log value)*

Does not apply to inorganic and ionic liquids and does not generally apply to mixtures.

It shall be indicated whether the reported value is based on testing or on calculation.

As regards nanoforms of a substance for which the n-octanol/water partition coefficient does not apply, the dispersion stability in different media shall be indicated.

(o) *Vapour pressure*

Vapour pressure shall generally be indicated at standard temperature.

As regards volatile fluids, the vapour pressure at 50 °C shall also be indicated.

In cases where one safety data sheet is used to cover variants of a liquid mixture or liquefied gas mixture, a range for the vapour pressure shall be indicated.

As regards liquid mixtures or liquefied gas mixtures, a range for the vapour pressure or at least the vapour pressure of the most volatile ingredient(s), where the vapour pressure of the mixture is predominantly determined by that or those ingredient(s), shall be indicated.

The saturated vapour concentration may also be indicated.

(p) *Density and/or relative density*

Only apply to liquids and solids.

Density and relative density shall generally be indicated at standard conditions of temperature and pressure.

The absolute density and/or the relative density based on water at 4 °C as reference (also referred to as the specific gravity) shall be indicated.

In cases where variations in density are possible, e.g. due to batch manufacture, or where one safety data sheet is used to cover several variants of a substance or mixture, a range may be indicated.

The safety data sheet shall indicate whether the absolute density (units e.g.  $g/cm^3$  or  $kg/m^3$ ) and/or the relative density (dimensionless) is being reported.

(q) *Relative vapour density*

Only applies to gases and liquids.

As regards gases, the relative density of the gas based on air at 20 °C as reference shall be indicated.

As regards liquids, the relative vapour density based on air at 20 °C as reference shall be indicated.

As regards liquids, the relative density  $D_m$  of the vapour/air-mixture at 20 °C may also be indicated.

(r) *Particle characteristics*

Only apply to solids.

The particle size (median equivalent diameter, method of calculation of the diameter (number-, surface- or volume-based) and the range in which this median value varies), shall be indicated. Other properties may also be indicated, such as size distribution (e.g. as a range), shape and aspect ratio, aggregation and agglomeration state, specific surface area and dustiness. If the substance is in nanoform or if the mixture supplied contains a nanoform, those characteristics shall be indicated in this subsection, or referred to if already specified elsewhere in the safety data sheet.

## 9.2. Other information

In addition to the properties mentioned in subsection 9.1, other physical and chemical parameters shall be indicated, such as the properties listed in subsections 9.2.1 and 9.2.2, if their indication is relevant for the safe use of the substance or mixture.

### 9.2.1. Information with regard to physical hazard classes

This subsection lists properties, safety characteristics and test results, which may be useful to include in the safety data sheet when a substance or mixture is classified in the respective physical hazard class. Data deemed relevant with regard to a specific physical hazard but not resulting in classification (e.g. negative test results close to the criterion), may also be appropriate to indicate.

The name of the hazard class to which the data relate may be indicated together with the data.

#### (a) Explosives

This point also applies to substances and mixtures referred to in Note 2 of section 2.1.3 of Annex I of Regulation (EC) No 1272/2008, and to other substances and mixtures which show a positive effect if heated under confinement.

The following information may be provided:

- (i) sensitivity to shock;
- (ii) effect of heating under confinement;
- (iii) effect of ignition under confinement;
- (iv) sensitivity to impact;
- (v) sensitivity to friction;
- (vi) thermal stability;
- (vii) package (type, size, net mass of substance or mixture), based on which the “division” within the explosive class was assigned, or based on which the substance or mixture was exempted from classification as explosive.

#### (b) Flammable gases

As regards pure flammable gas, the following information may be provided in addition to data on the explosion limits referred to in point (g) of subsection 9.1:

- (i) the  $T_{Ci}$  (maximum content of flammable gas which, when mixed with nitrogen, is not flammable in air, in mol. %);
- (ii) the fundamental burning velocity if the gas is classified as Category 1B based on fundamental burning velocity.

As regards a flammable gas mixture, the following information may be provided in addition to data on the explosion limits referred to in point (g) of subsection 9.1:

- (i) explosion limits, if tested, or an indication of whether the classification and category assignment is based on calculation;
- (ii) fundamental burning velocity if the gas mixture is classified as Category 1B based on fundamental burning velocity.

