

Guidance on the compilation of safety data sheets (third draft May 2011)

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CHAPTER 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 downstream users on chemical 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 REACH⁴ (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 Preparations Directive 1999/45/EC (DPD) (until 1 June 2015) or
- A substance is persistent, bioaccumulative and toxic or very persistent and very bioaccumulative (PBT, 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 according to Article 4(8) and Section 2.1 of Annex I of CLP certain articles (some explosive and pyrotechnic articles) should be classified and labelled according to CLP there is no requirement

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

² Third revised edition accessible at:

http://www.unece.org/trans/danger/publi/ghs/ghs_rev03/03files_e.html

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

arising from Article 31 of REACH for SDSs to be provided for these articles. However, suppliers may consider it useful to supply information in an SDS format for this particular type of article on a voluntary basis. 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.

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 users that are required to prepare a Chemical Safety Report, 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 (ES) 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 Chemical Safety Report under Article 37 of REACH and this results in the generation of an ES, this ES must be placed in an Annex to the SDS.

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, in particular detail what changes arise from the revisions of Annex II which come into force on 1 December 2010 and 1 June 2015
- The timetables for implementation of the various versions of Annex II
- 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 (and some articles) 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

1 useful information for recipients of an SDS. It is noted in this context that the
2 information provided by Safety Data Sheets will also help employers to meet their
3 obligations under Directive 98/24/EC on the protection of the health and safety of
4 workers from the risks related to chemical agents at work.

5
6 The SDS should enable users to take the necessary measures relating to protection
7 of human health and safety at the workplace, and protection of the environment
8

9 **1.4. Relation with CLP and GHS**

10
11 Regulation (EC) No 1272/2008 on classification, labelling and packaging of
12 substances and mixtures (CLP) harmonises the provisions and criteria for the
13 classification and labelling of substances and mixtures within the Community, taking
14 into account the classification criteria and labelling rules of the UN Globally
15 Harmonised System of Classification and Labelling of Chemicals (GHS). The CLP
16 Regulation contributes to the UN GHS aim of describing and communicating the
17 same hazards in the same way around the world.

18
19 In the EU, the SDS format is based on the Annex II of REACH which sets out the
20 requirements for safety data sheets. The requirements in Article 31 and Annex II of
21 REACH have been adapted to meet the GHS requirements. The CLP Regulation
22 entered into force on the 20th of January 2009. This version of the guidance on the
23 compilation of safety data sheets reflects the current text of the revision of Annex II of
24 REACH as published on 31 May 2010. A major driver for this revision of Annex II was
25 a wish to align as far as practicable the requirements of Annex II of REACH with the
26 “guidance on the preparation of safety data sheets (sds)” given in Annex 4 of the
27 GHS.
28
29
30
31

CHAPTER 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)⁵). 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 a full overview of all the sections and sub-sections in an SDS according to REACH. The table 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 legislation⁶.

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

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	Until 1 June 2015 in the case

⁵ Directive 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

⁶ Nevertheless, 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.

	<p>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.</p> <p>The inclusion of the EC number is optional.</p> <p>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).</p>	<p>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 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)</p>
1.2. Relevant identified uses of the substance or mixture, and uses advised against	<p>Suppliers must indicate the relevant identified use(s)⁷ of a substance using a brief (understandable) description of what the substance is intended to do. Uses advised against and why must be given if applicable.</p> <p>The intention is not to list all the combinations of use descriptors⁸, but rather to have a general description of uses.</p> <p>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 Scenario (ES) can be included here.</p>	<p>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 why must be given if applicable.</p> <p>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 Scenarios (ES) (or alternative documents consolidating exposure scenario information from components) can be included here.</p>
1.3 Details of the supplier of the safety	- For registrants, the information must be consistent with the	- email of the competent person responsible for the

⁷ "Identified use" is defined in REACH, Article 3, point 26.

⁸ See ".Guidance on information requirements and chemical safety assessment Chapter R.12: Use descriptor system at: http://guidance.echa.europa.eu/guidance4_en.htm

data sheet	<p>information on the identity of the manufacturer or importer or Only Representative provided in the registration dossier.</p> <p>- email of the competent person responsible for the SDS should be provided. It is recommended to use a generic email address</p>	<p>SDS should be provided. It is recommended to use a generic email address</p>
SECTION 2: Hazards identification	<p>Classification: From 1 December 2010 until 1 June 2015, the classification of a substance according to both the CLP Regulation and Dangerous Substances Directive (DSD) must be given. After June 1st, 2015, only classification according to CLP should be given. See Appendix 1 on transitional periods for more information.</p> <p>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. The symbol/pictogram(s) must be represented graphically.</p> <p>If the substance is subject to authorisation, the authorisation number must be included here.</p> <p>Information on whether the substance meets the criteria for PBT or vPvB in accordance with Annex XIII must be provided.</p>	<p>Classification:</p> <p>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 CLP before this date the CLP classification must also be included in this section. After June 1st, 2015, only classification according to CLP should be given.</p> <p>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.</p> <p>If any component substance(s) in the mixture is/are subject to authorisation, the authorisation number(s) must be included here⁹. Information on whether the mixture meets the criteria for PBT or vPvB in accordance with Annex XIII must be provided.</p>
SECTION 3: Composition / information on ingredients	<p>The chemical identity of the main constituents and any impurity, stabilising additive or individual constituent which is itself classified</p>	<p>The criteria for determining (on the basis of cut-off values / concentration limits) which component substances in a</p>

⁹ This is not required for substances in annex XIV present in the mixture below the concentrations indicated in Art. 56(6) of REACH

	<p>and contributes to the classification of the substance must be provided</p>	<p>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.</p> <p>In the case of mixtures, PBT/vPvB substances have to be disclosed if present at 0.1% or above with registration number (if applicable)</p> <p>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 individual registrant of a joint submission can be omitted from this section by any supplier of a mixture fulfilling certain specific conditions (See Chapter 4.3 for details).</p> <p>The classification(s) including the information on PBT and vPvB must also be mentioned.</p>
SECTION 7: Handling and storage	<p>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 scenarios annexed to the safety data sheet.</p> <p>If available, a reference to industry or sector specific guidance designed for specific uses may be mentioned.</p> <p>If an Exposure Scenario is attached, reference may be made to it.</p> <p>For substances designed for specific end use(s), detailed and</p>	<p>The SDS may include cross-references to an Exposure Scenario for the mixture where applicable.</p> <p>If available, a reference to industry or sector specific guidance designed for specific uses may be made where applicable.</p> <p>If an ES is attached, reference may be made to it.</p> <p>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.</p>

	operational recommendations relating to the identified use(s) referred to in subsection 1.2 must be made.	
SECTION 8: Exposure controls/ personal protection	<p>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.</p> <p>This information (other than OEL values) will mainly be available for registered substances which have been subjected to a Chemical Safety Assessment.</p> <p>Where a chemical safety report is required, the risk management measures for the identified uses must be consistent with the information in this section.</p>	<p>Where applicable for component substances, list DNELs, OELs, PNECs: 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.</p>
8.1. Control parameters	<p>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. . 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)</p>	<p>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.. 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)</p>
8.2. Exposure controls	Suppliers will mention here risk management measures for control of occupational and environmental exposure for the use of the	The risk management measures in this section and annexed exposure scenario(s) must be

	<p>substance.</p> <p>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.</p> <p>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.</p> <p>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.</p>	consistent.
SECTION 9: Physical and chemical properties	There are additional physical / chemical properties to be included in this section (consult Chapter 4 for more information).	There are additional physical / chemical properties to be included in this section (consult Chapter 4 for more information).
SECTION 11: Toxicological information	<p>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.</p> <p>If a CSR is required, the information should be consistent with it. Where appropriate, information on toxicokinetics, metabolism and distribution should be included.</p> <p>From 01/12/2010 there are 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.</p>	<p>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.</p> <p>From 01/06/2015 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.</p>

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	Substances subject to authorisation and details about any authorisation granted or denied must be given in the SDS. Uses of the substances subject to restrictions must be stated here. Indicate if a Chemical Safety Assessment has been carried out for the substance. Labelling information is no longer included here and has been moved to SECTION 2.	Information on authorisation and restrictions of any of the substances in the mixture should be given. Indicate if a Chemical Safety Assessment has been carried out for the mixture. Labelling information is no longer included here and has been moved to SECTION 2.
SECTION 16: Other information	(Note that from 01/12/2010, information on uses advised against must appear in section 1.2 rather than section 16). Advice on training for workers can also be included in this section. 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). From 1 June 2015 only

		<p>the CLP classification should be given, and only in section 2.</p> <p>Advice on training for workers may be included here.</p> <p>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).</p> <p>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.</p> <p>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.</p>
Exposure Scenario (annex)	<p>For substances for which a chemical safety assessment is required by REACH and has been completed, the relevant exposure scenario(s) (i.e. generally those for uses identified in Section 1 of the SDS) 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.</p>	<p>If an exposure scenario is prepared for a mixture¹⁰, it needs to be compiled by evaluating the relevant available information on the component substances including the information from the substances' suppliers. There are several options for how this may be done (see also paragraph 3.23 of Chapter 3).</p>

¹⁰ 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).

CHAPTER 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 3¹¹):

The SDS should provide comprehensive information about a substance or mixture for use in workplace chemical control regulatory frameworks. Both employers [and workers¹²] 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, 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.

¹¹ http://www.unece.org/trans/danger/publi/ghs/ghs_rev03/English/01e_part1.pdf ; Global Harmonized system of Classification and Labelling of Chemicals (GHS). Third Edition, 2009. United Nations.

¹² 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.

