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Guidance on the compilation of safety data sheets (draft)

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ISBN-13:

ISSN:

Reference: ECHA-2010-G-xx-EN

Date: xx/xx/2010

Language: EN

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CONTENTS

TABLES

FIGURES

APPENDICES

CHAPTER 1: GENERAL INTRODUCTION

1.1. The Safety Data Sheet

Safety data sheets (SDS) have been a well-accepted and effective method for the provision to downstream users of information 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 SDS provides a mechanism for transmitting appropriate safety information on substances and mixtures which meet the criteria for classification, as dangerous, are persistent, bioaccumulative and toxic or very persistent and very bioaccumulative, or are contained in the candidate list for eventual authorisation for any other reasons, and also under certain conditions some mixtures which do not meet the criteria for classification as dangerous (Article 31.3 of REACH).

No SDS have to be provided for articles, except those classified according to CLP regulation (explosive and pyrotechnical articles). Although the SDS format may, for a few specific articles, be used to convey safety information down the supply chain, it is not adapted to most articles.

The SDS follows a 16 section format which is internationally agreed. The SDS must be in the language of the country in which the product is placed on the market unless the Member State(s) concerned provide otherwise, (Article 31.5 of REACH).

The SDS includes information from the relevant Chemical Safety Report(s) if one exists. The information provided in the SDS shall be consistent with the information in the Chemical Safety Report, where one is required, as well as with the registration dossier. In addition, according to Article 31.7 of REACH, registrants and users that had to elaborate a Chemical Safety Report, shall place the relevant exposure scenario(s) into an annex of the Safety Data Sheet. Downstream users have to consider relevant exposure information received from suppliers when compiling their safety data sheets. There are several options for placing relevant exposure scenarios into an annex or for including relevant exposure information in the core chapters 1 – 16 of the SDS.

1.2. Aim of this guidance

The aim of this guidance is to assist industry in determining which tasks and obligations have to be complied with to fulfil their requirements under Article 31 of REACH (Requirements for safety data sheets (SDS)) and Annex II of REACH including an overview of elements required by Regulation (EC) No 1272/2008 (CLP)[2]. In addition to this, it also provides useful information on how an SDS may help the

[1] Corrigendum to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006); amended by Council Regulation (EC) No 1354/2007 of 15 November 2007 adapting Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) by reason of the accession of Bulgaria and Romania (OJ L 304, 22.11.2007, p. 1).

[2] 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 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).

recipient to assess any risk to the health and safety of workers arising from their use and ensure safe use of substances and mixtures.

This guidance provides information on:

- Who should develop the SDS and what competencies should the author have
- Who should receive and read the SDS and how to check incoming SDS on validity
- How and where to find key information
- How to apply safety information in the SDS and the Exposure Scenarios

Detailed information is given on what (mandatory and optional) information should and could be included in each section of the SDS. The document contains a special section on requirements for formulators.

Requirements and best industry practices are illustrated with examples throughout the document.

Finally, this document also provides links and references to useful sources of information.

1.3. Target audience of this guidance

While the REACH requirements regarding SDS are directed at suppliers of substances and mixtures, this document also provides useful information for recipients of an SDS. It is noted in this context that the information provided by Safety Data Sheets shall also meet the requirements set out in Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

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

1.4. Relation with CLP and GHS

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

In Europe, the SDS format is based on the Annex II of REACH which provides the requirements for safety data sheets (SDS). The requirements in Article 31 and Annex II of REACH have been adapted to meet the GHS requirements. The CLP Regulation entered into force on the 20th of January 2009. This draft of the guidance reflects the current update of Annex II of REACH as proposed by the Commission in the current comitology procedure, based on an agreement in the REACH Committee of 9 December 2009."

CHAPTER 2: WHAT IS NEW WITH RESPECT TO SDSs IN REACH AND CLP?

According to the REACH Annex II, new information needs to be entered into the SDS. Below you can find (per section) what will be new for the 'REACH SDS'.

The table 1 below provides an overview of the main changes to the different sections for substances / mixtures including new sub-headings. Sections without changes according to REACH are not covered in this chapter. Please see chapter 5 for a full overview of all the sections in an SDS.

Please note that where specific data is not used, or where data are not available, this shall be clearly stated in the corresponding section of the SDS.

Table 1: Overview of new elements for SDSs

SDS titles per section	New requirements for substances SDS	New requirements for mixtures SDS
1.1. Product identifier	One of the following **identifiers** needs to be included (in order of preference): • INDEX number (if substance is listed in CLP, Annex VI) • ID number of the C & L inventory • CAS number The inclusion of the EC number is optional. The **registration numbers** from substances will be mentioned by the manufacturers (when the substances are registered). The last four digits can be omitted by distributors and downstream users.	
1.2. Relevant identified uses of the substance or mixture, and uses advised against	Suppliers will mention the relevant **identified use(s)**[3] of a substance and the uses advised against if relevant. The description has to be understandable. The intention is not to list all the combinations of use descriptors[4], but rather to have a general description of uses. **This information shall be consistent with the identified uses and exposure scenarios** set	A compliance check of the uses covered must be done.

