ECHA
EUROPEAN CHEMICALS AGENCY

GUIDANCE

# Guidance on the compilation of safety data sheets

Version 2.1
February 2014

| Version | Changes | Date |
|---|---|---|
| Version 1.0 | First edition. | September 2011 |
| Version 1.1 | Corrigendum covering the following:<br>(1) Footnote 25 on page 24 has been corrected by expanding it to include a full listing of hazard classes or categories under (b), (c), (d) as well as those under (a) already given.<br>(2) In the discussion of M-factors for mixture components under 3.2 on page 51 a reference to preference for listing in 2.1 (which applies for substances) has been corrected to clarify that for mixtures M-factors for components should be indicated together with their classification information under 3.2. | December 2011 |
| Version 1.2 | Corrigendum of Spanish language version. | April 2013 |
| Version 2.0 | Update of the guidance covering in particular the extension of Appendix 2 of this guidance by transfer and update of information previously included in a separate guidance document (Part G of the *Guidance for IR&CSA*). The updated Appendix provides guidance on how to include exposure scenario information in an SDS and on how to extend an SDS by attaching the exposure scenario. Updated guidance is provided on the correlation between the exposure scenario and SDS sections.<br>The update also covers the following issues:<br>(1) Addition of a note in chapter 3.14 concerning the provision under Regulation No 649/2012 (PIC regulation) to provide an SDS in the language of the country or area of destination.<br>(2) Update of chapter 3.22 by deleting information already covered by the updated *Guidance for downstream users* (version 2.0).<br>(3) Update of chapter 3.23 to ensure consistency with the updated *Guidance for downstream users* (version 2.0). In particular one additional option for downstream users who need to forward information on mixtures has been added.<br>(4) Update of table 2 in Appendix 1 to delete information on transition periods which have already expired and to add clarifying detail in improved format on the retained information.<br>(5) Minor corrections to update hyperlinks and typographical errors.<br>(6) Change of format to a new ECHA corporate identity. | December 2013 |
| Version 2.1 | Corrigendum to the English language version only.<br>Deletion of the final part of the sentence within brackets in the second paragraph of chapter 3.22. It now reads as follows:*"(i.e. those fulfilling the PBT/vPvB criteria or the criteria for any of the listed hazard classes in Article 14(4) of REACH as amended by Article 58 of CLP)".* | February 2014 |

**Reference:** ECHA-13-G-11-EN
**ISBN**: 978-92-9244-003-9
**Publ. date:** February 2014
**Language:** EN

© European Chemicals Agency, 2014

Cover page © European Chemicals Agency

Reproduction is authorised provided the source is fully acknowledged in the form "Source: European Chemicals Agency, http://echa.europa.eu/", and provided written notification is given to the ECHA Communication Unit (publications@echa.europa.eu).

***Legal notice***
*This document contains guidance on REACH explaining the REACH obligations and how to fulfil them. However, users are reminded that the text of the REACH regulation is the only authentic legal reference and that the information in this document does not constitute legal advice. The European Chemicals Agency does not accept any liability with regard to the contents of this document.*

If you have questions or comments in relation to this document please send them (quote the reference and issue date) using the information request form. The information request form can be accessed via the Contact ECHA page at:
http://echa.europa.eu/web/guest/contact

**European Chemicals Agency**

Mailing address: P.O. Box 400, FI-00121 Helsinki, Finland
Visiting address: Annankatu 18, Helsinki, Finland

# Table of Contents

**1 General Introduction ..... 6**
1.1 The Safety Data Sheet ..... 6
1.2 Aim of this guidance ..... 7
1.3 Target audience of this guidance ..... 7
1.4 Relation with CLP and GHS ..... 8
**2 What is new with respect to SDSs in REACH and CLP ..... 9**
**3 Issues to consider when compiling an SDS ..... 16**
3.1 Definition of a Safety Data Sheet (an SDS) ..... 16
3.2 Responsibility for the content of an SDS ..... 16
3.3 Claiming an SDS as confidential ..... 17
3.4 Possibility of charging for supply of an SDS ..... 17
3.5 Who should compile an SDS ..... 17
3.5.1 Definition of a competent person ..... 17
3.5.2 Training and continued education of competent persons ..... 17
3.6 The sequence, naming and numbering of sections and sub-sections which must be used in an SDS19
3.7 Necessary degree of completeness when providing information in an SDS ..... 21
3.8 Need to update SDSs ..... 21
3.9 Need to communicate changes in the SDS ..... 21
3.10 Potential need to keep records of SDSs and their amendments ..... 22
3.11 Example of sequence for collecting and collating information for compiling the SDS ..... 22
3.12 How to help to ensure consistency and completeness of the SDS ..... 23
3.13 Ways in which, and by when, the SDS must be provided ..... 23
3.14 Language(s) in which the SDS must be provided ..... 24
3.15 Substances and mixtures for which an SDS must be provided without prior request ..... 25
3.16 Certain mixtures for which an SDS must be provided on request ..... 25
3.17 Labelling required for a mixture not classified as hazardous and not intended for the general public for which an SDS must be available and supplied on request ..... 26
3.18 SDSs for hazardous substances and mixtures made available to the general public ..... 26
3.19 Access to information in the SDS by workers ..... 27
3.20 Products for which an SDS is not required ..... 28
3.21 Possible compilation of an SDS for substances and mixtures even when not legally required ..... 28
3.22 When attachment of Exposure Scenarios to the SDS is required ..... 29
3.23 Alternative ways to include the Exposure Scenario information into the SDS for substance and mixtures ..... 30
3.24 Forms of assistance available in the compilation of SDSs ..... 32
3.25 Selected sources of substance data useful for the compilation of SDSs ..... 32
3.26 How to compile an SDS for a recovered substance or mixtures containing such a substance ..... 34
3.27 Testing for the purposes of generation of information for an SDS ..... 34
**4 Detailed information, section by section ..... 36**

4.1 SDS SECTION 1: Identification of the substance/mixture and of the company/undertaking ..... 36
4.2 SDS SECTION 2: Hazards identification..... 43
4.3 SDS SECTION 3: Composition/information on ingredients ..... 52
4.4 SDS SECTION 4: First aid measures ..... 61
4.5 SDS SECTION 5: Firefighting measures ..... 62
4.6 SDS SECTION 6: Accidental release measures ..... 64
4.7 SDS SECTION 7: Handling and storage ..... 68
4.8 SDS SECTION 8: Exposure controls/personal protection..... 72
4.9 SDS SECTION 9: Physical and chemical properties ..... 84
4.10 SDS SECTION 10: Stability and Reactivity..... 90
4.11 SDS SECTION 11: Toxicological information ..... 94
4.12 SDS SECTION 12: Ecological information ..... 103
4.13 SDS SECTION 13: Disposal considerations ..... 107
4.14 SDS SECTION 14 Transport Information ..... 110
4.15 SDS SECTION 15: Regulatory information..... 113
4.16 SDS SECTION 16: Other information ..... 116

**Appendix 1. Timetable for the application of CLP labelling and corresponding requirements for SDSs in amended versions of Annex II of REACH ..... 119**

**Appendix 2. Including relevant exposure scenario information into Safety Data Sheets ..... 121**

**Appendix 3. SDS for Special Mixtures ..... 128**

**Appendix 4. Specific issues relevant to the compilation of SDSs for recovered substances and mixtures. ..... 130**

**Appendix 5. Glossary / List of acronyms ..... 134**

## Figures

**Figure 1: Example sequence for compiling an SDS.....23**

## Tables

**Table 1: Overview of new requirements for SDSs .....9**

**Table 2: Transitional periods for the implementation of CLP labelling and corresponding requirements for SDSs. .....120**

**Table 3 Relationship between exposure scenario and SDS Sections .....124**

# 1 General Introduction

## 1.1 The Safety Data Sheet

Safety data sheets (SDSs) have been a well-accepted and effective method for the provision of information to recipients of substances and mixtures in the EU. They have been made an integral part of the system of Regulation (EC) No 1907/2006 (REACH)[1]. The original requirements of REACH for SDSs have been further adapted to take into account the rules for safety data sheets of the Global Harmonised System (GHS)[2] and the implementation of other elements of the GHS into EU legislation that were introduced by Regulation (EC) No 1272/2008 (CLP)[3] via an update to Annex II of REACH[4] (henceforth referred to as "Revision of Annex II").

The SDS provides a mechanism for transmitting appropriate safety information on substances and mixtures where:

- a substance (and from 1 June 2015 a mixture) meets the criteria for classification as hazardous according to CLP;
- a mixture meets the criteria for classification as dangerous according to the Dangerous Preparations Directive 1999/45/EC (DPD) (until 1 June 2015) or;
- a substance is persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB), according to the criteria given in Annex XIII of REACH, or;
- a substance is included in the candidate list for eventual authorisation according to Article 59 (1) of REACH for any other reasons.

  (See Article 31(1) of REACH).

Under certain conditions some mixtures which do not meet the criteria for classification as dangerous according to the DPD or as hazardous according to CLP also require an SDS (See Article 31(3) of REACH as amended by CLP).

SDSs do not have to be provided for articles. Although the SDS format may, for a few specific articles, be used to convey safety information down the supply chain, it is not adapted to most articles[5].

---

1Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, corrected version in OJ L136, 29.5.2007, p.3).

2Third revised edition accessible at: unece.org/trans/danger/publi/ghs/ghs_rev03/03files_e.html.

3Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p.1).

4 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) (O.J. L133 31.05.2010, p1-43)

5Although according to Article 4(8) and Section 2.1 of Annex I of CLP certain objects described in CLP using the word "article" (specifically in the combinations "explosive articles", "pyrotechnic article" or "substances, mixtures and articles ... ... which are manufactured with a view to producing a practical, explosive or pyrotechnic effect" as defined via point 2.1.1.1 (b) or (c) and 2.1.1.2 of Annex I to CLP) should be classified and labelled according to CLP, the usage of the word "article" in this combined context differs from the stand-alone definition of an "article" both under REACH (Article 3 (3))

The SDS follows a 16 section format which is internationally agreed. The SDS must be supplied in an official language of the Member State(s) where the substance or mixture is placed on the market, unless the Member State(s) concerned provide(s) otherwise (Article 31(5) of REACH).

Where a Chemical Safety Report (CSR) is required to be prepared for a substance, the information in the SDS for the substance must be consistent with that provided in the CSR as well as with that provided in the registration dossier. In addition, according to Article 31(7) of REACH, registrants and downstream users that are required to prepare a CSR, must place the relevant exposure scenario(s) into an annex to the Safety Data Sheet. Downstream users have to consider relevant exposure information received from suppliers when compiling their safety data sheets. For mixtures there are several options for placing relevant exposure scenarios into an annex or for including relevant exposure information in the core Sections 1 – 16 of the SDS. If however, a Downstream User is required to prepare his own CSR under Article 37 of REACH and this results in the generation of an exposure scenario, this exposure scenario must be placed in an annex to the SDS[6].

## 1.2 Aim of this guidance

The aim of this guidance is to assist industry in determining which tasks and requirements have to be complied with in order to fulfil their obligations under Article 31 of REACH (Requirements for safety data sheets) and Annex II of REACH, particularly as amended by Commission Regulation (EU) No. 453/2010. The amended Annex II requires alignment of the SDS with the applicable requirements arising from implementation of the changes in classification and labelling of substances and mixtures according to the CLP Regulation from 1 December 2010 and 1 June 2015 respectively.

This guidance provides information especially on:

- what is new in SDSs according to REACH by comparison with the previous legislation;
- issues to consider when compiling an SDS;
- details of the requirements for information to be included in each Section of an SDS, and in particular details of what changes in requirements arise from the revisions of Annex II of REACH (as amended by Commission Regulation 453/2010) which came into force on 1 December 2010 and will come into force on 1 June 2015 (see Appendix 1 for further details);
- the timetables for implementation of Annex II and its amended Annexes;
- who should compile the SDS and what competences the author should have.

## 1.3 Target audience of this guidance

The main target audience of this guidance is those compiling SDSs for use by suppliers of substances and mixtures for which SDSs are required by Article 31 of REACH. While the REACH requirements regarding SDSs are directed at suppliers of substances and mixtures, this document also provides useful information for recipients of an SDS. It is noted in this context that the information provided by Safety Data Sheets will also help employers to meet their

---

and under CLP (Article 2 (9)). For the purposes of REACH they are more likely to be considered as a combination of an article (the container/packaging) and a substance/mixture (see ECHA *Guidance on requirements for substances in articles*). If appropriate, in such cases the SDS would be supplied for the corresponding substance/mixture.

6 Detailed information on how downstream users can fulfil their obligations under REACH is provided in the *Guidance for downstream users* available at echa.europa.eu/guidance-documents/guidance-on-reach.

obligations under Directive 98/24/EC[7] on the protection of the health and safety of workers from the risks related to chemical agents at work.

The SDS should enable users to take the necessary measures relating to protection of human health and safety at the workplace, and protection of the environment.

## 1.4 Relation with CLP and GHS

Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP) harmonises the provisions and criteria for the classification and labelling of substances and mixtures within the Community, taking into account the classification criteria and labelling rules of the UN Globally Harmonised System of Classification and Labelling of Chemicals (GHS). The CLP Regulation contributes to the UN GHS aim of describing and communicating the same hazards in the same way around the world. The CLP Regulation entered into force on the 20th of January 2009.

In the EEA, the required SDS format and content are defined by Article 31 and Annex II of REACH. These have been adapted to align them with the GHS requirements, in particular with the "guidance on the preparation of safety data sheets (SDS)" given in Annex 4 of the GHS[8] as well as to be fully in line with the CLP Regulation. This version of the *Guidance on the compilation of SDSs* reflects text of the revision of Annex II of REACH as published on 31 May 2010.

7 Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC), OJ L131, 5..5.1998, p.11).

8 See: live.unece.org/trans/danger/publi/ghs/ghs_rev03/03files_e.html

# 2 What is new with respect to SDSs in REACH and CLP

The REACH Annex II requirements for safety data sheets retain, to a large extent, the traditional structure and format of previous legislation. However, REACH has introduced some important changes to the information required in a safety data sheet. Below there is a summary (by section) of what is new for the 'REACH SDSs' by comparison with the pre-REACH (and pre-CLP) legislation on SDSs in the EU.

Table 1 below provides an overview of the main changes to the different sections for substances / mixtures including new sub-headings. Please note that sections of the SDS for which there are no changes from the previous legislation according to REACH are not covered in this chapter. Also note that only **new** (or changed) requirements are given in the table – thus, for example, although the original Annex II in REACH requires a name *("The term used for identification shall be identical to that provided on the label as set out in Annex VI to Directive 67/548/EEC)*to be given in section 1.1 this is not mentioned in the table below as it was also a requirement of the previous legislation (i.e. Directive 91/155/EEC (SDS Directive) [9])

However, where there is an additional requirement or change arising from the Revision of Annex II, this is indicated with detail of the appropriate version of the revision e.g. "Revised Annex II from 1 December 2010" or "Revised Annex II from 1 June 2015" Thus, the new requirements for product identifiers in accordance with Article 18(2) of CLP to be given in Section 1.1 which arise from the Revised Annex II are indicated as such.

Please see chapter 4 for more detailed consideration of the sections and sub-sections in an SDS according to REACH. Table 1 below should **not** be considered as covering all relevant changes – it is aimed at giving an introductory overview of issues to be considered, and in particular is not a detailed analysis of all changes from previous legislation[10].

Please note that where specific data are not used, or where data are not available, this must be clearly stated in the corresponding sub-section of the SDS. The reasons given for a lack of information should of course be valid ones.

**Table 1: Overview of new requirements for SDSs**

| OVERVIEW OF NEW REQUIREMENTS FOR SDSs | | |
|---|---|---|
| **SDS section or sub-section title** | **New requirements for SDSs for substances** | **New requirements for SDSs for mixtures** |
| 1.1. Product identifier | From 1 December 2010 the product identifier must be provided in accordance with Article 18(2) of Regulation (EC) 1272/2008 (CLP). Details are given in chapter 4.1 of this document. | Until 1 June 2015 in the case of a mixture, the trade name or designation must be provided in accordance with Article 10(2.1) of Directive 1999/45/EC (DPD), (unless CLP classification and labelling of the mixture is implemented |

9Directive 91/155/EEC defining and laying down the detailed arrangements for the system of specific information relating to dangerous preparations in implementation of Article 10 of Directive 88/379/EEC, O.J. L 76, 22.03.1991 p. 35

10Nevertheless, since there had been no formal requirement for guidance at EU level on the compilation of SDSs according to Annex II of REACH, chapter 2 of the present document compares the changes in requirements for SDSs for **all** versions of Annex II under REACH with those of the previous legislation, including changes that were already requirements as of 1 June 2007. This is in contrast to chapter 4 of the present document, which refers **only** the two new versions of Annex II requirements that will be in force from 1 December 2010 to 1 June 2015 and from 1 June 2015 onwards respectively.

| OVERVIEW OF NEW REQUIREMENTS FOR SDSs | | |
|---|---|---|
| **SDS section or sub-section title** | **New requirements for SDSs for substances** | **New requirements for SDSs for mixtures** |
| | The inclusion of the EC number is optional.<br>The **registration numbers** of substances subject to registration must be mentioned by the suppliers once the substances are registered. The part of the registration number referring to the individual registrant of a joint submission (the last four digits of the original full registration number) can be omitted by distributors and downstream users under specific conditions (See chapter 4.1 and 4.3 of this document). | early). From 1 June 2015 the product identifier for a mixture must be provided in accordance with Article 18(3)a of Regulation (EC) 1272/2008 (CLP) |
| 1.2. Relevant identified uses of the substance or mixture, and uses advised against | Suppliers must indicate the relevant **identified use(s)**[11]of a substance using a brief (understandable) description of what the substance is intended to do. Uses advised against and reasons why must be given if applicable.<br>The intention is not to list all the combinations of use descriptors[12], but rather to have a general description of uses.<br>**This information must be consistent with the identified uses and exposure scenarios (**set out in the annex to the SDS (where one is required). A reference to the annexed exposure scenarios can be included here. | Suppliers must indicate the relevant **identified use(s)** of a mixture using a brief (understandable) description of what the mixture is intended to do. Uses advised against and reasons why must be given if applicable.<br>**This information must be consistent with the identified uses and exposure scenarios** set out in any annex(es) to the SDS (where they are required). A reference to the annexed exposure scenario (or alternative documents consolidating exposure scenario information from components) can be included here. |
| 1.3 Details of the supplier of the safety data sheet | - For registrants, the information must be consistent with the information on the identity of the manufacturer or importer or Only Representative provided in the registration dossier.<br>- **e-mail address** of the competent person responsible for the SDS should be provided. It is recommended to use a generic e-mail address | - **e-mail address** of the competent person responsible for the SDS should be provided. It is recommended to use a generic e-mail address |
| SECTION 2: Hazards identification | **Classification:**<br>From 1 December 2010 until 1 June 2015, the classification of a substance according to both the CLP Regulation and Dangerous Substances Directive (DSD) | **Classification:**<br>Until 1 June 2015, the classification of the mixture according to the DPD must be given. Where a mixture has been classified and labelled in accordance with |

11 "Identified use" is defined in REACH, Article 3, point 26.

12 See *Guidance on information requirements and chemical safety assessment Chapter R.12: Use descriptor system* accessible via: guidance.echa.europa.eu/docs/guidance_document/information_requirements_en.htm.

| OVERVIEW OF NEW REQUIREMENTS FOR SDSs | | |
|---|---|---|
| **SDS section or sub-section title** | **New requirements for SDSs for substances** | **New requirements for SDSs for mixtures** |
| | must be given.<br>After June 1st, 2015, only classification according to CLP is required. See Appendix 1 on transitional periods for more information.<br>**Label elements** information must be included here (new sub-heading; previously it was given in Section 15). From 1 December 2010 this must be that according to CLP.<br>The symbol/pictogram(s) must be represented graphically.<br>If the substance is subject to authorisation, the authorisation number must be included here.<br>Information on whether the substance meets the criteria for PBT or vPvB in accordance with Annex XIII must be provided. | CLP before this date the CLP classification must also be included in this section.<br>After June 1st, 2015, only classification according to CLP is required .<br>**Label elements** information must be included here (new sub-heading; previously it was given in Section 15), From 1 June 2015 this must be that according to CLP. The symbol/pictogram(s) must be represented graphically.<br>If any component substance(s) in the mixture is/are subject to **authorisation**, the authorisation number(s) must be included here[13].<br>Information on whether the mixture meets the criteria for PBT or vPvB in accordance with Annex XIII must be provided[14]. |
| SECTION 3: Composition / information on ingredients | The chemical identity of the main constituents and any impurity, stabilising additive or individual constituent which is itself classified and contributes to the classification of the substance must be provided | The criteria for determining (on the basis of cut-off values / concentration limits) which component substances in a mixture must be indicated together with their concentration (range) in this section are expanded from 1 December 2010 to include health or environmental hazards according to CLP as well as those according to 67/548/EEC. From 1 June 2015 only CLP criteria are applicable.<br>In the case of mixtures, PBT/vPvB substances and substances included in the candidate list, have to be disclosed if present at 0.1%[15] or above with registration number (if applicable)<br>The registration numbers of at least a certain predefined group of component substances in the mixture must be mentioned by the suppliers. The part of the registration number referring to the |

13 This is not required for substances subject to authorisation listed in Annex XIV of REACH if present in the mixture at a concentration below that indicated in Art. 56(6) of REACH.

14 In practice, for mixtures, information on whether the mixture contains PBT or vPvB substances at a concentration of 0.1% or greater assessed in accordance with the criteria of Annex XIII.

15 Note that the default value of 0.1% referred to here applies to substances listed in the candidate list ("in the list established in accordance with Article 59(1)") for reasons **other than** the hazards referred to in point (a) of 3.2.1 of Annex II. Otherwise it is the lowest concentration of the list of concentrations given in 3.2.1 (a) (i) – (viii) inclusive which needs to be considered (the applicable concentration **may** therefore **be above 0.1%).**

| OVERVIEW OF NEW REQUIREMENTS FOR SDSs | | |
|---|---|---|
| **SDS section or sub-section title** | **New requirements for SDSs for substances** | **New requirements for SDSs for mixtures** |
| | | individual registrant of a joint submission can be omitted from this section by **any** supplier of a mixture fulfilling specific conditions (See chapter 4.3 for details).<br><br>The classification(s) and the information on PBT and vPvB must also be mentioned. |
| SECTION 7: Handling and storage | Where a chemical safety report is required, the information in this section must be consistent with the information given for the identified uses in the chemical safety report and, where applicable, the exposure scenario s annexed to the safety data sheet.<br><br>If available, a reference to **industry or sector specific guidance** designed for specific uses may be mentioned.<br><br>If an exposure scenario is attached, reference may be made to it.<br><br>For substances designed for specific end use(s), detailed and operational recommendations relating to the identified use(s) referred to in subsection 1.2 must be made. | The SDS may include cross-references to an exposure scenario for the mixture where applicable.<br><br>If available, a reference to industry or sector specific guidance designed for specific uses may be made where applicable.<br><br>If an exposure scenario is attached, reference may be made to it.<br><br>For mixtures designed for specific end use(s), detailed and operational recommendations relating to the identified use(s) referred to in subsection 1.2 must be made. |
| SECTION 8: Exposure controls/ personal protection | List **applicable DNELs, OELs, and PNEC**: Substance specific information (the DNELs for human health hazards and the PNECs for hazards to the environment) need to be given under the appropriate sub-section in this section.<br><br>This information (other than OEL values) will mainly be available for registered substances which have been subjected to a Chemical Safety Assessment.<br><br>Where a chemical safety report is required, the risk management measures for the identified uses must be consistent with the information in this section. | The risk management measures given in the sub-sections of this section and any annexed exposure scenario(s) must be consistent. |
| 8.1. Control parameters | Where a **control banding approach** is used to decide on risk management measures in relation to specific uses, sufficient detail must be given to enable effective management of the risk.<br><br>The context and limitations of the specific control banding recommendation must be made clear. (See chapter 4.8 for more information on the control banding approach) | Where a **control banding approach** is used to decide on risk management measures in relation to specific uses, sufficient detail must be given to enable effective management of the risk.<br><br>The context and limitations of the specific control banding recommendation must be made clear. (See chapter 4.8 for more information on the control banding approach) |

| OVERVIEW OF NEW REQUIREMENTS FOR SDSs | | |
|---|---|---|
| **SDS section or sub-section title** | **New requirements for SDSs for substances** | **New requirements for SDSs for mixtures** |
| 8.2. Exposure controls | Suppliers will mention here **risk management measures** for control of occupational and environmental exposure for the use of the substance.<br><br>Either a summary of risk management measures should be given or (if applicable) reference to the exposure scenario in which they are given should be made.<br><br>Where the supplier has waived a test under Section 3 of Annex XI, he must indicate the specific conditions of use relied on to justify the waiving.<br><br>Where a substance has been registered as an isolated intermediate (on-site or transported), the supplier must 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 of REACH. | |
| SECTION 9: Physical and chemical properties | There are **additional physical / chemical properties** to be included in this section (consult chapter 4.9 for more information). | There are **additional physical / chemical properties** to be included in this section (consult chapter 4.9 for more information). |
| SECTION 11: Toxicological information | For substances subject to registration, summaries of the information derived from the application of Annexes VII to XI of REACH must be given. For substances subject to registration, the information must also include the result of the comparison of the available data with the criteria given in the CLP Regulation for CMR, categories 1A and 1B.<br><br>If a CSR is required, the information should be consistent with it. Where appropriate, information on toxicokinetics, metabolism and distribution should be included.<br><br>From 1 December 2010 there have been requirements to give information in SDSs for substances on Specific Target Organ Toxicity (STOT) for single exposure and repeated exposure. Also information must now be provided on the specified (extended) list of hazard classes. | If substances in a mixture may interact with each other in the body and alter any toxic action as a result, this must be taken into account when providing toxicological information in this section.<br><br>From 1 June 2015 there are requirements to give information in SDSs for mixtures on Specific Target Organ Toxicity (STOT) for single exposure and repeated exposure. Also information must now be provided on the specified (extended) list of hazard classes. |

| OVERVIEW OF NEW REQUIREMENTS FOR SDSs | | |
|---|---|---|
| **SDS section or sub-section title** | **New requirements for SDSs for substances** | **New requirements for SDSs for mixtures** |
| SECTION 12: Ecological information | Where a Chemical Safety Report is required, the results of the PBT and vPvB assessment, as set out in the chemical safety report, must be given. This information is only likely to exist when a chemical safety report has been generated. | If relevant, the available information on the component substances in a mixture will need to be compiled into this section of the SDS for mixtures. |
| SECTION 13: Disposal considerations | In addition to giving waste management measures in this section of the SDS, where an exposure assessment is required, the waste management measures must be consistent with the exposure scenarios in the annex. | The SDS will need to include the waste management measures of relevance for the use(s) of the mixture in the SDS in section 13. This needs to be consistent with the exposure scenario (s) in annex to the SDS. |
| SECTION 14: Transport Information | Certain specific elements of information on transport classification for each of the relevant EU implementations of the UN model regulations become requirements instead of optional information. | Certain specific elements of information on transport classification for each of the relevant EU implementations of the UN model regulations become requirements instead of optional information. |
| SECTION 15: Regulatory Information | **Information on substances subject to authorisation and details about any authorisation** granted or denied must be given in sub-section 15.1. Uses of the substances subject to restrictions must be stated here.<br>It must be indicated in sub-section 15.2 if a Chemical Safety Assessment has been carried out for the substance by the supplier.<br>Labelling information is no longer included in SECTION 15 and must now be given in SECTION 2. | Information on authorisation and restrictions of any of the substances in the mixture must be given in sub-section 15.1<br>It must be indicated in sub-section 15.2 if a Chemical Safety Assessment has been carried out for the mixture by the supplier.<br>Labelling information is no longer in SECTION 15 and must now be given in SECTION 2. |
| SECTION 16: Other information | (Note that from 01/12/2010, information on uses advised against must appear in sub-section 1.2 rather than SECTION 16).<br>Advice on training for workers can also be included in this section.<br>The full text of any R phrases, hazard statements, safety phrases and/or precautionary statements, which are not written out in full under Sections 2 to 15 must be given here. | Until 1 June 2015, information on CLP classification can, on a voluntary basis, be included here for mixtures for which full CLP labelling has not yet been implemented rather than in SECTION 2 (as SECTION 2 should be aligned with the current label).<br>From 1 June 2015 only the CLP classification should be given, and only in SECTION 2.<br>Advice on training for workers may be included here.<br>An indication of which methods were used to evaluate the classification of the mixture must be included here unless already included in another of Sections 1-15 (e.g. SECTION 2). |

| OVERVIEW OF NEW REQUIREMENTS FOR SDSs | | |
|---|---|---|
| **SDS section or sub-section title** | **New requirements for SDSs for substances** | **New requirements for SDSs for mixtures** |
| | | The full text of any R phrases, hazard statements, safety phrases and/or precautionary statements, which are not written out in full under Sections 2 to 15 must be given here. When a mixture is classified according to CLP an indication of which of the methods of evaluating information referred to in Article 9 of CLP was used for the purpose of classification must be given here. |
| Exposure Scenario (annex) | For substances for which a chemical safety assessment is required by REACH and has been completed, the relevant exposure scenario(s) must be attached as an Annex to the SDS. The exposure scenario extends the information given in the main body of the SDS, but needs to be considered together with (and be consistent with) the information within the SDS main body in order to maximise its usefulness. | If an exposure scenario is prepared for a mixture[16], it needs to be compiled by evaluating the relevant available information on the component substances including the information from the substances' suppliers.<br><br>(There are other options for how to deal with exposure scenario information for components in a SDS for a mixture, see also paragraph 3.22 of chapter 3 and Appendix 2; Furthermore chapter 7 of the *Guidance for downstream user* provides detailed guidance on how to forward information on mixtures downstream). |