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 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 appears 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

1 ensure the consistency of the SDS, especially if he acts as the coordinator of a group
2 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 products¹³, 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

¹³ For a list of relevant legislation on plant protection and biocidal products see Article 15 of REACH

- 1 ○ Detergent Regulation: Regulation (EC) No 648/2004
- 2 ○ Protection of young people at work: Directive 94/33/EC
- 3
- 4 3. **Relevant national or international guidelines** of the respective sector
- 5 association
- 6
- 7 4. **Physical and chemical properties:**
- 8 ○ Particularly properties as listed and discussed in the legal text below
- 9 under Section 9.1 of the revised Annex II. (See Chapter 4.9 of this
- 10 document).
- 11
- 12 5. **Toxicology/eco-toxicology:**
- 13 ○ Particularly properties as listed and discussed in the legal text below
- 14 under Section 11 and 12 of the revised Annex II. (See Chapter 4.11
- 15 and 4.12 of this document).
- 16
- 17 6. **First aid measures**
- 18 ○ (See Chapter 4.4 of this document)
- 19
- 20
- 21 7. **Accident prevention**
- 22 ○ Fire and explosion prevention, fire fighting, extinguishing media
- 23 ○ Measures in the event of accidental release
- 24 ○ (See Chapter 4.6 of this document)
- 25
- 26
- 27 8. Measures for **safe handling and storage**
- 28 ○ (See in particular Chapter 4.7 of this document)
- 29
- 30 9. **Transport provisions**
- 31 ○ Particularly as listed and discussed in the legal text below under
- 32 Section 14 of the revised Annex II. (See Chapter 4.14 of this
- 33 document).
- 34 ○ (Note that the provisions of Directive 96/35/EC and 2000/18/EC (on
- 35 the appointment and qualification of Safety Advisers for the transport
- 36 of dangerous goods by road, rail and inland waterways) apply
- 37 specifically to those directly involved in the transport of dangerous
- 38 goods. Depending on the supplier's organisational arrangements the
- 39 compiler of SDSs may or may not be a Safety Adviser as defined in
- 40 these regulations. It is not a legal requirement that the compiler of
- 41 SDSs be a qualified Safety Adviser in the meaning of these
- 42 Directives).
- 43
- 44
- 45 10. **National provisions**
- 46 a. Relevant national provisions, such as (this is a non-exhaustive list)
- 47 **In Germany:**
- 48 i. Water hazard classes (Wassergefährdungsklassen)
- 49 ii. Technical instruction air (TA-Luft)
- 50 iii. Technical rules for hazardous substances (Technische Regeln für
- 51 Gefahrstoffe)
- 52 **In France:**
- 53 i. Tableaux de maladies professionnelles
- 54 ii. Nomenclature des installations classées pour la protection de
- 55 l'environnement

In the Netherlands:

i. [De Algemene beoordelingsmethodiek Water \(ABM\)](#)

b. 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 1.1.1, 11.1.2, 11.1.11.2 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 updates to SDSs which are not specifically required by Article 31(9) of REACH, but such additional updates are not a legal requirement

1 Nevertheless, it is recommended to review the totality of the contents of an SDS at
2 regular intervals. The definition of these intervals is the responsibility of the actor who
3 issues the SDS – the intervals are not defined in the REACH Regulation. It might be
4 expected that the frequency of such reviews would be commensurate with the
5 hazards of the substance or mixture and that the review would be carried out by a
6 competent person.
7

8 **3.9. Need to communicate changes in the SDS**

9
10 The text of point 0.2.5 of the revised Annex II of REACH (in force as of 01/12/2010)
11 specifies that:

12 *“The date of compilation of the safety data sheet shall be given on the first page.*
13 *When a safety data sheet has been revised and the new, revised version is provided*
14 *to recipients, the changes shall be brought to the attention of the recipient in Section*
15 *16 of the safety data sheet, unless they have been indicated elsewhere. In that case,*
16 *the date of compilation identified as “Revision: (date)” as well as a version number,*
17 *revision number, supersedes date or other indication of what version is replaced shall*
18 *appear on the first page”.*

19 Thus, revisions must be identified as such on the first page and information on the
20 changes must be given either in section 16 or elsewhere in the SDS.
21

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

30 Version 1.0: initial issue

31 Version 1.1: first minor change

32 Version 1.2: second minor change

33 Version 2.0: first major change

34 Etc.

35 This is just an example of how to facilitate traceability of versions. There are many
36 other systems.
37

38 **3.10. Potential need to keep records of SDSs and their** 39 **amendments**

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

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

45 There is no reference in this text (or in the revision of Annex II) to a requirement for
46 the actors in the supply chain to keep copies of SDSs and/or outdated versions
47 thereof for any specified period. Both the suppliers of SDSs and potentially their
48 recipients should consider these documents as part of the *“the information he*
49 *requires to carry out his duties under this Regulation”* which is to be retained for a
50 minimum period of 10 years. The information used in the compilation of the SDS is
51 itself likely to constitute information required to carry out duties under REACH and
52 may in any case be required to be kept independently of its relation to the content of

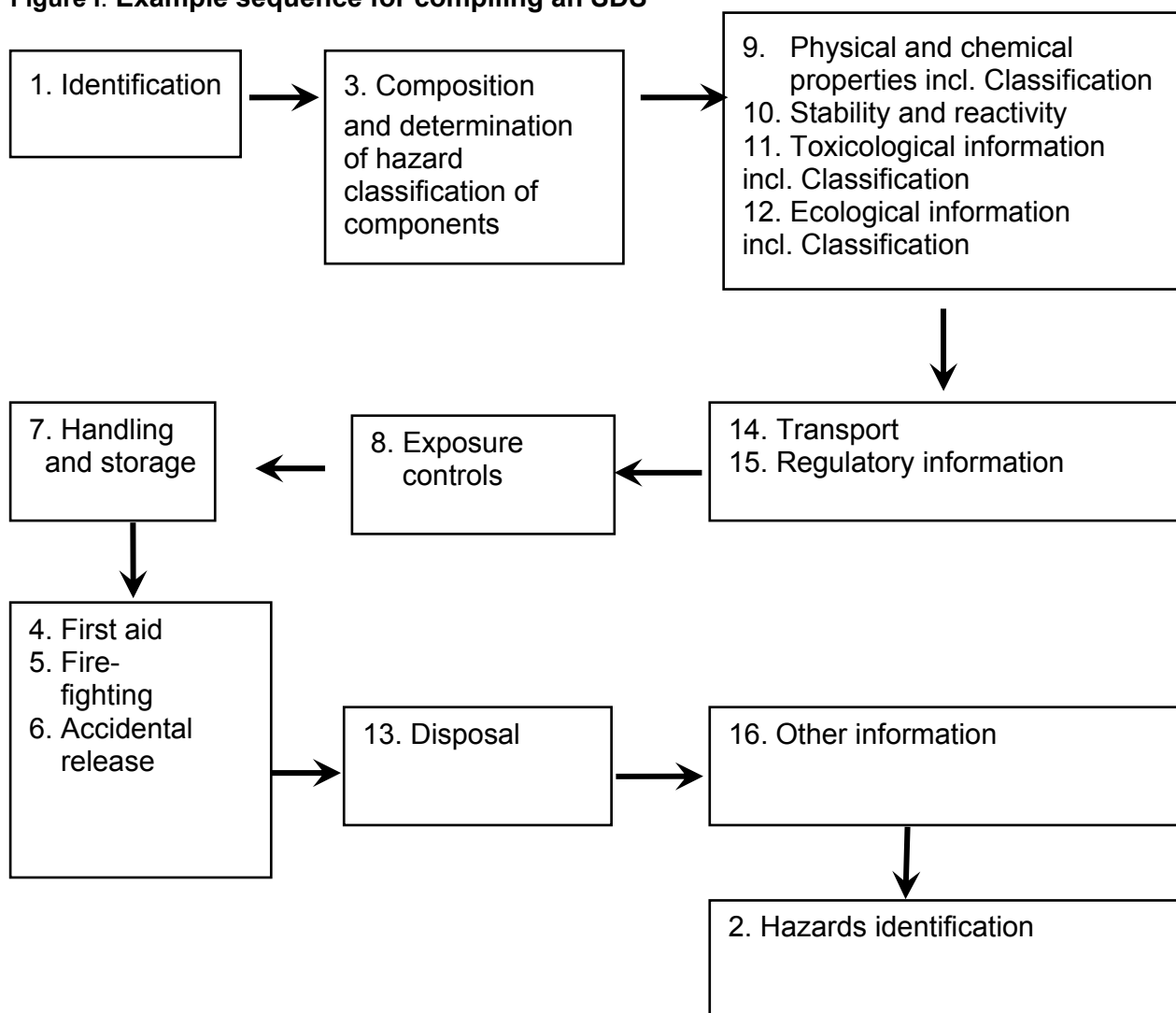
1 the SDS. Holders of both SDSs and other information may in any case decide that it
2 should be retained for product liability and other legal requirements and it might be
3 considered appropriate (for example for products with chronic effects) to keep this
4 information for a period of more than 10 years, depending on the applicable national
5 laws and regulations.
6
7

8 **3.11. Example of sequence for collecting and collating** 9 **information for compiling the SDS**

10
11 A suggestion for a step-wise approach to the creation of an SDS to ensure its internal
12 consistency is given in Figure I below (the numbers refer to the sections of the SDS):
13

14 The figure shows the process as a linear one to stress that, for example, the final
15 identification of hazards in Section 2 of the SDS is not likely to be possible until the
16 inputs to other sections have been considered. In reality the process is likely to be an
17 iterative one involving consideration of some aspects in different sequences to that
18 shown or even in parallel.
19

Figure I: 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

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

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

6 It should be noted however that in this context the wording “*shall be provided*” should
7 be understood as a positive duty on the supplier to actually deliver the SDS rather
8 than just make it available passively, for example on the internet or reactively by
9 delivering it on request. Therefore, ECHA’s Forum comprising national enforcement
10 representatives agreed that, for example, simply posting a copy of an SDS (or an
11 update to one) on a web site alone would not be considered as having complied with
12 the duty to “provide”.

13 Once an SDS has been supplied for a first delivery of a substance or mixture to a
14 particular recipient there is no need to supply a further copy of the SDS with
15 subsequent deliveries to the same recipient unless the SDS is revised.

18 **3.14. Language(s) in which the SDS must be provided**

19
20 According to REACH Article 31(5), “*The safety data sheet shall be supplied in an*
21 *official language of the Member State(s) where the substance or mixture is placed on*
22 *the market, unless the Member State(s) concerned provide otherwise*”. It should be
23 noted that it is for the recipient Member State (MS) to provide otherwise – i.e. for
24 example the existence of an exemption in the MS of manufacture does not give an
25 exemption in a different MS where the substance or mixture is placed on the market.
26 Even if the MS provides otherwise, it may be desirable to always provide (potentially
27 in addition) the SDS in the language of the country.

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

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

37 **3.15. Substances and mixtures for which an SDS be must be** 38 **provided without prior request**

39
40 According to Article 31 (1) of REACH (as amended by Articles 58(2)(a) and 59(2)(a)
41 of CLP) the criteria for when an SDS must be provided (even without request) are:

42
43 Between December 1st 2010 and May 31st, 2015:

44
45 “(a) where a substance meets the criteria for classification as hazardous in
46 accordance with Regulation (EC) No 1272/2008 or a mixture meets the criteria for
47 classification as dangerous in accordance with Directive 1999/45/EC; or
48 (b) where a substance is persistent, bioaccumulative and toxic or very persistent and
49 very bioaccumulative in accordance with the criteria set out in Annex XIII; or
50 (c) where a substance is included in the list established in accordance with Article
51 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"¹⁴ 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 $\geq 0,2$ % by volume for gaseous mixtures at least one substance posing human health or environmental hazards; or

(b) in an individual concentration of $\geq 0,1$ % 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 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 limit."

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 $\geq 0,2$ % by volume for gaseous mixtures at least one substance posing human health or environmental hazards; or

(b) in an individual concentration of $\geq 0,1$ % 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

¹⁴ http://echa.europa.eu/chem_data/authorisation_process/candidate_list_en.asp

1 *been included for reasons other than those referred to in point (a) in the list*
2 *established in accordance with Article 59(1); or*
3 *(c) a substance for which there are Community workplace exposure limits.”*

4
5 Note that such SDSs would potentially also be subject to the requirements for
6 attachment of any Exposure Scenarios where required by Article 14 or 37 of REACH
7 (see point 3.22 below).
8
9

10 **3.17. Labelling required for a mixture not classified as** 11 **hazardous and not intended for the general public for which** 12 **an SDS must be available and supplied on request**

13
14 For mixtures not classified as hazardous under CLP (or “dangerous” under DPD) and
15 not intended for the general public but which contain certain specified classified
16 components at above specified limits, for which a Safety Data Sheet must be
17 provided on request, the label on the packaging must bear information indicating the
18 availability of such SDSs.

