

II

(Non-legislative acts)

REGULATIONS

COMMISSION REGULATION (EU) No 453/2010

of 20 May 2010

**amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on 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⁽¹⁾, and in particular Article 131 thereof,

Whereas:

- (1) Safety data sheets have been a well-accepted and effective method for the provision of information on substances and mixtures in the Community and have been made an integral part of the system of Regulation (EC) No 1907/2006.
- (2) With a view to facilitating worldwide trade while protecting human health and the environment, harmonised criteria for classification and labelling and rules for safety data sheets have been carefully developed over a period of more than 10 years within the United Nations (UN) structure, resulting in the Globally Harmonised System of Classification and Labelling of Chemicals (hereinafter referred to as the GHS).

- (3) 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⁽²⁾ harmonises the provisions and criteria for the classification and labelling of substances, mixtures and certain specific articles within the Community, taking into account the classification criteria and labelling rules of the GHS.

- (4) Council Directive 67/548/EEC of 27 June 1967 on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances⁽³⁾ and Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations⁽⁴⁾ were amended several times. Directives 67/548/EEC and 1999/45/EC will be replaced over a transitional period according to which substances must be classified, labelled and packaged according to Regulation (EC) No 1272/2008 from 1 December 2010 and mixtures from 1 June 2015, although from 1 December 2010 until 1 June 2015 classification of substances according to both Directive 67/548/EEC and Regulation (EC) No 1272/2008 is required. Both Directives will be repealed in full by Regulation (EC) No 1272/2008 with effect from 1 June 2015.

- (5) Therefore Annex II to Regulation (EC) No 1907/2006 should be amended to adapt it to the criteria for classification and other relevant provisions laid down in Regulation (EC) No 1272/2008.

⁽¹⁾ OJ L 396, 30.12.2006, p. 1.

⁽²⁾ OJ L 353, 31.12.2008, p. 1.

⁽³⁾ OJ 196, 16.8.1967, p. 1.

⁽⁴⁾ OJ L 200, 30.7.1999, p. 1.

- (6) The requirements for safety data sheets laid down in Annex II to Regulation (EC) No 1907/2006 should moreover be adapted taking into account the rules for safety data sheets of the GHS, in order to allow the threefold mechanism of classification, labelling and safety data sheets to fulfil its role through interaction of its component parts.
- (7) Safety data sheets thus amended should continue to be an important element of hazard communication and provide a mechanism for transmitting appropriate safety information on substances and mixtures meeting the criteria for classification in accordance with applicable Community legislation, as well as certain substances and mixtures not meeting those criteria, taking into account information from any relevant chemical safety report, down the supply chain to the immediate downstream user.
- (8) The application of the requirement to include classification and labelling according to Regulation (EC) No 1272/2008 for substances and mixtures into the safety data sheet, as amended by this Regulation, should follow the staggered application of the classification and labelling provisions for substances and mixtures in accordance with Regulation (EC) No 1272/2008. Therefore, and because the classification and hazard communication for mixtures depends on the classification and hazard communication for substances, the requirement to include classification and labelling according to Regulation (EC) No 1272/2008 for mixtures should only be applied after the requirement to include classification and labelling according to Regulation (EC) No 1272/2008 for substances.
- (9) Suppliers of mixtures choosing to rely on the possibility to apply, on a voluntary basis, both the classification and the labelling in accordance with Regulation (EC) No 1272/2008 earlier than 1 June 2015 should provide in the relevant safety data sheet the classification in accordance with Regulation (EC) No 1272/2008 together with the classification in accordance with Directive 1999/45/EC.
- (10) Safety data sheets for substances providing classification and labelling information in accordance with Regulation (EC) No 1272/2008 should, before 1 June 2015, be required to provide classification information in accordance with Directive 67/548/EEC as well, in order to allow suppliers of mixtures not relying on the possibility to apply both the classification and the labelling in accordance with Regulation (EC) No 1272/2008 earlier, to classify and label those mixtures correctly.
- (11) 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

Regulation (EC) No 1907/2006 is amended as follows:

1. with effect from 1 December 2010:

- (a) Annex II is replaced by Annex I to this Regulation;
- (b) in Section 3.7 of Annex VI, in the title, the words ‘(see Safety Data Sheet heading 16)’ are replaced by ‘(see Section 1 of the safety data sheet)’;

2. with effect from 1 June 2015, Annex II to Regulation (EC) No 1907/2006 is replaced by Annex II to this Regulation.

Article 2

1. Until 1 December 2010, suppliers of substances applying Article 61(2) of Regulation (EC) No 1272/2008 may apply Annex II to Regulation (EC) No 1907/2006, as amended by point 1 of Article 1 of this Regulation.

2. Until 1 December 2010, suppliers of mixtures may apply Annex II to Regulation (EC) No 1907/2006, as amended by point 1 of Article 1 of this Regulation.