[3] „Identified use" is defined in REACH, article 3, No. 26.
[4] Please note that the use descriptor system is not finalised at the moment of writing this guidance. The latest version can be consulted at: http://guidance.echa.europa.eu/guidance4_en.htm

	out in the annex to the SDS. A reference to the annexed Exposure Scenario (ES) can be included here.	
1.3 Details of the supplier of the substance or mixture	- For registrants, the information shall be consistent with the information on the identity of the manufacturer or importer or OR provided in the registration dossier. - **email** of the competent person responsible for the SDS should be provided. It is recommended to use a generic email address	
2. HAZARD IDENTIFICATION	**Classification**: Until May 31st, 2015, the substance classification shall be mentioned according to both the CLP regulation and Dangerous Substances Directive (DSD). After June 1st, 2015, only classification according to CLP needs to be mentioned for both substances and mixtures. See Appendix 1 on transitional periods for more information. **Labelling information** should be included here (new sub-heading). The symbol/pictogram(s) must be represented graphically. If the substance is subject to **authorisation**, the authorisation number should be included here.	The mixture classification shall be mentioned according to the Dangerous Products Directive (DPD) or to both the CLP regulation and DPD when the CLP label is implemented) After June 1st, 2015, only classification according to the CLP regulation needs to be mentioned for both substances and mixtures. Labelling information should be included here (new sub-heading), including graphical representation of symbol/pictogram(s).
3. COMPOSITION / INFORMATION ON INGREDIENTS	Requirement to identify PBT/vPvB substances including constituents in this section.	The SDS of mixture will include a list of the hazardous substances which are above the concentration limits into this section (see table 3). In the case of mixtures, PBT/vPvB substances have to be disclosed if present at 0.1% or greater with registration number (if applicable) The registration number(s) – except the part referring to individual registrant in the Joint submission – shall be included. For imported mixtures, the full registration number shall be given. The classification(s) including the information on PBT and vPvB shall be mentioned too.
7.1. Precautions for safe handling	Advice on **specific precautions** for safe handling additionally includes **non** technical measures will be	

	found in the supplier SDS. Where a registration is required, the information in this section shall be consistent with the information given in the dossier, for the identified uses and exposure scenarios set out in the annex to the SDS.	
7.3. Specific use(s)	If available, a reference to **industry or sector specific guidance** designed for specific uses may be mentioned. If an ES is attached, reference may be made.	The SDS will need to include cross-references to the ES of the mixtures. If available, a reference to industry or sector specific guidance designed for specific uses may be mentioned. If an ES is attached, reference may be made.
8. EXPOSURE CONTROLS / PERSONAL PROTECTION	List **available DNELs, OELs, PNECs, EQSs and DMELs**: Substance specific information (the DNELs for human health hazards and the PNECs for hazards to the environment) need to be displayed in this section. This information (other than OEL values) will mainly be available for registered substances which have been subjected to a Chemical Safety Assessment. Where a chemical safety report is required, the risk management measures for the identified uses shall be consistent with the information in this section.	The substances with specific OEL and EQS above the concentration limits (given in Article 14(2) of REACH) will need to be mentioned in the SDS.
8.1. Control parameters	Where a **control banding approach** is recommended for providing protection in relation to specific uses, sufficient detail shall be given to enable effective management of the risk. The context and limitations of the specific control banding recommendation shall be made clear.	
8.2. Exposure controls	Suppliers will mention here **risk management measures** for control of occupational and environmental exposure for the use of the substance. Either summary of RMM or reference to the ES will be made.	If relevant, a consolidated set of risk management measures and the corresponding summaries which are taken from the relevant supplier exposure scenarios shall be included (taking into account the range and limits of each substance in the mixture). The risk management measures in

		this section and annexed exposure scenario(s) shall be consistent.
9. Physical and chemical properties	There are **additional physical / chemical properties** to be included in this section (consult chapter 5 for more information).	There are **additional physical / chemical properties** to be included in this section (consult chapter 5 for more information).
11. Toxicological information	Summarised **evaluation of the CMR** properties needs to be added: For substances subject to registration, summaries of the information derived from the application of Annexes VII to XI of REACH shall be given. If a CSR is required, the information should be consistent with it. Where appropriate, information on toxicokinetics, metabolism and distribution should be included.	If substances in a mixtures may interact with each other in the body and may altering any toxic action, this shall be taken into account by providing toxicological information in this section.
12. ECOLOGICAL INFORMATION	Include **results of any PBT/vPvB assessments**). The result of a PBT/vPvB assessment for a substance will be given in this section of the SDS. The information in this section shall be consistent with the information provided for in a registration where required and/or in a Chemical Safety Report where required. It will only be available when a Chemical Safety Report has been required.	If relevant, the available results from the substances will need to be compiled into this section of the SDS for mixtures. The information in this section shall be consistent with the information provided for in a registration where required and/or in a Chemical Safety Report where required. It will only be available when a Chemical Safety Report has been required.

1
2

1
2

SDS titles per section	Additional information provided by suppliers of substances	Additional information provided by suppliers of mixtures
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 shall 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.
15. REGULATORY INFORMATION	**Substances subject to authorisation and details about any authorisation** granted or denied shall be given in the SDS Uses of the substances subject to restrictions shall be stated here. Indicate if a Chemical Safety Assessment has been carried out for the substance (or a substance in the mixture). Labelling information is not included here anymore and has been moved to section 2.	Information on authorisation and restrictions of the substances in the mixture should be included
16. OTHER INFORMATION	Information on uses advised against has been included in section 1.2. Information on CLP classification can be included here for mixtures on voluntary basis in advance of full implementation (i.e. actual labelling of the product) rather than section 2 because section 2 should be aligned with label. Advice on training for workers can also be included in this section.	For formulators, any use advised against will be taken over from the supplier if relevant for the mixture. Information on CLP classification can be included here for mixtures on voluntary basis in advance of full implementation rather than section 2 because section 2 should be aligned with label. Advice on training for workers. An indication of which methods were used to evaluate the classification of the mixture.
Exposure Scenario (annex)	If required by REACH, the SDS will include exposure scenario(s) for the identified uses. The ES is complementary to the SDS. It contains only information that is use-specific, or relates to safety of consumer products, or relates to substances during article service life, or relates to detailed measures (summary to be in the main body) regarding environment. Thus it extends the SDS information, but needs to be considered together with the information in the SDS main body text in order to be useful.	If Exposure scenario(s) for mixtures are prepared, they need to be compiled by evaluating the relevant available information including the information from the substances' suppliers. Calculations of safe use need to be demonstrated with all RMM included.