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

22 For mixtures classified and labelled according to CLP the required text becomes:
23 “Safety Data Sheet available on request” (See CLP Annex II, point 2.10, text of
24 EUH210).
25
26

27 **3.18. SDSs for hazardous substances and mixtures made** 28 **available to the general public**

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

32 *“The safety data sheet need not be supplied where substances that are hazardous in*
33 *accordance with Regulation (EC) No 1272/2008 or mixtures that are dangerous in*
34 *accordance with Directive 1999/45/EC¹⁵, offered or sold to the general public, are*
35 *provided with sufficient information to enable users to take the necessary measures*
36 *as regards the protection of human health, safety and the environment, unless*
37 *requested by a downstream user or distributor”.*
38

39 From 1 June 2015 this is further amended by Article 59(2)(c) of CLP to read more
40 simply as follows:
41

42 *“The safety data sheet need not be supplied where hazardous substances or*
43 *mixtures offered or sold to the general public are provided with sufficient information*
44 *to enable users to take the necessary measures as regards the protection of human*
45 *health, safety and the environment, unless requested by a downstream user or*
46 *distributor.”*
47

¹⁵ From 1 June 2015 the text will refer 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.

1 Thus, it is not mandatory for a safety data sheet to be supplied for a
2 dangerous/hazardous substance or mixture made available to the general public¹⁶ if
3 the above conditions are complied with. However if the product is also supplied to a
4 downstream user or distributor and he requests an SDS it must be supplied to him. It
5 may be recommendable for the distributor (e.g. retailer) offering or selling these
6 substances or mixtures to be in possession of an SDS for each hazardous substance
7 or mixture which he sells. These SDSs also contain important information for him as
8 he has to store the substance or mixture and can give important information e.g. on
9 measures in case of an accident (or fire etc.). If the downstream user or distributor
10 feels that he needs an SDS for these or other purposes he can request one.

11 It should be noted that the actor who is specifically allowed to request the SDS by
12 this provision is the downstream user or distributor – it is **not** the member of the
13 public (“consumer”). The question of whether a particular customer for such a
14 substance or mixture is entitled to request and receive an SDS for it can therefore be
15 addressed on the basis of whether he qualifies as either a ‘downstream user’ or a
16 ‘distributor’ under the definitions given in Article 3 (13) and 3 (14) of the REACH
17 regulation respectively. A “consumer” is specifically excluded from the definition of a
18 downstream user. Whether a recipient qualifies as a downstream user with respect to
19 use of the substance or mixture “*in the course of his industrial or professional*
20 *activities*” may be determined for example on the basis of his professional
21 background. A reliable proof of the right to request an SDS could be an excerpt from
22 the trade register/register of companies or other professional accreditation or
23 potentially a VAT number (or holding of an account with the supplier), rather than
24 depending solely on quantities (which itself may serve as a first indicator).
25

26 **3.19. Access to information in the SDS by workers**

27
28 According to Article 35 of REACH:

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

33 The SDS (in the EU) is aimed at the employer, not the workers. The employer has a
34 responsibility to “translate” the information into suitable form to manage risks and
35 exposure etc.
36
37

38 **3.20. Products for which an SDS is not required**

39
40 The requirements to provide an SDS arise from Article 31 of the REACH Regulation.
41

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

44 “*The provisions of Title IV shall not apply to the following mixtures in the finished*
45 *state, intended for the final user:*

- 46 (a) *medicinal products for human or veterinary use, within the scope of Regulation*
47 *(EC) No 726/2004 and Directive 2001/82/EC and as defined in Directive 2001/83/EC;*
48 (b) *cosmetic products as defined in Directive 76/768/EEC;*

¹⁶ 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 – however in certain Member States national provisions may extend the right to request an SDS to members of the general public.

(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** other than those classified according to the CLP Regulation (explosive and pyrotechnical articles) for which there is a legal requirement to supply SDSs.

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

1 According to the first paragraph¹⁷ of Article 31(7) of REACH:

2 *“Any actor in the supply chain who is required to prepare a chemical safety report*
3 *according to Articles 14 or 37 shall place the relevant exposure scenarios (including*
4 *use and exposure categories where appropriate) in an annex to the safety data sheet*
5 *covering identified uses and including specific conditions resulting from the*
6 *application of Section 3 of Annex XI.”*
7

8 Thus, it is an obligation for these actors to place the relevant exposure scenarios in
9 an Annex to the SDS, whenever there is a requirement to prepare an exposure
10 scenario. It should be noted however that not all registrants who are required to carry
11 out a Chemical Safety Assessment (CSA) and prepare a Chemical Safety Report
12 (CSR)¹⁸ are necessarily required to prepare an exposure scenario (ES). Thus, for
13 example, although a CSA and CSR is generally required for all substances subject to
14 registration in quantities of 10 tonnes or more, an ES is **only** required for those for
15 which the further criteria given in Article 14 (4) also apply (i.e. after 1 December 2010
16 those fulfilling the criteria for any of the listed hazard classes in Article 14(4) of
17 REACH as amended by Article 58 of CLP from that same date). These criteria are:

18
19 *“4. If, as a result of carrying out steps (a) to (d) of paragraph 3, the registrant*
20 *concludes that the substance fulfils the criteria for any of the following hazard classes*
21 *or categories set out in Annex I to Regulation (EC) No 1272/2008:*
22

- 23 (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,*
24 *2.13 categories 1 and 2, 2.14 categories 1 and 2, 2.15 types A to F;*
25
26 (b) *hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility*
27 *or on development, 3.8 effect sother than narcotic effects, 3.9 and 3.10;*
28
29 (c) *hazard class 4.1;*
30
31 (d) *hazard class 5.1,”*
32

33 Thus, not all CSAs and CSRs necessarily lead to the need to generate an exposure
34 scenario to be attached to the SDS. Furthermore, the CSA and CSR would normally
35 be carried out as part of the preparations for a registration by the relevant deadline.
36 Exposure scenarios for particular substances on their own or in mixtures will
37 therefore normally only be attached to SDSs after the relevant substance has been
38 registered (or potentially slightly before if the supplier chooses to attach it as soon as
39 the registration dossier has been generated).

40 Once prepared the exposure scenario should be attached to SDSs as soon as
41 practicable and its attachment would then constitute a revision to the SDS. Where
42 the Exposure Scenario results in new risk management measures the SDS must be
43 re-issued retrospectively, see Art 31 (9)(a) of REACH and point 3.8 above.
44

45 **3.23. Alternative ways to incorporate the Exposure Scenario** 46 **information into the SDS for a mixture** 47

¹⁷ See 3.23 below for consideration of the consequences of the second paragraph of Article 31(7) with respect to alternative options for mixtures.

¹⁸ 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)

1 For the cases described in 3.22 above, Article 31.7 of REACH specifies that the
2 exposure scenario **must** be placed in an annex to the SDS.

3
4 However, the second and third paragraphs of Article 31.7 further state that:

5 *“Any downstream user shall include relevant exposure scenarios, and use other*
6 *relevant information, from the safety data sheet supplied to him when compiling his*
7 *own safety data sheet for identified uses.*

8 *Any distributor shall pass on relevant exposure scenarios, and use other relevant*
9 *information, from the safety data sheet supplied to him when compiling his own*
10 *safety data sheet for uses for which he has passed on information according to*
11 *Article 37(2).”*

12
13 For **downstream users** who are **not** required to carry out their own CSA for a
14 particular component substance (only) there are therefore alternative options for
15 inclusion of the Exposure Scenario information¹⁹.

16
17 The result is the following possible cases for actual inclusion of exposure scenario(s)
18 (ES) information (carried out by a Manufacturer/Importer or by a Downstream User
19 (DU)) into SDSs:

- 20
21 1. Attachment of the actual ES(s) resulting from a Chemical Safety Assessment
22 (CSA) for a substance as such or ES resulting from CSA for a substance in a
23 mixture in concentrations above the thresholds given in Article 14.
- 24 2. Integration of ES information resulting from consolidation of various ESs for
25 substances used in a mixture into the core Sections 1-16 of the SDS.
- 26 3. Attachment of ES resulting from the CSA for a special mixture²⁰.
- 27 4. (Potentially) Attachment of ES resulting from a CSA for a mixture under
28 Article 31(2) of REACH²¹.
- 29

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

32 It should further be noted that although all of the options above are allowed under the
33 specified conditions they may not all be equally suitable in practice as a means of
34 forwarding the relevant information – for example further downstream users may
35 prefer forwarding of ESs for substances in mixtures which they then formulate into
36 further mixtures instead of a consolidated documentation that only applies to the
37 mixture they receive.

38
39
40

¹⁹ 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 include*
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.

²⁰ See Appendix 3 for more information of “special mixtures”

²¹ 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,

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 Safety Data Sheets

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 consortium²² 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 is 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

²² Note that participation in a consortium is not mandatory.

the substances safely, for example. Information in the database is that provided by companies in their registration dossiers.

ESIS (<http://ecb.jrc.ec.europa.eu/esis/>) 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. and by substance name in the English language.

GESTIS (<http://www.dguv.de/bgia/en/gestis/stoffdb/index.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/safework/info/databases/lang--en/WCMS_113134/index.htm)

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 a mixtures containing such a substance

Appendix 4 of this document discusses specific issues relevant to the compilation of Safety Data Sheets for recovered substances and mixtures. The ECHA Guidance on waste and recovered substances²³ 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. *inter alia* to allow classification and labelling under CLP or 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 sub-section 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 is 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/EEC²⁴ and 2010/63/EU²⁵ of the 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.

²³ The Guidance on waste and recovered substances has been finalised (Version 2) and is available at: http://guidance.echa.europa.eu/guidance4_en.htm

²⁴ 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)

²⁵ Directive 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)

CHAPTER 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 sub-sections, there is no requirement to insert text in the actual SDS except in the sub-sections. 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.

1

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

4 *“The product identifier for a substance shall consist of at least the following:*

5 *(a) if the substance is included in Part 3 of Annex VI, a name and an identification*
6 *number as given therein;*

7 *(b) if the substance is not included in Part 3 of Annex VI, but appears in the*
8 *classification and labelling inventory, a name and an identification number as given*
9 *therein;*

10 *(c) if the substance is not included in Part 3 of Annex VI nor in the classification and*
11 *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 the 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 SDS²⁶.

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."

²⁶ Note that at 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: <http://ecb.jrc.ec.europa.eu/esis/index.php?PGM=cla>

However such an explanation is not mandatory.

For mixtures, until 1 June 2015 the requirement within this sub-section 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. 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 the identified uses²⁷ of the substance or mixture insofar as they are known. For registered substances this list of uses must be consistent with the uses included in the registration dossier.