3. Until 1 June 2015, suppliers of mixtures applying Article 61(2) of Regulation (EC) No 1272/2008 may apply Annex II to Regulation (EC) No 1907/2006, as amended by point 2 of Article 1 of this Regulation.

4. Until 1 June 2015, suppliers of mixtures applying paragraph 3 shall provide in subsection 3.2 of the relevant safety data sheets the classification of the substances indicated in that subsection in accordance with Directive 67/548/EEC, including indication of danger, symbol letter(s) and R phrases, in addition to the classification including hazard statements in accordance with Regulation (EC) No 1272/2008.

5. Until 1 June 2015, suppliers of mixtures applying paragraph 3 shall provide in subsection 2.1 of the relevant safety data sheets the classification of the mixture in accordance with Directive 1999/45/EC in addition to the classification including hazard statements in accordance with Regulation (EC) No 1272/2008.

Until 1 June 2015, suppliers of mixtures meeting the criteria for classification in accordance with Regulation (EC) No 1272/2008 shall, when applying paragraph 3, indicate the substances presenting a health or environmental hazard within the meaning of Directive 67/548/EEC in subsection 3.2 of the relevant safety data sheets if those substances are present in concentrations equal to or greater than the lowest of the values listed in point 3.2.1(a) of Annex II to this Regulation in addition to the substances mentioned in point 3.2.1 of that Annex.

Until 1 June 2015, suppliers of mixtures not meeting the criteria for classification in accordance with Regulation (EC) No 1272/2008 shall, when applying paragraph 3, indicate the substances presenting a health or environmental hazard within the meaning of Directive 67/548/EEC in subsection 3.2 of the relevant safety data sheets if those substances are present in an individual concentration equal to or greater than 1 % by weight in non-gaseous mixtures and 0,2 % by volume in gaseous mixtures in addition to the substances mentioned in point 3.2.2 of Annex II to this Regulation.

6. Without prejudice to Article 31(9) of Regulation (EC) No 1907/2006, for substances which are placed on the market before 1 December 2010 and which are not required to be

relabelled and repackaged in accordance with Article 61(4) of Regulation (EC) No 1272/2008, the safety data sheet need not be replaced with a safety data sheet complying with Annex I to this Regulation before 1 December 2012.

Without prejudice to Article 31(9) of Regulation (EC) No 1907/2006, for mixtures which are placed on the market before 1 June 2015 and which are not required to be relabelled and repackaged in accordance with Article 61(4) of Regulation (EC) No 1272/2008, the safety data sheet need not be replaced with a safety data sheet complying with Annex II to this Regulation before 1 June 2017.

7. Without prejudice to Article 31(9) of Regulation (EC) No 1907/2006, safety data sheets for mixtures provided to any recipient at least once before 1 December 2010 may continue to be used and need not comply with Annex I to this Regulation until 30 November 2012.

Article 3

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

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

Done at Brussels, 20 May 2010.

For the Commission
The President
José Manuel BARROSO

ANNEX I

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 provided in the safety data sheet shall be consistent with the information in the chemical safety report, where one is 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.

0.2. 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 Council 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 recipient in Section 16 of the safety data sheet, unless they have been indicated elsewhere. In that case, the date of compilation identified as "Revision: (date)" as well as a version number, revision number, supersedes date or other indication of what version is replaced shall appear on the first page.

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.

0.6. **Units**

The units of measurement as set out in Council Directive 80/181/EEC ⁽¹⁾ 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 prescribes 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**

In the case of a substance, the product identifier shall be provided in accordance with Article 18(2) of Regulation (EC) No 1272/2008 and as provided on the label in the official language(s) of the Member State(s) where the substance 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.

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
- (b) this supplier provides the full registration number to the Member State authority responsible for enforcement (hereinafter referred to as 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.

In the case of a mixture, the trade name or designation shall be provided in accordance with Article 10(2.1) of Directive 1999/45/EC.

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.

Other means of identification

Other names or synonyms by which the substance or mixture is labelled or commonly known, such as alternative names, numbers, company product codes, or other unique identifiers may be provided.

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

At least the identified uses relevant for the recipient(s) of the substance or mixture shall be indicated. This shall be a brief description of what the substance or mixture is intended to do, such as "flame retardant", "anti-oxidant".

The uses which the supplier advises against and 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⁾ OJ L 39, 15.2.1980, p. 40.

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

The supplier, 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 e-mail 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.

For registrants, the information shall be consistent with the information on the identity of the manufacturer or importer provided in the registration.

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

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 and Article 17 of Directive 1999/45/EC), 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**

In the case of a substance, the classification which arises from the application of the classification rules 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, the classification given in the safety data sheet shall be the same as the classification provided in that notification.

The classification of the substance according to Directive 67/548/EEC shall also be given.