3

CHAPTER 3: ISSUES TO CONSIDER WHEN DEVELOPING AN SDS

3.1. What is a Safety Data Sheet (an SDS)?

A Safety Data Sheet (SDS) is a document with a pre-defined format[5].

An SDS contains all important information about a chemical product (a substance or mixture of substances) which is needed for the adequate carrying out of activities involving chemical products. Furthermore, this information is intended to enable to determine any hazardous chemical agents which are present in the workplace, and to assess any risk to the health and safety of workers arising from their use and prevention of environmental impacts.

The information contained in the SDS has to be written in a clear and concise manner

SDSs will enable users to take the necessary measures relating to protection of human health and safety at the workplace, and protection of the environment and to ensure safe transport.

3.2. Who must provide an SDS?

Article 31.1 of REACH establishes the obligation to provide SDS for suppliers* of:

- substances or mixtures classified as hazardous according to the previous legislation (Dangerous Substances Directive (DSD)/ or the new Regulation on Classification and Labelling (CLP) as appropriate.
- substances classified as persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) according to the criteria of REACH Annex XIII
- substances, which are included for other than the above-mentioned reasons in the list to be established according to REACH Article 59 (1)[6]

*) Suppliers are defined by REACH Article 3.32 as: *any manufacturer, importer, downstream user or distributor placing on the market a substance, on its own or in a preparation or a preparation.* According to the REACH&CLP definitions of importer, DU and distributors, they have to be established in the Community.

See question 16 for more information.

3.3. Can the information in the SDS be claimed to be confidential?

No, the information that appears on the SDS cannot be considered as confidential.

3.4. Must the SDS be provided free-of-charge?

Yes, according to REACH Article 31.8 the SDS must be provided free-of-charge.

[5] See Appendix 1 for more information about valid formats and transitional periods.
[6] The so-called 'candidate list' can be consulted here: http://echa.europa.eu/chem_data/authorisation_process/candidate_list_en.asp. Please note that it is regularly updated

3.5. Who may prepare an SDS?

The supplier must ensure that the SDS is elaborated by competent person(s). The SDS must be fully completed in a professional way, and be updated regularly.

3.5.1. Who is a competent person?

Competent Persons are persons – or a coordinator of a group of people - who have, as a result of their training and continued education, sufficient knowledge for the elaboration of the respective sections of the SDS or of the entire SDS.
The supplier can delegate these duties to own staff or to third parties. It is not necessary that the expert knowledge is provided in full by one person.

3.5.2. Training and continued education of competent persons

The competent person does not need to attend a special course or pass an official examination but shall have received appropriate training, including refresher training.
Nevertheless, the competent person must be able to prove his expertise if required, e.g. through his professional qualification and relevant activity.

Training and continued education for these persons can be given internally or externally; It is recommended to lay down in writing the organizational flow in the elaboration and update of SDS in a company, e.g. by way of internal guidelines or operating procedures.

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 on additional competences, internal or external. The competent person should ensure the consistency of the SDS, especially if he acts as the coordinator of a group of people.

Specifically, competent persons should have understanding and access to adequate knowledge in fields such as (this is a non-exhaustive list):

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 elaboration of SDS, for instance (not an exhaustive list, examples as at February 2010):
    - REACH: Regulation (EC) No 1907/2006
    - 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 : Directive 2000/39/EC
    - Protection of workers from the risks related to exposure to carcinogens at work: Directive 90/394/EEC
    - 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
    - Detergent Regulation: Regulation (EC) No 648/2004

3. Relevant **national or international guidelines** of the respective sector association

4. **Physical and chemical properties** and hazard identification such as:
   - o Solubility in water and in organic solvents
   - o pH value
   - o Flash point
   - o Partition coefficient
   - o Ignition temperature
   - o Explosion behaviour of substances, mixtures and articles, explosion limits
   - o Surface tension, viscosity
   - o Stability, reactivity, decomposition

   - o Other related physical properties may be important such as:
     - Physical state
     - Formation of for, gas, vapours, mist, dusts (granulometry)
     - Odour
     - Density of vapours

5. **Toxicology/eco-toxicology** such as:
   - o Modes and targets of action of hazardous substances
   - o Exposure routes (oral, dermal, inhalative)
   - o Effects (local, systemic; acute, chronic; reversible, irreversible)
   - o Parameters (LD50, LC50, IC50, EC50, discriminatory dose)
   - o Special effects (mutagenic, carcinogenic, toxic to reproduction)
   - o Effect thresholds
   - o Test methods
   - o Accumulation potential, distribution behaviour, degradability
   - o Non-aquatic environment

6. **First aid** measures

7. **Accident prevention**
   - o Fire and explosion prevention, fire fighting, extinguishing media
   - o Measures in the event of accidental release

8. Measures for **safe handling**
   - o Technical measures
   - o Conditions for safe storage
   - o Exposure limitation and control, exposure limit values
   - o Personal protective equipment
   - o Disposal methods, EU waste code
   - o Protection of groups at special risk, occupation restrictions

9. **Transport** provisions

   Classification of the various modes of transport according to Directives 96/35/EC and 2000/18/EC
   - o IMDG (maritime transport)
   - o ADR (road transport)
   - o RID (rail transport)
   - o ICAO/IATA (air transport)
   - o ADN (inland waterways)

10. **National** provisions

    a. Relevant national provisions, 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 hazardous 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. De Algemene beoordelingsmethodiek Water (ABM)

ii. De Nederlandse Emissierichtlijn (NeR)

b. National product register (for example Finland, Italy, Sweden etc.?)

11. **Additional knowledge** on specific products is needed, if SDS are to be elaborated for explosives, biocides, plant protection products, pest control products or surfactants.