²⁷ Identified use is defined in REACH, Article 3 (26)

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”²⁸ in this section be avoided. Otherwise it could result in an unnecessarily lengthy 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 ES is provided as an annex’

The information in the sub- section 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 sub-section 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]²⁹; 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

²⁸ More information on use descriptors is available at:
http://guidance.echa.europa.eu/guidance4_en.htm

²⁹ 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

Member State, a full address and telephone number for that responsible person shall be given.

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

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

It should be noted that only details of the non-Community manufacturer or formulator are optional. The other information specified in this section must be given by all suppliers. Note also that in this context "the supplier" refers to the supplier of the SDS as indicated by the title of this section³⁰. It should be further noted that a "responsible person" is nominated by a "supplier" who by definition 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 sub-section 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
-National contact:

For the email address of the competent person responsible for the Safety Data Sheet, 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 Safety Data Sheet 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

1.4. Emergency telephone number

³⁰ 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

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 this case it may not be appropriate to give its telephone number on an SDS.

Additionally, when available, references to emergency information services belonging to the supplier may be indicated. In this case, the supplier should have the necessary competence available to answer enquiries regarding the substance / mixtures (articles) to which the SDS refers. Where no alternative is referred to, it is strongly recommended that at least the telephone number of the supplier be given here (potentially repeating that given in 1.3 to indicate that this is also the number to use in emergencies)³¹.

Any limitations on either the official advisory body or the supplier's own services (opening hours or types of information that may be provided) should 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/preparation referred to.

An example of how the structure of sub-sections 1.3 and 1.4 could look is given below:

³¹ It should be noted that 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 states that the 'employer shall ensure that information on emergency arrangements involving hazardous chemical agents is available. The relevant internal and external accident and emergency services shall have access to this information'. Therefore emergency information should already be available in those companies in which 'chemical agents [...] are present at the workplace or [which undertake] any work activity involving chemical agents'.

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
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 text above is considered as needing no further explanation].

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.

1

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

4 • **For a substance**

5

6 When a supplier has notified the information on the substance to the classification
7 and labelling inventory, the classification given in the safety data sheet must be the
8 same as that provided in his notification.

9 From 1 December 2010, the classification is to be given according to the rules in the
10 CLP Regulation: i.e. indication of hazard classes and categories and hazard
11 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 phrases³², and, for CMR effects, danger categories.

It is advisable to clearly identify both classifications (i.e. with sub headings) in the safety data sheet. Although not a legal requirement, information on which procedure was used for each endpoint classification (e.g. based on test data, human experience, expert judgement or minimum classification) would be useful here where available. Also, although not a legal requirement, as the M-factor is part of the classification of a substance it is strongly recommended that they are given in this sub-section where they are included in Annex VI to CLP or have been set by manufacturers, importers or downstream users.

An example of how the structure of this section could look for a **substance** is given below³³:

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

2.1.1 Classification 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

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

N ; R50

2.1.3 Additional information:

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

M-Factor (self-classification) = 10

• 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: symbol letter(s) and indication of danger and R phrases and, for CMR effects, danger categories. 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.

³² Full text or risk phrases numbers with reference to SECTION 16 for full text.

³³ Note that additional numbering and sub-structuring below the sub-section level is not a legal requirement

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

3
4 Note: If a supplier of a mixture chooses to identify and inform about the classification
5 according to the CLP Regulation in advance of using it for classification and labelling
6 on the package, this classification may be included in section 16.

7
8 When the safety data sheet is provided for a non classified mixture, this should be
9 indicated. An example statement to do this could be:

10 *'This product does not meet the criteria for classification in any hazard class*
11 *according to Regulation (EC) No 1272/2008 on classification, labelling and packaging*
12 *of substances and mixtures'.*

13
14 Please note that additional information on the components of mixtures is likely to
15 become available (e.g. as a result of new tests or other information exchanges) after
16 the first registration deadline (1st of December 2010) as result of SIEF, consortium
17 and/or individual registrant activities. This process of increasing availability of
18 information may continue until 2018 and beyond.

19
20 An example of how the structure of this section could look **during the transitional**
21 **period** (i.e. for a mixture for which full CLP labelling has not yet been implemented
22 between 01 December 2010 and 1 June 2015) is given below³⁴:

23 **SECTION 2: Hazards identification**

24
25 **2.1 Classification of the substance or mixture**

26
27 **2.1.1 Classification according to Regulation (EC) No 1272/2008 [CLP]**

28
29 *see SECTION 16*

30
31 **2.1.2. Classification according to Directive 1999/45/EC**

32
33 *F; R11*

34 *T; R23/24/25*

35 *T; R39/23/24/25*

36 *Repr. Cat. 2; R60-61*

37
38 **2.1.3 Additional information:**

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

40
41 **2.2. Label elements**

Text Annex II

³⁴ Note that additional numbering and sub-structuring below the sub-section level is not a legal requirement

[To 1 June 2015: “In the case of a substance, based on the classification, at least the following elements appearing on the label in accordance with Regulation (EC) No 1272/2008 shall be provided: hazard pictogram(s), signal word(s), hazard statement(s) and precautionary statement(s). A graphical reproduction of the full hazard pictogram in black and white or a graphical reproduction of the symbol only may be substituted for the colour pictogram provided in Regulation (EC) No 1272/2008.

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

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

[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.”]

1

2 For substances, from 1 December 2010 the label elements are to be indicated
3 according to the CLP Regulation. These elements must include **all** label elements
4 appearing on the label (i.e. including, where appropriate, the inner pack label
5 elements³⁵).

6 For mixtures, the label elements indicated in this section may be according to either
7 the DPD or according to the CLP Regulation (where the supplier has chosen to
8 implement CLP labelling earlier than required) until May, 31st 2015. In either case the
9 label elements indicated must be consistent with the corresponding label affixed to
10 the product. From 1 June 2015 the label elements listed (and the actual labelling)
11 must be according to the CLP Regulation, including all label elements as is the case
12 for substances.

13

14 Label elements according to the CLP Regulation include:

- 15 • Hazard pictogram(s), including graphical reproduction of the symbol or the full
16 pictogram(s), in black and white or in colour.
- 17 • Signal word
- 18 • Hazard statement(s), H and EUH, in full (or give in full in Section 16 if not
19 here)

³⁵ 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

- 1 • Precautionary statement(s), P, in full
- 2 • The applicable label elements in accordance with Articles 25 (i.e. according to
- 3 Annex II of CLP) and 32(6) of the CLP Regulation.
- 4 • The precautionary statements may be selected in accordance with the criteria
- 5 laid down in Part 1 of Annex IV of CLP taking into account the hazard statements and
- 6 the intended or identified use or uses of the substance or the mixture. Once selected,
- 7 the precautionary statements must be worded in accordance with Part 2 of Annex IV
- 8 of CLP.
- 9 • In selecting the precautionary statements in accordance with Articles 22 and
- 10 28 of CLP, suppliers may combine the Precautionary Statements, having regard to
- 11 clarity and comprehensibility of the precautionary advice (in this case the specific
- 12 wording of the component phrases combined should be retained). It should be noted
- 13 that according to Article 28(3) of CLP not more than six precautionary statements
- 14 should appear on the label unless necessary. For further information on selection of
- 15 precautionary statements see the ECHA Guidance on labelling and packaging in
- 16 accordance with Regulation (EC) 1272/2008³⁶
- 17 • It may be useful for industrial and professional users (not for consumers since
- 18 they do not receive SDSs) to include special precautionary statements into
- 19 appropriate Sections of the SDS main body in order to reduce the number of
- 20 precautionary statements on the label³⁷. Examples of such precautionary statements
- 21 that could, for example, be given in sub-section 7.1 "precautions for safe handling"
- 22 instead of on the label are as follows:

23 *Do not handle until all safety precautions have been read and*
 24 *understood. (P202)*

25 *Wash hands thoroughly after handling (P264)*

26 *Do not eat, drink or smoke when using this product (P270)*

27 *Contaminated work clothing should not be allowed out of the*
 28 *workplace. (P272)*

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

32 Symbol(s), full colour reproduction of the symbol as it appears on the label or in black
 33 and white (alternatively, particularly where graphics are not available, the symbol
 34 could be described in words e.g. "Symbol for Xi" or simply "Xi" in the symbol field).

35 Indication(s) of danger

36 Risk phrase(s) (R), in full or as a code with reference to and full text in SECTION 16

37 Safety advice (S), in full

38 The applicable label elements in accordance with sections A and B of annex V to the
 39 DPD.

41 According to REACH Article 65, holders of an authorisation, as well as downstream
 42 users referred to in Article 56(2) who include a substance subject to authorisation in a
 43 mixture, must include the authorisation number on the label of the respective

³⁶ Available at: http://guidance.echa.europa.eu/guidance_en.htm

³⁷ 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

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 section could look for a substance is given below³⁸.

2.2: Label elements³⁹

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

Hazard pictograms



Signal word:

Danger

Hazard statements:

May cause fire or explosion; strong oxidiser.
Causes severe skin burns and eye damage

Precautionary statements⁴⁰:

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

P221 Take 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.

³⁸ 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.

³⁹ Note that the product identifier, although a label element, is not given in sub-section 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.

⁴⁰ See next page for further information on how the number of precautionary statements has been reduced.

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 CENTER⁴¹ or doctor/physician.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P371+P380+P375 In case of major fire and large quantities: Evacuate area. Fight fire remotely due to the risk of explosion.

.
Supplemental Hazard information (EU)⁴²: Not 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 sub-section (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 CLP labelling and packaging guidance

NOTE: the reference number of pictograms, R and S phrases, and H and P statements (e.g. “H225”) do not need to appear on the label and in section 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 section 2.2 of the SDS.

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.

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.

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

⁴¹ (Note spelling of “center” is US, carried-over from GHS)

⁴² If applicable

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

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 applicable⁴³.

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)⁴⁴.

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.

⁴³ Whichever of these two sub-sections is not applicable becomes the only sub-section in the SDS which may be left completely blank.

⁴⁴ It is specifically **not** intended to require information to be given here on surfactant properties of (liquid or dissolved) substance or mixture.

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 mixtures) etc for impurities in a **substance** (by contrast to the case for mixtures covered by 3.2.3) since these should already have been taken into account in the classification of the substance as registered under REACH / notified under CLP.

An expanded illustrative example of how the structure of this section could look for a styrene monomer is given below⁴⁵:

SECTION 3: Composition/information on ingredients:
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 Number⁴⁶
Index number in CLP Annex VI	601-026-00-0	styrene	99.70 – 99.95	202-851-5
CAS number in CLP Annex VI ⁴⁷	100-41-4	ethylbenzene	0.05 maximum	202-849-4
CAS number	98-29-3	4- <i>tert</i> -butylbenzene-1,2-diol ⁴⁸	0.0015 (15 ppm) maximum	202-653-9
(Non-classified constituent)	Not applicable	Polymers	Max 0.0020	Not applicable

⁴⁵ 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.

⁴⁶ If all the first three columns in this example are populated this column is not a requirement – it is for information only.

⁴⁷ 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.