#### (c) Aerosols

The following total percentage (by mass) of flammable components may be provided, unless the aerosol is classified as Aerosol category 1 because it contains more than 1 % (by mass) flammable components or has a heat of combustion of at least 20 kJ/g and is not submitted to the flammability classification procedures (see the Note in Paragraph 2.3.2.2 of Annex I to Regulation (EC) No 1272/2008);

(d) Oxidising gases

As regards pure gas, the  $C_i$  (coefficient of oxygen equivalency) as per ISO 10156 “Gases and gas mixtures – Determination of fire potential and oxidizing ability for the selection of cylinder valve outlets”, or as per an equivalent method, may be provided;

As regards a gas mixture, the words “oxidising gas Category 1 (tested as per ISO 10156 (or as per an equivalent method))” may be indicated as regards tested mixtures, or the calculated oxidising power as per ISO 10156 or as per an equivalent method;

(e) Gases under pressure

As regards pure gas, critical temperature may be provided.

As regards gas mixture, pseudo-critical temperature may be provided;

(f) Flammable liquids

When the substance or mixture is classified as flammable liquid, data on the boiling point and flash point do not need to be provided under this point as that data are to be indicated in accordance with the subsection 9.1. Information on sustained combustibility may be provided.

(g) Flammable solids

The following information may be provided:

- (i) burning rate, or burning time as regards metal powders,
- (ii) statement on whether the wetted zone has been passed;

(h) Self-reactive substances and mixtures

In addition to the indication of the SADT as specified in point (j) of subsection 9.1, the following information may be provided:

- (i) decomposition temperature,
- (ii) detonation properties,
- (iii) deflagration properties,
- (iv) effect of heating under confinement,
- (v) explosive power, if applicable;

(i) Pyrophoric liquids

Information on whether spontaneous ignition or charring of filter paper occurs may be provided.

(j) Pyrophoric solids

The following information may be provided:

- (i) statement on whether spontaneous ignition occurs when poured or within five minutes thereafter, as regards solids in powder form,
- (ii) statement on whether pyrophoric properties could change over time.

(k) Self-heating substances and mixtures

The following information may be provided:

- (i) statement on whether spontaneous ignition occurs and the maximum temperature rise obtained,
- (ii) results of screening tests referred to in section 2.11.4.2 of Annex I to Regulation (EC) No 1272/2008, if relevant and available;

(l) Substances and mixtures, which emit flammable gases in contact with water

The following information may be provided:

- (i) identity of the emitted gas, if known,
- (ii) statement on whether the emitted gas ignites spontaneously,
- (iii) gas evolution rate;

(m) Oxidising liquids

Information on whether spontaneous ignition occurs when mixed with cellulose may be provided.

(n) Oxidizing solids

Information on whether spontaneous ignition occurs when mixed with cellulose may be provided.

(o) Organic peroxides

In addition to the indication of the SADT as specified in point (j) of subsection 9.1, the following information may be provided:

- (i) decomposition temperature,
- (ii) detonation properties,
- (iii) deflagration properties,
- (iv) effect of heating under confinement,
- (v) explosive power;

(p) Corrosive to metals

The following information may be provided:

- (i) metals that are corroded by the substance or mixture,
- (ii) corrosion rate and statement on whether it refers to steel or aluminium,
- (iii) reference to other sections of the safety data sheet with regard to compatible or incompatible materials.

(q) Desensitised explosives

The following information may be provided:

- (i) desensitising agent used,
- (ii) exothermic decomposition energy,
- (iii) corrected burning rate ( $A_c$ );
- (iv) explosive properties of the desensitised explosive in that state.

9.2.2. *Other safety characteristics*

Properties, safety characteristics and test results listed below may be useful to indicate as regards a substance or a mixture:

- (a) mechanical sensitivity;
- (b) self-accelerating polymerisation temperature;
- (c) formation of explosible dust/air mixtures;
- (d) acid/alkaline reserve;
- (e) evaporation rate;
- (f) miscibility;
- (g) conductivity;
- (h) corrosiveness;
- (i) gas group;
- (j) redox potential;
- (k) radical formation potential;
- (l) photocatalytic properties.

Other physical and chemical parameters shall be indicated if their indication is relevant for the safe use of the substance or mixture.

10. **SECTION 10: Stability and reactivity**

This section of the safety data sheet shall describe the stability of the substance or mixture and the possibility of hazardous reactions occurring under certain conditions of use and also if released into the environment, including, where appropriate, a reference to the test methods used. If it is stated that a particular property does not apply or if information on a particular property is not available, the reasons shall be given.