In the case of a mixture, the classification which arises from the application of the classification rules in Directive 1999/45/EC shall be given. If the mixture does not meet the criteria for classification in accordance with Directive 1999/45/EC, 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 and R phrases, is not written out in full, reference shall be made to Section 16 where the full text of each classification, including each hazard statement and R phrase, shall be given.

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

2.2. **Label elements**

In the case of a substance, 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.

In the case of a mixture, based on the classification, at least the appropriate symbol(s), indication(s) of danger, risk phrase(s) and safety advice appearing on the label in accordance with Directive 1999/45/EC shall be provided. The symbol may be provided as a graphical reproduction of the symbol in black and white.

The applicable label elements in accordance with Article 25 and Article 32(6) of Regulation (EC) No 1272/2008, in the case of a substance, or Sections A and B of Annex V to Directive 1999/45/EC, in the case of a mixture, shall be provided.

2.3. **Other hazards**

Information on whether the substance or mixture meets the criteria for PBT or vPvB in accordance with Annex XIII shall be provided.

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, 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.

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.

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.

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 when available, concentration or concentration ranges and 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, 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, this information shall be included under Section 2.

Where the use of an alternative chemical name has been allowed under Article 15 of Directive 1999/45/EC or under 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 Directive 1999/45/EC, the following substances 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 Directive 67/548/EEC and substances presenting a health or environmental hazard within the meaning of Regulation (EC) No 1272/2008, provided that information complying with the classification criteria of that Regulation has been made available to the supplier of the mixture, if those substances are present in concentrations equal to or greater than the lowest of any of the following:

- (i) the applicable concentrations defined in the table of Article 3(3) of Directive 1999/45/EC;
- (ii) the specific concentration limits given in Part 3 of Annex VI to Regulation (EC) No 1272/2008;

- (iii) if an 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;
 - (iv) the concentration limits given in Part B of Annex II to Directive 1999/45/EC;
 - (v) the concentration limits given in Part B of Annex III to Directive 1999/45/EC;
 - (vi) the concentration limits given in Annex V to Directive 1999/45/EC;
 - (vii) the specific concentration limits provided to the classification and labelling inventory established under 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 Community workplace exposure limits, which are not already included under point (a);
- (c) substances that are persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII, or substances included in the list established in accordance with Article 59(1) for reasons other than the hazards referred to in point (a), if the concentration of an individual substance is equal to or greater than 0,1 %.
- 3.2.2. For a mixture not meeting the criteria for classification in accordance with Directive 1999/45/EC, 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 Directive 67/548/EEC and substances which present a health or environmental hazard within the meaning of Regulation (EC) No 1272/2008, provided that information complying with the classification criteria of that Regulation has been made available to the supplier of the mixture; or
 - (ii) substances which are assigned Community workplace exposure limits;
 - (b) 0,1 % by weight for substances which are persistent, bioaccumulative and toxic in accordance with the criteria set out in Annex XIII, very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII, or included in the list established in accordance with Article 59(1) for reasons other than the hazards referred to in point (a).
- 3.2.3. For the substances indicated in subsection 3.2, the classification of the substance according to Directive 67/548/EEC, including indication of danger, symbol letter(s) and R phrases, shall be provided. 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 which are assigned in accordance with their physical, human health and environmental hazards, shall also be provided, provided that information complying with the classification criteria of that Regulation has been made available to the supplier of the mixture. The hazard statements and R phrases do not need to be written out in full in this section; 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 and R phrase 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 Community workplace exposure limit”.
- 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 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.

The EC number, if available, shall be given in accordance with Regulation (EC) No 1272/2008. The CAS number, if available, and 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 15 of Directive 1999/45/EC or 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 it can be understood and given by an untrained responder 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.

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 of the European Parliament and of the Council.

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; and
- (c) 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 instead of 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 Community occupational exposure limit values in accordance with Directive 98/24/EC, including any notations as referred to in Article 2(1) of Commission Decision 95/320/EC ⁽¹⁾;
 - 8.1.1.2. the national occupational exposure limit values that correspond to Community limit values in accordance with Directive 2004/37/EC, including any notations as referred to in Article 2(1) of Decision 95/320/EC;
 - 8.1.1.3. any other national occupational exposure limit values;
 - 8.1.1.4. the national biological limit values that correspond to Community biological limit values in accordance with Directive 98/24/EC, including any notations as referred to in Article 2(1) of Decision 95/320/EC;
 - 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.

⁽¹⁾ OJ L 188, 9.8.1995, p. 14.

8.1.4. Where a chemical safety report is required or 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 the present 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 as well as in accordance with 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 Council Directive 89/686/EEC ⁽¹⁾ 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.

⁽¹⁾ OJ L 399, 30.12.1989, p. 18.

(c) **R e s p i r a t o r y p r o t e c t i o n**

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) **T h e r m a l h a z a r d s**

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 Community 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. 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.