16 Even though there is no requirement arising from Articles 14 or 37 of REACH for a CSR (and therefore a corresponding exposure scenario) for a mixture these may be generated according to Article 31(2) of REACH (essentially solely for the purpose of the SDS).

# 3 Issues to consider when compiling an SDS

## 3.1 Definition of a Safety Data Sheet (an SDS)

An SDS is a document whose purpose and role within the harmonized system can be described as follows (based on the text in chapter 1.5 of the UN GHS revision 3[17]):

The SDS should provide comprehensive information about a substance or mixture for use in workplace chemical control regulatory frameworks. Both employers [and workers[18]] use it as a source of information about hazards, including environmental hazards, and to obtain advice on safety precautions. The SDS is product related and usually (in the absence of relevant attached exposure scenario(s)) is not able to provide specific information that is relevant for any given workplace where the product may finally be used, although where products have specialized end uses the SDS information may be more worker-specific. The information therefore enables the employer (a) to develop an active programme of worker protection measures, including training, which is specific to the individual workplace; and (b) to consider any measures which may be necessary to protect the environment.

In addition, the SDS provides an important source of information for other target audiences in the GHS. So certain elements of information may be used by those involved with the transport of dangerous goods, emergency responders (including poison centres), those involved in the professional use of pesticides and consumers. However, these audiences receive additional information from a variety of other sources such as the *UN Recommendations on the Transport of Dangerous Goods, Model Regulations and* package inserts for consumers and will continue to do so. The introduction of a harmonized labelling system therefore, is not intended to affect the primary use of the SDS which is for workplace users.

The required format and content of an SDS within the EU Member States in which the REACH Regulation directly applies (and in other countries which have adopted the REACH Regulation) is defined in Annex II of the REACH. The full text of the versions of Annex II which will be in force from 1 December 2010 and from 1 June 2015 are given in chapter 4 of this document. Further information on the transition periods and on the relation between these different versions of Annex II is given in Appendix 1 to this guidance.

The information contained in the SDS must be written in a clear and concise manner.

## 3.2 Responsibility for the content of an SDS

Where there is a chain of supply, the requirements of REACH in relation to the provision of safety data sheets apply at each stage of the supply chain. The initial responsibility for drawing up the safety data sheet falls on the manufacturer, importer or only representative who should anticipate, so far as it is reasonably practicable, the uses to which the substance or mixture may be put. Actors further down the supply chain should also provide a safety data sheet, drawing on, checking the adequacy of, and adding to, the information provided by their suppliers to cater for the specific needs of their customers. In all cases, suppliers of a

17 unece.org/trans/danger/publi/ghs/ghs_welcome_e.html; Global Harmonized system of Classification and Labelling of Chemicals (GHS).Third Edition, 2009.United Nations.

18 It should be noted that in the European Union regulatory framework the SDS is clearly targeted at the employer who should use it as the basis of information and instructions which he transmits to the employee under Article 8.1 4th indent of Directive 98/24/EC. However, the employee is NOT the primary target of the document and its provision to the employee does not release the employer from his obligations under Directive 98/24/EC.

substance or a mixture which requires a safety data sheet have the responsibility for its contents, even though they may not have prepared the safety data sheet themselves. In such cases, the information provided by their suppliers is clearly a useful and relevant source of information for them to use when compiling their own safety data sheets. However, they will remain responsible for the accuracy of the information on the safety data sheets they provide (this also applies to SDSs distributed in languages other than the original language of compilation)

## 3.3 Claiming an SDS as confidential

The information that that is required to appear in an SDS cannot be claimed as confidential.

## 3.4 Possibility of charging for supply of an SDS

According to Article 31(8) and 31(9) of REACH, the SDS and any required updates to it must be provided free of charge.

## 3.5 Who should compile an SDS

The text of the Revision of Annex II specifies in paragraph 0.2.3 that:

> *"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."*

### 3.5.1 Definition of a competent person

No specific definition of the "competent person" is given in the Regulation. However the term may usefully be defined in this context as meaning a person (or combination of persons) – or a coordinator of a group of people - who has or have, as a result of their training, experience and continued education, sufficient knowledge for the compilation of the respective sections of the SDS or of the entire SDS.

The supplier of the SDS can delegate this function to his own staff or to third parties. It is not necessary that the expert knowledge be provided in full by one single competent person.

It is understood that a single person very rarely has extensive knowledge in all the fields covered by an SDS. It is thus necessary that the competent person rely upon additional competences, either internal or external. The competent person should ensure the consistency of the SDS, especially if he acts as the coordinator of a group of people.

### 3.5.2 Training and continued education of competent persons

It should be noted (from the text quoted above) that there is a specific duty on the supplier of the substances and mixtures to ensure that the competent persons have received appropriate training and refresher training. There is no specific indication in the REACH Regulation of the training which the competent person should have or that he should attend a special course or pass an official examination. However attendance at such courses and any examination and certification may be useful in demonstrating the required competence.

Training and continued education for these persons may be given internally or externally. It is recommended to document the organizational flow in the compilation and update of SDSs

within a company, e.g. by way of internal guidelines or operating procedures.

If SDSs are to be compiled for explosives, biocides, plant protection products[19], or surfactants additional knowledge on specific products legislation applicable to them is needed.

The following (non-exhaustive) list gives an indication of various fields a knowledge of which a person wishing to demonstrate their competence could refer to:

1. **Chemical nomenclature**
2. **European Regulations and Directives** relevant to chemicals and their implementations into MS national legislation, applicable national legislation (in their valid current versions), to the extent that they are relevant in the compilation of SDSs, for instance (non-exhaustive list, shortened titles):
   - **REACH:** Regulation (EC) No 1907/2006(in particular as amended by Regulation (EU) No. 453/2010 with respect to SDSs)
   - **CLP:** Regulation (EC) No 1272/2008
   - **Dangerous Substances Directive:** Directive 67/548/EEC
   - **Dangerous Preparations Directive:** Directive 1999/45/EC
   - **Chemical Agents Directive:** Directive 98/24/EC
   - **Occupational exposure limits:** Directives 2000/39/EC,2006/15/EC and 2009/161/EU
   - **Protection of workers from the risks related to exposure to carcinogens or mutagens at work:** Directive 2004/37/EC
   - **Improvements in the safety and health of pregnant workers, workers who have recently given birth and women who are breastfeeding:** Directive 92/85/EEC
   - **Personal protective equipment:** Directive 89/686/EEC
   - **Classification of the various modes of transport:** Directives 96/35/EC and 2000/18/EC
   - **Inland transport of dangerous goods:** Directive 2008/68/EC
   - **Detergent Regulation:** Regulation(EC) No 648/2004
   - **Protection of young people at work:** Directive 94/33/EC
   - **Waste:** Directives 2006/12/EC and 2008/98/EC
3. **Relevant national or international guidelines** of the respective sector association
4. **Physical and chemical properties:**
   - Particularly properties as listed and discussed in the legal text below under Section 9.1 of the revised Annex II (see chapter 4.9 of this document).
5. **Toxicology / eco-toxicology:**
   - Particularly properties as listed and discussed in the legal text below under Section 11 and 12 of the revised Annex II (see chapter 4.11 and 4.12 of this document).

19 For a list of relevant legislation on plant protection and biocidal products see Article 15 of REACH.

6. **First aid measures**
   - (See chapter 4.4 of this document)
7. **Accident prevention**
   - Fire and explosion prevention, fire fighting, extinguishing media
   - Measures in the event of accidental release
   - (See chapter 4.6 of this document)
8. Measures for **safe handling and storage**
   - (See in particular chapter 4.7 of this document)
9. **Transport** provisions
   - Particularly as listed and discussed in the legal text below under Section 14 of the revised Annex II (see chapter 4.14 of this document).
   - Note that the provisions of Directive 96/35/EC and 2000/18/EC (on the appointment and qualification of Safety Advisers for the transport of dangerous goods by road, rail and inland waterways) apply specifically to those directly involved in the transport of dangerous goods. Depending on the supplier's organisational arrangements the compiler of SDSs may or may not be a Safety Adviser as defined in these regulations. It is not a legal requirement that the compiler of SDSs be a qualified Safety Adviser in the meaning of these Directives.
10. **National** provisions
    - Relevant national provisions, such as (this is a non-exhaustive list)

      In Germany:
      - Water hazard classes (Wassergefährdungsklassen)
      - Technical instruction air (TA-Luft)
      - Technical rules for hazardous substances (TechnischeRegelnfürGefahrstoffe)

      In France:
      - Tableaux de maladies professionnelles
      - Nomenclature des installations classées pour la protection de l'environnement

      In the Netherlands:
      - De Algemene Beoordelingsmethodiek Water (ABM)
    - National product registers (for example Denmark, Finland, Italy, Sweden etc.)

## 3.6 The sequence, naming and numbering of sections and sub-sections which must be used in an SDS

The name of each section and sub-section heading, of individual headings and sub-headings in the SDS is specified in each of the versions of Annex II. In particular Part B of the Annex II versions applicable from both 1 December 2010 to 1 June 2015 and from 1 June 2015 (as given in Commission Regulation (EU) No. 453/2010 of 20 May 2010) both require that:

*"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:"*

(See legal text for the full list of headings and sub-headings).

It should be noted that for the Section headings themselves the word "SECTION" is a part of the heading specified as being required i.e. for example the full heading for Section 1 of the SDS is:

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

No numbering at a level lower than the sub-heading is legally required, but this may be introduced by the supplier in the interests of clarity (e.g. in Section 14 to differentiate between different modes of transport).

In particular, the numbering of the sub-paragraphs and points in part A of each version of the Annex II legal text should not be confused with the required numbering of sections and sub-sections according to Part B.

Thus, for example in the case of SECTION 11 toxicological information, according to Part B the following heading and sub-headings must be used:

*"SECTION 11: Toxicological information*

*11.1. Information on toxicological effects"*

The presence of points ("sub-sub-paragraphs") numbered 11.1.1, 11.1.2, … … 11.1.12.2, … … etc in part A under the heading of SECTION 11 to facilitate discussion of the individual elements does not mean that the information discussed under these points needs to be included under an identical description or heading to that given in Part A at any level below the sub-section level. The structure of the SDS, as defined by the section and sub-section headings is only pre-defined to the extent given in Part B.

This also applies to all the examples given for the structuring of data within any sections and sub-sections of an SDS contained in this document. Any sub-structuring or titles of further sub-sections of data given beyond the parent SECTION and the first sub-section numbering is only an example of a possible structure.

The information that the SDS must contain within each of these headings and sub-headings is discussed in more detail in chapter 4 of this document. With the exception of subsections 3.1 and 3.2 (where either one or the other should contain information) some information must be entered in every sub-section, even if this "information" is only an explanation of why data is not available or confirmation of non-applicability etc. Information should be inserted into sub-sections, not directly under the parent section heading.

Where a document using the format of an SDS is produced for a substance or mixture that does not require an SDS according to Article 31 of REACH (e.g. as a convenient way of supplying information required by Article 32 or based on a commercial decision to supply "SDS-like" documents for all substances and mixtures supplied by an actor) the requirements for content in each of the sections would not apply. In such cases it may be advisable to explain that the document is outside the scope of Article 31 of REACH for the convenience of recipients and enforcing authorities.

## 3.7 Necessary degree of completeness when providing information in an SDS

The information requirements are explained in detail in chapter 4. It should be noted that where specific data are not used or where data are not available, this must be clearly stated.

## 3.8 Need to update SDSs

The conditions under which an SDS **must** be updated and re-issued are given in Article 31(9) of REACH as follows:

> *"9. Suppliers shall update the safety data sheet without delay on the following occasions:*
>
> *(a) as soon as new information which may affect the risk management measures, or new information on hazards becomes available;*
>
> *(b) once an authorisation has been granted or refused;*
>
> *(c) once a restriction has been imposed.*
>
> *The new, dated version of the information, identified as 'Revision: (date)', shall be provided free of charge on paper or electronically to all former recipients to whom they have supplied the substance or mixture within the preceding 12 months. Any updates following registration shall include the registration number."*

Thus, although there are industry documents available which give recommendations on when a change in an SDS is considered a "major" or a "minor" change, this terminology is not used in the REACH Regulation. Only the changes according to Article 31 (9) of REACH give rise to a legal obligation to provide updated versions to all recipients to whom the substance or mixture has been supplied within the preceding 12 months. Sector and branch organisations may provide their own guidance on when it is desirable to additionally send updated versions of SDSs which are not specifically required by Article 31(9) of REACH, but such additional updates are not a legal requirement

Nevertheless, it is recommended to review the totality of the contents of an SDS at regular intervals. The definition of these intervals is the responsibility of the actor who issues the SDS – the intervals are not defined in the REACH Regulation. It might be expected that the frequency of such reviews would be commensurate with the hazards of the substance or mixture and that the review would be carried out by a competent person.

## 3.9 Need to communicate changes in the SDS

The text of point 0.2.5 of the revised Annex II of REACH (in force as of 01/12/2010) specifies that:

> *"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".*

Thus, revisions must be identified as such on the first page and information on the changes must be given either in section 16 or elsewhere in the SDS.

As indicated in 3.8 above, for any revision to an SDS according to Article 31(9) of REACH the revised Safety Data Sheet must be provided to all former recipients who received the product within the preceding 12 months. A supplier may also choose to (additionally) re-issue SDSs retrospectively for other revisions which he may consider warrant such additional action. It is suggested that an incremental numbering system be used to identify new versions of an SDS. In such a system, changes to versions requiring provision of updates according to Article 31(9) could be identified by an increment by an integer, while other changes could be identified by an increment by a decimal, e.g.:

Version 1.0: initial issue

Version 1.1: first change(s) not requiring update and re-issue to former recipients

Version 1.2: second change(s) not requiring update and re-issue to former recipients

Version 2.0: first change requiring provision of update according to Article 31(9) to former recipients.

Etc.

This is just an example of how to facilitate traceability of versions. There are many other systems.

## 3.10 Potential need to keep records of SDSs and their amendments

The first sentence of Article 36(1) of REACH requires that:

> *"1. Each manufacturer, importer, downstream user and distributor shall assemble and keep available all the information he requires to carry out his duties under this Regulation for a period of at least 10 years after he last manufactured, imported, supplied or used the substance or mixture".*

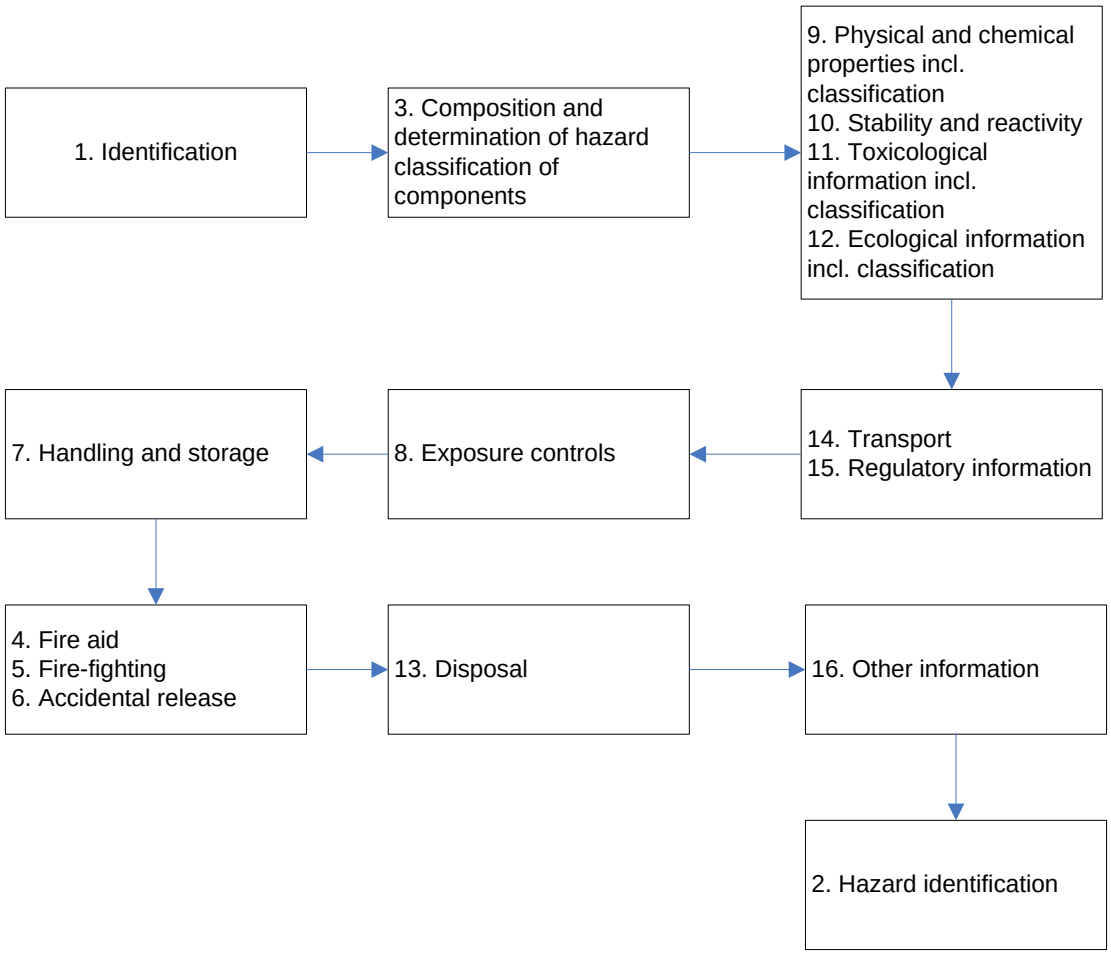
There is no reference in this text (or in the revision of Annex II) to a requirement for the actors in the supply chain to keep copies of SDSs and/or outdated versions thereof for any specified period. Both the suppliers of SDSs and potentially their recipients should consider these documents as part of the *"the information he requires to carry out his duties under this Regulation"* which is to be retained for a minimum period of 10 years. The information used in the compilation of the SDS is itself likely to constitute information required to carry out duties under REACH and may in any case be required to be kept independently of its relation to the content of the SDS. Holders of both SDSs and other information may in any case decide that it should be retained for product liability and other legal requirements and it might be considered appropriate (for example for products with chronic effects) to keep this information for a period of more than 10 years, depending on the applicable national laws and regulations.

## 3.11 Example of sequence for collecting and collating information for compiling the SDS

A suggestion for a step-wise approach to the creation of an SDS to ensure its internal consistency is given in Figure I below (the numbers refer to the sections of the SDS):

Figure 1 below shows the process as a linear one to stress that, for example, the final identification of hazards in Section 2 of the SDS is not likely to be possible until the inputs to other sections have been considered. In reality the process is likely to be an iterative one involving consideration of some aspects in different sequences to that shown or even in parallel.

**Figure 1: Example sequence for compiling an SDS**




## 3.12 How to help to ensure consistency and completeness of the SDS

The Safety Data Sheet gives information on a very wide range of aspects of occupational health and safety, transport safety and environmental protection. As SDSs are frequently not compiled by just one person but rather by several members of staff, unintended gaps or overlaps cannot be ruled out. Consequently, it is useful to subject the finished Safety Data Sheet and its annex (if applicable) to a consistency and plausibility check before providing it to recipients. It may be desirable for the final review to be carried out by a single competent person rather than separate individuals to allow an overview of the document as a whole.

## 3.13 Ways in which, and by when, the SDS must be provided

According to Article 31 (8) of REACH*"A safety data sheet shall be provided free of charge on paper or electronically no later than the date on which the substance or mixture is first supplied."*

Thus, the Safety Data Sheet can be provided on paper, for example by letter, by fax or electronically, for example by email.

It should be noted however that in this context the wording *"shall be provided"* is to be understood as a positive duty on the supplier to actually deliver the SDS (and every required update) rather than just make it available passively, for example on the internet or reactively by delivering it on request. Therefore, ECHA's Forum comprising national enforcement

representatives agreed that, for example, simply posting a copy of an SDS (or an update to one) on a web site alone would not be considered as having complied with the duty to "provide". In the case of electronic "provision", supply of the SDS (and any corresponding exposure scenario attachments) as an attachment to an e-mail in a format which is generally accessible to all recipients would therefore be acceptable. By contrast, sending an e-mail with a link to a general web-site where the SDS (or latest updated SDS) needs to be found and downloaded from would not be acceptable. Options for when a specific link leading directly to the SDS (or updated SDS) might be acceptable and conditions which would need to be applied to allow this in future (in particular as a means to deal with increasing numbers of attached exposure scenarios) are under discussion[20].

Once an SDS has been supplied for a first delivery of a substance or mixture to a particular recipient there is no need to supply a further copy of the SDS with subsequent deliveries to the same recipient unless the SDS is revised. Further information on communication of changes resulting from revisions is given in 3.9 above.

## 3.14 Language(s) in which the SDS must be provided

According to REACH Article 31(5), *"The safety data sheet shall be supplied in an official language of the Member State(s) where the substance or mixture is placed on the market, unless the Member State(s) concerned provide otherwise"*. It should be noted that it is for the recipient Member State (MS) to provide otherwise – i.e. for example the existence of an exemption in the MS of manufacture does not give an exemption in a different MS where the substance or mixture is placed on the market. Even if the MS provides otherwise, it may be desirable to always provide (potentially in addition) the SDS in the language of the country.

It should be noted that certain Member States require that the SDS be provided in additional official MS languages (of that MS, where there is more than one official language).

It should also be noted that as the annexed exposure scenario is considered to be an integral part of the SDS it is subject to the same translation requirements as the SDS itself – i.e. it must be supplied in an official language of the Member State(s) where the substance or mixture is placed on the market, unless the recipient Member State(s) concerned provide otherwise.

It should be further noted that according to the provisions of Article 17 (4) of the new Prior Informed Consent (PIC) Regulation[21] which enters into operation on 14 March 2014, for substances for which an SDS is required (in the format of Annex II to REACH) according to Article 17 (3) of the same regulation: "*The information on the label and on the safety data sheet shall as far as practicable be given in the official languages, or in one or more of the principal languages, of the* ***country of destination or of the area of intended use***" i.e. in such cases the language(s) in which the SDS is to be supplied may include (where practicable) languages which are not official languages of any EU Member State. Until the above date, the same provisions apply according to Articles 16 (3) and (4) of Regulation (EC) No 689/2008

20 Pre-conditions that could apply would be e.g. that the recipients of the SDS supplied (and updated) via such a mechanism need to be in agreement in advance, that each link provided must go only to the specific SDS appropriate to the recipient, that the relevant MS competent authority for enforcement is in agreement etc.