⁴⁸ This is the actual IUPAC name for the substance otherwise known as 4-*tert*-butyl catechol./ 4-*tert*-butyl pyrocatechol / TBC

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:
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 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 sub-section 3.1 with those for mixture information under sub-section 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) $\geq 10\%$;

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

<i>1.1 Hazard class and category</i>	<i>Concentration limit %</i>
<i>Acute toxicity, category 1, 2 and 3</i>	$\geq 0,1$
<i>Acute toxicity, category 4</i>	≥ 1
<i>Skin corrosion/irritation, category 1A, 1B, 1C and 2</i>	≥ 1
<i>Serious damage to eyes/eye irritation, category 1 and 2</i>	≥ 1
<i>Respiratory/skin sensitisation</i>	$\geq 0,1$
<i>Germ cell mutagenicity category 1A and 1B</i>	$\geq 0,1$
<i>Germ cell mutagenicity category 2</i>	≥ 1
<i>Carcinogenicity category 1A, 1B and 2</i>	$\geq 0,1$
<i>Reproductive toxicity, category 1A, 1B, 2 and effects on or via lactation</i>	$\geq 0,1$
<i>Specific target organ toxicity (STOT) - single exposure, category 1 and 2</i>	≥ 1
<i>Specific target organ toxicity (STOT) – repeated exposure, category 1 and 2</i>	≥ 1
<i>Aspiration hazard</i>	≥ 10
<i>Hazardous to the aquatic environment – Acute, category 1</i>	$\geq 0,1$
<i>Hazardous to the aquatic environment – Chronic, category 1</i>	$\geq 0,1$
<i>Hazardous to the aquatic environment – Chronic, category 2, 3 and 4</i>	≥ 1
<i>Hazardous for the ozone layer</i>	$\geq 0,1$

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

(iii) *if an M-factor has been given in Part 3 of Annex VI to Regulation (EC) No 1272/2008, the generic cut-off value in Table 1.1 of Annex I to that Regulation, adjusted using the calculation set out in Section 4.1 of Annex I to that Regulation;*

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

(viii) *the concentration limits set out in Annex II to Regulation (EC) No 1272/2008;*

(viii) *if an M-factor has been provided to the classification and labelling inventory established under Regulation (EC) No 1272/2008, the generic cut-off value in Table 1.1 of Annex I to that Regulation, adjusted using the calculation set out in Section 4.1 of Annex I to that Regulation.”]*

(b) *substances for which there are Community workplace exposure limits, which are not already included under point (a);*

(c) *substances that are persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII, or substances included in the list established in accordance with Article 59(1) for reasons other than the hazards referred to in point (a), if the concentration of an individual substance is equal to or greater than 0,1 %.*

[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.

1 It should be noted that although the legal text quoted above mentions generic cut-off
2 values and M-factors only in the context of deciding which substances (including their
3 concentration or concentration range in the mixture) need to be listed in the SDS, for
4 cases where an M-factor is available in practice it would be potentially useful and
5 therefore recommendable to also give the actual M-factor and indicate it as such (this
6 is preferably best indicated in sub-section 2.1).

8 The requirements for information on identifiers to be given under this sub-section 3.2
9 (as opposed to sub-section 1.1) for mixtures are different in the version of Annex II in
10 force from 1 December 2010 to 1 June 2015 and the version in force from 1 June
11 2015. In particular the qualification that the product identifier must be given "if
12 available" no longer applies as of 1 June 2015 (since by then product identifiers
13 [according to CLP] should be available for all component substances). In contrast
14 with the case for sub-section 1.1 there is no specific requirement that the product
15 identifier information for component substances of a mixture given in sub-section 3.2
16 should conform to the full requirements of either Article 18(2) or Article 18(3)(a) of
17 CLP.

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

25 In the case of mixtures, the part of the REACH registration number for component
26 substances referring to the individual registrant of a joint submission (the last four
27 digits of the original full registration number) can be omitted by **any** supplier (it should
28 be noted that in this case it is not a requirement that the supplier be a downstream
29 user or distributor as is the case for truncation of the registry number given for
30 substances in Section 1.1). It should be further noted that registration numbers are
31 only required in this sub-section for the substances referred to in points 3.2.1 or
32 3.2.2. However, if suppliers choose to list additional substances in the mixture under
33 Section 3.2, although they are not obliged to give the information specified in point
34 3.2.1 or 3.2.2 for these substances, they must then give the applicable information
35 specified in 3.2.3 and 3.2.4, including the registration numbers if available.

37 An example of how the structure of this section could look is given below⁴⁹:

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

40 **3.2 Mixtures**

41 *Description of the mixture:*

42 Mixture of Styrene and Ethylbenzene.

45 *Hazardous ingredients*

CAS	EC No	Index No.	REACH	%	Name	Classification
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⁴⁹ PLEASE NOTE: This example is given for the purposes of illustrating the format of entries in this sub-section, and in particular the difference by comparison of with an entry in sub-section 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.

No			Registration No.	[weight]		according to 67/548/EEC
100-42-5	202-851-5	601-026-00-0	01-XXXXXXXXXX-XX-YY-YYYY	60	styrene	R10 Xn; R20 Xi; R36/38
100-41-4	202-849-4	601-023-00-4	01-NNNNNNNNNN-NN-NN-YYY	40	ethylbenzene	F; R11 Xn; R20

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CAS No	EC No	Index No	REACH Registration No	% [weight]	Name	Classification according to Regulation (EC) No 1272/2008 [CLP]
100-42-5	202-851-5	601-026-00-0	01-XXXXXXXXXX-XX-YY-YYYY	60	styrene	Flam. Liq. 3 H226 Acute Tox. 4 * H332 Eye Irrit. 2 H319 Skin Irrit. 2 H315
100-41-4	202-849-4	601-023-00-4	01-NNNNNNNNNN-NN-NN-YYY	40	ethylbenzene	Flam. Liq. 2 H225 Acute Tox. 4 * H332

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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' or by presenting both classifications side by side (CLP and EU classification in two neighbouring columns)

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

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 public⁵⁰,

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

⁵⁰ 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: http://ec.europa.eu/enterprise/sectors/chemicals/files/docs/faq_detergent_regulation_march2009_en.pdf

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 sub-section 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 sub-section is for symptoms and effects - treatments are to be described in sub-section 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.

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

1 by an untrained responder and that if medical attention is required this must be
2 explicitly stated

3
4 Where it appears to be necessary to provide specific information for the doctor (e.g.
5 specific antidote treatment, positive airway pressure, prohibition of certain drugs,
6 eating, drinking or smoking, etc.) this information may be given under a heading such
7 as "Notes for the doctor" (symptoms, hazards, treatment). The information provided
8 under this heading may contain special medical terms which may be difficult to
9 understand for non-medical personnel, . Although not a specific requirement it may
10 also be indicated whether any recommendations for specific actions or treatments
11 can or cannot be carried out by first aiders as well as by medical doctors.

12 **4.5. SDS SECTION 5: Firefighting measures**

13

<i>Text Annex II</i>

<i>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.</i>
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16 **5.1. Extinguishing media**

17

<i>Text Annex II</i>

<i>Suitable extinguishing media:</i>

<i>Information shall be provided on the appropriate extinguishing media.</i>
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<i>Unsuitable extinguishing media:</i>
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<i>Indications shall be given whether any extinguishing media are inappropriate for a particular situation involving the substance or mixture.</i>
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19
20 Unsuitable extinguishing media are extinguishing media which must not be used for
21 safety reasons including media that may cause chemical or physical reactions
22 resulting in an additional potential hazard. For example, in the presence of
23 substances which in contact with water emit flammable or toxic gases (e.g. Calcium
24 carbide reacts with water to form Ethyne (Acetylene)).

27 **5.2. Special hazards arising from the substance or mixture**

28

<i>Text Annex II</i>

<i>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".</i>

29
30 This section includes information about any specific hazards arising from the
31 chemical (e.g. nature of any hazardous combustion products or vapour cloud
32 explosion risks.)

34 **5.3. Advice for firefighters**

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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.

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

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

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

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

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

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

26 When compiling this section, it should be considered whether spillage and fire-
27 fighting water could cause pollution of watercourses. If so, information should be
28 given on how to minimize their impact on the environment.
29

30

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

32

SECTION 5. Firefighting measures

33

34

5.1 Extinguishing media:

35

Suitable extinguishing media:

36

Unsuitable extinguishing media:

37

38

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*"⁵¹ and "*capping*"⁵² here have the meanings as defined in Annex 4 of the GHS⁵³.

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

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

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 below⁵⁴:

⁵¹ "*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.*"

⁵² "*i.e. providing a cover or protection (e.g. to prevent damage or spillage).*"

⁵³ Globally Harmonized Classification and Labelling system of Chemicals (GHS), Third revised edition 2009. Annex 4 – Guidance on the preparation of Safety Data Sheets, page 411.

1
2 **SECTION .: Accidental release measures**
3

4 **6.1 Personal precautions, protective equipment and emergency procedures**
5

6 **6.1.1 For non-emergency personnel**

7 Protective equipment:

8 Emergency procedures:
9

10 **6.1.2 For emergency responders**
11

12 **6.2 Environmental precautions:**
13

14 **6.3 Methods and material for containment and cleaning up**
15

16 **6.3.1 For containment:**
17

18 **6.3.2 For cleaning up:**
19

20 **6.3.3 Other information:**
21

22 **6.4 Reference to other sections**
23
24
25

⁵⁴ Note that additional numbering and sub-structuring below the sub-section 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.

(No additional clarification considered necessary).

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 section 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 sub-section 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 section 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 section should also include advice - if relevant - on quantity limits under storage conditions (arising e.g. *inter alia* from the Seveso II Directive as extended⁵⁵). In particular 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 section. 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 section could look is given below:

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

⁵⁵ 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.

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, all uses for which the product has been authorised may be indicated (e.g. wood preservation, disinfection, slime control, in-can preservation, etc.). If necessary, reference may be made to a technical fact sheet containing information concerning the quantity to be applied and the handling instructions for any kind of use.

If the SDS has the corresponding Exposure Scenarios attached, there is no need to use this section for specific recommendations for end uses.

For substances for which exposure scenarios are not required (e.g. substances for which no chemical safety assessment is required because they are not subject to registration at ≥ 10 t/a⁵⁶), this section may 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:

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"⁵⁷, 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.

⁵⁶ 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 ES is required, however these criteria will apply for most substances for which an SDS is required.

⁵⁷ 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

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 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 section 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 value⁵⁸, for Section 8 the requirement is that the national occupational exposure limit values that correspond to Community OELs must be listed. In cases where an Indicative Occupational Exposure Limit (IOELV) value 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.

⁵⁸ See point 3.2.1 (b) of text of Annex II text above.

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 States⁵⁹ is given below:

--	--	--	--	--	--

Substance	Acetone				
CAS No.	67-64-1				

	Limit value - Eight hours		Limit value - Short term*		
--	---------------------------	--	---------------------------	--	--

Country ⁶⁰	ppm	mg/m ³	ppm	mg/m ³	Legal basis ⁶¹
Austria	500	1200	2000	4800	
Belgium	500	1210	1000	2420	
Denmark	250	600	500	1200	
European Union⁶²	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	

--	--	--	--	--	--

Remarks :

⁵⁹ 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.

⁶⁰ 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).

⁶¹ 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.