3.6. What is essential in the preparation of an SDS?

The composition of the mixture and the impurity profile of the substances should be fully known. In practice, this is often quite difficult in particular where mixtures are prepared mixing other mixtures. Here, it is recommended to request relevant information from the upstream supplier - if not otherwise possible, sign confidentially agreements

For liquid mixtures, additional information on flammable properties and viscosity might be needed to enable a relevant correct classification under the hazardous chemicals law and transport law.

3.7. What sequence should items of information follow in the SDS?

The sequence of individual headings and sub-headings in the SDS is prescribed. The SDS must contain the headings as specified in the updated Annex II (see chapter 5 of this guidance for more information).

3.8. What degree of completeness is necessary when providing information in an SDS?

The information requirements are explained in detail in Chapter 5. It should be noted that where specific data are not used or where data are not available, this shall be clearly stated.

3.9. Is it necessary to continually update SDSs?

SDS must be updated without delay as soon as a major change occurs. Examples of major changes are given below[7]:

- Section 1: change in telephone number(s) (only for the affected countries)
- Section 2: change in user classification and labelling of the substance or preparation / mixture, (if it becomes more stringent)
- Section 2: addition of CLP-classification (if it becomes more stringent)
- Section 3: change/adding of a CMR 1 or 2 or PBT, vPvB, very toxic for the aquatic environment (i.e. R50/53)-classification or new SVHC
- Section 2-15: change in authorisation (granting-refusal) or restriction of substances

[7] Source: DUCC document: Revision Management of Safety Data Sheets for mixtures complying with REACH and CLP Regulations

- Section 8: change in Personal Protective Equipment or Exposure engineering controls or Emissions controls, (if they become more stringent)
- Section 14: change in transport classification of the substance / preparation / mixture (excl. technical name(s) after proper shipping name)
- Section 15: change in authorisation (granting-refusal) or restriction of substances (of very high concern)
- Annex: complete set of Exposure Scenarios available for all risk determining substances. On a case by case basis, information from exposure scenarios available for risk determining substances, focussing on risk management measures (on top of section 8 if relevant)

Editing minor changes (such as correcting typing errors) might warrant the issuing of a new version of the SDS. This does not require the issuing of the SDS to all customers. Examples of minor changes are given below:

- Lay out change
- Section 1: availability of registration number
- Section 2 and 15: deletion of DPD-classification after addition of CLP-classification after 2015
- Annex: availability of Exposure Scenario(s) for the classified substances of the preparation / mixture
- Changes with no effect on the PPE or Exposure engineering controls or Emissions controls
- Section 8: change in OEL values of a substance and/or PNECs

It is suggested to use an incremental numbering system to identify new versions. Major changes are identified by an increment by an integer, while minor changes are identified by an increment by a decimal, i.e.:
Version 1.0: initial issue
Version 1.1: first minor change
Version 1.2: second minor change
Version 2.0: first major change
Etc.
This is just an example of how to facilitate traceability of versions. There are many other systems.

When an SDS has undergone a major change, it must be provided to all former recipients to whom the substance or mixture has been supplied within the preceding 12 months (REACH Article 31(9)). The section above provides some examples of major changes.

Irrespective of the above, it is recommended to review SDS in regular intervals as to the totality of their contents. The definition of these intervals is the responsibility of the actor who issues the SDS.

3.10. Is there a need to communicate changes in the SDS?

When a new version of the SDS is produced, it is recommended to identify the new version by the statement "Revision … (date)" including the main changes of the version in section 16.

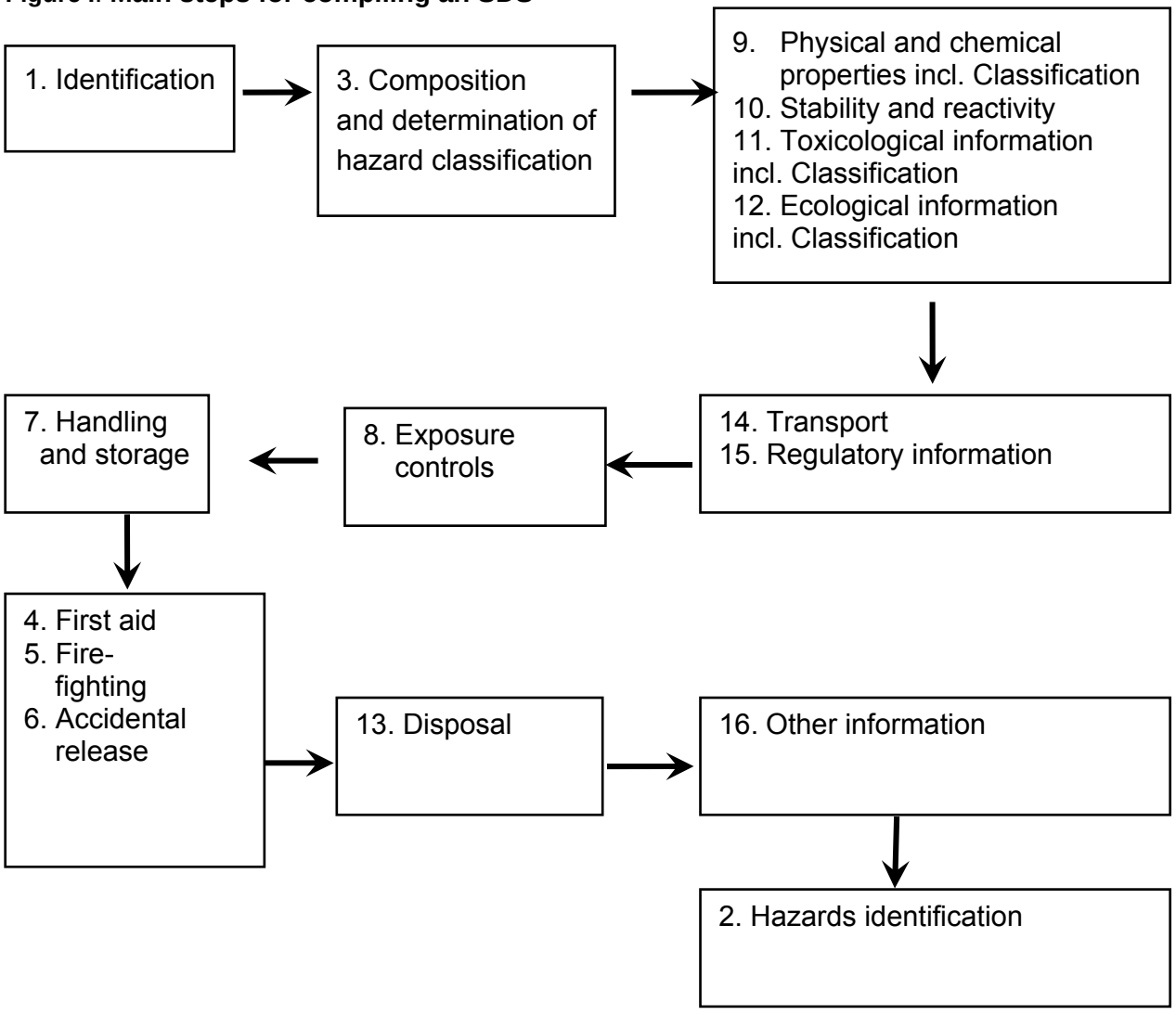
If this is a major revision, the revised Safety Data Sheet must be sent to all former recipients who received the product within the preceding 12 months. A major revision is given as soon as a major change occurs. For an indicative list of major changes, see section above.