21 Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals (recast); OJ L 201 27.07.2012 p 60. Available at eur-lex.europa.eu/Result.do?T1=V2&T2=2012&T3=649&RechType=RECH_naturel&Submit=Search.

concerning the export and import of dangerous chemicals[22].

## 3.15 Substances and mixtures for which an SDS must be provided without prior request

According to Article 31 (1) of REACH (as amended by Articles 58(2)(a) and 59(2)(a) of CLP) the criteria for when an SDS must be provided (even without request) are:

Between December 1st 2010 and May 31st, 2015:

*"(a) where a substance meets the criteria for classification as hazardous in accordance with Regulation (EC) No 1272/2008 or a mixture meets the criteria for classification as dangerous in accordance with Directive 1999/45/EC; or*

*(b) where a substance is persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII; or*

*(c) where a substance is included in the list established in accordance with Article 59(1) for reasons other than those referred to in points (a) and (b)."* (where the latter list corresponds to the so called "candidate list"[23] for authorization (list published on ECHA website, see link in the footnote).

As of June 1, 2015 (a) above changes to:

*"(a) where a substance or mixture meets the criteria for classification as hazardous in accordance with Regulation (EC) No 1272/2008; or"*

(and criteria (b) and (c) remain as above).

## 3.16 Certain mixtures for which an SDS must be provided on request

Article 31(3) of REACH specifies the conditions under which an SDS must be supplied on request (for certain mixtures). The text specifying these conditions changes in line with the appropriate applicable version of Annex II as of 1 June 2015 (see CLP Article 59(2)(b) amendment to REACH Article 31(3)). The relevant provisions are as follows:

Until 1 June 2015:

*"3. The supplier shall provide the recipient at his request with a safety data sheet compiled in accordance with Annex II, where a mixture does not meet the criteria for classification as dangerous in accordance with Articles 5, 6 and 7 of Directive 1999/45/EC, but contains:*

*(a) in an individual concentration of ≥ 1 % by weight for non-gaseous mixtures and ≥ 0,2 % by volume for gaseous mixtures at least one substance posing human health or environmental hazards; or*

*(b) in an individual concentration of ≥ 0,1 % by weight for non-gaseous mixtures at least one substance that is persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII or has been included*

22 Regulation (EU) No 689/2008 of the European Parliament and of the Council of 17 June 2008 concerning the export and import of dangerous chemicals; OJ L 204 31.07.2008 p 1. Available at eur-lex.europa.eu/Result.do?T1=V2&T2=2008&T3=689&RechType=RECH_naturel&Submit=Search.

23 echa.europa.eu/chem_data/authorisation_process/candidate_list_en.asp.

*for reasons other than those referred to in point (a) in the list established in accordance with Article 59(1); or*

*(c) a substance for which there are Community workplace exposure limits."*

From 1 June 2015:

*"3. The supplier shall provide the recipient at his request with a safety data sheet compiled in accordance with Annex II, where a mixture does not meet the criteria for classification as hazardous in accordance with Titles I and II of Regulation (EC) No 1272/2008, but contains:*

*(a) in an individual concentration of ≥ 1 % by weight for non-gaseous mixtures and ≥ 0,2 % by volume for gaseous mixtures at least one substance posing human health or environmental hazards; or*

*(b) in an individual concentration of ≥ 0,1 % by weight for non-gaseous mixtures at least one substance that is carcinogenic category 2 or toxic to reproduction category 1A, 1B and 2, skin sensitiser category 1, respiratory sensitiser category 1, or has effects on or via lactation or is persistent, bioaccumulative and toxic (PBT) in accordance with the criteria set out in Annex XIII or very persistent and very bioaccumulative (vPvB) in accordance with the criteria set out in Annex XIII or has been included for reasons other than those referred to in point (a) in the list established in accordance with Article 59(1); or*

*(c) a substance for which there are Community workplace exposure limits."*

## 3.17 Labelling required for a mixture not classified as hazardous and not intended for the general public for which an SDS must be available and supplied on request

For mixtures not classified as hazardous under CLP (or "dangerous" under DPD) and not intended for the general public but which contain certain specified classified components at above specified limits, for which a Safety Data Sheet must be provided on request, the label on the packaging must bear information indicating the availability of such SDSs.

For mixtures classified and labelled according to the DPD the required text to indicate this is: "Safety data Sheet available for professional user on request" (see Dangerous Preparations Directive 1999/45/EC, Annex V, Part C, no. 1).

For mixtures classified and labelled according to CLP the required text becomes:

"Safety Data Sheet available on request" (See CLP Annex II, point 2.10, text of EUH210).

## 3.18 SDSs for hazardous substances and mixtures made available to the general public

Article 31 (4) of REACH (as amended by Article 58(2)(b) of CLP) states for substances and mixtures sold to the general public:

*"The safety data sheet need not be supplied where substances that are hazardous in accordance with Regulation (EC) No 1272/2008 or mixtures that are dangerous in accordance with Directive 1999/45/EC[24], offered or sold to the general public, are provided*

24 The text in force from 1 June 2015 refers simply to "substances or mixtures" without reference to either the CLP regulation or DPD, since from that date both must be classified according to CLP.

*with sufficient information to enable users to take the necessary measures as regards the protection of human health, safety and the environment, unless requested by a downstream user or distributor".*

From 1 June 2015 this is further amended by Article 59(2)(c) of CLP to read more simply as follows:

*"The safety data sheet need not be supplied where hazardous substances or mixtures offered or sold to the general public are provided with sufficient information to enable users to take the necessary measures as regards the protection of human health, safety and the environment, unless requested by a downstream user or distributor."*

Thus, it is not mandatory for a safety data sheet to be supplied for a dangerous/hazardous substance or mixture made available to the general public[25] if the above conditions are complied with. However if the product is also supplied to a downstream user or distributor and he requests an SDS it must be supplied to him. It may be recommendable for the distributor (e.g. retailer) offering or selling these substances or mixtures to be in possession of an SDS for each hazardous substance or mixture which he sells. These SDSs also contain important information for him as he has to store the substance or mixture and can give important information e.g. on measures in case of an accident (or fire etc.). If the downstream user or distributor feels that he needs an SDS for these or other purposes he can request one.

It should be noted that the actor who is specifically allowed to request the SDS by this provision is the downstream user or distributor – it is **not** the member of the public ("consumer"). The question of whether a particular customer for such a substance or mixture is entitled to request and receive an SDS for it can therefore be addressed on the basis of whether he qualifies as either a 'downstream user' or a 'distributor' under the definitions given in Article 3 (13) and 3 (14) of the REACH regulation respectively. A "consumer" is specifically excluded from the definition of a downstream user. Whether a recipient qualifies as a downstream user with respect to use of the substance or mixture *"in the course of his industrial or professional activities"* may be determined for example on the basis of his professional background. A reliable proof of the right to request an SDS could be an excerpt from the trade register/register of companies or other professional accreditation or potentially a VAT number (or holding of an account with the supplier), rather than depending solely on quantities (which itself may serve as a first indicator).

## 3.19 Access to information in the SDS by workers

According to Article 35 of REACH:

*"Workers and their representatives shall be granted access by their employer to the information provided in accordance with Articles 31 and 32 in relation to substances or mixtures that they use or may be exposed to in the course of their work."*

The SDS (in the EU) is aimed at the employer. The employer has a responsibility to transform the information into suitable formats to manage risks at the specific workplace. Nonetheless access must be given to relevant SDS information to workers and their representatives according to Article 35 of REACH (as well as according to Article 8 of Directive 98/24/EC).

25 There are no provisions in REACH under which an SDS ever has to be supplied to a member of the general public (a "consumer"); there is also no provision to stop this being done on a voluntary basis by any actor in the supply chain.

## 3.20 Products for which an SDS is not required

The requirements to provide an SDS arise from Article 31 of the REACH Regulation.

Certain general exemptions from the need to supply information according to Title IV (therefore including SDSs according to Article 31) are given in Article 2 (6):

> *"The provisions of Title IV shall not apply to the following mixtures in the finished state, intended for the final user:*
>
> *(a) medicinal products for human or veterinary use, within the scope of Regulation (EC) No 726/2004 and Directive 2001/82/EC and as defined in Directive 2001/83/EC;*
>
> *(b) cosmetic products as defined in Directive 76/768/EEC;*
>
> *(c) medical devices which are invasive or used in direct physical contact with the human body in so far as Community measures lay down provisions for the classification and labelling of dangerous substances and mixtures which ensure the same level of information provision and protection as Directive 1999/45/EC;*
>
> *(d) food or feedingstuffs in accordance with Regulation (EC) No 178/2002 including use:*
>
> > *(i) as a food additive in foodstuffs within the scope of Directive 89/107/EEC;*
> >
> > *(ii) as a flavouring in foodstuffs within the scope of Directive 88/388/EEC and Decision 1999/217/EC;*
> >
> > *(iii) as an additive in feedingstuffs within the scope of Regulation (EC) No 1831/2003;*
> >
> > *(iv) in animal nutrition within the scope of Directive 82/471/EEC."*

Even more general exemptions from the whole of the REACH apply to other classes of products via Article 2(1) (radioactive substances, substances under customs supervision, non-isolated intermediates, products during carriage by rail, road, inland waterway, sea or air)

Waste as defined in Directive 2006/12/EC is also exempted in general by virtue of being excluded by Article 2(2) from being defined as a substance, mixture or article within the meaning of Article 3 of the REACH Regulation.

SDSs are also of course **not** required for products that do not conform either to the criteria given in Article 31(1) (a), (b) and (c) or to those in Article 31(3) for when SDSs **are** required (see Section 1.1 of the General Introduction above and the text of REACH for more detail on what the criteria are).

## 3.21 Possible compilation of an SDS for substances and mixtures even when not legally required

From marketing and/or logistical aspects it may in certain cases be useful for suppliers to have Safety Data Sheets available for all substances and mixtures, including those for which there is no legal obligation to provide an SDS. In such cases it may be desirable to indicate in the document that the substance or mixture does not legally require an SDS to avoid unnecessary compliance and conformity issues arising. It is **not** generally desirable to compile SDSs for **articles**.

It may also be useful to supply information required according to Article 32 of REACH concerning the duty to communicate information down the supply chain for substances on their own or in mixtures for which a safety data sheet is not required in the SDS format. However it should be noted that this is **not** required by the REACH Regulation and again in these cases it may be desirable to indicate in the document that the substance or mixture does not legally

require an SDS to avoid unnecessary compliance and conformity issues arising. Similarly it may be specifically indicated when such a document is being used to communicate information according to Article 32.

## 3.22 When attachment of Exposure Scenarios to the SDS is required

According to the first paragraph of Article 31(7) of REACH:

> *"Any actor in the supply chain who is required to prepare a chemical safety report according to Articles 14 or 37 shall place the relevant exposure scenarios (including use and exposure categories where appropriate) in an annex to the safety data sheet covering identified uses and including specific conditions resulting from the application of Section 3 of Annex XI."*

Thus, whenever there is a requirement for an actor (e.g. a registrant or a downstream user preparing a CSR according to Art 14 or 37.4 of REACH) to include exposure scenarios in his CSR, this actor has an obligation to place the relevant exposure scenarios in an Annex to the SDS. It should be noted however that not all registrants who are required to carry out a CSA and prepare a CSR[26] are necessarily required to prepare an exposure scenario. Thus, for example, although a CSA and a CSR are generally required for all substances subject to registration in quantities of 10 tonnes or more, an exposure scenario is **only** required for those for which the further criteria given in Article 14 (4) also apply (i.e. those fulfilling the PBT/vPvB criteria or the criteria for any of the listed hazard classes in Article 14(4) of REACH as amended by Article 58 of CLP). These criteria are[27]:

> *"4. If, as a result of carrying out steps (a) to (d) of paragraph 3, the registrant concludes that the substance fulfils the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008:*
>
> *(a) hazard classes 2.1 to 2.4, 2.6 and 2.7, 2.8 types A and B, 2.9, 2.10, 2.12, 2.13 categories 1 and 2, 2.14 categories 1 and 2, 2.15 types A to F;*
>
> *(b) hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10;*
>
> *(c) hazard class 4.1;*
>
> *(d) hazard class 5.1*
>
> *or is assessed to be a PBT or vPvB, … …"*

Thus, if the substance does not fulfil any of the criteria of the Article 14(4) (hazard classes, categories or properties) an exposure assessment is not needed and the registrant can directly document the hazard assessment and PBT/vPvB assessment in the chemical safety report

---

26 Note that there are cases where no CSA/CSR is needed at all (and thereby no ESs are to be provided), for instance in the case of substances exempted from registration under annex IV or V or for recovered substances exempted from presenting a registration dossier under art 2(7) (d).

27 The hazard classes or categories corresponding to the listing (where not already named in full in the text above) are: (a) explosives (2.1), flammable gases (2.2), flammable aerosols (2.3), oxidising gases (2.4), flammable liquids (2.6), flammable solids (2.7), self-reactive substances and mixtures types A and B (2.8 A + B), pyrophoric liquids (2.9), pyrophoric solids (2.10), substances and mixtures which in contact with water emit flammable gases (2.12), oxidising liquids categories 1 and 2 (2.13 1 + 2), oxidising solids categories 1 and 2 (2.14 1 + 2), organic peroxides types A to F (2.15 A to F inclusive); (b) acute toxicity (3.1), skin corrosion/irritation (3.2), serious eye damage/eye irritation (3.3) respiratory or skin sensitisation (3.4), germ cell mutagenicity (3.5), carcinogenicity (3.6), [3,7, 3.8 as above], specific target organ toxicity – repeated exposure (3.9), aspiration hazard (3.10); (c) hazardous to the aquatic environment (4.1); (d) hazardous to the ozone layer (5.1).

without the need to generate an exposure scenario. Furthermore, the CSA and CSR would normally be carried out as part of the preparations for a registration by the relevant deadline. Exposure scenarios for particular substances on their own or in mixtures will therefore normally only be attached to SDSs after the respective substance has been registered.

Once prepared, the exposure scenario should be attached to SDSs and its attachment would then constitute a revision to the SDS. Where the exposure scenario results in new risk management measures the SDS must be updated without delay and the revised version provided to former recipients within 12 months in accordance with the provisions of Article 31(9)(a) of REACH (see also chapter 3.8 above).

## 3.23 Alternative ways to include[28] the Exposure Scenario information into the SDS for substance and mixtures

For the cases described in 3.22 above, Article 31(7) of REACH specifies that the exposure scenario **must** be placed in an annex to the SDS.

However, the second and third subparagraphs of Article 31(7) further state that:

> *"Any downstream user shall include relevant exposure scenarios, and use other relevant information, from the safety data sheet supplied to him when compiling his own safety data sheet for identified uses.*
>
> *Any distributor shall pass on relevant exposure scenarios, and use other relevant information, from the safety data sheet supplied to him when compiling his own safety data sheet for uses for which he has passed on information according to Article 37(2)."*

For **downstream users** who are **not** required to carry out their own CSA for a particular (component) substance[29] there are therefore alternative options for inclusion of the exposure scenario information[30].

In the case of a mixture containing substances for which an exposure scenario was required, the inclusion of exposure scenario information in the SDS for the mixture must take into account at least those substances present above the thresholds given in Article 14 of REACH.

The result is the following possible cases for inclusion of exposure scenario(s) information (carried out by a Manufacturer/Importer or by a Downstream User (DU)) into SDSs:

1. attachment of the actual exposure scenario (s) resulting from a CSA for a substance as such or exposure scenario resulting from CSA for a substance in a mixture in concentrations above the thresholds given in Article 14. In this case, at least a summary of the relevant key information from the attached exposure scenario must be included into the core sections of the SDS, with a cross-reference to the details in the exposure scenario;

---

28 "Include" is used here to mean either attach the exposure scenario (s) as a whole to the SDS (as an annex) and/or integrate information from the exposure scenario into the main body (Sections 1 to 16 inclusive) of the SDS and/or append to the SDS safe use information for the mixture.

29 These alternative options are **only** available to such downstream users.

30 The change in wording from "*shall **place***" in the first paragraph of Article 31(7) with respect to those required both to carry out a CSA/CSR **and** prepare an exposure scenario to "*shall i**nclude** relevant exposure scenarios*" in the second paragraph with respect to downstream users is significant. The latter wording is to be interpreted as allowing (if the SDS compiler so chooses) "inclusion" of the relevant information from received exposure scenarios by methods **other than** attachment as an Annex to the SDS.

2. integration of exposure scenario information resulting from consolidation of various exposure scenario s for substances used in a mixture into the core Sections 1-16 of the SDS;
3. attachment of exposure scenario resulting from the CSA for a special mixture[31];
4. (potentially) attachment of exposure scenario resulting from a CSA for a mixture under Article 31(2) of REACH[32].
5. append safe use information for the mixture derived from the exposure scenarios of the component substances.

It should be noted that for a component of a mixture for which the downstream user is required to carry out a CSA option 2 above is not available.

It should further be noted that although all of the options above are allowed under the specified conditions they may not all be equally suitable in practice as a means of forwarding the relevant information – for example further downstream users may prefer to receive forwarded exposure scenarios for component substances in the mixtures that they receive rather than consolidated documentation. In this way when they then formulate these mixtures into further mixtures the component substances can be reconsidered together with the new components. Option 2 may be more appropriate e.g. when supplying professional end-users. Likewise, it is strongly recommended to use option 2 if the attachment of exposure scenarios for component substances in mixtures would otherwise lead to SDSs of such inordinate length that their recipients further down the supply chain would no longer be able to cope with the amount of information contained within them.

The actor compiling the SDS should keep in mind that recommendations from exposure scenarios give rise to specific obligations upon downstream users (Article 37(4)). In order for downstream users to be able to recognise such obligations (such as RMMs to be implemented), it is recommended that information originating from exposure scenario(s) – either incorporated in the body of the SDS or appended to the SDS - is indicated as such.

Appendix 2 provides more guidance to downstream users who need to “include” the exposure scenario information for a substance into a SDS.

Detailed guidance on options for downstream users on how to forward downstream information received from supplier(s) on the substance(s) as such or in a mixture(s) is provided in the *Guidance for Downstream users*[33].

Furthermore, a specific network has been established by ECHA and some sector organisations with the aim to develop and provide methodologies and tools to improve effective communication along the supply chain. More information is available on the ENES page of the ECHA website[34].

Appendix 2 to this guidance and, in more detail, Appendix 1 of the *Guidance for downstream users*, provide more information on the roles and obligations of distributors. They play an

31 See Appendix 3 for more information of “special mixtures”.

32 At present there is no guidance available on how to carry out such a CSA. Such a CSA for a mixture is foreseen by Article 31(2) of REACH for the purposes of generating consolidated information for an SDS. Neither Article 14 nor Article 37 of REACH generate a requirement for such a CSA to be prepared as part of a registration.

33 Available at: echa.europa.eu/web/guest/guidance-documents/guidance-on-reach.

34 Exchange Network on Exposure Scenario see: http://echa.europa.eu/web/guest/about-us/exchange-network-on-exposure-scenarios

important role in the communication flow up and down the supply chain.

## 3.24 Forms of assistance available in the compilation of SDSs

Suppliers may use an external service provider to access the services of competent persons for the compilation of SDSs, but of course retain responsibility for compliance with their own obligations for providing suitable SDSs.

Parties compiling and issuing SDSs may be supported by relevant software applications. These applications generally have a database function. These databases contain substance lists and libraries of standard phrases. Many software products include options for generating SDSs in several languages. Such software products may also support the management and consistency of information between the registration dossier (including the CSR) and the SDS.

An example of a source of standard phrases is the European Phrase Catalogue, which is available (at no charge) in German and English via http://www.euphrac.eu. Other service providers also offer libraries of standard phrases.

Some industry or trade associations offer support (e.g. via their internet homepages) with information regarding their specific sector.

## 3.25 Selected sources of substance data useful for the compilation of SDSs

A large part of the information necessary in order to compile the SDS should already be available to the supplier as it will have been necessary to gather it for the purposes of other chemicals control legislation, notably in order to determine e.g. the classification, labelling and packaging requirements according to CLP and according to international transport legislation and to comply with occupational health and safety legislation.

If the substance is subject to Registration under REACH and the supplier is a member of a Substance Information Exchange Forum (SIEF) or consortium[35] if one exists for that substance he may have shared access to additional information on the substance.

For downstream users of substances (and all formulators of mixtures), the key source of information is that provided by the supplier in the SDS for the specific (component) substance(s) or mixture(s).

Where it becomes apparent during compilation of the SDS that some data are not readily available to the compiler (particularly where an SDS is being prepared before a registration dossier is required e.g. for low-volume substances) there are also publicly available databases with relevant information (these may be consulted either to seek data that is not otherwise available or to check data supplied from upstream which seems inconsistent or implausible), for example:

The **ECHA** database on registered substances:
(http://apps.echa.europa.eu/registered/registered-sub.aspx)

This gives a variety of information on the substances which companies manufacture or import: their hazardous properties, their classification and labelling and how to use the substances safely, for example. Information in the database is that provided by companies

35 Note that participation in a consortium is not mandatory.

in their registration dossiers.

The **ECHA** classification and labelling inventory:

The Classification & Labelling (C&L) Inventory is a database that will contain basic classification and labelling information on notified and registered substances received from manufacturers and importers. It will also contain the list of harmonised classifications (Table 3.1 of Annex VI to CLP). The Inventory will be established and maintained by ECHA. See: http://echa.europa.eu/clp/c_l_inventory_en.asp

**ESIS**
(http://esis.jrc.ec.europa.eu)

The ESIS (European chemical Substances Information System) platform of the former European Chemicals Bureau (ECB) offers access to several databases – for searches by CAS no., by EINECS no. (EC no.)and by substance name in the English language.

**GESTIS**
(http://www.dguv.de/ifa/Gefahrstoffdatenbanken/GESTIS-Stoffdatenbank/index-2.jsp)

This database of the German Berufsgenossenschaften includes more than 7,000 hazardous substances alphabetically by name, with classification, labelling, limit values, measuring methods, information on personal protection equipment, workplace limit values and occupational medicine.

**International Chemical Safety Cards (ICSC)**
(http://www.ilo.org/dyn/icsc/showcard.home)

The International Labour Organisation (ILO) provides a database of International Chemical Safety Cards on its website. The primary aim of the Cards is to promote the safe use of chemicals in the workplace and the main target users are therefore workers and those responsible for health and safety in the workplace.

**eChemPortal**
(http://www.echemportal.org/echemportal/index?pageID=0&request_locale=en)

The eChemPortal is an effort of the Organisation for Economic Co-operation and Development (OECD) in collaboration with the European Commission (EC), the European Chemicals Agency (ECHA), the United States, Canada, Japan, the International Council of Chemical Associations (ICCA), the Business and Industry Advisory Committee (BIAC), the World Health Organization's (WHO) International Program on Chemical Safety (IPCS), the United Nations Environment Programme (UNEP) and environmental non-governmental organisations. eChemPortal provides free public access to information on properties of chemicals (including physical and chemical properties, environmental fate and behaviour, exotoxicity and toxicity) via simultaneous searching of reports and datasets.

**IPCS INCHEM**
(http://www.inchem.org/)

The International Programme on Chemical Safety (IPCS) INCHEM website gives Rapid access to internationally peer reviewed information on chemicals commonly used throughout the world, which may also occur as contaminants in the environment and food. It consolidates information from a number of intergovernmental organizations whose goal it

is to assist in the sound management of chemicals.

**TOXNET**
(http://toxnet.nlm.nih.gov/index.html)

Toxnet is the United States of America's National Library of Medicine's toxicology data network. It gives access to databases on toxicology, hazardous chemicals, environmental health, and toxic releases.

Attention should be paid to the potential variation in reliability of information from such sources.

It should be noted that in all cases (including when the information on component substances has been obtained from SDSs of suppliers of these substances – see chapter 3 paragraph 3.2 above) it is the supplier of the SDS that retains responsibility for the accuracy of its content.

## 3.26 How to compile an SDS for a recovered substance or mixtures containing such a substance

Appendix 4 of this document discusses specific issues relevant to the compilation of SDSs for recovered substances and mixtures. The ECHA *Guidance on waste and recovered substances*[36] contains additional information on issues that are specific to SDSs for recovered substances.

## 3.27 Testing for the purposes of generation of information for an SDS

The SDS is designed to provide comprehensive information about a substance or mixture for use in workplace chemical control regulatory frameworks (see paragraph 3.1 above). It consolidates this information into one document. The information required to be given in an SDS should either be available (because it is needed e.g. as part of the data set required for a registration under REACH) or a reason for it not being available should be given in the appropriate subsection of the SDS.

The process of compilation of the SDS may of course reveal that data which is required (for example to correctly classify under CLP) is unavailable (particularly in the case of phase-in substances for which a REACH registration dossier has not yet been completed).

In such cases, before any testing is initiated, the applicable "driver" legislation for compliance with which data are missing and additional testing is proposed should be consulted. Testing should **not** be initiated on the basis of a need to "fill-in empty fields" in an SDS.

In particular reference should be made to Title III of the REACH Regulation on *Data Sharing and Avoidance of Unnecessary Testing* and to Articles 7 and 8 of the CLP Regulation on *Animal and Human Testing* and *Generating new information for substances and mixtures*, respectively.

In particular, **no animal testing** should be initiated solely for the purposes of generating content for an SDS. The provisions of Council Directive 86/609/EEC[37]and 2010/63/EU[38] of the

36 The *Guidance on waste and recovered substances* is available at: echa.europa.eu/guidance-documents/guidance-on-reach.

37 Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes, (OJ L358, 18.12.1986 p.1).

EP and Council must be complied with. There is also no requirement arising directly from Annex II to REACH to generate non-animal test data (including that for physical hazards) solely for the purpose of completing fields of an SDS.

38Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (OJ L276, 20.10.2010 p33).

# 4 Detailed information, section by section

In this chapter of this guidance a quotation of the text relating to the relevant sub-section in part A of the Revised Annex II is given before it is further discussed.