**10.1. Reactivity**

10.1.1. The reactivity hazards of the substance or mixture shall be described. Specific test data shall be provided for the substance or mixture as a whole, where available. However, the information may also be based on general data for the class or family of substance or mixture if such data adequately represent the anticipated hazard of the substance or mixture.

10.1.2. If data for mixtures are not available, data on substances in the mixture shall be provided. In determining incompatibility, the substances, containers and contaminants that the substance or mixture might be exposed to during transportation, storage and use shall be considered.

**10.2. Chemical stability**

It shall be indicated if the substance or mixture is stable or unstable under normal ambient and anticipated storage and handling conditions of temperature and pressure. Any stabilisers which are, or may need to be, used to maintain the chemical stability of the substance or mixture shall be described. The safety significance of any change in the physical appearance of the substance or mixture shall be indicated. As regards desensitised explosives, information on the shelf life and instructions on how to verify desensitisation shall be provided, and it shall be indicated that removal of the desensitising agent will turn the product into an explosive.

**10.3. Possibility of hazardous reactions**

If relevant, it shall be stated if the substance or mixture may react or polymerise, releasing excess pressure or heat, or creating other hazardous conditions. The conditions under which the hazardous reactions may occur shall be described.

**10.4. Conditions to avoid**

Conditions such as temperature, pressure, light, shock, static discharge, vibrations or other physical stresses that might result in a hazardous situation shall be listed ("conditions to avoid") and if appropriate a brief description of measures to be taken to manage risks associated with such hazards shall be given. As regards desensitised explosives, information on measures to be taken in order to avoid the unintentional removal of the desensitising agent shall be provided, and conditions to avoid shall be listed if the substance or mixture is not sufficiently desensitised.

**10.5. Incompatible materials**

Families of substances or mixtures or specific substances, such as water, air, acids, bases, oxidising agents, with which the substance or mixture could react to produce a hazardous situation (like an explosion, a release of toxic or flammable materials, or a liberation of excessive heat), shall be listed and if appropriate a brief description of measures to be taken to manage risks associated with such hazards shall be given.

**10.6. Hazardous decomposition products**

Known and reasonably anticipated hazardous decomposition products produced as a result of use, storage, spill and heating shall be listed. Hazardous combustion products shall be included in section 5 of the safety data sheet.

**11. SECTION 11: Toxicological information**

This section of the safety data sheet is meant for use primarily by medical professionals, occupational health and safety professionals and toxicologists. A concise but complete and comprehensible description of the various toxicological (health) effects and the available data used to identify those effects shall be provided, including where appropriate information on toxicokinetics, metabolism and distribution. The information in this section shall be consistent with the information provided in the registration and/or in the chemical safety report where required, and with the classification of the substance or mixture.

**11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008**

The relevant hazard classes, for which information shall be provided, are:

- (a) acute toxicity;
- (b) skin corrosion/irritation;
- (c) serious eye damage/irritation;

- (d) respiratory or skin sensitisation;
- (e) germ cell mutagenicity;
- (f) carcinogenicity;
- (g) reproductive toxicity;
- (h) STOT-single exposure;
- (i) STOT-repeated exposure;
- (j) aspiration hazard.

These hazards shall always be listed on the safety data sheet.

For substances subject to registration, brief summaries of the information derived from the application of Annexes VII to XI shall be given, including, where appropriate, a reference to the test methods used. For substances subject to registration, the information shall also include the result of the comparison of the available data with the criteria given in Regulation (EC) No 1272/2008 for CMR, categories 1A and 1B, following point 1.3.1 of Annex I to this Regulation.

- 11.1.1. Information shall be provided for each hazard class or differentiation. If it is stated that the substance or mixture is not classified for a particular hazard class or differentiation, the safety data sheet shall clearly state whether this is due to lack of data, technical impossibility to obtain the data, inconclusive data or data which are conclusive although insufficient for classification; in the latter case the safety data sheet shall specify “based on available data, the classification criteria are not met”.
- 11.1.2. The data included in this subsection shall apply to the substance or mixture as placed on the market. In the case of a mixture, the data should describe the toxicological properties of the mixture as a whole, except if Article 6 (3) of Regulation (EC) No 1272/2008 applies. If available, the relevant toxicological properties of the hazardous substances in a mixture shall also be provided, such as the LD50, acute toxicity estimates or LC50.
- 11.1.3. Where there is a substantial amount of test data on the substance or mixture, it may be necessary to summarise results of the critical studies used, for example, by route of exposure.
- 11.1.4. Where the classification criteria for a particular hazard class are not met, information supporting this conclusion shall be provided.
- 11.1.5. *Information on likely routes of exposure*