REACH Article 36.1 establishes the obligation to keep information for at least 10 years after the last supply. Therefore, it is required to archive versions of Safety Data Sheets, which have become obsolete, for 10 years – to be able to present them for enforcement purposes or in disputes under liability law and employment law. Longer archiving periods may be appropriate for substances with chronic effects.

3.11. In what sequence should details be included in the various parts of the SDS?

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

Figure I: **Main steps for compiling an SDS**



3.12. Which items of information are most important?

All items of information are important. However, as the SDS serves primarily for occupational health and safety, the details on section 2 [hazards identification] and section 3 [composition/information on ingredients] are essential.

If a chemical safety assessment has to be performed for a substance or ingredients of a mixture, the related “instructions” for the safe handling of the product are addressed in exposure scenarios (in annex or included inter alia in chapters 7 and 8).

Also where the substance or the mixture does not meet the classification criteria, safety-relevant statements can become necessary. Many important items of information can be suitable for inclusion under several points/headings, but it is recommended not to repeat statements too often – this impairs clarity and easy legibility. In such cases, cross-referencing is useful. The question where recipients or users of Safety Data Sheets would look for certain information can be helpful in decision-making. See Figure II for more information.

If necessary information on certain properties cannot be determined, this should be stated (including the reasons why this information cannot be given).

3.13. Review of newly elaborated or updated SDSs

Safety Data Sheets are to be reviewed as to the validity of information given in the various sections. Contradictions are to be remedied. If necessary, technical departments are to be consulted or information is to be requested from upstream suppliers.

Where a property can not be determined and a reason is to be given on the SDS, provide the advice to ensure consistency with the reason that has been given in the Technical Dossier (for a registered substance).

3.14. In what way must the SDS be provided?

The Safety Data Sheet can be provided by letter, by fax or by email. It is also possible to put the Safety Data Sheet on an internet page which is accessible to the downstream users of chemicals. In the latter case, this form of providing the Safety Data Sheet needs to be agreed with the DU, and the DU’s attention needs to be drawn every time there is an important change in the Safety Data Sheet.

In future the structured electronic data exchange will become increasingly important because of the growing volume of information changes under REACH and GHS to decrease administrative costs along the supply chain. For this reason, it is recommendable to use a unique format including standard phrases.

Whatever the means used for the provision of SDS and, it is advised to keep records of the sending of SDS and/or the information of DUs about the revisions of SDS.

3.15. In what language must the SDS be provided?

According to REACH Article 31(5), the SDS shall be supplied in an official language of the Member State(s) where the substance or mixture is placed on the market, unless the recipient Member State(s)

concerned provide otherwise. Even if the MS provides otherwise, it is recommended to always provide in addition the SDS in the language of the country.

It should also be noted that certain MS require that the SDS is provided in additional official MS languages. It should also be noted that if the annexed exposure scenario is considered to be an integral part of the SDS this should also potentially be subject to translation.

3.16. For which products must an SDS be provided without request?

According to Article 31.1 of REACH:

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

- Substances meeting the criteria for classification as hazardous according to regulation (EC) n° 1272/2008 (CLP)
- Mixtures meeting the criteria for classification as hazardous according to directive 1999/45/EC (DPD)
- PBT and vPvB substances
- Substances that are included in the so called "candidate list"[8] for authorization (list published on ECHA website, see link in the footnote), and that are not already covered by the above bullet points

After June 1st, 2015:

- Substances and mixtures meeting the criteria for classification as hazardous according to regulation (EC) n° 1272/2008 (CLP)
- PBT and vPvB substances
- Substances that are included in the so called "candidate list" for authorization

3.17. For which products must an SDS be provided on request?

According to Article 31.3 of REACH:

Until May 31st 2015:

Mixtures which do not meet the criteria for classification as hazardous according to directive 1999/45/EC but contain at least:

- One substance hazardous for health or environment in an individual concentration of ≥ 1% by weight for non gaseous mixtures (≥ 0,2% by volume for gaseous mixtures)
- PBT, vPvB substances or substances with serious properties on health or environment, in an individual concentration of ≥ 0.1% by weight for non gaseous mixtures.
- A substance for which there are Community workplace exposure limits (EC Directives 2004/37/EC, 2000/39/EC, 2006/15/EC, 2009/161/EU).