In order to allow the reader to see a consolidated text of the two versions of the Annex II revision given in Commission Regulation (EU) No. 453/2010, which allows changes to be easily identified, where the quoted text does not change between the versions of the Revised Annex II which came into force on 1 December 2010 and that which comes into force on 1 June 2015 it is simply shown within the box "Text Annex II" in italics and without quotation marks. Where the text changes from 1 June 2015 both versions of the text are quoted within separate square brackets which first indicate the appropriate dates during which they are in force and then give the variable text within quotation marks.

It should be noted that although there may be text in Annex II discussing the content of certain sections as a whole which precedes subsections, there is no requirement to insert text in the actual SDS except in the subsections. However the title of the sections must be quoted as listed in the regulation – i.e. including the section number as explained above. Thus, for example, the correct heading for Section 10 of an SDS is *"SECTION 10: Stability and reactivity"* i.e. including the words "SECTION 10".

It should further be noted that although the full text of the Revised Annex II concerning specific sections and sub sections is quoted in full below, other parts of the revised Annex II (e.g. the introductory paragraphs to Part A, all of Part B) are not quoted in full below and neither is the full text of the rest of Commission Regulation (EU) No. 453/2010.

There may be places in the SDS where information will not be completed because of e.g. a data gap, or application can be questioned, etc. However, the SDS must contain an explanation or a justification of why the section has not been completed.

## 4.1 SDS SECTION 1: Identification of the substance / mixture and of the company / undertaking

| Text Annex II |
| --- |
| 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

**Text Annex II**

[Until 01/06/2015 only: *"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".*]

[From 01/06/2015: *"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.*

[Until 01/06/2015 only: *"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.*

The requirements for the product identifier **for substances** referred to above according to the CLP Regulation Article 18(2) are:

> *"The product identifier for a substance shall consist of at least the following:*
>
> *(a) if the substance is included in Part 3 of Annex VI, a name and an identification number as given therein;*
>
> *(b) if the substance is not included in Part 3 of Annex VI, but appears in the classification and labelling inventory, a name and an identification number as given therein;*
>
> *(c) if the substance is not included in Part 3 of Annex VI nor in the classification and labelling inventory, the number provided by the CAS (hereinafter referred to as 'the CAS number'), together with the name set out in the nomenclature provided by the IUPAC (hereinafter referred to as 'the IUPAC Nomenclature'), or the CAS number together with another international chemical name(s); or*

*(d) if the CAS number is not available, the name set out in the IUPAC Nomenclature or another international chemical name(s).*

*Where the name in the IUPAC nomenclature exceeds 100 characters, one of the other names (usual name, trade name, abbreviation) referred to in section 2.1.2 of Annex VI to REACH may be used provided that the notification in accordance with Article 40 of CLP includes both the name set out in the IUPAC Nomenclature and the other name used."*

The identification numbers should be given according to the hierarchy given above (i.e. (a) before (b), before (c)). However **no** further indication is given of which of the identification numbers allowed is to be used when choosing within any of the 3 (a), (b) and (c) options. For instance, if option (b) applies **any** of the identification numbers given within the classification and labelling inventory can be used, as long as in all cases the number quoted matches the identification number used on the label.

Thus, for example, whereas for beryllium compounds covered by index number 004-002-00-2 in part 3 of Annex VI of CLP, the index number itself would be used as the identifier according to (a) (since there is no EC number or CAS number *"given therein"* for this entry), in the specific case of beryllium oxide (index number 004-003-00-8) either this index number **or** the EC number (215-133-1) **or** the CAS number (1304-56-9) could be used **as long as** the same identification number appears on the label.

In the case where scenario (b) applies it should be noted that again "**an** identification number" as given therein refers to **any** of the allowed identifiers which are included in the notification to the inventory. In particular it should be noted that in practice it is unlikely to be convenient to choose the reference number attributed during (or as a result of) the process of a CLP notification as this will be unavailable in advance of its assignment. Choice of an alternative identifier such as (where applicable) EC number or CAS number that will also be included as identifiers in the CLP notification may be advisable in order to minimise the need for revision of the SDS.

It should further be noted that when a name from Annex VI is used it is subject to the same translation requirements as apply to the rest of an SDS[39].

If no registration number is given, an explanation as to why this is the case may be added to avoid questioning of the reason for its absence, for example:

*"No registration number is given for this substance since it is exempted from the registration requirements according to REACH Title II and also exempted from titles V and VI as it is a recovered substance and fulfils the criteria of Article 2(7)(d) of REACH."*

*"No registration number is given yet for this pre-registered phase-in substance since the transition period for its registration according to Article 23 of REACH has not yet expired"*

*"This substance is exempted from Registration according to the provisions of Article 2(7)(a) and Annex IV of REACH.*

However such an explanation is not mandatory.

**For mixtures**, until 1 June 2015 the requirement within this subsection 1.1 is only for the trade name or designation to be provided in accordance with Article 10(2.1) of the DPD, i.e.

39 Note that although at the time of writing names in Table 3.1 and 3.2 of Annex VI are not translated in the published versions, the translations of entries can be viewed (after pre-selecting the required language before doing a search in the option "search Annex VI") via the JRC web-site at: esis.jrc.ec.europa.eu/index.php?PGM=cla.

simply the trade name or designation of the mixture.

From 1 June 2015, the same requirement stems from Article 18(3)(a) of CLP:

> *"3. The product identifier for a mixture shall consist of both of the following:*
>
> *(a) the trade name or the designation of the mixture; … … …"*
>
> (For further requirements concerning information on the components of mixtures, including requirements for registration numbers see the discussion of Section 3 of the SDS below.)

An example of how the structure of this section may look for a substance is given below.

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

1.1 Product identifier:

Substance name:

EC No.:

REACH Registration No.: XX-XXXXXXXXXX-XX-XXXX

CAS No.:

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

**Text Annex II**

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.

The SDS must include at least the identified uses[40] of the substance or mixture relevant for the recipient(s) insofar as they are known. For registered substances for which a CSR is required this list of uses must be consistent with the uses identified in the CSR and exposure scenario.

To comply with the requirement for this description of identified uses to be brief, it is recommended that inclusion of a potentially long comprehensive list of formal "use descriptors"[41] in this section be avoided. Otherwise it could result in an unnecessarily lengthy

40 Identified use is defined in REACH, Article 3 (26).

41 More information on use descriptors is given in Chapter R.12 of the ECHA *Guidance on Information Requirements and Chemical Safety Assessment* available at:

block of text diluting critical information on the front page of the SDS. An alternative is to have a more generic list of applications and a reference to any Exposure Scenario(s) attached. An index or table of contents could be added to section 16 with a reference in this section for the exposure scenario details e.g. generic list of applications plus a note such as *'see SECTION 16 for a complete list of uses for which an exposure scenario is provided as an annex'*

The information in the subsection on uses advised against must be consistent with the information in section 3.6 of IUCLID (Uses Advised Against) for substances for which a registration is required. Note that where a use is advised against the reason why is also a requirement where applicable. Uses advised against may also be reported using elements of the Use Descriptor system, and/or with a generic description of the use(s). An example of how this subsection could look, including an illustrative entry is given below:

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

*Relevant identified uses:* Consumer uses [SU 21][42]; Ink and Toners [PC18].

*Uses advised against*: Consumer uses [SU 21]; Coatings and paints, thinners, paint removers [PC9a].

Reason *why uses advised against*: Use on large surface area would potentially give excessive exposure to vapour.

It may also be useful to indicate whether the use is being advised against on the basis of being (i) use advised against according to Annex I of REACH point 7 2.3 (substances that have undergone CSA), (ii) a non statutory recommendation by a supplier according to Annex VI of REACH point 3.7 or, (iii) for non-registered substances or mixtures containing them merely a non statutory recommendation by the supplier, which might also have its basis in technical reasons.

### 1.3 Details of the supplier of the Safety Data Sheet

**Text Annex II**

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.

guidance.echa.europa.eu/docs/guidance_document/information_requirements_en.htm.

42 The full title of [and code for] the use descriptors as given in the *Guidance on information requirements and chemical safety assessment Chapter R.12: Use descriptor system* is given here for reference but is not a legal requirement within the SDS.

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

It should be noted that only details of the non-Community manufacturer or formulator are optional. The other information specified in this section must relate to at least one supplier from the supply chain. Note also that in this context "the supplier" refers to the supplier of the SDS as indicated by the title of this section[43]. It should be further noted that a "responsible person" is nominated by a "supplier" who, according to the definition of a "supplier" under REACH is located in one Member State. Such a "responsible person" can therefore be described for practical purposes as "any person that the supplier from one Member State may have chosen to appoint in a different Member State to deal with any enquiries concerning SDSs which arise in that different Member State"

The information for this subsection may be structured as follows:

1.3. Details of the Supplier of the Safety Data Sheet

- Manufacturer/Supplier

- Street address/P.O. Box

- Country ID/Postcode/Place

- Telephone number (if possible, indicate telefax)

- e-mail address of competent person responsible for the SDS

-National contact:

For the email address of the competent person responsible for the SDS, it is advisable to use a dedicated generic (non-personal) email address that can be then checked by various persons - e.g. SDS@companyX.com. There is no specific requirement that this competent person should be located within the territory of the European Union or European Economic Area.

In addition to the legal requirements specified above an additional department/contact person (e.g. internal or external health and safety consultant) responsible for the contents of the SDS could be indicated under "SECTION 16: Other information" (including telephone number as minimum contact information)

There is no requirement to mention the name of a physical person in an SDS, the *"supplier"* referred to above can be a physical (natural) or legal person

43 Article 31 (1) of the REACH text defines the person required to supply the SDS as *"the supplier of the substance or a mixture*". Article 3 (32) then defines "*supplier of a substance or a mixture*" as "*any manufacturer, importer, downstream user or distributor placing on the market a substance, on its own or in a mixture, or a mixture*;" The person placing on the market is also therefore the "supplier" of the SDS in this context.

### 1.4 Emergency telephone number

| Text Annex II |
| --- |
| 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 |

Please note that although the official advisory body may be appropriate, there may also be cases where certain Member States have an advisory body for medical personnel only to contact. In such cases if the telephone number is given in an SDS it should also be explicitly stated in the SDS that it is intended for use by medical professionals only. In any case it should be confirmed with the relevant body that its number can be given and whether any conditions apply (e.g. possibly prior supply of a copy of all SDSs or other information).

Please also note that at ECHA's invitation, and on a voluntary basis, certain Member States have listed links to the telephone number(s) of appropriate national emergency information services to be listed in subsection 1.4 of the SDS in their entries on the ECHA web-page listing of national helpdesks at: http://echa.europa.eu/help/nationalhelp_contact_en.asp.

The supplier must provide a reference to emergency information services. If an official advisory body as defined in the legal text above exists reference to it must be made. Otherwise (or in addition) reference to an emergency service belonging to the supplier himself or to a competent third party provider of such a service must be made. Where the supplier provides his own emergency information service, be it alone or in combination with an official advisory body or other provider, the necessary competence should be available.

Any limitations on any the official advisory body, the supplier's own, or any third party's services (opening hours or types of information that can be provided) must be indicated e.g.:

(1) Only available during office hours.

(2) Only available during the following office hours: xx - xx

It is desirable to indicate time-zones for office hours quoted, particularly where the offices are located in a Member State with a different time zone from the Member State where the product is being put on the market, and especially if they are outside the EU.

These services should be able to address requests/calls in the official language(s) of the Member State(s) for which the SDS is intended. Appropriate international dialling codes should of course be indicated as part of telephone numbers outside the country of supply of the substance/mixture referred to.

An example of how the structure of subsections 1.3 and 1.4 could look is given below:

1.3 Details of the supplier of the safety data sheet:

Supplier (manufacturer/importer/only representative/downstream user/distributor):

Street address/P.O. Box

Country ID/Postcode/Place

Telephone number

e-mail address of competent person for safety data sheet

National contact:

1.4 Emergency telephone number

Opening hours:

Other comments (e.g. language(s) of the phone service)

## 4.2 SDS SECTION 2: Hazards identification

**Text Annex II**

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.

The information on classification and labelling given in Section 2 of the SDS must of course be consistent with that on the actual labels for the substance/mixture in question.

### 2.1 Classification of the substance or mixture

**Text Annex II**

[Until 01 June 2015 only: *"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."]*

[From 01/06/2015 only: *"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.*

The variations in the texts above reflect the synchronisation of the timetables for the change in requirements in the SDS with those of the CLP Regulation.

**For a substance**

When a supplier has notified the information on the substance to the classification and labelling inventory, the classification given in the SDS must be the same as that provided in his notification.

From 1 December 2010, the classification is to be given according to the rules in the CLP Regulation: i.e. indication of hazard classes and categories and hazard statements.

Until 1 June 2015, the classification according to Directive 67/548/EEC must also be given: i.e. indication of danger, symbol letter(s) (e.g. "Xi"), and R phrases[44], and, for CMR effects, danger categories.

It is advisable to clearly identify both classifications (i.e. with sub headings) in the SDS. Although not a legal requirement, information on which procedure was used for each endpoint classification (e.g. based on test data, human experience, minimum classification, summation method or specified bridging principles etc.) should preferably be given here where available. Also, although not a legal requirement, as the M-factor must be determined[45] for any substance classified as Aquatic Acute 1 and/or Aquatic Chronic 1 it is strongly recommended that they be given within the subsection concerning Classification according to CLP[46].

44Full text or risk phrases numbers with reference to SECTION 16 for full text.

45 See Article 10(2) of CLP; also note that M-factors are already available in Annex VI to CLP for some substances.

46 Although, strictly speaking, the M-factor is not part of the "*classification*" itself, its determination for these substances and mixtures is an essential integral part of the classification procedure to ensure that mixtures containing such substances are correctly classified. ECHA therefore gives the strongest possible recommendation that information on M-factors be given in the SDS.

An example of how the structure of this section could look for a **substance** is given below[47]:

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

2.1.1Classification according to Regulation (EC) No 1272/2008 [CLP]

Flam. Liq. 2, H225

Acute Tox. 3, H301

Acute Tox. 3, H311

Acute Tox. 3, H331

STOT SE 1, H370

Aquatic Acute 1, H400 (M-Factor (self-classification) = 10)

2.1.2. Classification according to Directive 67/548/EEC (see SECTION 16 for full text of risk phrases)

Highly flammable; F; R11

Toxic; T; R23/24/25

Toxic; T; R39/23/24/25

Dangerous for the environment; N; R50

2.1.3Additional information:

For full text of R-phrases and Hazard- and EU Hazard-statements: see SECTION 16.

**For a mixture**

If the mixture is labelled according to the DPD [allowed until May 31st, 2015], the classification must be indicated according to that Directive: i.e. symbol letter(s) and R phrases and, for CMR effects, danger categories[48]. See note below.

If the mixture is labelled according to the CLP Regulation, the classification is given according to that Regulation: indication of hazard classes and categories and hazard statements.

In the latter case, the classification according to the DPD must also be indicated until May 31st, 2015. Both classifications should be clearly identified.

Note: If a supplier of a mixture chooses to identify and inform about the classification according to the CLP Regulation in advance of using it for classification and labelling on the

47 Note that additional numbering and sub-structuring below the subsection level is not a legal requirement.

48 Note that, by contrast to the information required to define a "classification" according to the DSD for a substance in subsection 2.1 above, in the case of classification of a mixture according to the DPD in this subsection 2.2 the "indication of danger" is not part of the required information.

package, this classification may be included in SECTION 16.

When the SDS is being provided on request for a non-classified mixture (according to the requirements of Article 31(3) of REACH), this should be indicated. It may also be desirable to indicate the specific reason for inclusion of the mixture within the scope of Article 31(3). An example of a statement to do this, in a case according to Article 31(3) (c), could be:

> *'This product does not meet the criteria for classification in any hazard class according to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures. However a safety data sheet is being supplied for it on request as it contains a component for which there is a Community workplace exposure limit'.*

Please note that additional information on the components of mixtures is likely to become available (e.g. as a result of new tests or other information exchanges) after the first registration deadline (30th November 2010) as result of SIEF, consortium and/or individual registrant activities. This process of increasing availability of information may continue until 2018 and beyond.

An example of how the structure of this section could look ***during the transitional period*** (i.e. for a mixture for which CLP labelling has not yet been implemented between 01 December 2010 and 1 June 2015) is given below[49]:

SECTION 2: Hazards identification

2.1Classification of the substance or mixture

2.1.1Classification according to Regulation (EC) No 1272/2008 [CLP]

see SECTION 16

2.1.2.Classification according to Directive 1999/45/EC

Highly Flammable; F; R11

Toxic; T; R23/24/25

Toxic; T; R39/23/24/25

Toxic for reproduction; Repr. Cat. 2; R60-61

Additional information:

For full text of R- phrases: see SECTION 16.

## 2.2 Label elements

| Text Annex II |
| --- |
| [To 1 June 2015: *"In the case of a substance, based on the classification, at least the following* |

49 Note that additional numbering and sub-structuring below the subsection level is not a legal requirement.

*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."]*

[From 1st of June 2015: *"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."]*

For substances, from 1 December 2010 the label elements are to be indicated according to the CLP Regulation[50]. These elements must include **all** label elements appearing on the label (i.e. including, where appropriate, the inner pack label elements[51]).

For mixtures, the label elements indicated in this section may be according to either the DPD or according to the CLP Regulation (where the supplier has chosen to implement CLP labelling earlier than required[52]) until May, 31st 2015. In either case the label elements indicated must be consistent with the corresponding label affixed to the product. If the supplier wishes to give information about future (or former) labelling, which is not currently applied, he should give this information in SECTION 16. From 1 June 2015 the label elements listed (and the actual labelling) must be according to the CLP Regulation, including all label elements as is the case for substances.

Label elements according to the CLP Regulation include:

- Hazard pictogram(s)[53],
- Signal word;
- Hazard statement(s), H and EUH, in full (or give in full in Section 16 if not here);
- Precautionary statement(s), P, in full

50 Unless both the actual labelling of the packs and the SDS referring to it qualify for the relevant transitional provisions for substances already placed on the market before 1 December 2010 according to Article 61(4) of CLP and Article 2(6) of Regulation (EU) No. 453/2010 respectively, up to 1 December 2012 at the latest.

51 i.e. including, for example, hazard pictograms which do not have to appear on the outer packs according to Article 33(1) of CLP because they relate to the same hazard as in the rules for transport of dangerous goods

52 i.e. by implementing early the version of Annex II that comes into force on 1 June 2015 for his mixture according to the provisions of Article 2(3) of Regulation 453/2010.

53 According to Article 2(3) of CLP " 'hazard pictogram' means a graphical composition that includes a symbol plus other graphic elements, such as a border, background pattern or colour that is intended to convey specific information on the hazard concerned; "

- Any additional applicable label elements in accordance with Article 25 of CLP on "Supplemental information on the label"

As indicated in the legal text quoted above, the hazard pictogram may be replaced by a graphical reproduction of the full hazard pictogram in black and white or a graphical reproduction of the symbol only.

The precautionary statements may be selected in accordance with the criteria laid down in Part 1 of Annex IV of CLP taking into account the hazard statements and the intended or identified use or uses of the substance or the mixture. Once selected, the precautionary statements must be worded in accordance with Part 2 of Annex IV of CLP.

In selecting the precautionary statements in accordance with Articles 22 and 28 of CLP, suppliers may combine the Precautionary Statements, having regard to clarity and comprehensibility of the precautionary advice (in this case the specific wording of the component phrases combined should be retained). It should be noted that according to Article 28(3) of CLP not more than six precautionary statements should appear on the label unless necessary. For further information on selection of precautionary statements see the ECHA *Guidance on labelling and packaging in accordance with Regulation (EC) 1272/2008*[54]

It may be useful for industrial and professional users (not for consumers since they do not receive SDSs) to include special precautionary statements into appropriate Sections of the SDS main body in order to reduce the number of precautionary statements on the label[55][56]. Examples of such precautionary statements that could, for example, be given in sub-section 7.1 "precautions for safe handling" instead of on the label are as follows:

- Do not handle until all safety precautions have been read and understood. (P202)
- Wash hands thoroughly after handling (P264)
- Do not eat, drink or smoke when using this product (P270)
- Contaminated work clothing should not be allowed out of the workplace. (P272)

Label elements according to the DPD which are to be included in this sub-section include at least:

- Symbol(s), (either a full colour reproduction of the symbol as it appears on the label or a reproduction of it in black and white)
- Indication(s) of danger;
- Risk phrase(s) (R), in full or as a code with reference to and full text in SECTION 16;
- Safety advice (S), in full;
- The applicable label elements in accordance with sections A and B of annex V to the DPD.

According to REACH Article 65, holders of an authorisation, as well as downstream users

54 Available at: guidance.echa.europa.eu/guidance_en.htm.

55 Note that the p-number (e.g. "P202") is not itself a part of the precautionary statement, but it may be useful to indicate it in brackets after the statement for ease of reference.

56 Precautionary statements should be provided in the SDS (and not on the label) only when they would not be necessary on the label itself to reflect the nature and severity of hazards (see the conditions in Article 28(3) of CLP).

referred to in Article 56(2) who include a substance subject to authorisation in a mixture, must include the authorisation number on the label of the respective substance or mixture before it is placed on the market. In such cases the authorisation number becomes a mandatory label element according to CLP (via Article 32(6) of CLP concerning “label element requirements resulting from other Community acts”) and must therefore be included in this section of the SDS. Required Label elements according to REACH Annex XVII (such as "Restricted to professional users" are also examples of label elements which should be included in the SDS, in subsection 2.2. for substances and mixtures labelled according to CLP, and in Section 15 for mixtures labelled according to Directive 1999/45/EC. Label elements potentially arising out of national legislation may also be given here.

An example of how the structure of this subsection could look for a substance is given below[57]:

57 Sodium peroxide has been used as an actual example to further illustrate reduction of the number of precautionary statements. This is therefore **not** an example of a substance subject to authorisation.

*2.2: Label elements*[58]

*Labelling according to Regulation (EC) No 1272/2008 [CLP]*

*Hazard pictograms*

*Signal word:*

***Danger***

*Hazard statements:*

H271[59]May cause fire or explosion; strong oxidiser.

H314 Causes severe skin burns and eye damage

*Precautionary statements*[60]:

P210 Keep away from heat/sparks/open flames/hot surfaces. – No smoking.

P221Take any precaution to avoid mixing with combustibles.

P280 Wear protective gloves/protective clothing/eye protection/ face protection.

P301+P330+P331 IF SWALLOWED: rinse mouth. Do NOT induce vomiting.

P303+P361+P353+310 IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower. Immediately call a POISON CENTER[61] or doctor/physician.

P305+P351+P338IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P371+P380+P375In case of major fire and large quantities: Evacuate area. Fight fire remotely due to the risk of explosion.

*Supplemental Hazard information (EU)*[62]: *Not applicable.*

58 Note that the product identifier, although a label element, is not given in subsection 2.2 as it is not specified as one of the elements which should appear here. It is to be given in section 1.1.

59 Note the reference number of pictograms, R and S phrases, and H and P statements (e.g. “H271”) do not need to appear on the label and in subsection 2.2 of the SDS; only their full text is required. However, in order to be able to check and/or compare labelling information, it is recommended to quote these numbers in sub-section 2.2 of the SDS.

60 See next page for further information on how the number of precautionary statements has been reduced.

61 (Note spelling of “center” is US, carried-over from GHS).

62 If applicable.

**Reduction of the number of precautionary statements**

According to Article 28(3) of CLP *"Not more than six precautionary statements shall appear on the label, unless necessary to reflect the nature and the severity of the hazards".*

The determination of which precautionary statements appear on the label should be carried out in compliance with the CLP regulation. The requirement of Annex II of REACH with respect to their inclusion in an SDS is simply that the statements which appear on the label be given in this subsection (2.2) of the SDS.

Further information on how the number of precautionary statements can be reduced to as close as reasonable to the target number of a maximum of six is given in the ECHA *Guidance on labelling and packaging in accordance with Regulation (EC) No 1272/2008*[63].

## 2.3 Other hazards

| Text Annex II |
| --- |
| Information on whether the substance or mixture meets the criteria for PBT or vPvB in accordance with Annex XIII shall be provided.<br><br>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. |

The information on other hazards which do not result in classification, but which must be given here, includes, for example information on the presence of sensitizers according to Article 25(6) of CLP (and corresponding DPD provisions).

An example of how the structure of this subsection could look, including some phrases that can be used if appropriate is given below:

2.3 Other hazards

Risk of blindness after swallowing the product

Substance meets the criteria for vPvB according to Regulation (EC) No 1907/2006, Annex XIII

Substance is phototoxic

63 Available at: guidance.echa.europa.eu/guidance_en.htm.

## 4.3 SDS SECTION 3: Composition/information on ingredients

**Text Annex II**

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.

Either section 3.1 or 3.2 must be included below as appropriate for only one of either a substance or mixture as applicable[64].

It should be noted that the term "surface chemistry" as used in the text above is intended to refer to properties that may arise as a result of the particular surface properties of a (solid) substance or mixture (e.g. due to having certain dimensions in the nano range)[65].

### 3.1 Substances

**Text Annex II**

*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.*

The chemical identifiers of the main constituent need to be added in this section (information from section 1.1).

Note that it is **not** a requirement to separately give the classification (or indication of danger which applies in any case only to components of mixtures) etc for impurities in a **substance** (by contrast to the case for mixtures covered by point 3.2.3 in the legal text below) since these should already have been taken into account in the classification of the substance as registered under REACH / notified under CLP.

64 Whichever of these two subsections is not applicable becomes the only subsection in the SDS which may be left completely blank.

65 It is specifically **not** intended to require information to be given here on surfactant properties of (liquid or dissolved) substances or mixtures.