⁶² 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, but this is not actually a requirement

European Union	Bold-type: Indicative Occupational Exposure Limit Values [2,3] and Limit Values for Occupational Exposure [4] (for references see bibliography)
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/en/gestis/limit_values/index.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 follows⁶³:

Country	(Country information where available)
Austria	http://www.dguv.de/ifa/en/gestis/limit_values/pdf/au.pdf
Belgium	http://www.dguv.de/ifa/en/gestis/limit_values/pdf/be.pdf
Denmark	(Not available)
European Union	(Not available)
France	http://www.dguv.de/ifa/en/gestis/limit_values/pdf/fr.pdf
Germany (AGS)	http://www.dguv.de/ifa/en/gestis/limit_values/pdf/ags.pdf
Hungary	http://www.dguv.de/ifa/en/gestis/limit_values/pdf/hu.pdf
Italy	(Not available)
Poland	(Not available)
Spain	http://www.dguv.de/ifa/en/gestis/limit_values/pdf/es.pdf
Sweden	(Not available)
The Netherlands	http://www.dguv.de/ifa/en/gestis/limit_values/pdf/nl.pdf
United Kingdom	http://www.dguv.de/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 section must also include the currently recommended monitoring or observation methods at least for the most relevant substances. These

⁶³ 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

1 monitoring methods can be: personal air monitoring, room air monitoring, biological
2 monitoring etc according to agreed standards. The specific standard should be
3 referenced, for example:
4

5 “BS EN 14042:2003 Title Identifier: Workplace atmospheres. Guide for the
6 application and use of procedures for the assessment of exposure to chemical and
7 biological agents.”
8

9 It should be noted that since the applicable limits and their legal basis are those of
10 individual Member States on whose market the substance or mixture is being placed,
11 the monitoring methods of the country for which the SDS is being provided should
12 take precedence over those of the originating country where there is a difference in
13 methods.
14

15 For mixtures, it may be considered to be useful to provide information here for those
16 constituent substances which are required to be listed in the Safety Data Sheet
17 according to Section 3, if available⁶⁴.
18

19 The Derived No Effect Levels (DNELs) and Predicted No Effect Concentrations
20 (PNECs) applicable to the exposure scenarios in any required annex(es) to the SDS
21 for a specific substance or mixture can be listed together with - and in the same way
22 as - the OELs discussed above, or can be listed or tabled separately, depending on
23 the supplier's preference.
24

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

27 An example of how the required information on DNELs and PNECs in this section
28 could be structured is given below:
29
30
31

⁶⁴ For certain types of substances and mixtures (e.g. complex petroleum derivatives) such methods are unlikely to be available.

1 Substance name

2 EC number: CAS number:

3 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 <u>or</u> ii) hazard identified but no DNEL available <u>or</u> iii) no exposure expected, iv) no hazard identified								

4

5 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 <u>or</u> ii) hazard identified but no PNEC available <u>or</u> iii) no exposure expected <u>or</u> iv) no hazard identified	

The control banding approach

According to the International Labour Organisation, Control Banding can be described as follows⁶⁵:

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

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.*

⁶⁵ See: http://www.ilo.org/legacy/english/protection/safework/ctrl_banding/whatis.htm

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 section, 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 section 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 sub-section 8.2 of the SDS which aids an employer in developing the required risk management and risk reduction measures according to his obligations under Directive 98/24/EC 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 (sub-section 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 Section 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 exposure scenarios. In the case of mixtures the information given should reflect a consolidation of the information for components.

Any additional or specific measures such as skin protection schemes may also be specified here.

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/EEC⁶⁶ 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.

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

Note: the blue symbols included below are only for illustration purposes. It is not mandatory to include any such symbols in the SDS

(Also 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

⁶⁶ 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.

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 sub-section 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 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 sub-section.

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. Give information on the assigned protection factor (APF) that should be used in the particular scenario. 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 section includes the information required by the employer to fulfil his obligations under environmental protection legislation. If appropriate, a reference to the section 6 of the Safety Data Sheet may be included.

An example of how the structure of this sub-section could look is given below⁶⁷:

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:

8.2.2.1 Eye and face protection:

⁶⁷ Please note that numbering below the level of the sub-section 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 sub-sections.

8.2.2.2 Skin protection:

Hand protection:

Other skin protection:

8.2.2.3 Respiratory protection:

8.2.2.4 Thermal hazards:

8.2.3 Environmental exposure controls:

Product 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 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 chemical safety report 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

1 stated if not obvious, and not on the absence of information. A clear differentiation
2 should also be made between cases where no information is available to the
3 compiler (e.g. "no information available"), and cases where actual negative test
4 results are available.

5
6 The data should preferably have been generated in accordance with the test
7 methods referred to in the REACH Regulation, transport provisions or international
8 principles or procedures for the validation of information, so as to ensure quality and
9 comparability of the results and consistency with other requirements at international
10 or Community level. Where this information is available from testing for the purposes
11 of a REACH registration or to determine classification under CLP this will be an ideal
12 basis to ensure the required consistency.

13
14 As specified in the relevant test methods, critical information such as test
15 temperature and methods used, which affect the value of physical-chemical
16 properties and safety characteristics, should be provided for all test results and, if
17 available, for data acquired from the literature.

18
19 For mixtures, where information does not apply to the mixture as a whole the entries
20 must clearly indicate to which substance in the mixture the data apply.

21 22 **9.1. Information on basic physical and chemical properties**

23 *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 (m²/mass), surface charge/zeta potential and crystalline phase. 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 section 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 section. E.g. physical state: solid (nanomaterial).

(Note that the inclusion of granulometric and specific surface area by volume information in sub-section 9.1 is a new requirement of the amended Annex II). 'Further guidance in regards to the respective parameters listed above can be found from the OECD-WPMN guidance to Sponsorship Programme (ENV/MONO(2009) 25, at:

[http://www.oecd.org/officialdocuments/displaydocumentpdf/?cote=env/jm/mono\(2009\)20/rev&doclanguage=en](http://www.oecd.org/officialdocuments/displaydocumentpdf/?cote=env/jm/mono(2009)20/rev&doclanguage=en) '.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 sub-section 9.2 is a new requirement of the amended Annex II)

c) Odour threshold

(New requirement of the amended Annex II)

d) pH

1 **e) Melting point / freezing point**

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

3 **g) Flash point**

4 **h) Evaporation rate**

5 (New requirement of the amended Annex II)

6

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

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

9 (New requirement of the amended Annex II)

10

11 **k) Vapour pressure;**

12 An indication of the temperature at which this was measured should be given (at ...
13 °C);

14 It should be stated whether the value indicated has been measured or calculated,
15 and 9in the case of mixtures) to which substance(s) it refers.

16

17 **l) Vapour density;**

18 **m) Relative density;**

19 An indication of the temperature at which this was measured should be given (at ...
20 °C);

21 For gases: Relative density (air = 1).

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

24

25 **n) Solubility(ies)**

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

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

31

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

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

35 **p) Auto-ignition temperature**

36 (New requirement of the amended Annex II)

37 **q) Decomposition temperature**

38 (New requirement of the amended Annex II)

39 **r) Viscosity**

For certain product groups it may be appropriate to provide data concerning the viscosity (dynamic viscosity in mPas or kinematic viscosity in mm²/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 sub-section 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 guidance to Sponsorship Programme (ENV/MONO(2009) 25, [http://www.oecd.org/officialdocuments/displaydocumentpdf/?cote=env/jm/mono\(2009\)20/rev&doclanguage=en](http://www.oecd.org/officialdocuments/displaydocumentpdf/?cote=env/jm/mono(2009)20/rev&doclanguage=en)).

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) or in Section 8 (e.g. exposure controls in sub-section 8.2). 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 (see Table 2 at the end of this chapter for more information).

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.

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.

(No additional clarification considered necessary).

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 sub-section for stable substances or mixtures include:

- "Under normal conditions, 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 SECTION 2 and 9, and there is therefore a need to check for consistency/potential overlap.

There is also potential overlap between sub-section "10.1 Reactivity" which also relates to reactivity hazards and the present 10.3 "Possibility of hazardous reactions". Entry of information in 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 10.1 which implies e.g. an intrinsic risk of hazardous reaction with bases. 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 sub-section potentially overlaps with sub-section 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 safety data sheet. 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 can help with in this.

The content of this sub-section potentially overlaps with elements dealing with handling of incompatible substances and mixtures within sub-section 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 in this sub-section 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

1
2
3

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.”]

1

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

11

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

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

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

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

28 If no data are available for certain hazard classes or differentiations the reasons for
29 the absence of data should be given⁶⁸.

⁶⁸ 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 and feasible search for such information if he does not have it already.

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 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 section, for example using a structure as follows:

1

2 $ATE_{mix} (oral) = \quad \quad \quad xxx \text{ mg/kg}$
3 $ATE_{mix} (dermal) = \quad \quad \quad xxx \text{ mg/kg}$
4 $ATE_{mix} (inhal.) = \quad \quad \quad x \text{ mg/l/4 h (vapours)}$

5

6 If information on the mixture itself is not available for a certain endpoint but several
7 substances in it have the same health effect, this effect may be mentioned for the
8 mixture and not for the individual substances.

9 In the absence of specific data on the mixture regarding interactions between
10 component substances, assumptions must **not** be made and instead the relevant
11 health effects of each substance must be listed separately (see Annex II section
12 11.1.12.2)

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

16

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

- 19 • Section 2 Hazards identification
20 • Section 4 First aid measures
21 • Section 6 Accidental release measures
22 • Section 7 Handling and storage
23 • Section 8 Exposure controls/personal protection
24 • Section 9 Physical and Chemical properties
25 • Section 13 Disposal considerations
26 • Section 14 Transport information
27 • Section 15 Regulatory information

28

29

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

32

33 *SECTION 11: Toxicological information*

34 35 36 *11.1 Information on toxicological effects*

37

- 38 • *Acute toxicity:*
39 • *Skin corrosion/irritation:*
40 • *Serious eye damage/irritation:*
41 • *Respiratory or skin sensitisation*
42 • *germ cell mutagenicity;*
43 • *carcinogenicity;*
44 • *reproductive toxicity;*
45 • *Summary of evaluation of the CMR properties;*
46 • *STOT-single exposure;*
47 • *STOT-repeated exposure;*
48 • *aspiration hazard:*
49

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:

11.1.1⁶⁹ 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,.

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

⁶⁹ Note that additional numbering and sub-structuring below the sub-section level is not a legal requirement

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.

1

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

4

5 **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.

6

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

9

10 **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.

11

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”

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, it is classified according to the criteria that have been agreed for substances, but only for acute hazard.

Classification of mixtures by using LC₅₀ or EC₅₀ data for the mixture as a whole is not possible for chronic categories since both toxicity data and environmental fate data are needed, and there are no degradability and bioaccumulation data for mixtures as a whole. It is not possible to apply the criteria for chronic classification because the data from degradability and bioaccumulation tests of mixtures cannot be interpreted; they are meaningful only for single substances (See CLP Regulation point 4.1.3.3.1)

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 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 K_{ow}, 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

Long-term Ecotoxicity:

12.2 Persistence and degradability

Abiotic Degradation:

Physical- and photo-chemical elimination:

Biodegradation:

12.3 Bioaccumulative potential

Partition coefficient n-octanol /water (log K_{OW}):

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) Code⁷⁰.