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

The following properties shall be clearly identified including, where appropriate, a reference to the test methods used and specification of appropriate units of measurement and/or reference conditions. If relevant for the interpretation of the numerical value, the method of determination shall also be provided (for example, the method for flash point, the open-cup/closed-cup method):

(a) **A p p e a r a n c e:**

The physical state (solid (including appropriate and available safety information on granulometry and specific surface area if not already specified elsewhere in this safety data sheet), liquid, gas) and the colour of the substance or mixture as supplied shall be indicated;

(b) **O d o u r:**

If odour is perceptible, a brief description of it shall be given;

(c) **O d o u r t h r e s h o l d:**

(d) **p H:**

The pH shall be indicated of the substance or mixture as supplied or of an aqueous solution; in the latter case, the concentration shall be indicated;

(e) **M e l t i n g p o i n t / f r e e z i n g p o i n t:**

(f) **I n i t i a l b o i l i n g p o i n t a n d b o i l i n g r a n g e:**

(g) **F l a s h p o i n t:**

(h) **E v a p o r a t i o n r a t e:**

(i) **F l a m m a b i l i t y (s o l i d , g a s):**

(j) **U p p e r / l o w e r f l a m m a b i l i t y o r e x p l o s i v e l i m i t s:**

(k) **V a p o u r p r e s s u r e:**

(l) **V a p o u r d e n s i t y:**

(m) **R e l a t i v e d e n s i t y:**

(n) **S o l u b i l i t y (i e s):**

(o) **P a r t i t i o n c o e f f i c i e n t: n - o c t a n o l / w a t e r:**

(p) **A u t o - i g n i t i o n t e m p e r a t u r e:**

(q) **D e c o m p o s i t i o n t e m p e r a t u r e:**

- (r) Viscosity;
- (s) Explosive properties;
- (t) Oxidising properties.

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.

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 a registration where one is required.

In the case of a mixture, the entries shall clearly indicate to which substance in the mixture the data apply, unless it is valid for the whole mixture.

9.2. **Other information**

Other physical and chemical parameters shall be indicated as necessary, such as miscibility, fat solubility (solvent — oil to be specified), conductivity, or gas group. Appropriate and available safety information on redox potential, radical formation potential and photocatalytic properties shall be indicated.

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.

10.3. **Possibility of hazardous reactions**

If relevant, it shall be stated if the substance or mixture will 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 and if appropriate a brief description of measures to be taken to manage risks associated with such hazards shall be given.

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 toxicological effects**11.1.1. Substances**

11.1.1.1. 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.

11.1.1.2. 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.

11.1.2. Mixtures

11.1.2.1. The relevant effects, for which information shall be provided, are:

- (a) acute toxicity;
- (b) irritation;
- (c) corrosivity;
- (d) sensitisation;
- (e) repeated dose toxicity;
- (f) carcinogenicity;
- (g) mutagenicity;
- (h) toxicity for reproduction.

11.1.2.2. For the health effects of carcinogenicity, mutagenicity and toxicity for reproduction, classification for a given health effect based on the conventional method outlined in Article 6(1)(a) of Directive 1999/45/EC, and relevant information for the substances listed under Section 3 shall be provided.

- 11.1.2.3. For other health effects, if a mixture has not been tested as a whole for a given health effect, information relevant to that health effect relating to substances listed under Section 3 shall be provided, if relevant.
- 11.1.3. Information shall be provided for each hazard class, differentiation or effect. If it is stated that the substance or mixture is not classified for a particular hazard class, differentiation or effect, 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".
- 11.1.4. The data included in this subsection shall apply to the substance or mixture as placed on the market. 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.
- 11.1.5. 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.
- 11.1.6. Where the classification criteria for a particular hazard class are not met, information supporting this conclusion shall be provided.
- 11.1.7. *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.
- 11.1.8. *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".
- 11.1.9. *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, animal data shall be summarised and the species clearly identified. It shall be indicated whether toxicological data is based on human or animal data.
- 11.1.10. *Interactive effects*
Information on interactions shall be included if relevant and available.
- 11.1.11. *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.
- 11.1.12. *Mixture versus substance information*
- 11.1.12.1. 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 section of the safety data sheet.

11.1.12.2. Classification of mixtures as having effects of carcinogenicity, mutagenicity or toxicity for reproduction must be calculated from available information regarding substances in the mixture. For other health effects, 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.

11.1.13. *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 describe the information provided to evaluate the environmental impact of the substance or mixture where it is released to the environment. Under subsections 12.1 to 12.6 of the safety data sheet a short summary of the data shall be provided 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 or if information on a particular property is not available, the reasons shall be indicated.

Information on bioaccumulation, persistence and degradability shall be given, where available and appropriate, for each relevant substance in the mixture. 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.

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 macro-organisms 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.

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

12.2. **Persistence and degradability**

Persistence and 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. 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.

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 (Kow) and bioconcentration factor (BCF), if available.

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 constituents 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 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, Koc values can be predicted from octanol/water partition coefficients (Kow). 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.