After June 1st, 2015:

Mixtures which do not meet the criteria for classification as hazardous in accordance with Titles I and II of regulation (EC) n° 1272/2008 but contain at least:

- One substance hazardous for health or environment in an individual concentration of ≥ 1% by weight for non gaseous mixtures (≥ 0.2% by volume for gaseous mixtures)
- Substances in an individual concentration of ≥ 0.1% by weight for non gaseous mixtures, which are PBT, vPvB, presenting serious properties on health or environment, (see above) or are classified:
  - Carcinogenic, category 2
  - Toxic to reproduction, category 1A, 1B or 2

[8] http://echa.europa.eu/chem_data/authorisation_process/candidate_list_en.asp

- Skin or respiratory sensitiser, category 1
- As having effects on or via lactation

o A substance for which there are Community workplace exposure limits (EC Directives 2004/37/EC, 2000/39/EC, 2006/15/EC, 2009/161/EU).

3.18. For which special substances and mixtures should an SDS be provided on request?

According to annex I section 3.4.3.3.2 of the CLP Regulation, for mixtures which are not classified as sensitising but contain at least 0.1% by weight of a sensitising substance

3.19. How can consistency and completeness be ensured?

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 prepared 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 sending.
See Appendix 2 for a consistency check-list.

3.20. What labelling is required for a product where the SDS is available on request for professional users?

For mixtures, which are not classified as hazardous but for which a Safety Data Sheet must be provided on the request of a professional user, the label on the packaging must bear the following information: "Safety Data Sheet available for professional user on request" (see EC Preparations Directive 1999/45/EC, Annex V, Part C, no. 1). Reference to CLP Annex II, 2.10, EUH210.

Please note that the wording is different in the DPD and the CLP “Safety data sheet available on request.”

3.21. Is an SDS required for products available to the general public?

In principle, for hazardous substances or mixtures, which are available to the general public in the retail trade and already bear sufficient information in the label, a Safety Data Sheet must be provided only if this is demanded by a party who professionally places these substances/mixtures on the market or by a professional user (see REACH Article 31.4)

3.22. For which products are SDSs not required?

No Safety Data Sheet is required for products which are usually sold to final consumers and whose use is regulated by special regulations, e.g. those included in Article 2 of REACH such as:

- cosmetic products
- medicinal products requiring authorisation or registration (according to REACH Article 2.5(a))
- wastes for disposal and waste oil
- radioactive waste
- waste water
- medical devices

SDSs are also not required for products that are not hazardous and do not contain hazardous substances above the relevant concentration thresholds.

3.23. Is it useful to prepare an SDS for all products, even if it is not legally required?

From marketing and/or logistical aspects it may be generally useful to have Safety Data Sheets available for all products, even for those for which there is no legal obligation to provide an SDS.

According to REACH Article 32, any supplier of a substance on its own or in a mixture who does not have to supply a Safety Data Sheet in accordance with Article 31 shall provide the recipient with the following information:

- the registration number(s), if available.
- if the substance is subject to authorisation and details of any authorisation granted or denied in the supply chain
- details of any restriction
- any other available and relevant information about the substance that is necessary to enable appropriate risk management measures to be identified and applied including specific conditions resulting from the application of section 3 of Annex XI (General rules for adaptation of the standard testing regime set out in REACH Annexes VII to X).

Especially where mixtures are concerned, a general and systematic development and regular reviews of Safety Data Sheets avoid potential infringements, should new findings come to light regarding individual components.

3.24. When do I need to attach Exposure Scenarios to the SDS?

According to Article 31.7 of REACH, ES must be annexed to the SDS by any actor in the supply chain who is required to prepare a chemical safety Report (CSR) according to Article 14 (registrant above 10 tonnes/year of a classified, PBT or vPvB substance).

The ES are attached to the SDS by the registrants after submission of the CSR as part of the registration dossier to ECHA.

3.25. How to include the ES?

Article 31.7 of REACH specifies that the ES must be placed in an annex to the SDS. This is applicable for registrants having the obligation to carry out a CSR as part of the registration dossier (see REACH Article 14).

For downstream users, there are several options for placing relevant exposure scenarios: into an annex or including relevant exposure information in the core chapters 1 – 16 of the SDS.

3.26. What forms of assistance are available in the creation of SDSs?

Companies can rely on competent persons who offer this type of service. But finally the party who places the product on the market is responsible for the content of the Safety Data Sheet. For this reason, generally speaking, competent staff of the party who places the product on the market should prepare Safety Data Sheets - especially because manufacturers are usually highly familiar with the product properties.

Parties issuing Safety Data Sheets can be supported by relevant software applications. These applications generally have a database function and are usually composed of several modules. These databases contain substance lists and standard phrases in the form of glossaries.

An example of a source of standard phrases is the European Phrase Catalogue, which is available free-of-charge in German and English. This catalogue contains – in a well-structured form – phrases which have been shown to be useful for the preparation of Safety Data Sheets. The catalogue is being updated continuously and is available at: www.euphrac.eu

Some industry associations are offering support on their homepages for information regarding their specific sector. Suppliers are encouraged to contact their relevant trade association and request for any available information on SDS.

3.27. What further assistance can be given by standard software?

Many software products include options for writing Safety Data Sheets in several languages, and operating instructions under hazardous substances law, printing labels for containers, and sending Safety Data Sheets to customers after updates.
Such software products also support the management and consistency of information between the registration dossier (including the CSR) and the SDS.

3.28. Where can you find the substance data that you need in the creation of Safety Data Sheets?

For Downstream users, the key source of information is that provided by the supplier in his SDS.

If the substance is subject to Registration under REACH, most of the information on the substance properties will come from the SIEF during the preparation of the joint registration dossier. As mentioned, there needs to be consistency between the SDS and the information from the registration dossier.