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 should⁷¹ 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 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.

⁷⁰ 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)

⁷¹ “should” is used here rather than “must” since the legal text requires such disposal to be discouraged, not for it to be prohibited.

Relevant information (e.g. the related H-codes as defined in Annex III “Properties of waste which render it hazardous” of Directive 2008/98/EC⁷²) 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 below⁷³:

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:
13.1.5 Other disposal recommendations:

4.14. SDS SECTION 14 Transport Information

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)⁷⁴, Regulations concerning the International Carriage of Dangerous Goods by Rail (RID)⁷⁵, European Agreement concerning the

⁷² Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives

⁷³ Note that additional numbering and sub-structuring below the sub-section level is not a legal requirement

⁷⁴ United Nations, Economic Commission for Europe, version applicable as from 1 January 2009, ISBN-978-92-1-139131-2.

⁷⁵ 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.

⁷⁶ Version as revised as of 1 January 2007.

International Carriage of Dangerous Goods by Inland Waterways (ADN)⁷⁶, 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 goods⁷⁷, International Maritime Dangerous Goods (IMDG Code⁷⁸) (sea), and Technical Instructions for the Safe Transport of Dangerous Goods by Air (ICAO-TI)⁷⁹ (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 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)⁸⁰ and the International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk (International Bulk Chemical Code) (IBC Code)⁸¹.

⁷⁷ OJ L 260, 30.9.2008, p. 1.

⁷⁸ International Maritime Organisation, 2006 edition, ISBN 978-92-8001-4214-3.

⁷⁹ IATA, 2007-2008 edition.

⁸⁰ MARPOL 73/78 — Consolidated edition 2006, London, IMO 2007, ISBN 978-92-801-4216-7.

⁸¹ IBC Code, 2007 edition, London, IMO 2007, ISBN 978-92-801-4226-6.

⁸² MEPC.2/Circular, Provisional categorisation of liquid substances, version 14, effective 1 January 2009.

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/Circular⁸². 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 Section 14.6 is already given elsewhere in the SDS a cross-reference to its location may be made to avoid repetition. (A sub-section 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 vessel, e.g. for Environmental hazards the GHS criteria acute 2, acute 3 and chronic 3. This information is only relevant for bulk liquids filled in cargo tanks of tank vessels and classified dangerous according ADN criteria.

If applicable, this extended classification information is included as hazard code 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 an "Not otherwise specified" ("N.O.S.") entry not included in the list of substances listed under this segregation group

Further information IBC-Code (IMSBC Code):

The IBC Code provides an international standard for the safe carriage by sea of marine pollutant, dangerous and noxious liquid chemicals in bulk tankers. It regulates dangerous goods and non dangerous goods according IMDG-Code.

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

An example of how the structure of this sub-section could look is given below (apply only relevant sections):

Land transport (ADR/RID):

UN-No.:

Proper shipping name

Class

Classification Code:

Packing group:

Hazard label(s):

Environmental Hazard:

Special provision(s):

Inland water ways transport (ADN):

UN-No.:

Proper Shipping Name:

Class:

Classification Code:

Packing group:

Environmental Hazardous:

Hazard Label(s):

Special provision(s):

Inland water ways transport in tank vessels (ADN):

UN-No.:

Proper Shipping Name:

Class:

Classification Code: if applicable

Packing group: if applicable
 Hazard Label(s) and Hazard Code(s):
 Special provision(s): if documentation relevant

 Sea transport (IMDG Code):
 UN-No.:
 Proper Shipping Name:
 Class(es):
 Packing group:
 Marine Pollutant:
 Special provision(s):

 Air transport (ICAO-TI/IATA-DGR):
 UN-No.:
 Proper Shipping Name:
 Class(es)
 Packing group - if applicable:
 Special provisions: if documentation relevant

 Additional information:
 ...

Note that the structure in the example above would need expansion of the Sea transport section in case transport in bulk according to Annex II of MARPOL 73/78 and the IBC code applies. IBC code information may be given voluntarily in other cases, but is not a requirement.

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 2037/2000⁸³ 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).

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

⁸³ [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).

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.

1

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

5 • National laws of the relevant Member States which implement provisions
6 such as the young worker directive and directive on pregnant workers, since these
7 may require that that young workers or pregnant workers do not work with certain
8 substances and mixtures.

9 • Information from the plant protection and biocides legislation, such as
10 approval/authorisation status/numbers, additional labelling information from the
11 specific legislation.

12 • Information on applicable elements of the Water Framework Directive.

13 • Information on EU Directive(s) related to Environmental Quality Standards
14 (EQS) - e.g. Directive 2008/105/EC⁸⁴ – where applicable)

15 • For paint and varnish products, if applicable a reference to Directive
16 2004/42/EC⁸⁵ on the limitation of emissions of volatile organic compounds may be
17 included here.

18 • For detergents, the ingredient declaration according to the Detergent
19 Regulation 648/2004/EC⁸⁶

20 • National information on the regulatory status of the substance or mixture
21 (including the substances in the mixture), including advice regarding action that
22 should be taken by the recipient as a result of these provisions

⁸⁴ 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)

⁸⁵ 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)

⁸⁶ 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 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 (Technische Regeln für Gefahrstoffe)

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 voortplanting giftige stoffen SZW.

ii. De Algemene beoordelingsmethodiek Water (ABM)

iii. De Nederlandse Emissierichtlijn (NeR)

In Denmark:

Lister over stoffer og processer, der anses for at være kræftfremkaldende

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):

Technische Anleitung Luft (TA-Luft):

Other regulations, restrictions and prohibition regulations:

15.2 Chemical Safety Assessment:

No Chemical Safety Assessment has been carried out.

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 may be used to include any additional information that was not mentioned in the previous Sections such as:

- Indication of changes, revision of the SDS
- Key literature references and sources of data
- List of relevant hazard statements and risk phrases
- In the case of mixtures, method used to derive a classification

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

Advice on training for workers may be included here.

In the case of mixtures, details may be provided here on the basis used to determine the classification of the mixture for the hazard classes where the classification criteria are met. 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 given under 16.4 and in the table in the example below could also be placed in Section 2).

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*

An example of how the structure of this SECTION could look is given below.

Note that in the particular case of SECTION 16 there are **no** specified sub-section 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.

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]:*

Example for an aqueous solution:

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

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

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

(vi) *Training advice:*

1
2 (vii) *Further information:*
3
4

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

7 On basis of test data

8 Calculation method.

9 Bridging principle "Dilution".

10 Bridging principle "Batching".

11 Bridging principle "Concentration of highly hazardous mixtures".

12 Bridging principle "Interpolation within one toxicity category".

13 Bridging principle "Substantially similar mixtures".

14 Bridging principle "Aerosols".

15 Expert judgement

16 Weight of evidence

17 Human experience

18 Minimum classification
19

APPENDIX 1: Timetable for the application of CLP labelling and 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
- **2010 I** = Annex I of Commission Regulation (EU) No. 453/2010 amending Annex II of REACH: *for substances until the end of the transition period (1st June 2015) and for mixtures labelled DPD*
- **2010 II** = Annex II of 2010 Commission Regulation (EU) No. 453/2010 amending Annex II of REACH: *for substances after 1st June 2015 and for mixtures labelled CLP (with additions until 1st June 2015).*

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 by the requirements to mention classification and labelling according to different systems during the transition period. The differences are particularly reflected in the contents of Sections 2, 3 and 16.

The annexed table 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) need to be mentioned in the SDS.

In order not to overload this table, the requirements to mention the classification in the SDS are indicated only when an additional classification to the one corresponding to the one reflected on the label is required, generally DSD/DPD in the case of CLP labelling.

For mixtures labelled according to CLP, the requirement to mention CLP classification in the SDS is not repeated as it is clearly mentioned in the text of the relevant version of Annex II of REACH (2010 II). However, the requirement to include DSD/DPD classifications until 1 June 2015 in sections 2.1 and 3.1 (when CLP classification is applied in advance of 1 June 2015 for the mixture) is specified with “also” as this is a required addition to the text of 2010 II.

	1/12/2010	1/12/2012	1/06/2015	1/06/2017
Substances (general rule)	Labelling: DSD SDS: 2006 or Labelling: CLP SDS: 2006, with CLP and DSD classification, or 2010 I [CLP + DSD classifications in 2-1]	Labelling: CLP SDS: 2010 I [CLP + DSD classifications in 2-1]		Labelling: CLP SDS: 2010 II
Substances already on the market on 1/12/10 (on the shelves)		Labelling: DSD SDS: 2006 or Labelling: CLP SDS: 2010 I [CLP + DSD classifications in 2-1]	Labelling: CLP SDS: 2010 I [CLP + DSD classifications in 2-1]	Labelling: CLP SDS: 2010 II
Mixtures (general rule)	Labelling: DPD SDS: 2006 or 2010 I* or Labelling: CLP SDS: 2006 or 2010 II both with also DPD and DSD (components) classifications (in resp. 2-I and 3-2 for 2010 II)	Labelling: DPD SDS: 2010 I* or Labelling: CLP SDS: 2010 II with also DPD classification in 2-I and DSD classification in 3-2 (components)		Labelling: CLP SDS: 2010 II
Mixtures marketed before 1/12/10	Labelling: DPD SDS: 2006 or 2010 I* or Labelling: CLP SDS: 2006 or 2010 II both with also DPD and DSD (components) classifications (in resp. 2-I and 3-2 for 2010 II)		Labelling: DPD SDS: 2010 I* or Labelling: CLP SDS: 2010 II with also DPD classification in 2-I and DSD classification in 3-2 (components)	Labelling: CLP SDS: 2010 II
Mixtures already on the market on 1/6/15 (on the shelves)			Labelling: DPD SDS: 2010 I* or Labelling: CLP SDS: 2010 II	Labelling: CLP SDS: 2010 II

* Possibility: CLP classification information in SECTION 16

APPENDIX 2: SDS (sub-)sections consistency check with Exposure Scenario sections

For SDSs which require attachment of an exposure scenario, Table 2 below shows the different sections of the ES, and the corresponding (sub-) sections of the SDS that need to be checked for consistency with the ES sections:

Table 2: Consistency check between Exposure Scenario and SDS sections

ES section ⁸⁷	SDS Section/Sub-section
Title	1.2
Free short title of the exposure scenario	1.2
Free short title of the generic exposure scenario	1.2
Systematic title based on use descriptor	1.2
For substances and substances in preparations / mixtures	1.2
For article service life	1.2
For downstream use leading to inclusion in article	
Use of substances by workers and consumers	
PNECs and DNELs	8
PBT/vPvB data	12
Operational conditions and risk management measures	7 + 8
Control of worker exposure	8.1
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
Engineering controls:	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
Control of consumer exposure	8⁸⁸
Control of environmental exposure	8
Worker:	
Product characteristic	7 + 8
Amounts used	7 + 8
Frequency and duration of use	7 + 8
Environmental factors not influenced by risk management	
<i>Flow rate of receiving surface water:</i>	

⁸⁷ Guidance on the ES format is available on the ECHA web-site at: http://guidance.echa.europa.eu/guidance_en.htm (within the guidance on Guidance on Information Requirements and Chemical Safety Assessment – specific document at: http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_ESformat_en.pdf)

⁸⁸ Note that specific information on **consumer** exposure in Section 8 of the SDS is not a legal requirement.