Where experimental data is available, that data shall, in general, take precedence over models and predictions.

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. 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, endocrine disrupting potential and/or global warming potential.

13. SECTION 13: Disposal considerations

This section of the safety data sheet shall describe 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 in accordance with Directive 2008/98/EC of the European Parliament and of the Council⁽¹⁾ of 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

(a) Waste treatment containers and methods shall be specified including the appropriate methods of waste treatment of both the substance or mixture and any contaminated packaging (for example, incineration, recycling, landfilling);

(b) Physical/chemical properties that may affect waste treatment options shall be specified;

(c) Sewage disposal shall be discouraged;

(d) Where appropriate, any special precautions for any recommended waste treatment option shall be identified.

⁽¹⁾ OJ L 312, 22.11.2008, p. 3.

Any relevant Community provisions relating to waste shall be referred to. 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 transporting/shipment of substances or mixtures mentioned under Section 1 by road, rail, sea, inland waterways or air. Where information is not available or relevant this shall be stated.

Where relevant, it shall provide information on the transport classification for each of the UN Model Regulations: European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR)⁽¹⁾, Regulations concerning the International Carriage of Dangerous Goods by Rail (RID)⁽²⁾, European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways (ADN)⁽³⁾, all three of which have been implemented by Directive 2008/68/EC of the European Parliament and of the Council of 24 September 2008 on the inland transport of dangerous goods⁽⁴⁾, International Maritime Dangerous Goods (IMDG) Code⁽⁵⁾ (sea), and Technical Instructions for the Safe Transport of Dangerous Goods by Air (ICAO)⁽⁶⁾ (air).

14.1. UN number

The UN number (i.e. the four-figure identification number of the substance, mixture or article preceded by the letters "UN") from the UN Model Regulations shall be provided.

14.2. UN proper shipping name

The UN proper shipping name from the UN Model Regulations shall be provided, unless it has appeared as the product identifier in subsection 1.1.

14.3. Transport hazard class(es)

The transport hazard class (and subsidiary risks) assigned to the substances or mixtures according to the predominant hazard that they present in accordance with the UN Model Regulations shall be provided.

14.4. Packing group

The packing group number from the UN Model Regulations shall be provided, if applicable. 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 the IMDG Code, ADR, RID and ADN) and/or a marine pollutant according to the IMDG Code. If 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 with which a user should or must comply or be aware of in connection with transport or conveyance either within or outside his premises.

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

This subsection only applies when cargoes are intended to be carried in bulk according to the following International Maritime Organisation (IMO) instruments: Annex II of the International Convention for the Prevention of Pollution from Ships, 1973, as modified by the Protocol of 1978 relating thereto (MARPOL 73/78)⁽⁷⁾ and the International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk (International Bulk Chemical Code) (IBC Code)⁽⁸⁾.

⁽¹⁾ United Nations, Economic Commission for Europe, version applicable as from 1 January 2009, ISBN-978-92-1-139131-2.

⁽²⁾ Annex 1 to Appendix B (Uniform Rules concerning the Contract for International Carriage of Goods by Rail) of the Convention concerning International Carriage by Rail, version with effect from 1 January 2009.

⁽³⁾ Version as revised as of 1 January 2007.

⁽⁴⁾ OJ L 260, 30.9.2008, p. 1.

⁽⁵⁾ International Maritime Organisation, 2006 edition, ISBN 978-92-8001-4214-3.

⁽⁶⁾ IATA, 2007-2008 edition.

⁽⁷⁾ MARPOL 73/78 — Consolidated edition 2006, London, IMO 2007, ISBN 978-92-801-4216-7.

⁽⁸⁾ IBC Code, 2007 edition, London, IMO 2007, ISBN 978-92-801-4226-6.

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 Marine Environment Protection Committee (MEPC).2/Circular⁽¹⁾. Ship type required and pollution category shall be indicated.

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 2037/2000 of the European Parliament and of the Council of 29 June 2000 on substances that deplete the ozone layer⁽²⁾, 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⁽³⁾ or Regulation (EC) No 689/2008 of the European Parliament and of the Council of 17 June 2008 concerning the export and import of dangerous chemicals⁽⁴⁾).

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

Information regarding relevant Community safety, health and environmental provisions (for example, Seveso category/named substances in Annex I of Council Directive 96/82/EC⁽⁵⁾) or national information on the regulatory status of the substance or mixture (including the substances in the mixture), including advice regarding action that should be taken by the recipient as a result of these provisions shall be provided. 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 protection of human health or the environment at Community level (such as authorisations given under Title VII or restrictions under Title VIII) these provisions shall be mentioned.

15.2. **Chemical safety assessment**

It shall be indicated if a chemical safety assessment has been carried out for the substance or the mixture by the supplier.