Information shall be provided on likely routes of exposure and the effects of the substance or mixture via each possible route of exposure, that is, through ingestion (swallowing), inhalation or skin/eye exposure. If health effects are not known, this shall be stated.
- 11.1.6. *Symptoms related to the physical, chemical and toxicological characteristics*

Potential adverse health effects and symptoms associated with exposure to the substance or mixture and its ingredients or known by-products shall be described. Available information shall be provided on the symptoms related to the physical, chemical, and toxicological characteristics of the substance or mixture following exposure. The first symptoms at low exposures through to the consequences of severe exposure shall be described, such as “headaches and dizziness may occur, proceeding to fainting or unconsciousness; large doses may result in coma and death”.
- 11.1.7. *Delayed and immediate effects as well as chronic effects from short and long-term exposure*

Information shall be provided on whether delayed or immediate effects can be expected after short- or long-term exposure. Information on acute and chronic health effects relating to human exposure to the substance or mixture shall also be provided. Where human data are not available, information on the experimental data shall be summarised, with details on either animal data and the species clearly identified or the in vitro tests and the cell types clearly identified. It shall be indicated whether toxicological data is based on human or animal data or on in vitro tests.

#### 11.1.8. *Interactive effects*

Information on interactions shall be included if relevant and available.

#### 11.1.9. *Absence of specific data*

It may not always be possible to obtain information on the hazards of a substance or mixture. In cases where data on the specific substance or mixture are not available, data on similar substances or mixtures, if appropriate, may be used, provided the relevant similar substance or mixture is identified. Where specific data are not used, or where data are not available, this shall be clearly stated.

#### 11.1.10. *Mixtures*

For a given health effect, if a mixture has not been tested for its health effects as a whole, relevant information on relevant substances listed under section 3 shall be provided.

#### 11.1.11. *Mixture versus substance information*

11.1.11.1. The substances in a mixture may interact with each other in the body, resulting in different rates of absorption, metabolism and excretion. As a result, the toxic actions may be altered and the overall toxicity of the mixture may be different from that of the substances in it. This shall be taken into account when providing toxicological information in this subsection of the safety data sheet.

11.1.11.2. It is necessary to consider whether the concentration of each substance is sufficient to contribute to the overall health effects of the mixture. The information on toxic effects shall be presented for each substance, except for the following cases:

- (a) if the information is duplicated, it shall be listed only once for the mixture overall, such as when two substances both cause vomiting and diarrhoea;
- (b) if it is unlikely that these effects will occur at the concentrations present, such as when a mild irritant is diluted to below a certain concentration in a non-irritant solution;
- (c) where information on interactions between substances in a mixture is not available, assumptions shall not be made and instead the health effects of each substance shall be listed separately.

### 11.2 **Information on other hazards**

#### 11.2.1. *Endocrine disrupting properties*

Information on adverse health effects caused by endocrine disrupting properties shall be provided, where available, for the substances identified as having endocrine disrupting properties in Subsection 2.3. This information shall consist of brief summaries of the information derived from application of the assessment criteria laid down in the corresponding Regulations ((EC) No 1907/2006, (EU) 2017/2100, (EU) 2018/605), that is relevant to assess endocrine disrupting properties for human health.

#### 11.2.2. *Other information*

Other relevant information on adverse health effects shall be included even when not required by the classification criteria.

## 12. **SECTION 12: Ecological information**

This section of the safety data sheet shall provide information to enable evaluation of the environmental impact of the substance or mixture where it is released to the environment. Subsections 12.1 to 12.7 of the safety data sheet shall provide a short summary of the data including, where available, relevant test data and clearly indicating species, media, units, test duration and test conditions. This information may assist in handling spills, and evaluating waste treatment practices, control of release, accidental release measures and transport. If it is stated that a particular property does not apply (because the available data shows that the substance or mixture does not meet the criteria for classification) or if information on a particular property is not available, the reasons shall be indicated. Additionally, if a substance or mixture is not classified for other reasons (for example, due to the technical impossibility of obtaining the data or to inconclusive data) this should be clearly stated on the safety data sheet.



Some properties are substance specific, i.e. bioaccumulation, persistence and degradability, and that information shall be given, where available and appropriate, for each relevant substance in the mixture (i.e. those which are required to be listed in section 3 of the safety data sheet and are hazardous to the environment or PBT/vPvB – substances). Information shall also be provided for hazardous transformation products arising from the degradation of substances and mixtures.