Other given operational conditions affecting environmental exposure	7
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
Consumer:	
Product characteristic	7 + 8
Amounts used	7 + 8
Frequency and duration of use	7 + 8
Environmental factors not influenced by risk management	8 + 12
<i>Flow rate of receiving surface water:</i>	8 + 12
Other given operational conditions affecting environmental exposure	8 + 12
Conditions and measures related to municipal sewage treatment plant	8 + 12
Conditions and measures related to external treatment of waste for disposal	13
Conditions and measures related to external recovery of waste	13
Exposure estimation and reference to its source	
Routes of exposure and environmental compartments	
Human exposure prediction (oral, dermal, inhalative)	
Environmental exposure prediction (soil/water, air)	12
Exposure assessment tool reference	
Guidance to DU to evaluate whether he works inside the boundaries set by the ES	
<i>Service life of substances in articles</i>	

APPENDIX 3: SDS for Special Mixtures

Introduction: What are Special Mixtures?

Special Mixtures⁸⁹ 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 (for further information, please see the ECHA guidance for DU http://guidance.echa.europa.eu/docs/guidance_document/du_en.htm?time=1260778014 Eurometaux guidance on Exposure Scenarios for alloys <http://www.reach-metals.eu/>, EIMAG 2009). Release estimates and how these are considered in the context of Exposure Scenarios will be documented in the CSR.

⁸⁹ “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

1 **Where will the Special Mixture concept have an impact on the SDS content?**

2
3 'Inclusion in the matrix' and its influence on availability of the constituents can
4 currently be considered in Section 8 of the SDS "Exposure controls/personal
5 protection". Proposed risk management measures can be refined provided that
6 there are reliable data and information documenting release, availability and/or
7 different toxicity expression. In the absence of reliable data, the special mixture
8 will be considered by default as a simple mixture, and the mixture rules will apply.

9
10 *Placeholder: work is ongoing on assessing the possibility of including*
11 *bioavailability considerations when classifying an alloy as a Special Mixture. This*
12 *may have some impact on the information given in Section 2: Hazard*
13 *identification.*

14
15 How to refine the proposed measures for controlling exposure/personal protection
16 with

17 Special Mixtures data:

- 18
19 ○ Usually, the production of a Special Mixture can involve a series of
20 constituents. The Special Mixture producer, who has to generate an SDS
21 for the Special Mixture, may receive a significant amount of information
22 from which it will be difficult to identify and to extract key and relevant
23 information to include in his SDS because of different properties, different
24 exposure scenarios, etc.
25 ○ As a first step, it is suggested that the formulator responsible for preparing
26 an SDS for an alloy should compile all relevant information about the
27 mixture's constituents and the mixture as a whole in a spreadsheet or
28 similar format (see the example table given for a substance in the
29 discussions of DNELS and PNECS under sub-section 8.1 in Chapter 4 of
30 this document) and then extract the information required for the respective
31 constituents SDS sections.

32
33 Depending on the information collected and the quality/reliability of the
34 information, the formulator will have to decide whether or not he has the
35 knowledge to consider his mixture as a Special Mixture (with possible refinements
36 of RMMs). This will need to be documented, to enable the user of the SDS to
37 understand any refinements that result from the use of availability data.

from the text of Recital 31 of REACH (as amended – it originally referred to "special preparations") and Annex I on CSA (point 0.11).

1 Example: availability data can be used to refine RMMs and OC.
2
3

4 ***Exposure to alloy powders and massives***
5

6 When coarser (non-respirable/inhalable) powders and massives ($>20\ \mu\text{m}$) are
7 handled, the inhalation route is less relevant. In this case, oral and dermal
8 exposures are more relevant for human health hazards. Toxicity resulting from
9 these exposure routes depends on the availability of ions at target sites. This
10 availability can be estimated in vitro by measuring ion release from the alloy in
11 the gastric fluid and sweat and compared with release from the constituents. The
12 results of availability tests on alloys can be used to refine actual exposure
13 considerations from the “alloy” versus actual exposure from the “metals in the
14 alloy. If exposure is reduced by inclusion in the matrix, then less stringent risk
15 reduction measures could be applied.

APPENDIX 4: Specific issues relevant to the compilation of Safety Data Sheets for recovered substances and mixtures.⁹⁰

Reason for the inclusion of this Appendix

Article 2(2) of REACH provides that "waste as defined in Directive 2006/12/EC⁹¹ 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 waste⁹².

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.⁹³

Similarly, the requirement to carry out a Chemical Safety Assessment, complete a Chemical Safety Report and potentially to generate an Exposure Scenario for certain substances which arises in particular from Article 14(4) of REACH (which is also part of Title II), can be the subject of an exemption under Article 2(7)(d).

⁹⁰ This Appendix should be read in conjunction with the ECHA Guidance on Waste and Recovered Substances (available at: http://guidance.echa.europa.eu/guidance_en.htm)

⁹¹ Repealed by Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (Waste Framework Directive).

⁹² Further explanation on this exemption is given in the guidance on registration, http://guidance.echa.europa.eu/docs/guidance_document/registration_en.htm (section 1.6.3.4).

⁹³ See the text and examples given in Chapter 4 in the discussion of sub-section 1.1 in this guidance

1 Title II refers to the Registration of substances, Title V to requirements for
2 Downstream users and Title VI to Evaluation. These exemptions notably do not
3 cover Title IV (Information in the supply chain) which includes Article 31
4 requirements (as well as Article 32 requirements) for the provision of SDSs where
5 applicable for recovered substances and mixtures which have ceased to be waste
6 (as well as Article 32 requirements).

7 However although, by definition, to benefit from the exemptions the information on
8 the substance or mixture required by Article 31 or 32 has to be available to the
9 establishment undertaking the recovery there are some specific issues arising (e.g.
10 from changes in the impurity profile or other aspects of the composition of the
11 recovered substance by comparison with the substances as originally registered)
12 which may affect the content of the SDS compiled for a recovered substance or
13 mixture. There are also issues arising from the discontinuity in transfer of information
14 on exposure scenarios down a supply chain which is interrupted by temporary
15 change of a substance or mixture's status as waste or "ceased to be waste". These
16 issues are considered in more detail below insofar as they affect the content of the
17 SDS.

19 **Composition of recovered substances and mixtures**

20 For recovered materials that are composed primarily of substances which are not
21 chemically modified by the recovery process, these component substances on their
22 own or in mixtures will generally be known and have been registered.

23 However, during original manufacture various other substances (potentially including
24 stabilizing additives) may have been combined with the primary substance(s). Most
25 of the substances (or additives) will still be in production and will therefore be
26 registered under REACH. However, others will have been phased-out of production,
27 either through voluntary or regulatory action, although they may continue to be
28 present in waste materials for a number of years.

29 Some sectors carrying out recovery activities already have relatively easy access to
30 the necessary information on the substances/mixtures that they produce and supply,
31 to allow them to compile an SDS complying with Art 31 and Annex II of REACH. For
32 others, further consideration of issues such as "sameness" may be needed.

34 **Evaluating the applicability of available SDS information and the "sameness"** 35 **of recovered substances**

37 **EVEN WHEN COMPILING HIS OWN SDS BASED ON AVAILABLE SDSS FOR**
38 **SUBSTANCES RECOVERED FROM THE WASTE THE RECOVERY OPERATOR**
39 **WOULD NEED TO SATISFY HIMSELF THAT ANY INFORMATION HE RELIES**
40 **UPON TO COMPILE IT RELATES TO SUBSTANCES WHICH ARE THE SAME AS**
41 **THOSE IN THE RECOVERED MATERIAL.**

42 Further discussion of "sameness" in the context of recovered substances is given in
43 the ECHA Guidance on Waste and Recovered Substances. This in particular notes
44 that *"the decision on the sameness should be based on the main constituents.*
45 *Information about the impurities does not in principle change the conclusion about*
46 *the sameness"*⁹⁴.

⁹⁴ Information about the impurities must be taken into account for issues such as
Classification and Labelling and drafting of SDSs

1 **Compilation of SDSs using generic information**

2 In case generic information on the input material is used to produce an SDS, there
3 should be a process to establish confidence in the reliability of this information. Such
4 a process could for example comprise:

- 6 • Assess what is known about the waste material from which the substance is
7 to be recovered. This includes information on the composition of the waste,
8 and any known relevant history of the material such as, where applicable:
 - 9 - the previous application,
 - 10 - handling and storage during the use, waste and transport stages
 - 11 - any treatment carried out (e.g. during reprocessing).
- 12 • Assess and where relevant record all known content, including the original
13 material(s) as well as anything likely to be present from additives used in the
14 original application (e.g. alloying substances, coatings, colorants, or
15 stabilisers). Information on the substances and mixtures present in the waste
16 and their relative quantities will enable Safety Data Sheet information on
17 relevant materials to be obtained and used as the basis of the Safety Data
18 Sheet for the recycled material. For example, if there are substances subject
19 to restriction, meeting the classification criteria as dangerous, CMRn PBT,
20 vPvB or candidate list substances in the recycled material then the chemical
21 composition of all such content should be established
- 22 • Characterise the incoming raw material and the recovered substance(s) to
23 establish average content for each relevant substance and the likely range of
24 its content in any mixture (maximum and minimum). Alternatively the hazard
25 profile of the recovered mixture as such could be established. This
26 information can be used to assess risks and set out risk management
27 measures in the Safety Data Sheet for accepted uses.

29 For recovered substances (as for other substances) containing impurities that are
30 classified and contribute to the classification, the impurities have to be indicated.

31 It is worth noting that the presence of impurities as such does not itself give rise to an
32 obligation to supply an SDS under Article 31(1) of REACH. Such obligations may
33 only arise through Article 31(3) requirements.

35 **Other consequences of an Article 2(7)(d) exemption relevant to SDSs**

36 A recovery operator who has the required information available for the same
37 substance and can therefore rely on exemptions according to Article 2(7)(d) of
38 REACH (even if the use of a recovered substance is not covered by the registration
39 of the same substance), is not required to:

- 41 • generate an exposure scenario for the use of the recovered substance;
- 42 • register the recovered substance;
- 43 • notify the use of the recovered substance.

45 However he should take account of the available information and must provide
46 information on appropriate risk management measures in the SDS, if applicable.

48 The Safety Data Sheet should be compiled in accordance with the text of Article 31
49 and Annex II of REACH. Where appropriate guidance set out in the main body of this

1 document together with additional guidance for specific issues set out in this
2 Appendix or in the Guidance on waste and recovered substances should be
3 consulted.

4 Trade Associations representing specific material recovery sectors may provide their
5 members with examples of how to use this guidance. They may wish to develop
6 further guidance for any issues specific to their material stream.
7

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
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
ES	Exposure Scenario
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
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 http://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
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

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