16. **SECTION 16: Other information**

This section of the safety data sheet shall describe the information relevant to the compilation of the safety data sheet. It shall incorporate other information that is not included in Sections 1 to 15, including information on revision of the safety data sheet such as:

- (a) in 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 maintain an explanation of the changes and provide it 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) list of relevant R phrases, hazard statements, safety phrases 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.

If in accordance with Article 31(10) a supplier of a mixture chooses to identify and inform about the classification necessary from 1 June 2015 in advance of using it for classification and labelling on the package, he may include this classification in this section.

⁽¹⁾ MEPC.2/Circular, Provisional categorisation of liquid substances, version 14, effective 1 January 2009.

⁽²⁾ OJ L 244, 29.9.2000, p. 1.

⁽³⁾ OJ L 158, 30.4.2004, p. 7.

⁽⁴⁾ OJ L 204, 31.7.2008, p. 1.

⁽⁵⁾ OJ L 10, 14.1.1997, p. 13.

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 3.2 need 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 toxicological effects

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. Other adverse effects

SECTION 13: Disposal considerations

- 13.1. Waste treatment methods

SECTION 14: Transport information

- 14.1. UN 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. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

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'

ANNEX II

'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 provided in the safety data sheet shall be consistent with the information in the chemical safety report, where one is 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.

0.2. 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 Council 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 recipient in Section 16 of the safety data sheet, unless they have been indicated elsewhere. In that case, the date of compilation identified as "Revision: (date)" as well as a version number, revision number, supersedes date or other indication of what version is replaced shall appear on the first page.

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.

0.6. Units

The units of measurement as set out in Council Directive 80/181/EEC ⁽¹⁾ 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 prescribes 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.

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
- (b) this supplier provides the full registration number to the Member State authority responsible for enforcement (hereinafter referred to as 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.

Other means of identification

Other names or synonyms by which the substance or mixture is labelled or commonly known, such as alternative names, numbers, company product codes, or other unique identifiers may be provided.

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

At least the identified uses relevant for the recipient(s) of the substance or mixture shall be indicated. This shall be a brief description of what the substance or mixture is intended to do, such as "flame retardant", "anti-oxidant".

The uses which the supplier advises against and 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, 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 e-mail address for a competent person responsible for the safety data sheet.

⁽¹⁾ OJ L 39, 15.2.1980, p. 40.

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.

For registrants, the information shall be consistent with the information on the identity of the manufacturer or importer provided in the registration.

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

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 arises from the application of the classification rules 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, the classification given in the safety data sheet shall be the same as the classification provided in that notification.

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 physicochemical, human health and environmental effects shall be listed consistent with Sections 9 to 12 of the safety data sheet, in 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 and Article 32(6) of Regulation (EC) No 1272/2008 shall be provided.

2.3. **Other hazards**

Information on whether the substance or mixture meets the criteria for PBT or vPvB in accordance with Annex XIII shall be provided.

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, 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.

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.

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.

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, concentration or concentration ranges and 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, 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, this information shall be included under Section 2.

Where the use of an alternative chemical name has been allowed under Article 15 of Directive 1999/45/EC or under 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 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:
 - (ia) the generic cut-off values set out in Table 1.1 of Regulation (EC) No 1272/2008;
 - (ib) the generic concentration limits given in parts 3 to 5 of Annex I to Regulation (EC) No 1272/2008 and for aspiration hazard (Section 3.10 of Annex I to Regulation (EC) No 1272/2008) $\geq 10\%$;

List of hazard classes, hazard categories and concentration limits (including generic cut-off values in Table 1.1 of Regulation (EC) No 1272/2008 and generic concentration limits given in parts 3 to 5 of Annex I to that Regulation) for which a substance shall be listed as a substance in a mixture in subsection 3.2.

1.1. — Hazard class and category	Concentration limit (%)
Acute toxicity, category 1, 2 and 3	≥ 0,1
Acute toxicity, category 4	≥ 1
Skin corrosion/irritation, category 1A, 1B, 1C and 2	≥ 1
Serious damage to eyes/eye irritation, category 1 and 2	≥ 1
Respiratory/skin sensitisation	≥ 0,1
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 and 2	≥ 1
Specific target organ toxicity (STOT) — repeated exposure, category 1 and 2	≥ 1
Aspiration hazard	≥ 10
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

(ii) the specific concentration limits given in Part 3 of Annex VI to Regulation (EC) No 1272/2008;

(iii) if an 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;

(vii) the specific concentration limits provided to the classification and labelling inventory established under Regulation (EC) No 1272/2008;

(viii) 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 Community workplace exposure limits, which are not already included under point (a);

(c) substances that are persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII, or substances included in the list established in accordance with Article 59(1) for reasons other than the hazards referred to in point (a), if the concentration of an individual substance is equal to or greater than 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 which are assigned Community workplace exposure limits;

(b) 0,1 % by weight for substances which are persistent, bioaccumulative and toxic in accordance with the criteria set out in Annex XIII, very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII, or included in the list established in accordance with Article 59(1) for reasons other than the hazards referred to in point (a).