The information in this section shall be consistent with the information provided in the registration and/or in the chemical safety report where required, and with the classification of the substance or mixture.

Where reliable and relevant experimental data are available, that data shall be provided and take precedence over information obtained from models.

#### 12.1. **Toxicity**

Information on toxicity using data from tests performed on aquatic and/or terrestrial organisms shall be provided when available. This shall include relevant available data on aquatic toxicity, both acute and chronic for fish, crustaceans, algae and other aquatic plants. In addition, toxicity data on soil micro- and macroorganisms and other environmentally relevant organisms, such as birds, bees and plants, shall be included when available. Where the substance or mixture has inhibitory effects on the activity of microorganisms, the possible impact on sewage treatment plants shall be mentioned.

Where experimental data are not available, the supplier shall consider whether reliable and relevant information obtained from models can be provided.

For substances subject to registration, summaries of the information derived from the application of Annexes VII to XI of this Regulation shall be included.

#### 12.2. **Persistence and degradability**

Degradability is the potential for the substance or the appropriate substances in a mixture to degrade in the environment, either through biodegradation or other processes, such as oxidation or hydrolysis. Persistence is the lack of demonstration of degradation in the situations defined in Sections 1.1.1 and 1.2.1 of Annex XIII. Test results relevant to assess persistence and degradability shall be given where available. If degradation half-lives are quoted it must be indicated whether these half-lives refer to mineralisation or to primary degradation. The potential of the substance or certain substances in a mixture to degrade in sewage treatment plants shall also be mentioned.

Where experimental data are not available, the supplier shall consider whether reliable and relevant information obtained from models can be provided.

This information shall be given where available and appropriate, for each individual substance in the mixture, which is required to be listed in section 3 of the safety data sheet.

#### 12.3. **Bioaccumulative potential**

Bioaccumulative potential is the potential of the substance or certain substances in a mixture to accumulate in biota and, eventually, to pass through the food chain. Test results relevant to assess the bioaccumulative potential shall be given. This shall include reference to the octanol-water partition coefficient ( $K_{ow}$ ) and bioconcentration factor (BCF), or other relevant parameters related to bioaccumulation, if available.

Where experimental data are not available, it shall be considered whether model predictions can be provided.

This information shall be given where available and appropriate, for each individual substance in the mixture which is required to be listed in section 3 of the safety data sheet.

#### 12.4. **Mobility in soil**

Mobility in soil is the potential of the substance or the components of a mixture, if released to the environment, to move under natural forces to the groundwater or to a distance from the site of release. The potential for mobility in soil shall be given where available. Information on mobility in soil can be determined from relevant mobility data such as adsorption studies or leaching studies, known or predicted distribution to environmental compartments, or surface tension. For example, soil adsorption coefficient ( $K_{oc}$ ) values can be predicted from  $K_{ow}$ . Leaching and mobility can be predicted from models.

This information shall be given where available and appropriate, for each individual substance in the mixture which is required to be listed in section 3 of the safety data sheet.

**12.5. Results of PBT and vPvB assessment**

Where a chemical safety report is required, the results of the PBT and vPvB assessment as set out in the chemical safety report shall be given.

**12.6. Endocrine disrupting properties**

Information on adverse effects on the environment caused by endocrine disrupting properties shall be provided where available, for the substances identified as having endocrine disrupting properties in subsection 2.3. This information shall consist of brief summaries of the information derived from application of the assessment criteria laid down in the corresponding Regulations ((EC) No 1907/2006, (EU) 2017/2100, (EU) 2018/605), that is relevant to assess endocrine disrupting properties for the environment.

**12.7. Other adverse effects**

Information on any other adverse effects on the environment shall be included where available, such as environmental fate (exposure), photochemical ozone creation potential, ozone depletion potential or global warming potential.

**13. SECTION 13: Disposal considerations**

This section of the safety data sheet shall provide information for proper waste management of the substance or mixture and/or its container to assist in the determination of safe and environmentally preferred waste management options, consistent with the requirements of Directive 2008/98/EC of the European Parliament and of the Council <sup>(8)</sup> by the Member State in which the safety data sheet is being supplied. Information relevant for the safety of persons conducting waste management activities shall complement the information given in section 8.

Where a chemical safety report is required and where a waste stage analysis has been performed, the information on the waste management measures shall be consistent with the identified uses in the chemical safety report and the exposure scenarios from the chemical safety report set out in the annex to the safety data sheet.