An expanded illustrative example of how the structure of this section could look for a styrene monomer is given below[66]:

| SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS<br>3.1 SUBSTANCES | | | | |
|---|---|---|---|---|
| **Product identifier type in accordance with Article 18(2) of Regulation (EC) No 1272/2008** | **Identifier number** | **Identification name** | **Weight % content (or range)** | **EC Number[67]** |
| Index number in CLP Annex VI | 601-026-00-0 | styrene | 99.70 – 99.95 | 202-851-5 |
| CAS number in CLP Annex VI[68] | 100-41-4 | ethylbenzene | 0.05 maximum | 202-849-4 |
| CAS number | 98-29-3 | 4-tert-butylbenzene-1,2-diol[69] | 0.0015 (15 ppm) maximum | 202-653-9 |
| (Non-classified constituent) | Not applicable | Polymers | Max 0.0020 | Not applicable |

In practice, for the particular case given above, since the components other than styrene are present at a level below that to be taken into account for classification, the example could be reduced to the following where the supplier does not wish to use the SDS to additionally give specification information:

| SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS:<br>3.1 SUBSTANCES | | |
|---|---|---|
| **Name** | **Index number in CLP Annex VI** | **Weight % content (or range)** |
| styrene | 601-026-00-0 | > 99.5 % |

This example above, for a substance with impurities can be contrasted with that given below

66 Note that the field names need not in practice be as pedantic as those used for illustration here and that a more "classical" listing with multiple identifiers would also be acceptable, as long as the content of the fields conforms with the requirements – see reduced example on next page.

67 If all the first three columns in this example are populated this column is not a requirement – it is for information only.

68 Ethylbenzene has of course also an index number in Annex VI of CLP – the CAS number has been chosen here to illustrate the principle that any of the identifiers given in the Annex can be used – in practice consistency might be desirable in choice of available numbers.

69 This is the actual IUPAC name for the substance otherwise known as 4-tert-butyl catechol./ 4-tert-butyl pyrocatecol / TBC.

for a mixture containing some of the same components (styrene and ethylbenzene). This may help to clarify the difference in requirements for substance information under subsection 3.1 with those for mixture information under subsection 3.2.

### 3.2 Mixtures

**Text Annex II**

[From 1 December 2010 to 1 June 2015: *"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."*]

[From 1 June 2015: *"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.*

[To 1 June 2015: *"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 Council 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.*]

[From 1 June 2015:

*"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) ≥ 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 | ≥ 0,1 |

| | |
|---|---|
| lactation | |
| 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;*

*(viia) 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 %.*

[Until 1 June 2015:

*"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 Council 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"*]

[From 1 June 2015:

*"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).*

[Until 1 June 2015 *"3.2.3.For the substances indicated in Subsection 3.2, the classification of the substance according to Council 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."*]

[From 1 June 2015 *"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.*

It should be noted that the legal text quoted above mentions generic cut-off values and M-factors only in the context of deciding which substances (including their concentration or concentration range in the mixture) need to be listed in the SDS. Nevertheless, for cases where an M-factor is availablein practice it would be potentially useful and therefore recommendable to also give the actual M-factor and indicate it as such (in the case of M-factors for components of mixtures this is preferably best indicated together with the classification information on the relevant component in this subsection 3.2)[70].

The requirements for information on identifiers to be given under this subsection 3.2 (as opposed to sub-section 1.1) for mixtures are different in the version of Annex II in force from 1 December 2010 to 1 June 2015 and the version in force from 1 June 2015. In particular the qualification that the product identifier must be given only "when available" no longer applies as of 1 June 2015 (by then product identifiers [according to CLP] should be available for all component substances)[71].

The term "if technically possible" as used in the context of the requirement to give concentrations of the substances in a mixture as either exact percentages or ranges of percentages in descending order should be taken to mean that this should be done if e.g. the SDS-generating software allows this ranking with the available composition information. It does not mean that all technical steps (including e.g. analysis) need to be exhausted in order to determine precise information necessary for such a ranking where it is not otherwise available.

In the case of mixtures, the part of the REACH registration number for component substances referring to the individual registrant of a joint submission (the last four digits of the original full registration number) can be omitted by **any** supplier (it should be noted that in this case it is not a requirement that the supplier be a downstream user or distributor as is the case for truncation of the registry number given for substances in subsection 1.1). It should be further noted that registration numbers are only required in this subsection for the substances referred to in points 3.2.1 or 3.2.2. However, if suppliers choose to list additional substances in the mixture under sub-section 3.2, although they are not obliged to give the information specified in point 3.2.1 or 3.2.2 for these substances, they must then give the applicable information specified in points 3.2.3 and 3.2.4, including the registration numbers if available.

The "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 %" in the legal text quoted above are the so-called "candidate list" substances (see chapter 3, para 3.15 of this document for more information).

---

70 Although, strictly speaking, the M-factor is not part of the "*classification*" itself, its determination for these substances and mixtures is an essential integral part of the classification procedure to ensure that mixtures containing such substances are correctly classified. ECHA therefore gives the strongest possible recommendation that information on M-factors be given in the SDS.

71 Note that In contrast with the case for listing of substance identities in SDSs for **a substance** in subsection 1.1 there is no specific requirement that the product identifier information for **component substances of a mixture** given in subsection 3.2 should conform to the full requirements of either Article 18(2) [or Article 18(3)(a)] of CLP.

An example of how the structure of this subsection could look is given below for a mixture during the transition period between 1 December 2010 and 1 June 2015 (after 1 June 2015 the information on classification according to 67/548/EEC is no longer required)[72]:

**SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS**
**3.2 Mixtures**

**Description of the mixture:Mixture of Styrene and Ethylbenzene.**
**Hazardous ingredients:**

| CAS No | EC No | Index No. | REACH Registration No. | % [weight] | Name | Classification according to 67/548/EEC | Classification according to Regulation (EC) No 1278/2008 (CLP). |
|---|---|---|---|---|---|---|---|
| 100-42-5 | 202-851-5 | 601-026-00-0 | 01-XXXXXXXXXX-XX-YYYY | 60 | styrene | Flammable; R10<br>Harmful; Xn; R20<br>Irritant; Xi; R36/38 | Flam. Liq. 3<br>H226<br>Acute Tox. 4<br>H332<br>Eye Irrit. 2<br>H319<br>Skin Irrit. 2<br>H315 |
| 100-41-4 | 202-849-4 | 601-023-00-4 | 01-NNNNNNNNNN-NN-ZZZZ | 40 | Ethylbenzene | Highly flammable; F; R11<br>Harmful; Xn; R20 | Flam. Liq. 2<br>H225<br>Acute Tox. 4<br>H332 |

*Additional information:*

*For full text of H-statements and R-phrases: see SECTION 16.*

Note that since only one of CAS, EC or index number is required, this table could alternatively be simplified by replacing the three columns (one for each type of number) by two columns: one for "number type" and a second for "number". Alternatively these example tables can be presented in other ways, e.g. by using two columns for 'number type' and 'number'.

It should be noted that the classification given for a component substance in the final two

72 PLEASE NOTE: This example is given for the purposes of illustrating the format of entries in this subsection, and in particular the difference by comparison of with an entry in subsection 3.1 for a substance with impurities. IT IS NOT TO BE TAKEN AS AN INDICATION THAT SUCH A MIXTURE WOULD BE STABLE AGAINST POLYMERISATION OR OTHER REACTIONS.

columns should be that of the pure (100%) substance.

Weight ranges may be given instead of actual weight percentages – in this case the classification derived for the particular concentration range should be based on the highest concentration in the range quoted.

It should be noted that the table given in the text of Annex II applicable from 1 June 2015 quoted above under the title *"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."* gives the values above which the specified substances must be **listed in an SDS**. These are **not** necessarily the generic limits for classification – the values in this particular table have been adjusted to incorporate the notes in the CLP regulation requiring provision of an SDS in certain cases **even when** the value is below that leading to classification. For example, in the case of Reproductive toxicity, category 1A, 1B, 2 and effects on or via lactation the value given in the table is ≥ 0.1, even though according to Table 3.7.2 *"Generic concentration limits of ingredients of a mixture classified as reproduction toxicants or for effects on or via lactation that trigger classification of the mixture"* in Annex I of the CLP Regulation gives a value of **≥ 0.3** for the concentration limit for classification. This is because this table incorporates the relevant *Note 1* below the table which states that *"If a Category 1 or Category 2 reproductive toxicant or a substance classified for effects on or via lactation is present in the mixture as an ingredient at a concentration above* **0,1 %**, *a SDS shall be available for the mixture upon request"*. It is this latter value which appears in the table referred to above, since its aim is to indicate the value relevant to the SDS, not that determining classification.

Where an alternative chemical name is being used according to the provisions of Article 24 of CLP for a substance in a mixture it is recommended that this be indicated in this subsection (or in Sections 15 or 16) in order to avoid enquiries on its use from recipients or from enforcement authorities.

Sub-section 3.2 of the SDS may also be used to provide certain information on the composition of detergents intended to be used in the industrial and institutional sector, and not made available to members of the general public[73].

With respect to listing under subsection 3.2 it should be noted that the legal requirement (for substances not already listed for other reasons) is to be listed when they are *"(b) substances for which there are Community workplace exposure limits…"* i.e. it is a **Community** limit which determines listing. However compilers may voluntarily list substances in this subsection (or in SECTIONS 15 or 16) for which a national, but no Community limit has been assigned (contrast the case discussed below for subsection 8.1 where it is information on **national** limits that **must** be provided, regardless of whether a corresponding Community limit exists).

73 Ingredients required to be listed according to the Detergents Regulation can be displayed under subsection 3.2. of the SDS, providing that these are clearly distinguished from each other by means of suitable subheadings indicating to which piece of legislation they apply. For more information see: ec.europa.eu/enterprise/sectors/chemicals/documents/specific-chemicals/detergents/index_en.htm#h2-6.

## 4.4 SDS SECTION 4: First aid measures

**Text Annex II**

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

**Text Annex II**

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.

The information in this subsection may be structured as follows:

4.1 Description of first aid measures

- general notes
- following inhalation
- following skin contact
- following eye contact
- following ingestion
- self-protection of the first aider

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

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

It should be noted that this subsection is for symptoms and effects - treatments are to be described in subsection 4.3.

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

| Text Annex II |
| --- |
| 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.<br><br>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. |

It should be noted that (as indicated in the legal text introducing section 4 as a whole) the initial care must be described in such a way that it can be understood and given by an untrained responder and that if medical attention is required this must be explicitly stated

Where it appears to be necessary to provide specific information for the doctor (e.g. specific antidote treatment, positive airway pressure, prohibition of certain drugs, eating, drinking or smoking, etc.) this information may be given under a heading such as “Notes for the doctor” (symptoms, hazards, treatment). The information provided under this heading may contain special medical terms which may be difficult to understand for non-medical personnel. Although not a specific requirement it may also be indicated whether any recommendations for specific actions or treatments can or cannot be carried out by first aiders as well as by medical doctors.

## 4.5 SDS SECTION 5: Firefighting measures

| Text Annex II |
| --- |
| 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

| Text Annex II |
| --- |
| Suitable extinguishing media:<br><br>Information shall be provided on the appropriate extinguishing media.<br><br>Unsuitable extinguishing media:<br><br>Indications shall be given whether any extinguishing media are inappropriate for a particular situation involving the substance or mixture. |

Unsuitable extinguishing media are extinguishing media which must not be used for safety reasons including media that may cause chemical or physical reactions resulting in an additional potential hazard. For example, in the presence of substances which in contact with water emit flammable or toxic gases (e.g. Calcium carbide reacts with water to form Ethyne (Acetylene)).

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

| Text Annex II |
| --- |
| 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”. |

This subsection includes information about any specific hazards arising from the chemical (e.g. nature of any hazardous combustion products or vapour cloud explosion risks.)

### 5.3 Advice for firefighters

| Text Annex II |
| --- |
| 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. |

It can be emphasized that no chemical protective clothing will afford protection against all chemicals. Depending upon the respective hazards of substances, levels of protection advised can be divided into three categories.

- Self-Contained Breathing Apparatus (SCBA) with chemical resistant gloves.
- SCBA with a chemical protection suit only where personal (close) contact is likely.
- SCBA with gas-tight suit when close proximity to the substance or its vapours is likely.

The gas-tight suit represents the highest level of chemical protective clothing. Such suits may be manufactured from neoprene, vinyl rubber or other materials and are used with SCBA. Protection will be afforded from many chemicals but not all. If in any doubt, specialist advice should be sought.

For incidents involving deeply refrigerated and many other liquefied gases where contact will cause frostbite and severe damage to eyes, thermally insulated undergarments including thick textile or leather gloves, and eye protection should be worn. Similarly, for incidents involving significant heat radiation, it is recommended that heat reflective suits be used.

Fire fighter's clothing conforming to European standard EN469 provides a basic level of protection for chemical incidents and includes helmets, protective boots and gloves. Clothing not conforming to EN469 may not be suitable in any chemical incident.

Additionally, one may include recommended measures for isolating the area affected, for limiting damage in the event of fire or for the disposal of residues of extinguishing media.

When compiling this section, it should be considered whether spillage and fire-fighting water could cause pollution of watercourses. If so, information should be given on how to minimize their impact on the environment.

An example of how the structure of this section could look like is given below:

SECTION 5. Firefighting measures

5.1 Extinguishing media:

Suitable extinguishing media:

Unsuitable extinguishing media:

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products:

5.3 Advice for firefighters

## 4.6 SDS SECTION 6: Accidental release measures

**Text Annex II**

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.

[The text above is considered as needing no further explanation].

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

**Text Annex II**

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”).

[The text above is considered as needing no further explanation].

### 6.2 Environmental precautions

**Text Annex II**

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.

[The text above is considered as needing no further explanation].

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

**Text Annex II**

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 …'.

Note that the list of techniques is not exhaustive, notably absorbents may be used as well as adsorbents.

Also note that *"bunding"*[74] and *"capping"*[75] here have the meanings as defined in Annex 4 of the GHS[76].

Some examples of the kind of recommendations that could be included in this subsection are:

- Wet clean or vacuum up solids.
- Don't use a brush or compressed air for cleaning surfaces or clothing.
- Clear spills immediately

74 "*A* ***bund*** *is a provision of liquid collection facilities which, in the event of any leak or spillage from tanks or pipe work, will capture well in excess of the volume of liquids held, e.g. an embankment. Bunded areas should drain to a capture tank which should have facilities for water/oil separation.*"

75 "*i.e. providing a cover or protection (e.g. to prevent damage or spillage).*"

76 Globally Harmonized Classification and Labelling system of Chemicals (GHS), Fourth revised edition 2011. Annex 4 – *Guidance on the compilation of safety data sheets*, page 415; See: unece.org/trans/danger/publi/ghs/ghs_rev04/04files_e.html.

### 6.4 Reference to other sections

| Text Annex II |
| --- |
| If appropriate Sections 8 and 13 shall be referred to. |

It should be noted that the only sections for which (cross)-references are required here (and then only if appropriate) are sections 8 and 13 – i.e. cross-references should be made to information on exposure control and personal protection and disposal considerations, respectively, which are relevant to potential accidental release. The intention here is to avoid duplication of information – not to require such duplication. Any additional references to other sections that may be made here are not a requirement of the Regulation.

An example of how the structure of this section could look is given below[77]:

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

6.1.1 For non-emergency personnel

Protective equipment:

Emergency procedures:

6.1.2 For emergency responders

6.2 Environmental precautions:

6.3 Methods and material for containment and cleaning up

6.3.1 For containment:

6.3.2 For cleaning up:

6.3.3 Other information:

6.4 Reference to other sections

77 Note that additional numbering and sub-structuring below the subsection level is not a legal requirement.

## 4.7 SDS SECTION 7: Handling and storage

**Text Annex II**

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

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

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

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

[The text above is considered as needing no further explanation]

### 7.1 Precautions for safe handling

**Text Annex II**

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.

This subsection should provide information concerning protective measures for safe handling and recommended technical measures such as containment, measures to prevent aerosol and dust generation and fire, measures required to protect the environment (e.g. use of filters or scrubbers on exhaust ventilation, use in a bonded area, measures for collection and disposal of spillages, etc.) and any specific requirements or rules relating to the substance or mixture (e.g. procedures or equipment which are prohibited or recommended). If possible, give a brief description of the measure.

An example of how the structure of this subsection could look is given below:

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Protective measures:

Measures to prevent fire:

Measures to prevent aerosol and dust generation:

Measures to protect the environment:

Advice on general occupational hygiene:

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

**Text Annex II**

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)anti-oxidants.

(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.

This subsection should, if relevant, specify the conditions for safe storage such as:

- specific design for storage rooms or vessels (including retention walls and ventilation)
- incompatible materials
- conditions of storage (humidity limit/range, light, inert gas, etc.)
- special electrical equipment and prevention of static electricity

The subsection should also include advice - if relevant - on quantity limits under storage conditions (or e.g. an indication of threshold quantities above which the Seveso II Directive as extended[78] would apply to the substance or substance class). This subsection should further indicate any special requirements such as the type of material used in the packaging/containers of the substance or mixture.

It should be noted that in the context of the content of information to be given in subsection 7.2 the term “incompatibilities” should be taken to include incompatibilities of the substance or mixture with packaging materials with which they are likely to come into contact.

Some suppliers may choose to indicate here information about national storage class systems. The storage class is derived from the classification of the pure substance or mixture - the packaging should not be taken into account for this purpose.

It is not recommended to add quality-related storage information to this subsection. If this information is added, it should be clearly indicated that it is quality and not safety related information.

An example of how the structure of this subsection could look is given below:

78 Directive 2003/105/EC of the European Parliament and of the Council of 16 December 2003 amending Council Directive 96/82/EC on the control of major-accident hazards involving dangerous substances. OJ L 345, 31.12.2003, p. 97–105.

7.2 Conditions for safe storage, including any incompatibilities

Technical measures and storage conditions:

Packaging materials:

Requirements for storage rooms and vessels:

Storage class:

Further information on storage conditions:

### 7.3 Specific end use(s)

**Text Annex II**

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.

For biocidal products, as an example of substances and mixtures designed for specific end uses, in addition to identified uses listed in subsection 1.2 which must be listed, any additional uses for which the product has been authorised may be indicated (e.g. wood preservation, disinfection, slime control, in-can preservation, etc.). Additional reference may be made to any technical fact sheet containing further information concerning the quantity to be applied and the handling instructions for any kind of use.

If the SDS has corresponding exposure scenarios attached, which give the necessary recommendations relating to safe handling and use, and reference is made to it there is no need to use this subsection for detailed recommendations for specific end uses.

For substances for which exposure scenarios are not required (e.g. substances for which no CSA is required because they are not subject to registration at ≥ 10 t/a[79]), this section may additionally be used to include similar or equivalent information to that which would otherwise be given more fully in an exposure scenario. This section can also be of potential use in the case of SDSs for mixtures for which no consolidating document equivalent to an “exposure scenario for the mixture” is attached.

An example of how the structure of this sub-section could look is given below:

79 Note: Even for substances at > 10 t/a for which a CSA is required there are further criteria according to Article 14 (4) before an exposure scenario is required, however these criteria will apply for most substances for which an SDS is required.

7.3 Specific end use(s):

Recommendations:

Industrial sector specific solutions:

## 4.8 SDS SECTION 8: Exposure controls/personal protection

Note: for those compiling SDSs for "special mixtures"[80], additional information on how to adapt Section 8 is given in Annex 3.

**Text Annex II**

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

**Text Annex II**

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 ;

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 Commission 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

80 Special mixtures are those in which a common feature is that the properties of the constituent substances are modulated by their inclusion within the matrix of the mixture. The availability for exposure of the constituent substances and their potential to express any ecotoxicological/toxic properties may be affected following their inclusion in the matrix.

Article 2(1) of Commission 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.

**Occupational Exposure limit values**

This subsection should include currently applicable specific control parameters including occupational exposure limit values and/or biological limit values. Values must be given for the Member State where the substance or mixture is placed on the market.

It should be noted that although for Section 3 of the SDS the requirement is clearly to list substances with a Community limit value[81], for Section 8 the requirement is that the national occupational exposure limit values that correspond to Community OELs must be listed **and** that even in the absence of a Community OEL any relevant national limit must be listed (see points 8.1.1.1 + 8.1.1.2. and 8.1.1.3. of the legal text quoted above, respectively). In cases where an Indicative Occupational Exposure Limit Value (IOELV) has been proposed by the European Commission but has not yet been transposed into individual Member State national law it is desirable to give the Community value, although not specifically required.

An example of how this information may be displayed in an SDS for the case of a single substance placed on the market in multiple Member States[82] is given below:

81 See point 3.2.1 (b) of text of Annex II text above.

82 Point 8.1.1 of the legal text quoted above specifies that the OEL's of the MS where the SDS is being provided must be listed. This means that if an SDS is compiled only for supply to a single MS, only this country's OEL need be given. However as many suppliers may use the same SDS content (suitably translated) in several countries and several languages version many SDSs will in practice need to give the OELs for multiple countries.

**SUBSTANCE: ACETONE**
**CAS NO. 67-64-1**

| | Limit value - Eight hours | | Limit value - Short term* | | |
|---|---|---|---|---|---|
| **Country**[83] | **ppm** | **mg/m³** | **ppm** | **mg/m³** | **Legal basis**[84] |
| Austria | 500 | 1200 | 2000 | 4800 | |
| Belgium | 500 | 1210 | 1000 | 2420 | |
| Denmark | 250 | 600 | 500 | 1200 | |
| **European Union**[85] | **500** | **1210** | | | |
| France | **500** | **1210** | **1000** | **2420** | |
| Germany (AGS) | 500 | 1200 | 1000 (1) | 2400 (1) | |
| Hungary | | 1210 | | 2420 | |
| Italy | 500 | 1210 | | | |
| Poland | | 600 | | 1800 | |
| Spain | 500 | 1210 | | | |
| Sweden | 250 | 600 | 500 | 1200 | |
| The Netherlands | | 1210 | | 2420 | |
| United Kingdom | 500 | 1210 | 1500 | 3620 | |

83 It is desirable to repeat values even where they are the same for multiple MSs since otherwise there is the danger of creating the misconception that no OEL is available for that specific MS (or country in general if non-MS values included).

84 This information has not yet been inserted in the example, but would need to be inserted in practice. “Legal basis” in this context means the national legislation or other provision which gives rise to the limit.

85 It should be noted that only national values are required to be given based on Regulation EU 453/2010 – it can be considered to be useful practice to give the EU value, where there is a corresponding one.

| Remarks | |
|---|---|
| *European Union* | *Bold-type: Indicative Occupational Exposure Limit Values [2,3] and Limit Values for Occupational Exposure [4] (for references see bibliography*[86]*)* |
| *France* | *Bold type: Restrictive statutory limit values* |
| Germany (AGS) | (1) 15 minutes average value |
| | * Short term is 15 minutes unless otherwise specified. |

Source: Based on GESTIS International Limit values Database via http://www.dguv.de/ifa/Gefahrstoffdatenbanken/GESTIS-Internationale-Grenzwerte-f%C3%BCr-chemische-Substanzen-limit-values-for-chemical-agents/index-2.jsp.

The GESTIS International Limit values Database may be particularly useful as a source of this type of information as it also gives links to information on the legislative context of the Occupational exposure limit values where this is available. Thus, for the example above, the relevant country information where available (at July 2010) was as follows[87]:

| Country | (Country information where available) |
|---|---|
| Austria | http://www.dguv.de/medien/ifa/en/gestis/limit_values/pdf/at.pdf |
| Belgium | http://www.dguv.de/medien/ifa/en/gestis/limit_values/pdf/be.pdf |
| Denmark | (Not available) |
| **European Union** | http://www.dguv.de/medien/ifa/en/gestis/limit_values/pdf/scoel.pdf |
| France | http://www.dguv.de/medien/ifa/en/gestis/limit_values/pdf/fr.pdf |
| Germany (AGS) | http://www.dguv.de/medien/ifa/en/gestis/limit_values/pdf/ags.pdf |
| Hungary | http://www.dguv.de/medien/ifa/en/gestis/limit_values/pdf/hu.pdf |

86 Available at: dguv.de/medien/ifa/en/gestis/limit_values/bibliography.pdf.
87 Note: while databases from non-regulatory organisations are a useful source of reference, due care should be exercised to confirm that the data is up to date and accurate.

| | |
|---|---|
| Italy | (Not available) |
| Poland | http://www.dguv.de/medien/ifa/en/gestis/limit_values/pdf/pl.pdf |
| Spain | http://www.dguv.de/medien/ifa/en/gestis/limit_values/pdf/es.pdf |
| Sweden | (Not available) |
| The Netherlands | http://www.ser.nl/nl/taken/adviserende/grenswaarden.aspx |
| United Kingdom | http://www.dguv.de/medien/ifa/en/gestis/limit_values/pdf/uk.pdf |

Another source of available information on Occupational Exposure Limits from Member States is the OSHA (European Agency for Safety and Health at work) website: http://osha.europa.eu/en/topics/ds/oel/index.stm/members.stm.

There are also commercial databases available where this type of information is available on a subscription or other payment basis.

### Information on monitoring procedures

The information in this subsection must also include the currently recommended monitoring or observation methods at least for the most relevant substances. These monitoring methods can be: personal air monitoring, room air monitoring, biological monitoring etc according to agreed standards. The specific standard should be referenced, for example:

| |
|---|
| "BS EN 14042:2003 Title Identifier: Workplace atmospheres. Guide for the application and use of procedures for the assessment of exposure to chemical and biological agents." |

It should be noted that since the applicable limits and their legal basis are those of individual Member States on whose market the substance or mixture is being placed, the monitoring methods of the country for which the SDS is being provided should take precedence over those of the originating country where there is a difference in methods.

For mixtures, it should be considered that the requirement that *"Information on currently recommended monitoring procedures shall be provided at least for the most relevant substances"* means that it must be provided at least for those constituent substances which are required to be listed in subsection 3.2 of the SDS, if available[88].

88 For certain types of substances and mixtures (e.g. complex UVCBs) such methods may not be available.

The Derived No Effect Levels (DNELs) and Predicted No Effect Concentrations (PNECs) applicable to the exposure scenarios in any required annex(es) to the SDS for a specific substance or mixture can be listed together with - and in the same way as - the OELs discussed above, or can be listed or tabled separately, depending on the supplier's preference.

It should be noted that only the applicable DNELs, and PNECs should be listed - the others should be removed from the list as appropriate.