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 which are assigned in accordance with their physical, human health and environmental hazards, shall be provided. The hazard statements do not need to be written out in full in this section; 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 Community workplace exposure limit".

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 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.

The EC number, if available, shall be given in accordance with Regulation (EC) No 1272/2008. The CAS number, if available, and 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 15 of Directive 1999/45/EC or 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 it can be understood and given by an untrained responder 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.

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 of the European Parliament and of the Council.

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; and
- (c) 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 instead of 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 Community occupational exposure limit values in accordance with Directive 98/24/EC, including any notations as referred to in Article 2(1) of Commission Decision 95/320/EC⁽¹⁾;
- 8.1.1.2. the national occupational exposure limit values that correspond to Community limit values in accordance with Directive 2004/37/EC, including any notations as referred to in Article 2(1) of Decision 95/320/EC;
- 8.1.1.3. any other national occupational exposure limit values;
- 8.1.1.4. the national biological limit values that correspond to Community biological limit values in accordance with Directive 98/24/EC, including any notations as referred to in Article 2(1) of Decision 95/320/EC;
- 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 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 the present 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 as well as in accordance with 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.

⁽¹⁾ OJ L 188, 9.8.1995, p. 14.

8.2.2.2. Taking into account Council Directive 89/686/EEC ⁽¹⁾ 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 Community 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. 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.

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

The following properties shall be clearly identified including, where appropriate, a reference to the test methods used and specification of appropriate units of measurement and/or reference conditions. If relevant for the interpretation of the numerical value, the method of determination shall also be provided (for example, the method for flash point, the open-cup/closed-cup method):

(a) *Appearance:*

The physical state (solid (including appropriate and available safety information on granulometry and specific surface area if not already specified elsewhere in this safety data sheet), liquid, gas) and the colour of the substance or mixture as supplied shall be indicated;

(b) *Odour:*

If odour is perceptible, a brief description of it shall be given;

⁽¹⁾ OJ L 399, 30.12.1989, p. 18.

- (c) Odour threshold;
- (d) pH:
The pH shall be indicated of the substance or mixture as supplied or of an aqueous solution; in the latter case, the concentration shall be indicated;
- (e) Melting point/freezing point;
- (f) Initial boiling point and boiling range;
- (g) Flash point;
- (h) Evaporation rate;
- (i) Flammability (solid, gas);
- (j) Upper/lower flammability or explosive limits;
- (k) Vapour pressure;
- (l) Vapour density;
- (m) Relative density;
- (n) Solubility(ies);
- (o) Partition coefficient: n-octanol/water;
- (p) Auto-ignition temperature;
- (q) Decomposition temperature;
- (r) Viscosity;
- (s) Explosive properties;
- (t) Oxidising properties.

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.

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 a registration where one is required.

In the case of a mixture, the entries shall clearly indicate to which substance in the mixture the data apply, unless it is valid for the whole mixture.

9.2. **Other information**

Other physical and chemical parameters shall be indicated as necessary, such as miscibility, fat solubility (solvent — oil to be specified), conductivity, or gas group. Appropriate and available safety information on redox potential, radical formation potential and photocatalytic properties shall be indicated.

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.

10.3. Possibility of hazardous reactions

If relevant, it shall be stated if the substance or mixture will 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 and if appropriate a brief description of measures to be taken to manage risks associated with such hazards shall be given.

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 toxicological effects

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.

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, animal data shall be summarised and the species clearly identified. It shall be indicated whether toxicological data is based on human or animal data.
- 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 section 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.

11.1.12. *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 describe the information provided to evaluate the environmental impact of the substance or mixture where it is released to the environment. Under subsections 12.1 to 12.6 of the safety data sheet a short summary of the data shall be provided 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 or if information on a particular property is not available, the reasons shall be indicated.

Information on bioaccumulation, persistence and degradability shall be given, where available and appropriate, for each relevant substance in the mixture. 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.

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 macro-organisms 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.

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

12.2. **Persistence and degradability**

Persistence and 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. 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.

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 (Kow) and bioconcentration factor (BCF), if available.

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 constituents 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 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, Koc values can be predicted from octanol/water partition coefficients (Kow). 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.

Where experimental data is available, that data shall, in general, take precedence over models and predictions.

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. 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, endocrine disrupting potential and/or global warming potential.

13. SECTION 13: Disposal considerations

This section of the safety data sheet shall describe 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 in accordance with Directive 2008/98/EC of the European Parliament and of the Council ⁽¹⁾ of 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

- (a) Waste treatment containers and methods shall be specified including the appropriate methods of waste treatment of both the substance or mixture and any contaminated packaging (for example, incineration, recycling, landfilling);
- (b) Physical/chemical properties that may affect waste treatment options shall be specified;
- (c) Sewage disposal shall be discouraged;
- (d) Where appropriate, any special precautions for any recommended waste treatment option shall be identified.