**13.1. Waste treatment methods**

This subsection of the safety data sheet shall:

- (a) specify waste treatment containers and methods including the appropriate methods of waste treatment of both the substance or mixture and any contaminated packaging (for example, incineration, recycling, landfilling);
- (b) specify the physical/chemical properties that may affect waste treatment options;
- (c) discourage sewage disposal;
- (d) identify, where appropriate, any special precautions for any recommended waste treatment option.

Any relevant Union provisions relating to waste or, in their absence, any relevant national or regional provisions in force shall be referred to.

**14. SECTION 14: Transport information**

This section of the safety data sheet shall provide basic classification information for the transport/shipment of substances or mixtures mentioned in section 1 by road, rail, sea, inland waterways or air. Where such information is not available or relevant this shall be stated.

Where relevant, this section shall provide information on the transport classification for each of the following international agreements which are transposing the UN Model Regulations for specific transport modes: the Agreement concerning the International Carriage of Dangerous Goods by Road (ADR), the Regulations concerning the International Carriage of Dangerous Goods by Rail (RID) and the European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways (ADN), all three of which have been implemented by Directive 2008/68/EC of the European Parliament and of the Council <sup>(9)</sup>, as well as

<sup>(8)</sup> Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (OJ L 312, 22.11.2008, p. 3).

<sup>(9)</sup> Directive 2008/68/EC of the European Parliament and of the Council of 24 September 2008 on the inland transport of dangerous goods (OJ L 260, 30.9.2008, p. 13).

the International Maritime Dangerous Goods (IMDG) Code <sup>(10)</sup> for the transport of packaged goods and the relevant IMO codes for the transport of bulk cargo by sea <sup>(11)</sup> and the Technical Instructions for the Safe Transport of Dangerous Goods by Air (ICAO TI) <sup>(12)</sup>.

#### 14.1. **UN number or ID number**

The UN number or the ID number (i.e. the four-figure identification number of the substance, mixture or article preceded by the letters “UN” or “ID”) from the UN Model Regulations, IMDG, ADR, RID, ADN or ICAO TI shall be provided.

#### 14.2. **UN proper shipping name**

The proper shipping name as provided in column 2, “Name and description”, of Table A of Chapter 3.2 Dangerous Goods List of the UN Model Regulations, in ADR, in RID and in Tables A and C of Chapter 3.2 of ADN, supplemented, when applicable, with the technical name in brackets as required, shall be provided, unless it was used as the product identifier in subsection 1.1. If the UN number and the proper shipping name remain unchanged in different transport modes, it is not necessary to repeat this information. As regards maritime transport, in addition to the UN proper shipping name, the technical name for goods to be transported covered by the IMDG Code shall be indicated, where appropriate.

#### 14.3. **Transport hazard class(es)**

The transport hazard class (and subsidiary risks) assigned to the substances or mixtures on the basis of the predominant hazard that they present according to the UN Model Regulations shall be provided. As regards inland transport, the transport hazard class (and subsidiary risks) assigned to the substances or mixtures on the basis of the predominant hazard that they present according to ADR, RID and ADN shall be provided.

#### 14.4. **Packing group**

The packing group number from the UN Model Regulations shall be provided, if applicable, as required by the UN Model Regulations, ADR, RID and ADN. The packing group number is assigned to certain substances in accordance with their degree of hazard.

#### 14.5. **Environmental hazards**

It shall be indicated whether the substance or mixture is environmentally hazardous according to the criteria of the UN Model Regulations (as reflected in ADR, RID and ADN), and whether it is a marine pollutant according to the IMDG Code and the Emergency Response Procedures for Ships Carrying Dangerous Goods. If the substance or mixture is authorised or intended for carriage by inland waterways in tank-vessels, it shall be indicated whether the substance or mixture is environmentally hazardous in tank-vessels only according to ADN.

#### 14.6. **Special precautions for user**

Information shall be provided on any special precautions, which a user should or must take or be aware of in connection with transport or conveyance either within or outside his premises, for all relevant modes of transport.

<sup>(10)</sup> Compliance with the IMDG Code is mandatory for the carriage of packaged dangerous goods by sea as provided for in Chapter VII/Reg. 3 of SOLAS and MARPOL Annex III Prevention of Pollution by Harmful Substances Carried by Sea in Packaged Form.