There are also publicly available databases with relevant information for example:

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

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

On the platform ESIS (European chemical Substances Information System) 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 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, labeling, limit values, measuring methods, information on personal protection equipment, workplace limit values and occupational medicine.

International Chemical Safety Cards (ICSC)
(http://www.ilo.org/public/english/protection/safework/cis/products/icsc/dtasht/index.htm)

N-Class (http://apps.kemi.se/nclass/default.asp)

H-Class (http://apps.kemi.se/hclass/Main.aspx)

ChemPortal (http://webnet3.oecd.org/eChemPortal/Results2.aspx?SubstanceId=140664)

3.29. How to prepare an SDS for recovered substances and mixtures?

Appendix 4 provides more information on this topic. The ECHA Guidance on waste and recovered substances[9] also contains useful information on this topic.

[9] The Guidance on waste and recovered substances is currently under review. More information: http://guidance.echa.europa.eu/guidance4_en.htm

CHAPTER 4: RECEIVING AN SDS

The SDS is intended for professional downstream users (DU) in order to give them the information necessary to use the product (substance or mixture) safely. It is an essential document to provide data relevant to the protection of health and the environment.

When the DU does not receive an SDS from his supplier, he should check whether an SDS is required for the product or not. In some cases, he may ask his supplier to receive the SDSs which then have to be provided on request (see chapter 3 for more detailed information).

Upon receipt of an SDS, the DU should check:

- That it is in the official language of his Member State

- If an exposure scenario (ES) is attached to the SDS, which corresponds to his use of the product. If this is not the case, the recipient has several options:
    - o to contact the supplier and ask whether the use will be identified and shall be covered by an updated ext-SDS
    - o Prepare his own Chemical Safety Report (CSR)
    - o - Rely on an exemption according to Article 37 paragraph 4

- If there is an exposure scenario which corresponds to his use of the product, the DU has 12 months to implement the RMM included in the ES (REACH Article 39).

- Due to his workplace safety obligations the DU is obliged to make a short general plausibility check of the SDS content

The ECHA guidance for Downstream users[10] includes interesting information:

- Section 1.1.2: What should you do when you receive a safety data sheet?
- Section 4.2: Workflow on actions from information on substances or mixtures (Note b – Check safety data sheets)
- Table 2: Information in the safety data sheet relevant for compliance with downstream user obligations (see at the end of the section)

The content of the SDS is described in the figure 2 below which indicates to which section of the SDS the DU has to refer to find the information addressing specific needs.

[10] http://guidance.echa.europa.eu/docs/guidance_document/du_en.htm?time=1267779240

Figure II: Where to find information in an SDS for downstream users

General information	**Section**
▪ Name of the chemical and of the supplier	**1**
▪ Chemical composition	**3**
▪ Physical and chemical properties	**9**

Hazards, classification	**Section**
▪ Flammability, explosivity, reactivity	**2, 9 and 10**
▪ Health: toxicity	**2 and 11**
▪ Environment: ecotoxicity	**2 and 12**

Elimination	**Section**
▪ Residues / waste, recycling	**13**

Use	**Section**
▪ Identified uses, uses advised against	**1**
▪ Handling and storage	**7**
▪ User protection	**8**
▪ Occupational exposure limits	**8**
▪ Limitations of marketing and use, regulations	**15**

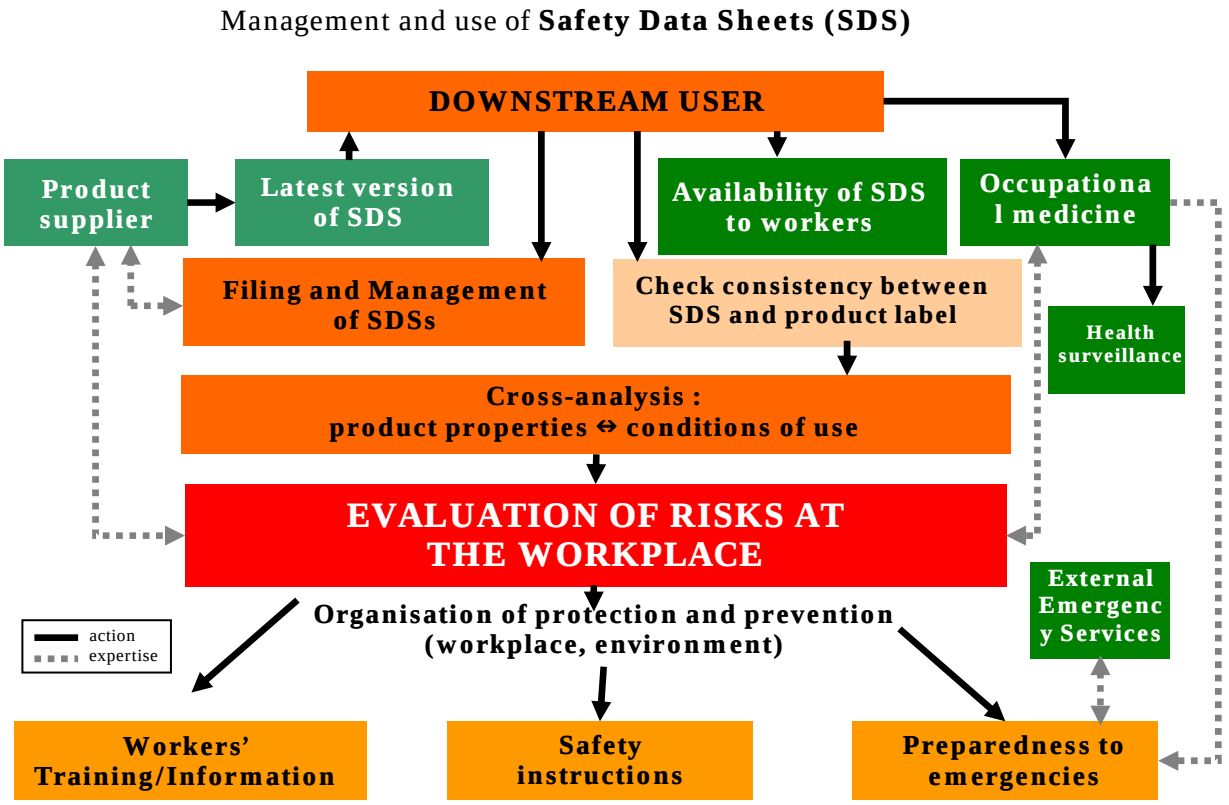
Emergency situations	**Section**
▪ First aid	**4**
▪ Fire	**5**
▪ Leaks / spillage	**6**