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

⁽¹⁾ OJ L 312, 22.11.2008, p. 3.

14. SECTION 14: Transport information

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

Where relevant, it shall provide information on the transport classification for each of the UN Model Regulations: European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR) ⁽¹⁾, Regulations concerning the International Carriage of Dangerous Goods by Rail (RID) ⁽²⁾, European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways (ADN) ⁽³⁾, all three of which have been implemented by Directive 2008/68/EC of the European Parliament and of the Council on the inland transport of dangerous goods ⁽⁴⁾, International Maritime Dangerous Goods (IMDG) Code ⁽⁵⁾ (sea), and Technical Instructions for the Safe Transport of Dangerous Goods by Air (ICAO) ⁽⁶⁾ (air).

14.1. UN number

The UN number (i.e. the four-figure identification number of the substance, mixture or article preceded by the letters "UN") from the UN Model Regulations shall be provided.

14.2. UN proper shipping name

The UN proper shipping name from the UN Model Regulations shall be provided, unless it has appeared as the product identifier in subsection 1.1.

14.3. Transport hazard class(es)

The transport hazard class (and subsidiary risks) assigned to the substances or mixtures according to the predominant hazard that they present in accordance with the UN Model Regulations shall be provided.

14.4. Packing group

The packing group number from the UN Model Regulations shall be provided, if applicable. 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 the IMDG Code, ADR, RID and ADN) and/or a marine pollutant according to the IMDG Code. If 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 with which a user should or must comply or be aware of in connection with transport or conveyance either within or outside his premises.

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

This subsection only applies when cargoes are intended to be carried in bulk according to the following International Maritime Organisation (IMO) instruments: Annex II of the International Convention for the Prevention of Pollution from Ships, 1973, as modified by the Protocol of 1978 relating thereto (MARPOL 73/78) ⁽⁷⁾ and the International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk (International Bulk Chemical Code) (IBC Code) ⁽⁸⁾.

⁽¹⁾ United Nations, Economic Commission for Europe, version applicable as from 1 January 2009, ISBN-978-92-1-139131-2.

⁽²⁾ Annex 1 to Appendix B (Uniform Rules concerning the Contract for International Carriage of Goods by Rail) of the Convention concerning International Carriage by Rail, version with effect from 1 January 2009.

⁽³⁾ Version as revised as of 1 January 2007.

⁽⁴⁾ OJ L 260, 30.9.2008, p. 1.

⁽⁵⁾ International Maritime Organisation, 2006 edition, ISBN 978-92-8001-4214-3.

⁽⁶⁾ IATA, 2007-2008 edition.

⁽⁷⁾ MARPOL 73/78 — Consolidated edition 2006, London, IMO 2007, ISBN 978-92-801-4216-7.

⁽⁸⁾ IBC Code, 2007 edition, London, IMO 2007, ISBN 978-92-801-4226-6.

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⁽¹⁾. Ship type required and pollution category shall be indicated.

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 2037/2000 of the European Parliament and of the Council of 29 June 2000 on substances that deplete the ozone layer⁽²⁾, 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⁽³⁾ or Regulation (EC) No 689/2008 of the European Parliament and of the Council of 17 June 2008 concerning the export and import of dangerous chemicals⁽⁴⁾).

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

Information regarding relevant Community safety, health and environmental provisions (for example, Seveso category/named substances in Annex I of Council Directive 96/82/EC⁽⁵⁾) or national information on the regulatory status of the substance or mixture (including the substances in the mixture), including advice regarding action that should be taken by the recipient as a result of these provisions shall be provided. 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 protection of human health or the environment at Community level (such as authorisations given under Title VII or restrictions under Title VIII) these provisions shall be mentioned.

15.2. **Chemical safety assessment**

It shall be indicated if a chemical safety assessment has been carried out for the substance or the mixture by the supplier.

16. **SECTION 16: Other information**

This section of the safety data sheet shall describe the information relevant to the compilation of the safety data sheet. It shall incorporate other information that is not included in Sections 1 to 15, including information on revision of the safety data sheet such as:

- (a) in 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 maintain an explanation of the changes and provide it 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) 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 3.2 need to be included as appropriate:

⁽¹⁾ MEPC.2/Circular, Provisional categorisation of liquid substances, version 14, effective 1 January 2009.

⁽²⁾ OJ L 244, 29.9.2000, p. 1.

⁽³⁾ OJ L 158, 30.4.2004, p. 7.

⁽⁴⁾ OJ L 204, 31.7.2008, p. 1.

⁽⁵⁾ OJ L 10, 14.1.1997, p. 13.

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 toxicological effects

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. Other adverse effects

SECTION 13: Disposal considerations

- 13.1. Waste treatment methods

SECTION 14: Transport information

- 14.1. UN 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. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

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'