<sup>(11)</sup> The IMO has developed various legal instruments related to dangerous and polluting goods differentiating between how the goods are carried (packaged and bulk) and by type of cargo (solid, liquid and liquefied gases). Rules on the carriage of dangerous cargoes and the ships that carry these cargoes are found in the International Convention for the Safety of Life at Sea (SOLAS, 1974), as amended, and the International Convention on Maritime Pollution (MARPOL 73/78), as amended. These conventions are supplemented by the following codes: IMDG, IMSBC, IBC and IGC.

<sup>(12)</sup> IATA, 2007-2008 edition.

#### 14.7. **Maritime transport in bulk according to IMO instruments**

This subsection only applies when cargoes are intended to be carried in bulk according to IMO instruments: Chapter VI or Chapter VII of SOLAS <sup>(13)</sup>, Annex II or Annex V of MARPOL, the IBC Code <sup>(14)</sup>, the IMSBC Code <sup>(15)</sup>, and the IGC Code <sup>(16)</sup> or its earlier versions, namely EGC Code <sup>(17)</sup> or GC Code <sup>(18)</sup>.

As regards liquid bulk cargoes, the product name shall be provided (if different from that given in subsection 1.1) as required by the shipment document and in accordance with the name used in the lists of product names given in chapters 17 or 18 of the IBC Code or the latest edition of the IMO's Maritime Environment Protection Committee (MEPC).2/Circular <sup>(19)</sup>. Ship type required and pollution category shall be indicated, as well as the IMO hazard class, in accordance with Annex I (3) B (a) of Directive 2002/59/EC of the European Parliament and of the Council <sup>(20)</sup>.

As regards solid bulk cargoes, the bulk cargo shipping name shall be provided. It shall be indicated whether or not the cargo is considered harmful to the marine environment (HME) according to Annex V of MARPOL, whether it is a material hazardous only in bulk (MHB) <sup>(21)</sup> according to the IMSBC Code, and as which cargo group it should be considered according to the IMSBC.

As regards liquefied gas cargoes in bulk, the product name and the ship type required according to the IGC Code or its earlier versions, namely EGC Code or GC Code shall be provided.

#### 15. **SECTION 15: Regulatory information**

This section of the safety data sheet shall describe the other regulatory information on the substance or mixture that is not already provided in the safety data sheet (such as whether the substance or mixture is subject to Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer <sup>(22)</sup>, Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC <sup>(23)</sup> or Regulation (EC) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of dangerous chemicals <sup>(24)</sup>).

##### 15.1. **Safety, health and environmental regulations/legislation specific for the substance or mixture**

Information shall be provided regarding relevant Union safety, health and environmental provisions (for example, Seveso category/named substances in Annex I to Council Directive 96/82/EC <sup>(25)</sup>) or regarding the national regulatory status of the substance or mixture (including the substances in the mixture), including advice on action that should be taken by the recipient as a result of these provisions. Where relevant the national laws of the relevant Member States which implement these provisions and any other national measures that may be relevant shall be mentioned.

If the substance or mixture covered by this safety data sheet is the subject of specific provisions in relation to the protection of human health or the environment at Union level (such as authorisations given under Title VII or restrictions under Title VIII) these provisions shall be mentioned. Where an authorisation granted under Title VII imposes conditions or monitoring arrangements to a downstream user of the substance or mixture, they shall be provided.

<sup>(13)</sup> SOLAS means the International Convention for the Safety of Life at Sea, 1974, as amended.

<sup>(14)</sup> IBC Code means the International Code for the Construction and Equipment of Ships carrying dangerous Chemicals in Bulk, as amended.

<sup>(15)</sup> IMSBC Code means the International Maritime Solid Bulk Cargoes Code, as amended.

<sup>(16)</sup> IGC Code means the International Code for the Construction and Equipment of Ships Carrying Liquefied Gases in Bulk, including applicable amendments in accordance with which the vessel has been certified.

<sup>(17)</sup> EGC Code means the Code for Existing Ships Carrying Liquefied Gases in Bulk, as amended.

<sup>(18)</sup> GC Code means the Code for the Construction and Equipment of Ships Carrying Liquefied Gases in Bulk (Gas Carrier Code), as amended.

<sup>(19)</sup> MEPC.2/Circular, Provisional categorisation of liquid substances, version 19, effective 17 December 2013.

<sup>(20)</sup> Directive 2002/59/EC of the European Parliament and of the Council of 27 June 2002 establishing a Community vessel traffic monitoring and information system and repealing Council Directive 93/75/EEC (OJ L 208, 5.8.2002, p. 10).