An example of how the required information on DNELs and PNECs in this section could be structured is given below:

| SUBSTANCE NAME | |
|---|---|
| EC number: | CAS number: |

**DNELs**

| | Workers | | | | Consumers | | | |
|---|---|---|---|---|---|---|---|---|
| Route of exposure | Acute effect local | Acute effects systemic | Chronic effects local | Chronic effects systemic | Acute effects local | Acute effects systemic | Chronic effects local | Chronic effects systemic |
| Oral | **Not required** | | | | | | | |
| Inhalation | | | | | | | | |
| Dermal | | | | | | | | |
| Each of the cells should contain one of the following information: i) DNEL value with unit or ii) hazard identified but no DNEL available or iii) no exposure expected, iv) no hazard identified | | | | | | | | |

**PNECs**

| Environmental protection target | PNEC |
|---|---|
| Fresh water | |
| Freshwater sediments | |
| Marine water | |
| Marine sediments | |
| Food chain | |
| Microorganisms in sewage treatment | |
| Soil (agricultural) | |
| Air | |

Each of the cells should contain one of the following information: i) PNEC value with unit or ii) hazard identified but no PNEC available or iii) no exposure expected or iv) no hazard identified

**The control banding approach**

According to the International Labour Organisation, Control Banding can be described as follows[89]:

It is a complementary approach to protecting worker health by focusing resources on exposure controls. Since it is not possible to assign a specific Occupational Exposure Limit to every chemical in use, a chemical is assigned to a "band" for control measures, based on its hazard classification according to international criteria, the amount of chemical in use, and its volatility/dustiness. The outcome is one of four recommended control strategies:

1. Employ good industrial hygiene practice
2. Use local exhaust ventilation
3. Enclose the process
4. Seek the advice of a specialist

It should be noted that use of the control banding approach is not mandatory. However, when it is used in addition to the legally required information as explained above then sufficient detail must be given to enable effective management of the risk and the context and limitations of the specific control banding recommendation must be made clear.

## 8.2 Exposure controls

**Text Annex II**

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 Articles 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

89 See: ilo.org/legacy/english/protection/safework/ctrl_banding/whatis.htm.

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 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.

"Exposure control" should here be taken to mean all protective measures and precautions to be taken during use of the substance or mixture in order to minimise worker and environmental exposure. Therefore any information available concerning workplace exposure should be indicated in this subsection, unless it is included in an attached exposure scenario in which case reference to it should be made.

Where design regulations concerning technical facilities are required for exposure control in addition to the guidance provided in Section 7." Handling and storage" they should be amended in the form of "Additional guidance on the design of technical facilities".

This subsection can include cross-references to the information provided in Section 7 of the SDSs "Handling and storage" if appropriate.

**Appropriate engineering controls** (point 8.2.1 in legal text above)

Information should be given in subsection 8.2 of the SDS which aids an employer in developing the required risk management and risk reduction measures according to his obligations under Directives 98/24/EC and 2004/37/EC[90] concerning the design of appropriate working methods and technical control facilities as well as the use of suitable work equipment and materials, based on the identified uses (subsection 1.2 of the SDS). These include, for example the implementation of means of collective protection at the hazard source, and of individual protective measures including the provision of personal protective equipment.

Suitable information on these measures must be provided to enable a proper risk assessment to be carried out under Article 4 of Directive 98/24/EC. This information should be consistent with that given in subsection 7.1 of the SDS. If one or more exposure scenario(s) is/are attached to the SDS for a substance then the information given should also be consistent with that given in the ESs. In the case of mixtures the information given should reflect a consolidation of the information for components.

**Personal Protection** (point 8.2.2 in legal text above)

It is a requirement that detailed specifications of equipment which provides adequate and suitable protection be given where personal protection is needed, taking into account Directive 89/686/EEC[91] and referring to relevant CEN standards.

The equipment must be specified in sufficient detail (e.g. in terms of kind, type and class) to ensure that it will provide adequate and suitable protection during the foreseen uses.

---

90 Corrigendum to Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual

Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (codified version) OJ L 229, 29.6.2004, p. 23.

91 Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to personal protective equipment OJ L 399, 30.12.1989, p. 18.

A useful source of such information may be the suppliers or manufacturers of protection equipment who may have help-lines or websites available.

Note that detailed requirements given in the legal text are not re-quoted in full below unless further clarification is being given.

### Eye/face protection

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

### Skin protection

Information on skin protection may be sub-divided into (i) "hand protection" and ii) "other" (along the lines suggested by the legal text, which requires both to be included if necessary). In this context it should be noted that "skin, other" is covered by "body protection" as a subsection of the information on skin protection, unless otherwise specified.

Again the equipment must be specified based on hazard and potential for contact and potential duration and amount of exposure.

It should be noted that when calculating the maximum time that skin protection (e.g. gloves) can be worn it is necessary to take into account the maximum time of exposure to the relevant substance(s) and not simply the total working time.

In some cases, reference to gauntlets (i.e. gloves with an extended cuff covering part of the forearm) may need to be included. Note that in this case, since protection is additionally given to a part of the body other than the hand itself, this would be under the "other" sub-division of this subsection.

### Respiratory protection

Specify the type of protective equipment to be used, such as self contained breathing apparatus or respirator, including the type of filter needed. It is recommended that information on the assigned protection factor (APF) that should be used in the particular scenario be given, if available. It should be noted that filter masks may be of limited use in cases of high or unknown exposure.

### Environmental Exposure Controls (point 8.2.3 in legal text)

This subsection includes the information required by the employer to fulfil his obligations under environmental protection legislation. If appropriate, a reference to SECTION 6 of the SDS may be included[92].

92 Note that the measures to be described under subsection 8.2 are those to be implemented under normal operation, whereas those in SECTION 6 are for accidental release. They may therefore be very different.

An example of how the structure of this subsection could look is given below[93]:

8.2 Exposure controls

8.2.1 Appropriate engineering controls:

Substance/mixture related measures to prevent exposure during identified uses:

Structural measures to prevent exposure:

Organisational measures to prevent exposure:

Technical measures to prevent exposure:

8.2.2 Personal protection equipment:

8.2.2.1Eye and face protection:

8.2.2.2Skin protection:

Hand protection:

Other skin protection:

8.2.2.3Respiratory protection:

8.2.2.4Thermal hazards:

8.2.3 Environmental exposure controls:

Substance/mixture related measures to prevent exposure:

Instruction measures to prevent exposure:

Organisational measures to prevent exposure:

Technical measures to prevent exposure:

## 4.9 SDS SECTION 9: Physical and chemical properties

**Text Annex II**

[Until 1 June 2015: *"This section of the safety data sheet shall describe the empirical data relating to the substance or mixture, if relevant."*]

[From 1 June 2015: *"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*

93 Please note that numbering below the level of the subsection 8.2 is in the example is **not** a legal requirement – it has been inserted for clarity. See also note in chapter 3.6 of this guidance on numbering of subsections.

*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.*

It is thus a primary requirement that the information in this section be consistent with the information provided in the registration dossier and in the CSR where required, and also with the classification of the substance or mixture – it should therefore support any transport classification given in Section 14 as well as the classification and labelling information in Section 2.

In the context of deciding whether specific information should appear in Section 9 or Section 10 of the SDS, historically the practice has been for Section 9 to contain numerical (measured) values for physical and chemical properties, whereas Section 10 should give a description of the intrinsic (qualitative) properties (including potentially hazardous interactions with other substances) that result from (or are related to) these values.

The requirement that *"this section of the SDS shall describe the empirical data of the substance or mixture, if relevant"* should be interpreted to mean that values which are likely to be within a range relevant to the classification and the hazards of a substance or mixture should be given in this section. Thus, for example, the flash point of a volatile organic liquid that is likely to be classified as flammable should be given, whereas there is no need to determine this for a high melting-point solid. Where any statement is made to indicate that a particular property does not apply this should be based on a clear lack of relevance, the reason for which should be stated if not obvious, and not on the absence of information. A clear differentiation should also be made between cases where no information is available to the compiler (e.g. "no information available"), and cases where actual negative test results are available.

The data should preferably have been generated in accordance with the test methods referred to in the REACH Regulation, transport provisions or international principles or procedures for the validation of information, so as to ensure quality and comparability of the results and consistency with other requirements at international or Community level. Where this information is available from testing for the purposes of a REACH registration or to determine classification under CLP this will be an ideal basis to ensure the required consistency.

As specified in the relevant test methods, critical information such as test temperature and methods used, which affect the value of physical-chemical properties and safety characteristics, should be provided for all test results and, if available, for data acquired from the literature.

For mixtures, where information does not apply to the mixture as a whole the entries must clearly indicate to which substance in the mixture the data apply.

## 9.1 Information on basic physical and chemical properties

**Text Annex II**

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;

(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.

(Note: further notes on the legal text requirements are only given below where the legal text above is not considered to be fully self-explanatory)

For further information on the determination of physical and chemical properties in the context of classification and labelling see the *Guidance on the Application of the CLP Criteria* at: http://echa.europa.eu/clp/clp_help_en.asp

**a) Appearance**

In describing "granulometry" further available and appropriate information on properties referred to in the OECD-WPMN of nanomaterials such as size and size distribution, shape, porosity, pour density, aggregation/agglomeration state, morphology, surface area ($m^2$/mass), surface charge/zeta potential and crystalline phase should be taken into account. The available and appropriate information on the specific surface area refers to the specific surface area by volume which is derived as a ratio of the surface area by mass and the relative density can be added here where considered to be relevant. In particular this subsection may be used to indicate substances or mixtures that have nanoforms put on the market. If the substance is supplied as nanomaterial, this may be indicated in this subsection. E.g. physical state: solid (nanomaterial).

(Note that the inclusion of granulometric and specific surface area by volume information in subsection 9.1 is a new requirement of the amended Annex II). Further guidance in regards to the respective parameters listed above can be found in the OECD-WPMN first revision of the Guidance Manual for the Testing of Manufactured Nanomaterials (ENV/MONO(2009)20/REV), at: oecd.org/env/ehs/nanosafety/publicationsintheseriesonthesafetyofmanufacturednanomaterials.htm.

Although it is a requirement that the colour of the substance or mixture as supplied be indicated, the term "various" or "diverse" is acceptable if stated for a group of products which are all covered by the same SDS; for example, in the case of varnishes with different colours but otherwise having the same classification and labelling.

**b) Odour**

If odour is perceptible, a brief description of it must be given.

Phrases like "characteristic" or "typical" should ideally not be used here, since they add no value to anyone who does not already know the odour of the substance.

(Note that the inclusion of odour information in subsection 9.1 is a new requirement of the amended Annex II)

**c) Odour threshold**

(New requirement of the amended Annex II)

**d) pH**

**e) Melting point / freezing point**

**f) Initial boiling point and boiling range**

**g) Flash point**

**h) Evaporation rate**

(New requirement of the amended Annex II)

**i) Flammability (solid, gas)**

**j) Upper/lower flammability or explosive limits;**

(New requirement of the amended Annex II)

**k) Vapour pressure;**

An indication of the temperature at which this was measured should be given (at … °C);

It should be stated whether the value indicated has been measured or calculated, and (in the case of mixtures) to which substance(s) it refers.

**l) Vapour density;**

**m) Relative density;**

An indication of the temperature at which this was measured should be given (at … °C);

For gases: Relative density (air = 1).

The bulk density of solids may be specified additionally/alternatively under this heading.

**n) Solubility(ies)**

In the case of mixtures which are composed of component substances with different solubility in specific solvents for which information is given, additional explanation may be necessary.

(Note that this section now merges the previously separate “Solubility” and “Water Solubility” of the original Annex II).

**o) Partition coefficient: n-octanol/water**

For mixtures, this is useful information with respect to the individual component substances only.

**p) Auto-ignition temperature**

(New requirement of the amended Annex II)

**q) Decomposition temperature**

(New requirement of the amended Annex II)

**r) Viscosity**

For certain product groups it may be appropriate to provide data concerning the viscosity (dynamic viscosity in mPas or kinematic viscosity in $mm^2/s$) or the flow times (in s) including the measurement temperature.

For mixtures containing hydrocarbons in an overall concentration of 10% or more, the flow time or the kinematic viscosity at 40 °C should be specified in accordance with Section 3.10 of Annex I to the CLP Regulation in order to allow an assessment of possible aspiration hazard.

(Information on viscosity in subsection 9.1 is a new requirement of the amended Annex II)

**s) Explosive properties;**

**t) Oxidising properties**

**9.2 Other information**

| Text Annex II |
| --- |
| 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. |

Further guidance in regard to appropriate and available information in view of nanomaterials put on the market and their redox potential, radical formation potential and photocatalytic properties can be found from the OECD-WPMN first revision of the Guidance Manual for the Testing of Manufactured Nanomaterials (ENV/MONO(2009)

20/REV (in particular in its Annex II), available at: http://www.oecd.org/science/nanosafety/publicationsintheseriesonthesafetyofmanufacturednanomaterials.htm.

This section needs to be checked for consistency with the following sections:

- SECTION 2: Hazards identification
- SECTION 5: Fire fighting measures
- SECTION 6: Accidental release measures
- SECTION 7: Handling and storage
- SECTION 11: Toxicological information: (i.e. extreme pH/corrosive properties)
- SECTION 12: Ecological information: (i.e. log Kow / bioaccumulation)
- SECTION 13: Disposal considerations
- SECTION 14: Transport information

## 4.10 SDS SECTION 10: Stability and Reactivity

| Text Annex II |
| --- |
| 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. |

Stability and reactivity are a function of the physical and chemical properties measured to determine values quoted in Section 9 of the SDS. However, although not explicitly stated in the Regulation, historically the practice has been to use Section 9 to indicate measurable properties derived from test procedures whereas Section 10 gives (qualitative) descriptions of possible consequences. Thus, as already explained in sub-chapter 4.9, Section 9 invites information on “properties” or “parameters” whereas Section 10 specifies that a “description” should be given.

Similarly some information may also be given in Section 7 of the SDS (e.g. on incompatibilities in sub-section 7.2). In such cases repetition may be avoided by cross-references, with the content of Section 10 focusing on **description** of hazards and their consequences. Where information is correctly already inserted in a different section of the SDS a cross-reference to it can be made without the need to repeat it. Thus, for example, certain information on hazard classes is included in Section 9 or Section 7. Additionally, information on protection measures is given under sub-section 8.2. “exposure controls”. Therefore a lot of information relevant to Section 10 may already be given in other sections.

As the information must be written in a clear and concise manner, repetitions should be avoided.

### 10.1 Reactivity

| Text Annex II |
| --- |
| 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.<br><br>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. |

[The text above is considered as needing no further explanation]

### 10.2 Chemical stability

| Text Annex II |
| --- |
| 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. |

Examples of common standard phrases which may be used in this subsection for stable substances or mixtures include:

- “Under storage at normal ambient temperatures (minus 40° C to + 40° C), the product is stable.”
- “No hazardous reaction when handled and stored according to provisions.”
- “No known hazardous reactions”

### 10.3 Possibility of hazardous reactions

| Text Annex II |
| --- |
| 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. |

Note that information e.g. on dust explosion hazard is given in sections 2 and 9, and there is therefore a need to check for consistency/potential overlap.

There is also potential overlap between subsection “10.1 Reactivity” which also relates to reactivity hazards and the present 10.3 “Possibility of hazardous reactions”. Entry of information in sub-section 10.3 may be restricted to hazardous outcomes resulting from

specific reactivity. Thus clearly, for example, a substance may be described as a strong acid in sub-section 10.1 which implies e.g. an intrinsic risk of hazardous reaction with bases. Sub-section 10.3 may be reserved for the specific outcomes of reactivity listed (polymerisation leading to excess pressure or heat and for information on reaction conditions. There is no need to duplicate content in both sub-sections.

### 10.4 Conditions to avoid

| Text Annex II |
| --- |
| 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. |

The content of this subsection potentially overlaps with subsection 7.2*"Conditions for safe storage, including any incompatibilities"* and there is therefore a need to check for consistency/potential overlap,

The advice provided must be consistent with the physical and chemical properties described in Section 9 of the SDS. If relevant, advice must 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) anti-oxidants.

(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

### 10.5 Incompatible materials

| Text Annex II |
| --- |
| 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. |

Note that it is not necessarily good practice to give a long list of “incompatible materials” which includes many substances with which the product is unlikely ever to come into contact. A balance should be sought between diluting the message about relevant incompatibilities with too long a list and the potential risks from omission of a specific incompatible material. Use of substance types or classes (e.g. “aromatic solvents”) rather than listing individual substances may be preferable and can avoid long lists of individual substances.

The content of this subsection potentially overlaps with elements dealing with handling of incompatible substances and mixtures within subsection 7.1 “Precautions for safe handling” and there is therefore a need to check for consistency/potential overlap.

### 10.6 Hazardous decomposition products

| Text Annex II |
| --- |
| 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. |

The possibility of degradation to unstable products should be addressed in this sub-section.

Examples of common standard phrases which may be used where appropriate in this subsection for stable substances or mixtures include:

- "Does not decompose when used for intended uses."
- "No known hazardous decomposition products."

An example of how the structure of this section could look is given below:

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

This section needs to be checked for consistency in particular with the following sections;

- Section 2 Hazards identification
- Section 5 Fire fighting measures
- Section 6 Accidental release measures
- Section 7 Handling and storage
- Section 13 Disposal considerations

## 4.11 SDS SECTION 11: Toxicological information

**Text Annex II**

*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.*

[Until 1 June 2015: *"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 sensitization;*

*(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"*]

[From 1 June 2015:

*"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 sensitization;*

*(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 related to the intended uses specified in Subsection 1.2. The first symptoms at the lowest 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."*]

Please note: Although much of the content of subsection 11.1 is the same in the version of Annex II applicable from 1 December 2010 to 1 June 2015 as that applicable from 1 June 2015 there are significant differences in the structure of the layout of the text (as shown in the box above). These differences result from the different treatment of substances and mixtures in the two texts. In the earlier text the two are treated separately as they have different applicable requirements (for example STOT-single and repeated exposure and aspiration hazard do not have to be taken into account for mixtures before 1 June 2015, whereas these requirements are the same for substances and mixtures thereafter).

This section is of great importance during the process of compilation of an SDS as it should reflect the information gathered and conclusions arrived at during the assessment of the substance or mixture for the purposes of determining its hazards and consequent classification and labelling.

It follows from the introductory text to Section 11 that, for mixtures containing substances subject to registration the information given in this section for such substances should also be consistent with that given in the relevant registrations for the individual substances.

Since a large quantity of information may need to be provided under this section, particularly in an SDS for a mixture, it is advisable to arrange its layout in such a way that a clear separation is established between the data that apply to a mixture as a whole (where applicable) and that for individual (component) substances. Information concerning the different hazard classes should be clearly and separately reported.

Clear and concise presentation of key information and critical studies provided can, for example, be achieved by using text boxes or tables.

If no data are available for certain hazard classes or differentiations the reasons for the absence of data should be given[94].

94 As required by point 11.1.3 of the legal text quoted above from 01 December 2010 (corresponding to point 11.1.1 of the further text in force from 01 June 2015 also quoted).

Note that for the requirements given under points 11.1.10 (of text applicable to 15 June 2015; [11.1.8 of text from 15 June 2015]) the phrase *"if relevant and available"* in the context of information on interactive effects is to be understood as meaning that the compiler of the SDS is expected to make a reasonable search for such information if he does not have it already.

## TOXICOLOGICAL (HEALTH) EFFECTS

In this subsection of the SDS the potential adverse health effects/symptoms after exposure to the substance, mixture and known by-products must be described. The symptoms caused by the physical, chemical, and toxicological characteristics of the substance or mixture must be listed. Symptoms occurring after exposure should be arranged in a sequential order of exposure levels (either from high to low or from low to high), indicating if occurrence of the effects is immediate or delayed.

## FOR SUBSTANCES

Information (such as for example key results) must be provided, for the relevant hazard classes or differentiations, as specified in the legal text quoted above. This should be separated according to the route of exposure, species (rat, mouse, human …), and study duration and study method. In the case of information on specific target organ toxicity (STOT), the information should obviously include indication of the specific target organ. If data are not available for a specific substance and read-across or QSAR's are applied this should be clearly mentioned. For substances subject to registration brief summaries of the information derived from application of Annex VII to XI (to REACH – i.e. of the results of testing (including non-animal testing) or other alternative means of generating information required for registration purposes) must be given with a short reference, where appropriate, to the test methods used.

It should be noted that it is a requirement that other relevant information on adverse health effects **must** be included even when not required by the classification criteria.

## FOR MIXTURES

For mixtures, it should be noted that the requirements for information are different according to Annex I and Annex II of Commission Regulation (EU) No. 453/2010 (i.e. the versions of Annex II of REACH in force from 1 December 2010 and that in force from 1 June 2015). Until 1 June 2015 it is information on **relevant effects** (based on DPD), as listed above, which must be provided. From 1 June 2015 the **relevant hazard classes** (based on CLP) for which information must be provided are the same as for substances (indeed the corresponding legal text no longer differentiates between the requirements for substances and mixtures with respect to these hazard classes). However it should be noted that in the case of mixtures for which relevant information on the component substances is available (e.g. LD50, acute toxicity estimates (ATE), LC50) this must also be provided **in addition to** information applying to the mixture as placed on the market.

For further information on how mixtures should be classified reference should be made to the CLP regulation itself (in particular Article 6 of CLP).

When a mixture has been classified according to CLP using an Acute Toxicity Estimate (ATE), the value of the calculated $ATE_{mix}$ should be included in this subsection, for example using a structure as follows:

| | | |
|---|---|---|
| $ATE_{mix}$ (oral) | = | xxx mg/kg |
| $ATE_{mix}$ (dermal) | = | yyy mg/kg |
| $ATE_{mix}$ (inhal.) | = | z mg/l/4 h (vapours) |

If information on the mixture itself is not available for a certain hazard class or differentiation but several substances in it have the same health effect, this effect may be mentioned for the mixture and not for the individual substances.

In the absence of specific data on the mixture regarding interactions between component substances, assumptions must **not** be made and instead the relevant health effects of each substance must be listed separately (see Annex II point 11.1.12.2.)

It should be noted that, as for substances, it is a requirement that other relevant information on adverse health effects **must** be included even when not required by the classification criteria.

This section needs to be checked for **consistency** in particular with the following sections:

- Section 2 Hazards identification
- Section 4 First aid measures
- Section 6 Accidental release measures
- Section 7 Handling and storage
- Section 8 Exposure controls/personal protection
- Section 9 Physical and Chemical properties
- Section 13 Disposal considerations
- Section 14 Transport information
- Section 15 Regulatory information

An example of how the structure of this section could look for the case of a substance is given below:

SECTION 11: Toxicological information

11.1 Information on toxicological effects

- Acute toxicity:
- Skin corrosion/irritation:
- Serious eye damage/irritation:
- Respiratory or skin sensitisation
- germ cell mutagenicity;
- carcinogenicity;
- reproductive toxicity;
- Summary of evaluation of the CMR properties;
- STOT-single exposure;
- STOT-repeated exposure;
- aspiration hazard:

Within each of the above relevant hazard classes the sub-structure could then be as follows, using the entry for Acute Toxicity as an example:

11.1.1[95] Acute Toxicity:

Method:

Species:

Routes of exposure:

Effective Dose:

Exposure time:

Results:

In the case of mixtures the structure can be similar to that given above for a substance, but it should be made clear whether data that is given apply to the mixture or its components.

95 Note that additional numbering and sub-structuring below the subsection level is not a legal requirement.

## 4.12 SDS SECTION 12: Ecological information

**Text Annex II**

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.

No further clarification considered necessary (see General comments on entries in Section 12 as a whole at the end of this section)

### 12.1 Toxicity

**Text Annex II**

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 micro-organisms, 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.

No further clarification considered necessary (see General comments on entries in Section 12 as a whole at the end of this section)

### 12.2 Persistence and degradability

**Text Annex II**

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.

No further clarification considered necessary (see General comments on entries in Section 12 as a whole at the end of this section)

### 12.3 Bioaccumulative potential

**Text Annex II**

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.

No further clarification considered necessary (see General comments on entries in Section 12 as a whole at the end of this section)

### 12.4 Mobility in soil

**Text Annex II**

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.

No further clarification considered necessary (see General comments on entries in Section 12 as a whole at the end of this section)

### 12.5 Results of PBT and vPvB assessment

| Text Annex II |
| --- |
| 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. |

It should be noted that it is not necessary to give detailed information on the data used to come to the conclusion about the PBT or vPvB properties, particularly where the conclusion is that the product does not have these properties. A simple statement to this effect should suffice, for example:

*"According to the results of its assessment, this substance is not a PBT or a vPvB"* or

*"This mixture does not contain any substances that are assessed to be a PBT or a vPvB"*

However, where the criteria for PBT are met it is recommended to briefly indicate here the reasons for which they are met as part of the results of the assessment which must in any case be given.

### 12.6 Other adverse effects

| Text Annex II |
| --- |
| 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. |

### General comments on entries in Section 12 as a whole

When preparing SDS for mixtures, it needs to be clear whether the data applies to the ingredients or to the mixture in its totality.

Particular attention needs to be paid when the mixture as a whole has been tested to determine its aquatic toxicity, in such a case adequate acute toxicity $LC_{50}$ or $EC_{50}$can be used to determine acute hazard according to the criteria that have been agreed for substances, but not for long-term hazard. It is not possible to apply acute toxicity in combination with environment fate test data (degradability and bioaccumulation) for long-term hazard classification because the data from degradability and bioaccumulation tests of mixtures cannot be interpreted; they are meaningful only for single substances (See CLP Regulation points 4.1.3.3.1. and 4.1.3.3.2.).

Commission Regulation (EU) No 286/2011[96] amending CLP also allows for the

96 Commission Regulation (EU) No 286/2011 of 10 March 2011, amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures, O.J. L83, 30.03.2011 p1.

classification of mixtures for long-term hazard based on adequate chronic toxicity data (see point 4.1.3.3.4. of the amending regulation). For further information on classification of mixtures for environmental hazards, see the (draft update) to the ECHA *Guidance on the Application of the CLP Criteria*[97].

When writing this section, it should be specified whether the mentioned data originates from testing results or bridging rules.