<sup>(21)</sup> Materials hazardous only in bulk (MHB) means materials which may possess chemical hazards when carried in bulk other than materials classified as dangerous goods in the IMDG Code.

<sup>(22)</sup> OJ L 286, 31.10.2009, p. 1.

<sup>(23)</sup> OJ L 158, 30.4.2004, p. 7.

<sup>(24)</sup> OJ L 201, 27.7.2012, p. 60.

<sup>(25)</sup> OJ L 10, 14.1.1997, p. 13.

**15.2. Chemical safety assessment**

This subsection of the safety data sheet shall indicate whether the supplier has carried out a chemical safety assessment for the substance or the mixture.

**16. SECTION 16: Other information**

This section of the safety data sheet shall contain other information that is not included in sections 1 to 15, including information on the revision of the safety data sheet such as:

- (a) in the case of a revised safety data sheet, a clear indication of where changes have been made to the previous version of the safety data sheet, unless such indication is given elsewhere in the safety data sheet, with an explanation of the changes, if appropriate. A supplier of a substance or mixture shall be able to provide an explanation of the changes upon request;
- (b) a key or legend to abbreviations and acronyms used in the safety data sheet;
- (c) key literature references and sources for data;
- (d) in the case of mixtures, an indication of which of the methods of evaluating information referred to in Article 9 of Regulation (EC) No 1272/2008 was used for the purpose of classification;
- (e) a list of relevant hazard statements and/or precautionary statements. Write out the full text of any statements, which are not written out in full under sections 2 to 15;
- (f) advice on any training appropriate for workers to ensure protection of human health and the environment.

**PART B**

The safety data sheet shall include the following 16 headings in accordance with Article 31(6) and in addition the subheadings also listed except section 3, where only subsection 3.1 or subsection 3.2 needs to be included as appropriate:

**SECTION 1: Identification of the substance/mixture and of the company/undertaking**

- 1.1. Product identifier
- 1.2. Relevant identified uses of the substance or mixture and uses advised against
- 1.3. Details of the supplier of the safety data sheet
- 1.4. Emergency telephone number

**SECTION 2: Hazards identification**

- 2.1. Classification of the substance or mixture
- 2.2. Label elements
- 2.3. Other hazards

**SECTION 3: Composition/information on ingredients**

- 3.1. Substances
- 3.2. Mixtures

**SECTION 4: First aid measures**

- 4.1. Description of first aid measures
- 4.2. Most important symptoms and effects, both acute and delayed
- 4.3. Indication of any immediate medical attention and special treatment needed

## SECTION 5: Firefighting measures

- 5.1. Extinguishing media
- 5.2. Special hazards arising from the substance or mixture
- 5.3. Advice for firefighters

## SECTION 6: Accidental release measures

- 6.1. Personal precautions, protective equipment and emergency procedures
- 6.2. Environmental precautions
- 6.3. Methods and material for containment and cleaning up
- 6.4. Reference to other sections

## SECTION 7: Handling and storage

- 7.1. Precautions for safe handling
- 7.2. Conditions for safe storage, including any incompatibilities
- 7.3. Specific end use(s)

## SECTION 8: Exposure controls/personal protection

- 8.1. Control parameters
- 8.2. Exposure controls

## SECTION 9: Physical and chemical properties

- 9.1. Information on basic physical and chemical properties
- 9.2. Other information

## SECTION 10: Stability and reactivity

- 10.1. Reactivity
- 10.2. Chemical stability
- 10.3. Possibility of hazardous reactions
- 10.4. Conditions to avoid
- 10.5. Incompatible materials
- 10.6. Hazardous decomposition products

## SECTION 11: Toxicological information

- 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008
- 11.2. Information on other hazards

## SECTION 12: Ecological information

- 12.1. Toxicity
- 12.2. Persistence and degradability
- 12.3. Bioaccumulative potential
- 12.4. Mobility in soil
- 12.5. Results of PBT and vPvB assessment
- 12.6. Endocrine disrupting properties
- 12.7. Other adverse effects

## SECTION 13: Disposal considerations

- 13.1. Waste treatment methods

## SECTION 14: Transport information

- 14.1. UN number or ID number
- 14.2. UN proper shipping name
- 14.3. Transport hazard class(es)
- 14.4. Packing group
- 14.5. Environmental hazards
- 14.6. Special precautions for user
- 14.7. Maritime transport in bulk according to IMO instruments

## SECTION 15: Regulatory information

- 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture
- 15.2. Chemical safety assessment

## SECTION 16: Other information'

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