This section needs to be checked for consistency in particular with the following sections:

- SECTION 2 Hazards identification
- SECTION 3 Composition/information on ingredients
- SECTION 6 Accidental release measures – (i.e. precautions for environmental protection)
- SECTION 7 Handling and storage – (i.e. measures to prevent emissions (filters…))
- SECTION 9 Physical and Chemical properties – (i.e. log Kow, miscibility)
- SECTION 13 Disposal considerations
- SECTION 14 Transport information
- SECTION 15 Regulatory information

An example of how the structure of this section could look is given below:

SECTION 12: Ecological information

12.1 Toxicity

Acute (short-term) toxicity:

Fish:

Crustacea:

Algae/aquatic plants:

Other organisms:

Chronic (long-term) toxicity:

Fish:

Crustacea:

Algae/aquatic plants:

Other organisms:

97 Available at: guidance.echa.europa.eu/guidance4_en.htm (page 145 on "4.1.4.3 Classification criteria for mixtures hazardous to the aquatic environment based on test data on the mixture as a whole".

12.2 Persistence and degradability

Abiotic Degradation:

Physical- and photo-chemical elimination:

Biodegradation:

12.3 Bioaccumulative potential

Partition coefficient n-octanol /water (log Kow):

Bioconcentration factor (BCF):

12.4 Mobility in soil

Known or predicted distribution to environmental compartments:

Surface tension:

Adsorption/Desorption:

12.5 Results of PBT and vPvB assessment

12.6 Other adverse effects

12.7 Additional information

## 4.13 SDS SECTION 13: Disposal considerations

**Text Annex II**

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 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.

To ensure that risks are adequately controlled at the waste stage, disposal must be in accordance with current applicable laws and regulations and material characteristics at the time of disposal. It should be kept in mind that insofar as the substance becomes a waste, REACH ceases to apply and waste legislation becomes the correct legal framework within which to operate.

If the treatment of the substance or mixture at the waste stage (surplus or waste

resulting from the foreseeable use) presents a hazard, a description of the hazards arising and information on how to ensure safe handling should be given.

The appropriate treatment methods for both the substance or mixture waste itself and (where applicable) for any contaminated packaging waste (including nominally "empty" but un-cleaned packaging waste which still contains some of the substance or mixture) should be indicated, taking into account the waste hierarchy as defined in the Waste Framework Directive (i.e. preparation for re-use; recycling; other recovery, e.g. energy recovery; disposal).

Where other recommendations are applicable to the disposal of the substance or mixture used for its intended purpose, these recommendations may be quoted separately.

Where the use recommended by the distributor permits prediction of the origin of the waste it may be considered desirable to specify the relevant List of Wastes (LoW) Code[98].

### 13.1 Waste treatment methods

**Text Annex II**

(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.

It should be noted that the phrase *"Sewage disposal shall be discouraged"* in the legal text above (which is carried-over from the GHS text) is of course intended to indicate that disposal of the substance or mixture into sewerage systems is to be discouraged, rather than disposal of sewage per se as a literal reading might imply. This requirement to positively discourage can, for example, be implemented by including a phrase such as *"Waste should*[99] *not be disposed of by release to sewers".*

Suitable means for neutralising or deactivating product residues and waste may be specified. Special risks to safety, health or the environment that can arise when handling

98 The European Waste Catalogue (EWC) was replaced by a combined European List of Wastes (LoW) via the Commission Decision of 3 May 2000 replacing Decision 94/3/EC establishing a list of wastes pursuant to Article 1(a) of Council Directive 75/442/EEC on waste and Council Decision 94/904/EC establishing a list of hazardous waste pursuant to Article 1(4) of Council Directive 91/689/EEC on hazardous waste (OJ L 226, 6.9.2000, p. 3).

99 "should" is used here rather than "must" since the legal text requires such disposal to be discouraged, not for it to be prohibited.

waste should be specified, e.g. risk of self ignition arising from interaction with certain materials.

Means of handling waste from used product or contaminated packaging waste which are known to be unsuitable should be stated if applicable.

Relevant information (e.g. the related H-codes as defined in Annex III "Properties of waste which render it hazardous" of Directive 2008/98/EC[100]) may be given to indicate whether or not any remaining quantities of unused substance or mixture are to be regarded as hazardous waste. Where this is done it should be made clear to recipients that where additional contaminants may be present as a result of the use of the substance/mixture they will need to be taken into account and assigned any additional H-codes applicable.

Local, national and European waste management legislation for the particular form of containment used must be complied with.

It should be noted that final decisions on the appropriate waste management method, in line with regional, national and European legislation, and possible adaptation to local conditions, remains the responsibility of the waste treatment operator.

An example of how the structure of this section could look is given below[101]:

SECTION 13: Disposal considerations

13.1 Waste treatment methods

13.1.1 Product / Packaging disposal:

Waste codes / waste designations according to LoW:

13.1.2 Waste treatment-relevant information:

13.1.3 Sewage disposal-relevant information:

13.1.4 Other disposal recommendations:

100 Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives.

101 Note that additional numbering and sub-structuring below the subsection level is not a legal requirement.

## 4.14 SDS SECTION 14 Transport Information[102]

**Text Annex II**

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 Regulations: European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR)[103], Regulations concerning the International Carriage of Dangerous Goods by Rail (RID)[104], European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways (ADN)[105], 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[106], International Maritime Dangerous Goods (IMDG Code[107]) (sea), and Technical Instructions for the Safe Transport of Dangerous Goods by Air (ICAO-TI)[108] (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 Regulations as mentioned above shall be provided.

14.2. UN proper shipping name

The UN proper shipping name from the Regulations as mentioned above shall be provided.

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 Regulations as mentioned above shall be provided.

14.4. Packing group

The packing group number from the Regulations as mentioned above 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

---

102PLEASE NOTE THAT WHERE FOOTNOTES (SUCH AS THOSE BELOW HERE) ARE GIVEN AS PART OF THE QUOTED ORIGINAL LEGAL TEXT THEY ARE REPRODUCED IN THEIR ORIGINAL FORM, EVEN WHERE UPDATES TO THE DOCUMENTS CITED MAY ALREADY BE AVAILABLE.

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

104 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.

105 Version as revised as of 1 January 2007.

106 OJ L 260, 30.9.2008, p. 1.

107 International Maritime Organisation, 2006 edition, ISBN 978-92-8001-4214-3.

108 IATA, 2007-2008 edition.

the criteria of Regulations as mentioned above and e.g. marine pollutant according to the IMDG Code. If authorized 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)[109] and the International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk (International Bulk Chemical Code) (IBC Code)[110].

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[111]. Ship type required and pollution category shall be indicated.

It should be noted with respect to the air transport information that the IATA Dangerous Goods Regulations (IATA DGR) incorporate all the requirements of the ICAO (in fact the footnote in the legal text currently refers to an IATA publication rather than an ICAO original).

Information is specifically required on UN number, proper shipping name, transport Hazard Classes, Packing group, Environmental Hazards, Special precautions for users and information on transport in bulk by sea when applicable.

In practice, additional information which would normally be included in this Section could include:

- For ADR/RID/ADN: Digit of the hazard labels (main hazard and sub hazard if existing), classification code in case of class 1.
- For ADN tank vessels: The digits of the hazard labels and hazard Codes as shown in column 5 of table C in ADN chapter 3.2
- For IMDG Code: Class and subsidiary risks (and indication of marine pollutant if applicable).
- For ICAO-TI /IATA-DGR: Class and subsidiary risk.

Where information on "Special precautions for user" that would otherwise appear in sub-section 14.6 is already given elsewhere in the SDS a cross-reference to its location may

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

110 IBC Code, 2007 edition, London, IMO 2007, ISBN 978-92-801-4226-6.

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

be made to avoid repetition. (A subsection may not simply be left empty).

In addition, other applicable information (e.g. transport category; tunnel restriction code in accordance with ADR/RID, segregation group according to IMDG chapter 5.4.1.5.11.1 as well as special provisions, exemptions (viscous substances, multilateral agreements, etc.) might be useful if appropriate and if documentation is relevant. Where such additional information is provided which goes beyond the actual requirements of the legislation the compiler should be confident that he will be able to keep it current. Otherwise reference can be made to the relevant effective amendments of the full text of the applicable regulations.

Guidance on transport information is only relevant for tank-vessel carriage according to ADN. According to ADN, extended classification criteria are required for liquids carried in tank vessels, e.g. for Environmental hazards the GHS criteria acute 2, acute 3 and chronic 3. This information is only relevant for bulk liquids filled into cargo tanks of tank vessels and classified as dangerous according the ADN criteria.

If applicable, this extended classification information is included as hazard code(s) in the dangerous goods description according to ADN 5.4.1.1.2, e.g.

*UN 1114 BENZENE, 3 (N3, CMR), II*

For materials only intended to be carried in packages or tanks (tank containers or tank vehicles), indication of classification for tank-vessels only is not necessary.

**Additional information IMDG:**

According to section 5.4.1.5.11.1 of the IMDG Code, the segregation group needs to be indicated for substances which belong - in the opinion of the consignor - to one of the segregation groups named in 3.1.4.4, but are classified under a “Not otherwise specified” (“N.O.S.”) entry not included in the list of substances listed under this segregation group[112].

**Further information on transport in bulk and on the IBC Code:**

The IBC Code provides an international standard for the safe carriage by sea of marine pollutant, dangerous and noxious liquid chemicals[113] in bulk tankers.

Only substances named in the IBC Code or intended to be included in the IBC Code are allowed to be shipped in bulk tankers. Therefore, this information is only necessary for substances which are intended to be carried in bulk tankers.

Where a product was not classified to be a dangerous good for any mode of transport, this condition may also be indicated under the “other relevant information” heading; the

112 There is, however, no explicit requirement under REACH to transfer this segregation group information to the SDS, although it may be desirable to do so.

113 The IBC code specifically deals with **liquid** cargoes. The International Maritime Solid Bulk Cargoes (IMSBC) Code which was adopted in December 2008 by IMO resolution MSC.268(85) and whose application has been recommended since 1 January 2009, deals with **solid** cargoes. Some of its provisions have been in force since 1 January 2011, but information on these is not yet required in SDSs according to REACH. Information on these provisions could be given on a voluntary basis either within this subsection 14.7 or elsewhere in the SDS (e.g. in Sections 15 or 16).

classifications structured according to mode of transport will not be necessary in this case. Besides, special handling methods may be indicated here.

An example illustrating the required subsection headings for Section 14 is given below:

"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"

Note that if it is not intended that the substance/mixture be transported in bulk a statement to this effect should be made under subsection 14.7 as (like all subsections) it should not be left completely blank.

## 4.15 SDS SECTION 15: Regulatory information

| Text Annex II |
| --- |
| 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[114] of the European Parliament and of the Council of 29 June 2000 on substances that deplete the ozone layer , 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 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 ). |

114 [N.B. This footnote is **NOT** part of the legal text quoted above] Regulation (EC) No 2037/2000 was repealed as of 1 January 2010 and recast as regulation (EC) 1005/2009 (O.J. l286/1 31.10.2009).

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

**Text Annex II**

Information regarding relevant Community safety, health and environmental provisions (for example Seveso category/named substances in Annex I of Directive 96/82/EC) 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.

In addition to the information on specific provisions and regulations given in the legal text above the following type of information may be included in this subsection (this is a non-exhaustive list):

- national laws of the relevant Member States which implement provisions such as the young worker directive and directive on pregnant workers, since these may require that that young workers or pregnant workers do not work with certain substances and mixtures;
- information from the plant protection and biocides legislation, such as approval/authorisation status/numbers, additional labelling information from the specific legislation;
- information on applicable elements of the Water Framework Directive;
- information on EU Directive(s) related to Environmental Quality Standards (EQS) - e.g. Directive 2008/105/EC[115] – where applicable;
- for paint and varnish products, if applicable a reference to Directive 2004/42/EC[116] on the limitation of emissions of volatile organic compounds may be included here;
- for detergents, the ingredient declaration according to the Detergent Regulation 648/2004/EC[117] (if not already given in subsection 3.2);

115 Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy, amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive 2000/60/EC of the European Parliament and of the Council (O.J. L 348/84 24.12.2008, pages 84-97).

116 Directive 2004/42/EC of the European Parliament and of the Council of 21 April 2004 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC (O.J. L 143/87 30.4.2004, pages 87-96).

117 Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents (O.J. L 104/1 8.4.2004, pages 1-35).

- 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;
- national laws of the relevant Member States which implement these provisions;
- any other national measures that may be relevant e.g. such as (this is a non-exhaustive list):

**In Germany:**

i. Water hazard classes (Wassergefährdungsklassen)

ii.Technical instruction air (TA-Luft)

iii.Technical rules for dangerous substances (TechnischeRegelnfürGefahrstoffe)

**In France:**

i. tableaux de maladies professionnelles

ii. nomenclature des installations classées pour la protection de l'environnement

**In the Netherlands:**

i. Lijst van kankerverwekkende, mutagene, en voor de voortplantinggiftigestoffen SZW.

ii. De Algemenebeoordelingsmethodiek Water (ABM)

iii. De NederlandseEmissierichtlijn (NeR)

**In Denmark:**

Lister over stofferog processer, der anses for at værekræftfremkaldende

## 15.2 Chemical Safety Assessment

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

An example of how the structure of this section could look like is given below:

SECTION 15: Regulatory Information

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

EU regulations

Authorisations and/or restrictions on use:

Authorisations:

Restrictions on use:

Other EU regulations:

Information according 1999/13/EC about limitation of emissions of volatile organic compounds (VOC-guideline)

National regulations (Germany):

Restrictions of occupation:

Störfallverordnung (12.BImSchV):

Wassergefährdungsklasse (water hazard class):

TechnischeAnleitungLuft (TA-Luft):

Other regulations, restrictions and prohibition regulations:

15.2 Chemical Safety Assessment:

No Chemical Safety Assessment has been carried out for this substance/mixture by the supplier.

## 4.16 SDS SECTION 16: Other information

**Text Annex II**

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.

This section must be used to include any additional relevant information, of the types listed in the legal text above that has not already been included in any of the previous Sections.

This section may additionally include an index table or table of contents for the attached exposure scenarios. If this is included here, a reference to it can be introduced in sub-section 1.2.

In the case of mixtures, details must be provided here on the basis used to determine the classification of the mixture for the hazard classes where the classification criteria are met and where the classification(s) has been given under sub-sections 2.1 or 3.2 without the method used to derive it/them[118]. It is not necessary to list the basis for determining that a mixture does not meet the classification criteria for a particular hazard class. The example structure including the table below provides an example of how this information may be presented. Note that elements of information concerning the classification assigned and the procedure used to derive it, given in the heading and in the table under SECTION 16 bullet (iv) within the example below, could alternatively be placed in SECTION 2 of the SDS.

If companies wish to include disclaimers in the SDS, these may be placed in SECTION 16, or alternatively be placed outside any of the defined Sections to make clear that they are not part of the specified format and content.

Examples of possible disclaimers are:

- This information is based upon the present state of our knowledge
- This SDS has been compiled and is solely intended for this product

Note that in the particular case of SECTION 16 there are **no** specified subsection numbers or titles in Part B of Annex II. Any additional numbering and sub-structuring within this SECTION is at the compiler's discretion and not a legal requirement.

An example of how the structure of this SECTION could look is given below. The example is populated (under point (iv) only) to illustrate both a possible layout and content of the sub-structuring of the information on classification and procedure for classification of a simple mixture (e.g. an aqueous solution) within this SECTION.

118 If both the relevant classifications and the methods used to derive them have already been given elsewhere in the SDS then this information need not be duplicated here.

SECTION 16: Other information

(i) Indication of changes:

(ii) Abbreviations and acronyms:

(ii) Key literature references and sources for data

(iv) Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

| Classification according to Regulation (EC) Nr. 1272/2008 | Classification procedure |
|---|---|
| Flam. Liq. 2, H225 | On basis of test data |
| Acute Tox. 3, H301 | Calculation method |
| Acute Tox. 3, H311 | Calculation method |
| Acute Tox. 3, H331 | Calculation method |
| STOT SE 1, H370 | Calculation method |

(v) Relevant R-phrases and/or H-statements (number and full text):

(vi) Training advice:

(vii) Further information:

Other possible evaluation methods to be used for classifications (see Article 9 of the CLP Regulation) are for example:

- On basis of test data
- Calculation method.
- Bridging principle "Dilution".
- Bridging principle "Batching".
- Bridging principle "Concentration of highly hazardous mixtures".
- Bridging principle "Interpolation within one toxicity category".
- Bridging principle "Substantially similar mixtures".
- Bridging principle "Aerosols".
- Expert judgement
- Weight of evidence
- Human experience
- Minimum classification

# Appendix 1. Timetable for the application of CLP labelling and corresponding requirements for SDSs in amended versions of Annex II of REACH

There are three versions of Annex II of REACH taken into account in this guidance document:

- **2006 =** the original Annex II, as published with the REACH regulation prior to the 2010 amendment[119].
- **2010 I =** Annex I of Commission Regulation (EU) No. 453/2010 amending Annex II of REACH.
- **2010 II =** Annex II of Commission Regulation (EU) No. 453/2010 amending Annex II of REACH.

Due to the transition periods it is to be expected that, until 1 June 2017, there will be different valid formats of SDS in co-existence. These must reflect the appropriate classification and labelling of substances and mixtures to which they refer during and after the transition period.

The 2010 I and 2010 II versions of Annex II of REACH differ mainly regarding their requirements to mention classification and labelling according to different systems during the relevant transition periods. The differences are particularly reflected in the contents of SECTIONS 2, 3 and 16.

Table 2 shows the different requirements and possibilities during the transition periods, for both labelling and SDS. It highlights in particular, for substances and mixtures labelled according to CLP, when both classifications (CLP and DSD/DPD[120]) need to be mentioned in the SDS.

119 As the transition period for implementing certain changes in both format and content of SDSs from the initial 2006 version of Annex II expired on 1 December 2012, references to options allowed only up to this date which have now already expired have been removed from the summary table below in the updated 2013 version of this guidance document.

120 For mixtures (voluntarily) labelled according to CLP - in advance of the 1 June 2015 deadline for doing so - the requirement to include DSD/DPD classifications until 1 June 2015 in subsections 2.1 and 3.2 does **not** arise from the Annex text of 2010 II itself, but rather arises from taking the option (afforded by Article 2(3) of COMMISSION REGULATION (EU) No 453/2010) to label according to CLP "early" and therefore needing to **additionally** conform with the requirement to also give the DPD classification in 2.1 until 01/06/2015 (according to Article 2(5) of COMMISSION REGULATION (EU) No 453/2010) and the DSD classification (of component substances) in 3.2 (according to Article 2(4) of COMMISSION REGULATION (EU) No 453/2010).

**Table 2: Transitional periods for the implementation of CLP labelling and corresponding requirements for SDSs.**

<table>
<tr><td rowspan="3">Substances</td><td></td><td>Until 01/06/2015</td><td colspan="2">From 01/06/2015</td></tr>
<tr><td>Label</td><td>CLP</td><td colspan="2">CLP</td></tr>
<tr><td>SDS</td><td>Version: 2010 I<br>Section 2.1: CLP and DSD classifications<br>Section 2.2: CLP labelling elements (only[121])</td><td colspan="2">Version: 2010 II<br>Section 2.1: CLP classification<br>Section 2.2: CLP labelling elements (only[120])</td></tr>
<tr><td rowspan="5">Mixtures</td><td></td><td colspan="2">Until 01/06/2015: all mixtures<br>Until 01/06/2017: mixtures already on the market before 01/06/2015 (“on the shelves”)</td><td rowspan="2">From 01/06/2015: mixtures placed on the market after 01/06/2015 ; or optionally all mixtures<br>From 01/06/2017: all mixtures</td></tr>
<tr><td></td><td>Option 1</td><td>Option 2</td></tr>
<tr><td>Label</td><td>DPD</td><td>CLP (i.e. “early” implementation of CLP label)</td><td>CLP</td></tr>
<tr><td>SDS</td><td>Version: 2010 I<br>Section 2.1: DPD classification<br>Section 2.2: DPD labelling elements (only[120])<br>Section 3.2: DSD classification (components). CLP classification of components if provided by supplier<br>Section 16 (optional): CLP classification of mixture</td><td>Version: 2010 II<br>Section 2.1: CLP and[122] DPD classification<br>Section 2.2: CLP labelling elements (only[120])<br>Section 3.2: CLP and DSD classification (components)</td><td>Version: 2010 II<br>Section 2.1: CLP classification<br>Section 2.2: CLP labelling elements<br>Section 3.2: CLP classification (components)</td></tr>
</table>

121 In all cases whichever (single) set of labelling elements (either DSD/DPD or CLP) is quoted in Section 2.2 of the SDS should correspond to that actually used on the label for the substance or mixture to which the SDS refers, as supplied.
122 See footnote 119 on previous page.

# Appendix 2. Including relevant exposure scenario information into Safety Data Sheets

Possible options for inclusion of relevant exposure scenario information for a substance into a safety data sheet have been explained in chapters 3.22 and 3.23 of this guidance. This Appendix provides additional guidance on this topic.

**Transmission of information on safe use down the supply chain**

The CSR for a substance may include one or more exposure scenarios in its heading 9 Exposure Assessment. The exposure scenarios in the CSR are meant to document the conditions of safe use (operational conditions (OC) and risk management measures (RMM)) that have been assessed by the registrant. Each of the exposure scenarios addresses one or more identified uses. Exposure estimate and, where feasible, risk characterisation are required for each exposure scenario in order to demonstrate adequate control of risks for human health and for the environment. REACH requires that the registrant (or any actor in the supply chain who is required to prepare a CSR) places the relevant exposure scenarios in an annex to the SDS (making it an extended safety data sheet) he supplies his downstream users further down the supply chain. The purpose of the exposure scenario in the communication to downstream users is to provide guidance on how to use the substance in a way that control of risks is ensured. For this reason, the information in the exposure scenarios annexed to the SDS for a substance should be focused on what the recipients of the SDS need to know in order to ensure safe use of the substance. It is however also required that there be consistency between the exposure scenario information in the CSR and the exposure scenario(s) attached to the SDS. The exposure scenario(s) attached to the SDS must cover all uses at all life cycle stages that are relevant for the recipient of the substance. This means that the exposure scenario(s) has/(have) to address specific uses of immediate downstream users and uses further down the supply chain for which conditions of safe use have been documented in the CSR [123]. In order to fulfil this requirement, registrants (or downstream users preparing the CSR) need to understand the supply chain of the substance in the market, the uses of the substance by their customers and foreseeable uses of the substance further down the supply chain. Conditions of safe use (and related exposure scenarios) may be different for each individual use or they may be the same for a group of uses. For this reason, the number of exposure scenarios included in the SDS for a specific substance may vary depending on the number of individual uses or groups of uses covered for the substance[124]. If a substance ends up in different supply chains (with different uses and conditions of use), exposure scenarios attached to the SDS have to cover uses and use conditions that are relevant for each supply chain. Communication within the supply chain and support from sector organizations are key elements to help registrants (or downstream users preparing the CSR) to identify relevant exposure scenarios to be attached to the SDSs. The attachment to SDSs of all exposure scenarios covering all identified uses without taking into account their relevance for downstream users to whom they are addressed should be avoided.

When a registrant considers the use of scaling to be applicable for his substance he has to explicitly indicate, for each specific use (and exposure scenario), applicable scaling options including which determinants of the exposure can be modified by scaling and the specific scaling tool(s) that can be used (e.g. an algorithm or an IT tool)[125]. It is furthermore important

---

123 Additional information on ESs for SDS and exposure scenario for and CSR is available in the ECHA *Guidance on information requirement and CSA Part D* echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment.

124 Note that for a supplier of a substance manufactured or imported at an annual volume of below 10 tpa and therefore not requiring a CSA there may legitimately be no ESs at all attached to the SDS.

125 See *Guidance for downstream users* for more details (echa.europa.eu/guidance-documents/guidance-on-reach).

that information on scaling is communicated by downstream users when extended SDSs are prepared by them for communication of safety information to their customers further down the supply chain.

The information in the extended SDS may include advice that refers to uses and life cycle stages beyond "downstream uses" as intended by REACH (e.g. uses by consumers, life cycle of articles, waste stage etc..). In such a case, downstream users receiving extended SDS information are expected to:

- inform/instruct users of substances or mixtures who are members of the general public, i.e., consumers, even though no safety data sheet is required to be provided to them,
- fulfil their duties related to safety or emission behaviour of articles supplied by them, as laid down in other legislation (e.g. toys, construction products), and to comply with their duties under Article 33 (if they are article producers) and
- fulfil their duty to select appropriate waste disposal routes.

**Inclusion into the SDS of exposure scenario information relevant for the immediate downstream user and subsequent users**

The ultimate aim of a supplier of a substance who provides an extended SDS to his immediate downstream users is to communicate clear and understandable information on how the substance (either as such or in a mixture) can be used "safely" by them. Registrants or downstream users preparing a CSR for a substance for which an exposure scenario is required, are required to attach relevant exposure scenario(s) to the safety data sheet for the products (containing the substance) they deliver to their immediate downstream users. Additional information is available in chapters 3.22 and 3.23.

When a downstream user receives an exposure scenario for a substance from his supplier, he has to check if his use and conditions of use are covered by the exposure scenario. Practical advice on how to check whether a use is covered and how to choose and carry out the appropriate action is provided in chapters 4 and 5 of the *Guidance for downstream users* and in the Practical guide *"How downstream users can handle exposure scenarios"*[126].

A downstream user of a substance may supply that substance in his products further down the supply chain. This is typically the case for formulators using substances in their mixtures and supplying mixtures to other formulators and/or to end users. A downstream user supplying a substance (e.g. in a mixture), for which an extended SDS has been provided by the supplier of the substance, has to check whether the foreseeable uses of his mixtures (containing the substance) are covered in the exposure scenarios he has received for the substance. If uses are covered, the downstream user has to include the exposure scenario (of the substance) into the SDS of his mixtures if:

- an SDS is required for the mixture and
- the concentration of the substance in the mixture exceeds the limits indicated in Article 14 of REACH.

Depending on how diverse the OCs and RMMs for the substances in the mixture will be further downstream, the ***inclusion*** of the exposure scenario can be carried out in

126 At echa.europa.eu/practical-guides.

different ways, as described in chapter 3.23.

Downstream users may have different levels of technical competence to identify, apply and recommend appropriate measures to control risks identified in the SDS supplied to them. Thus, when compiling the extended SDS for a substance, the supplier (manufacturer, importer or downstream user) will need to anticipate the role of his immediate downstream user in the supply chain and to present the information in a way that enables the immediate downstream user to *identify* the measures that are relevant to *recommend* to his own customers.

It is therefore crucial that the supplier prepares an exposure scenario that contains practically useful information related to the downstream user's processes, structured in a "possibly standardized" format and written in a technical language that is understandable to the downstream user. More detailed information on exposure scenarios for communication can be found in Chesar user manual 2[127]. Furthermore, guidance for formulators on how to forward information on mixtures down the supply chain is provided in the *Guidance for Downstream users*[128] (chapter 7).

The supplier is expected to phrase the OC and RMMs so that they can be *included* and *recommended* in the SDS for a mixture without need for re-phrasing[129] by the immediate downstream users (e.g. using so called "standard phrases"[130]).

**Distributors**

Distributors, even though they are not downstream users under REACH, have a fundamental role in the communication flow up and down the supply chain, including via the SDS. They have a key position as they may have direct contact with the manufacturer/importer and the end-user of the substance. Under REACH, the customer of a distributor is considered as an *immediate* downstream user of the registrant. It is therefore recommended that the registrant actively approach the distributors to seek agreement on how the registrant can increase his knowledge on the conditions of use in the distributor's market, for the purposes of the exposure scenario and other SDS information without requiring the distributor to disclose confidential business information (CBI). More detailed information on the role and obligations of the distributor are provided in the *Guidance for downstream users*.

**The exposure scenario and corresponding Sections in the safety data sheet.**

Table 3 gives an overview of the relationship between the SDS sections and the standard entries of the exposure scenario.

Depending on the hazard profile of the substance, the broadness of the market and the structure of the supply chain, there is a variety of options to modify the principal organisation of information in the exposure scenarios and the extended SDSs, e.g.:

- Section 2 of the exposure scenario could be further differentiated into exposure routes and exposure patterns. It can also be useful to link the risk management

127 Available at chesar.echa.europa.eu/support. Please note that it is up to the individual registrant to decide which exposure scenario format he wants to use, as long as the content of the exposure scenario is compliant with the requirements set out in Annex I of REACH.
128 echa.europa.eu/guidance-documents/guidance-on-reach.
129 The standard phrases for risk management measures (as contained in the RMM catalogue indicated in the last section of this Appendix) should therefore be constructed in such a way that they are understandable to all actors in the supply chain.

130 See the last chapter of this annex for more information on one available catalogue of standard phrases.

advice per route of exposure and endpoint directly with the relevant DNEL and exposure prediction.

- In a broad exposure scenario for a substance with only one or two hazard endpoints of concern, it may also be possible to list the specific RMMs for certain activities in Section 2 of one exposure scenario.

**Table 3 Relationship between exposure scenario and SDS Sections**

| ES section | SDS Section |
|---|---|
| Short title of the exposure scenario | 1.2 |
| Operational conditions and risk management measures | 7 + 8 |
| **Control of workers exposure** | |
| Product characteristic | 7 + 8 + 9 |
| Amounts used | 7 + 8 |
| Frequency and duration of use | 7 + 8 |
| Human factors not influenced by risk management | 7 + 8 |
| Technical conditions and measures at process level (source) to prevent release | 7 + 8 |
| Technical conditions and measures to control dispersion from source towards the worker | 7 + 8 |
| Organisational measures to prevent/limit releases, dispersion and exposure | (5, 6), 7, 8 |
| Conditions and measures related to personal protection, hygiene and health evaluation | (5, 6), 7, 8 |
| Other conditions affecting workers exposure | 7 + 8 |
| **Control of consumer exposure**[131] | |
| Product characteristic | 7 + 8 + 9 |
| Amounts used | 7 + 8 |
| Frequency and duration of use | 7 + 8 |
| Other conditions affecting consumers exposure | 7 + 8 |
| **Control of environmental exposure** | |
| Product characteristic | 7 + 8 + 9 |
| Amounts used | 7 + 8 |

131 Note that specific information on **consumer** exposure in Section 8 of the SDS is not a legal requirement.

| | |
|---|---|
| Frequency and duration of use | 7 + 8 |
| Environmental factors not influenced by risk management | |
| Technical conditions and measures at process level (source) to prevent release | 7 |
| Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil | 7 + 8 |
| Organisational measures to prevent/limit release from site | 6 + 7 + 8 |
| Conditions and measures related to municipal sewage treatment plant | 8 + 13 |
| Conditions and measures related to external treatment of waste for disposal | 13 |
| Conditions and measures related to external recovery of waste | 13 |
| Other given operational conditions affecting environmental exposure | 7 |

Annex II to REACH sets the requirements for how to structure the measures for safe handling, protecting the environment and controlling of risks in Sections 7 and 8 of the SDS. These sections are described in detail in paragraph 4.7 and 4.8 of this guidance. Annex II of REACH indicates also (for Sections 7 and 8 of the SDS) that where a CSR is required for the substance, the information in these sections has to be consistent with the information given in the CSR for the identified uses and related Exposure Scenario and that where an exposure scenario is attached to the SDS, information on exposure controls (subsection 8.2) can be provided in the exposure scenario only and it does not have to be duplicated in section 8.2 of the SDS.

In order to implement these requirements in a consistent and user-friendly way, the following guidelines[132] should be applied:

- Annex II distinguishes between occupational conditions in Sections 7.1 - “precautions for safe handling” of the substance or mixture - and “exposure controls” in Section 8.2). Certain measures however are mentioned in both sections.
- Annex II requires that the language used in an SDS is clear and specific. For example statements like “avoid breathing vapours” or “avoid skin contact” would not fulfil the requirements for description of how prevention or control of exposure can be achieved[133].
- The description of RMMs related to all uses covered in the annexed exposure scenarios must be included in Section 8 or in the exposure scenarios attached to the SDS (if applicable). When RMM information is provided in the exposure scenario, it is recommended to provide specific reference to relevant exposure scenarios containing the information in subsection 8.2 of the SDS. It is also recommended to provide a summary of RMM (e.g. type of RMM) in subsection 8.2. NOTE: REACH requires that all specific provisions for exposure controls indicated in Annex II (section 8.2 of Annex II and all related subsections) are to be provided either in subsection 8.2 of

[132] Please note that the recommendations reported here do not preclude that new and up to date practical recommendations for transferring exposure scenario information into the body of the SDS will be elaborated as outcome of current and future projects. In this case the present guidance will be updated.
133 See e.g. point 0.2.4 of Part A of Annex II.

the SDS or in the attached exposure scenarios. In case part of the information required in subsection 8.2 of Annex II is not provided in the attached exposure scenario, it has to be provided in subsection 8.2 of the SDS.

- Section 7.1 of the SDS should contain measures to control risks during handling of substances and mixtures. This includes a whole range of actions, such as for example: design and organisation of work systems; suitable equipment and regular maintenance of it; minimisation of duration and extent of exposure through organisational measures; general ventilation and appropriate hygiene measures[134]. It is recommended not to repeat descriptions of these measures in each exposure scenario annexed to the SDS, since they are not geared to an individual use unless they are relevant for the specific exposure scenario (e.g. because they are derived from the assessment).
- Subsection 7.3 is of limited relevance in the case of an extended SDS since it contains specific guidance for specific end uses and information should be contained in the exposure scenario related to the end use of the substance (e.g. in a mixture) or article service life (in cases where the substance ends up in an article). In this subsection reference to the relevant exposure scenario should be made. However if a registrant has available information on safe use of his substance in end-products (e.g. a risk management package related to handling of isocyanides containing products) he can make a reference here.
- Subsection 8.2 contains measures related to use of individual protection measures (such as personal protective equipment (PPE)). Use of PPE is usually considered as the last resort to control risks, in existing community legislation on occupational health. PPE should be used in conjunction with other control measures such as process design (e.g. level of containment, closed process, local extraction), product design (e.g. low dust grades), workplace (dilution ventilation) or work method (automation). PPE should be used as additional RMM when other measures are insufficient to guarantee control of risks or, as sole RMM in particular cases (e.g. short term low frequency activities, or use by professionals) such as cleaning and maintenance, installation of new equipment or manual spraying outside industrial settings. If several exposure scenarios are annexed to the SDSs, PPE may or may not be required depending on the OCs of each exposure scenario which may be different. It is therefore recommended to indicate, in each exposure scenario, the type and technical specification of PPE required (if it is required), for which tasks/activities it is needed (e.g. cleaning / maintenance) and its effectiveness, while in sub-section 8.2 the types of PPE that are required to guarantee protection from substance-specific hazards should be indicated.
- Annex II does not specifically mention RMMs and OCs related to consumers but it is indicated that the RMMs for all identified uses must be described in Section 8 of the SDS. Potential exposure of consumers to a substance is to be covered in the CSR for a substance if it is foreseen that the substance may end up in consumer products (mixtures or articles). It is therefore recommended to add information (or to give an information that exposure scenarios for consumer uses are annexed) under subsection 8.2 (e.g. by adding a new headline “consumer uses” after the point 8.2.3 indicated in Annex II) in the extended SDS to include measures related to consumer uses of the substance (as such or in mixtures), to the service life of the substance in articles or to information in product label (e.g. in the case of biocides or plant protection products). This information is relevant under REACH for the DUs if i) they place mixtures for use by the general public on the market and/or ii) they process substances or mixtures into articles. It may also facilitate the communication related to substances of very high concern, for which risk management advice for consumer

134 For further detail see part I Chapter 2 of the EU Practical Guidelines related to the Directive 98/24/EC.

uses and substances in articles may be required under Article 7 and Article 33 of REACH.

### Standard phrases for exposure scenario information

Sector organisations, registrants and downstream users at various levels are working for the creation of a "standard phrases catalogue" with the aim to streamline and improve the effectiveness of communication in the supply chain. The use of standard phrases facilitates harmonisation of risk communication and enables the translation of the risk management advice in all the national languages (as required by REACH). A harmonised catalogue of phrases for communication of risk management advice (ESCom) has been published on the CEFIC website[135]. Users of ECHA's tool for Chemical Safety Assessment and Reporting (Chesar) can import this catalogue for using the harmonised phrases when generating their exposure scenarios for communication[136].

135 euphrac.eu.
136 The tool and supporting material is available at chesar.echa.europa.eu/.

# Appendix 3. SDS for Special Mixtures

### Introduction: What are Special Mixtures?

Special Mixtures[137] are those in which a common feature is that the properties of the constituent substances are modulated by their inclusion **within the matrix of the mixture** (polymer, ceramic, or metal matrices). In particular, the **availability** for exposure of the constituent substances and their potential to express any ecotoxicological/toxic properties may be affected following their inclusion in solid matrices. Examples of special mixtures are: alloys, rubber compounds.

*Note: Most experience on special mixtures is with alloys, and consequently this Appendix mainly refers to the drafting of SDS for "alloys as Special Mixtures". Supported by preliminary evidence, however, it is believed that a similar reasoning could be followed for the other Special Mixtures. It is nevertheless strongly recommended - and beyond the possibilities and scope of this Appendix based solely on the experiences of the metals sector to check the validity of the suggested way forward with the other examples of Special Mixtures.*

The result of its inclusion in a matrix is that the simple presence of a metal or inorganic ion in a special mixture will not necessarily impart to that special mixture the biological properties of the metal/inorganic ion; it will be 1) the availability of the ion at the site of action in the organism that is the most important factor determining toxicity for metals and minerals, and 2) the potential for different toxicity properties of special mixture particles.

Information on availability can be derived from *in vivo* sources (toxicokinetic or toxicological tests providing exposure and effect data) or *in vitro* methods. In vitro, the release of metal or mineral ion in simulated biological fluids (e.g. gastric juice, intestinal fluid, artificial sweat, lung lavage/alveolar fluid, etc. *bioaccessibility tests*) or in water (*Transformation Dissolution Protocol*) will be measured, as a reflection of their availability. Using these settings, it is possible to compare the release of ions from the individual constituents vs. that from the constituents included in the matrix (e.g. the metal constituents of the alloy vs. metals in the alloy).

Reliable data showing differences in release or toxicity expression should be used in exposure scenarios in order to refine the proposed RMMs and OCs, using e.g. the Critical Component Approach. Release estimates and how these are considered in the context of Exposure Scenarios will be documented in the CSR.

### Where will the Special Mixture concept have an impact on the SDS content?

'Inclusion in the matrix' and its influence on availability of the constituents can currently be considered in Section 8 of the SDS "Exposure controls/personal protection". Proposed risk management measures can be refined provided that there are reliable data and information documenting release, availability and/or different toxicity expression. In the absence of reliable data, the special mixture will be considered by default as a simple mixture, and the mixture rules will apply.

*Placeholder: work is ongoing on assessing the possibility of including bioavailability considerations when classifying an alloy as a Special Mixture. This may have some impact on*

137 "Special mixtures" are not defined as such in e.g. Article 3 of REACH. However, the type of compositions that the term is intended to refer to within the REACH regulation can be inferred from the text of Recital 31 of REACH (as amended – it originally referred to "special preparations") and Annex I on CSA (point 0.11).

*the information given in Section 2: Hazard identification.*

How to refine the proposed measures for controlling exposure/personal protection with Special Mixtures data:

- Usually, the production of a Special Mixture can involve a series of constituents. The Special Mixture producer, who has to generate an SDS for the Special Mixture, may receive a significant amount of information from which it will be difficult to identify and to extract *key and relevant information* to include in his SDS because of different properties, different exposure scenarios, etc.
- As a first step, it is suggested that the formulator responsible for preparing an SDS for an alloy should compile all relevant information about the mixture's constituents and the mixture as a whole in a spreadsheet or similar format (see the example table given for a substance in the discussions of DNELS and PNECS under subsection 8.1 in chapter 4 of this document) and then extract the information required for the respective constituents SDS sections.

Depending on the information collected and the quality/reliability of the information, the formulator will have to decide whether or not he has the knowledge to consider his mixture as a Special Mixture (with possible refinements of RMMs). This will need to be documented, to enable the user of the SDS to understand any refinements that result from the use of availability data.

Example: availability data can be used to refine RMMs and OC.

***Exposure to alloy powders and massives***

When coarser (non-respirable/inhalable) powders and massives (>20 µm) are handled, the inhalation route is less relevant. In this case, oral and dermal exposures are more relevant for human health hazards. Toxicity resulting from these exposure routes depends on the availability of ions at target sites. This availability can be estimated in vitro by measuring ion release from the alloy in the gastric fluid and sweat and compared with release from the constituents. The results of availability tests on alloys can be used to refine actual exposure considerations from the "alloy" versus actual exposure from the "metals in the alloy. If exposure is reduced by inclusion in the matrix, then less stringent risk reduction measures could be applied.

# Appendix 4. Specific issues relevant to the compilation of SDSs for recovered substances and mixtures.[138]

**Reason for the inclusion of this Appendix**

Article 2(2) of REACH provides that *"waste as defined in Directive 2006/12/EC[139] of the European Parliament and of the Council is not a substance, preparation or article within the meaning of Article 3 of this Regulation."* Therefore, REACH requirements for substances, mixtures and articles do not apply to waste[140].

However, where a substance or mixture is recovered from waste and material 'ceases to be waste', REACH requirements in principle apply in the same way as to any other material, with a number of conditionally granted exceptions. The relevant legislation applying to these transitions and the conditions for granting of exceptions are discussed in more detail in the *Guidance on waste and recovered substances*. In particular the *Guidance on waste and recovered substances* includes a decision tree which allows confirmation of whether or not an SDS is required for a recovered substance under REACH. These criteria, and the required content of the resulting SDS are essentially the same as for any other substance or mixture (as discussed in further detail in the rest of this guidance document) once it has been established that the recovered substance or mixture has ceased to be waste.

If a "new" substance is generated during the recovery process then it is subject to the normal provisions for registration under REACH.

Where it has been established that a substance or mixture has indeed ceased to be waste Article 2(7) (d) of REACH allows certain exemptions as follows:

> *"2.7. The following shall be exempted from Titles II, V and VI:*
>
> *[…]*
>
> *(d) Substances, on their own, in mixtures or in articles, which have been registered in accordance with Title II and which are recovered in the Community if:*
>
> *(i) the substance that results from the recovery process is the same as the substance that has been registered in accordance with Title II; and*
>
> *(ii) the information required by Articles 31 or 32 relating to the substance that has been registered in accordance with Title II is available to the establishment undertaking the recovery."*

As a consequence a recovery operator may produce an SDS which quotes no registration number. He may wish to explain why this is so within the SDS.[141]

Similarly, the requirement to carry out a CSA, complete a CSR and potentially to generate an Exposure Scenario for certain substances which arises in particular from Article 14(4) of

---

138 This Appendix should be read in conjunction with the ECHA *Guidance on waste and recovered substances* (available at: echa.europa.eu/guidance-documents/guidance-on-reach).

139Repealed by Directive 2008/98/ECof the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (Waste Framework Directive).

140 Further explanation on this exemption is given in the *Guidance on registration*,

echa.europa.eu/guidance-documents/guidance-on-reach (chapter 1.6.3.4).

141 See the text and examples given in chapter 4 in the discussion of subsection 1.1 in this guidance.

REACH (which is also part of Title II), can be the subject of an exemption under Article 2(7)(d).

Title II refers to the Registration of substances, Title V to requirements for Downstream users and Title VI to Evaluation. These exemptions notably do not cover Title IV (Information in the supply chain) which includes Article 31 requirements (as well as Article 32 requirements) for the provision of SDSs where applicable for recovered substances and mixtures which have ceased to be waste (as well as Article 32 requirements).

However although, by definition, to benefit from the exemptions the information on the substance or mixture required by Article 31 or 32 has to be available to the establishment undertaking the recovery there are some specific issues arising (e.g. from changes in the impurity profile or other aspects of the composition of the recovered substance by comparison with the substances as originally registered) which may affect the content of the SDS compiled for a recovered substance or mixture. There are also issues arising from the discontinuity in transfer of information on exposure scenarios down a supply chain which is interrupted by temporary change of a substance or mixture's status as waste or "ceased to be waste". These issues are considered in more detail below insofar as they affect the content of the SDS.

### Composition of recovered substances and mixtures

For recovered materials that are composed primarily of substances which are not chemically modified by the recovery process, these component substances on their own or in mixtures will generally be known and have been registered.

However, during original manufacture various other substances (potentially including stabilizing additives) may have been combined with the primary substance(s). Most of the substances (or additives) will still be in production and will therefore be registered under REACH. However, others will have been phased-out of production, either through voluntary or regulatory action, although they may continue to be present in waste materials for a number of years.

Some sectors carrying out recovery activities already have relatively easy access to the necessary information on the substances/mixtures that they produce and supply, to allow them to compile an SDS complying with Art 31 and Annex II of REACH. For others, further consideration of issues such as "sameness" may be needed.

### Evaluating the applicability of available SDS information and the "sameness" of recovered substances

**EVEN WHEN COMPILING HIS OWN SDS BASED ON AVAILABLE SDSS FOR SUBSTANCES RECOVERED FROM THE WASTE THE RECOVERY OPERATOR WOULD NEED TO SATISFY HIMSELF THAT ANY INFORMATION HE RELIES UPON TO COMPILE IT RELATES TO SUBSTANCES WHICH ARE THE SAME AS THOSE IN THE RECOVERED MATERIAL.**

Further discussion of "sameness" in the context of recovered substances is given in the ECHA *Guidance on waste and recovered substances*. This in particular notes that *"the decision on the sameness should be based on the main constituents. Information about the impurities does not in principle change the conclusion about the sameness"*[142].

142 Information about the impurities must be taken into account for issues such as Classification and Labelling and drafting of SDSs.

### Compilation of SDSs using generic information

In case generic information on the input material is used to produce an SDS, there should be a process to establish confidence in the reliability of this information. Such a process could for example comprise:

- Assess what is known about the waste material from which the substance is to be recovered. This includes information on the composition of the waste, and any known relevant history of the material such as, where applicable:
    - the previous application,
    - handling and storage during the use, waste and transport stages
    - any treatment carried out (e.g. during reprocessing).
- Assess and where relevant record all known content, including the original material(s) as well as anything likely to be present from additives used in the original application (e.g. alloying substances, coatings, colorants, or stabilisers). Information on the substances and mixtures present in the waste and their relative quantities will enable SDS information on relevant materials to be obtained and used as the basis of the SDS for the recycled material. For example, if there are substances subject to restriction, meeting the classification criteria as dangerous according to the DPD or as hazardous according to CLP, CMR, PBT, vPvB or candidate list substances in the recycled material then the chemical composition of all such content should be established
- Characterise the incoming raw material and the recovered substance(s) to establish average content for each relevant substance and the likely range of its content in any mixture (maximum and minimum). Alternatively the hazard profile of the recovered mixture as such could be established. This information can be used to assess risks and set out risk management measures in the SDS for accepted uses.

For recovered substances (as for other substances) containing impurities that are classified and contribute to the classification, the impurities have to be indicated.

It is worth noting that the presence of impurities as such does not itself give rise to an obligation to supply an SDS under Article 31(1) of REACH. Such obligations may only arise through Article 31(3) requirements.

### Other consequences of an Article 2(7)(d) exemption relevant to SDSs

A recovery operator who has the required information available for the same substance and can therefore rely on exemptions according to Article 2(7)(d) of REACH (even if the use of a recovered substance is not covered by the registration of the same substance), is not required to:

- generate an exposure scenario for the use of the recovered substance;
- register the recovered substance;
- notify the use of the recovered substance.

However he should take account of the available information and must provide information on appropriate risk management measures in the SDS, if applicable.

The SDS should be compiled in accordance with the text of Article 31 and Annex II of REACH. Where appropriate guidance set out in the main body of this document together with additional

guidance for specific issues set out in this Appendix or in the *Guidance on waste and recovered substances* should be consulted.

Trade Associations representing specific material recovery sectors may provide their members with examples of how to use this guidance. They may wish to develop further guidance for any issues specific to their material stream.

# Appendix 5. Glossary / List of acronyms

| List of Acronyms | |
|---|---|
| ATE | Acute Toxicity Estimate |
| ADR | European Agreement concerning the International Carriage of Dangerous Goods by Road |
| ADN | European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways |
| CEN | European Committee for Standardisation |
| C&L | Classification and Labelling |
| CLP | Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008 |
| CAS# | Chemical Abstracts Service number |
| COM | European Commission |
| CMR | Carcinogen, Mutagen, or Reproductive Toxicant |
| CSA | Chemical Safety Assessment |
| CSR | Chemical Safety Report |
| DNEL | Derived No Effect Level |
| DPD | Dangerous Preparations Directive 1999/45/EC |
| DSD | Dangerous Substances Directive 67/548/EEC |
| DU | Downstream User |
| DUCC | Downstream Users of Chemicals Co-ordination platform |
| EEA | European Economic Area (EU + Iceland, Liechtenstein and Norway) |
| ECB | European Chemicals Bureau |

| | |
|---|---|
| ECHA | European Chemicals Agency |
| EC-Number | EINECS and ELINCS Number (see also EINECS and ELINCS) |
| EINECS | European Inventory of Existing Commercial Substances |
| ELINCS | European List of notified Chemical Substances |
| EN | European Standard |
| EP | European Parliament |
| EQS | Environmental Quality Standard |
| ext-SDS | Extended Safety Data Sheet (SDS with ES attached) |
| EU | European Union |
| Euphrac | European Phrase Catalogue |
| EWC | European Waste Catalogue (replaced by LoW – see below) |
| GES | Generic Exposure Scenario |
| GHS | Globally Harmonized System |
| HH | Human Health |
| IATA | International Air Transport Association |
| ICAO-TI | Technical Instructions for the Safe Transport of Dangerous Goods by Air |
| IMDG | International Maritime Dangerous Goods |
| IMSBC | International Maritime Solid Bulk Cargoes |
| IT | Information Technology |
| IUCLID | International Uniform Chemical Information Database |

| | |
|---|---|
| IUPAC | International Union for Pure Applied Chemistry |
| JRC | Joint Research Centre |
| Kow | octanol-water partition coefficient |
| LC50 | Lethal Concentration to 50 % of a test population |
| LD50 | Lethal Dose to 50% of a test population (Median Lethal Dose) |
| LE | Legal Entity |
| LoW | List of Wastes (see ec.europa.eu/environment/waste/framework/list.htm) |
| LR | Lead Registrant |
| M/I | Manufacturer / Importer |
| MS | Member States |
| MSDS | Material Safety Data Sheet |
| OC | Operational Conditions |
| OECD | Organization for Economic Co-operation and Development |
| OECD-WPMNM | OECD Working Party on Manufactured Nanomaterials |
| OEL | Occupational Exposure Limit |
| OH | Occupational Health |
| OR | Only Representative |
| OSHA | European Agency for Safety and Health at work |
| PBT | Persistent, Bioaccumulative and Toxic substance |
| PEC | Predicted Effect Concentration |

| | |
|---|---|
| PNEC(s) | Predicted No Effect Concentration(s) |
| PPE | Personal Protection Equipment |
| (Q)SAR | Qualitative Structure Activity Relationship |
| REACH | Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006 |
| RID | Regulations concerning the International Carriage of Dangerous Goods by Rail |
| RIP | REACH Implementation Project |
| RMM | Risk Management Measure |
| SC | Supply Chain |
| SCBA | Self-Contained Breathing Apparatus |
| SDS | Safety Data Sheet |
| SIEF | Substance Information Exchange Forum |
| SME | Small and Medium sized Enterprises |
| STOT | Specific Target Organ Toxicity |
| (STOT) RE | Repeated Exposure |
| (STOT) SE | Single Exposure |
| SVHC | Substances of Very High Concern |
| UIC | Union des Industries Chimiques |
| UN | United Nations |
| VCI | Verband der Chemischen Industrie |
| vPvB | Very Persistent and Very Bioaccumulative |

EUROPEAN CHEMICALS AGENCY
ANNANKATU 18, P.O. BOX 400,
FI-00121 HELSINKI, FINLAND
ECHA.EUROPA.EU

LOREM IPSUM DOLOR SIT AMET