Transport	**Section**
▪ **Transport hazard classes**	**14**
▪ **Precautions and advice**	**14**

The SDS is an evolving document. It is necessary to ensure always having the most recent edition.
It is advised to organise the management of the SDS and to file all the successive versions of the SDS of a given product (useful for traceability and liability reasons).

The following figure 3 shows an example of how to manage and use an SDS within a DU company.

Figure III: Management of SDSs within a downstream user company



Source: UIC

Incoming SDS should be checked regarding content consistency/plausibility – particular attention should be paid to the following points:

1. Classification (including transport classification) – If further information is needed, contact your supplier.

2. Consistency between information given in sections 9, 11 and 12 and the classification of the final product.

3. Appropriateness of the RMMs: according to Article 34 of REACH, the DU needs to report back to his supplier if they are not appropriate.

In general: sufficient check of incoming safety data sheets is in line with good product safety especially the more the downstream users are located at the end of the supply chain. For an actor who is the last link in the chain, such as e.g. an article manufacturer, safety data sheets are virtually the sole source of important information to ensure end-use product safety.

Table 2: Information in the SDS relevant for compliance with downstream user obligations (source ECHA; headings adapted to current Annex II))

SDS heading	Information relevant for meeting your obligations under REACH	Action	Chapter of the DU guidance for more information
1. Identification of substance/mixture and of company	Registration number of the substance if registered. Known uses of the substance; where a chemical safety report is required, all identified uses Contact information for the supplier	Obligations start to apply as of 1st June 2007. Requirements of Article 37 of REACH apply at the latest one year after you receive a registration number **Voluntary**: If your use is not listed, you may wish to identify it to your supplier	8
2. Hazards identification	Most important adverse physicochemical, human health and environmental effects of the substance as such or of the mixture	Supply any new information on hazards to the next actor up the supply chain Report to ECHA if you classify differently	10
3. Composition / information on ingredients	Hazards of the components of the mixture	Supply any new information on hazards to the next actor up the supply chain Report to ECHA if you classify differently	10
4. First aid measures	Measures to treat the effects of accidents	No changes to current practice	
5. Fire fighting measures	Measures to ensure safety in case of fire	No changes to current practice	
6. Accidental release measures	Measures to address the risks of accidental releases	No changes to current practice	
7. Handling and storage	Information to help devise suitable working procedures and organisational measures to manage risk	No changes to current practice	
8. Exposure controls/personal protection	Exposure limit values and risk management measures. The information must be consistent with the information set out in the exposure scenario, if one is attached to the	Implement appropriate risk management measures Inform your supplier if you have information calling into question the risk management	11

	safety data sheet.	measures	
9. Physical and chemical properties	Important health, safety and environmental information	Supply any new information on hazards to the next actor up the supply chain	10
10. Stability and reactivity	Conditions and materials to avoid	Supply new information on hazards to the next actor up the supply chain	10
11. Toxicological information	Information on potential risks to health	Supply new information on hazards to the next actor up the supply chain	10
12. Ecological information	Information on potential risks to the environment	Supply new information on hazards to the next actor up the supply chain	10
13. Disposal considerations	Appropriate methods of disposal	Check if there is information that should be passed on to your waste disposal organisation	
14. Transport information	Any special precautions for transport	No changes to current practice	
15. Regulatory information	Whether the substance as such or in a mixture is subject to authorisation or to restrictions Indication of whether a chemical safety assessment has been carried out.	Check compliance with authorisation Check compliance with restrictions	12 13
16. Other information	Recommended (non-statutory) restrictions on use	Check compliance with restrictions Supply any new information on hazards to the next actor up the supply chain	13 10
Annex	Exposure scenario(s) for the identified uses relevant for you	You have to implement the conditions of use described in the exposure scenarios unless you have developed your own chemical safety re-port and relevant	5

		exposure scenario, or exemptions for this apply to you.	

1
2

CHAPTER 5: DETAILED INFORMATION BY SECTION

In each section, the text of the currently proposed amendment to Annex II is included at the beginning of the section as reference.

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 shall contain an explanation or justification why the section has not been completed.

The European Phrase Catalogue (EuPhrac www.euphrac.com) includes some examples of this type of phrases, especially for section 9, 11 and 12.

5.1. 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
In the case of a substance, the product identifier shall be provided in accordance with Article 18(2) of Regulation (EC) No 1272/2008 and as provided on the label in the official language(s) of the Member State(s) where the substance is placed on the market, unless the Member State(s) concerned provide(s) otherwise. *For substances subject to registration, the product identifier shall be consistent with that provided in the registration and the registration number assigned under Article 20(3) of this Regulation shall also be indicated.* *Without affecting the obligations of downstream users laid down in Article 39 of this Regulation, the part of the registration number referring to the individual registrant of a joint submission may be omitted by a supplier who is a distributor or a downstream user provided that:* *(a) this supplier assumes the responsibility to provide the full registration number upon request for enforcement purposes or, if the full registration number is not available to him, to forward the request to his supplier, in line with point (b); and* *(b) this supplier provides the full registration number to the Member State authority responsible for enforcement (hereinafter referred to as the "enforcement authority") within 7 days upon request, received either directly from the enforcement authority or forwarded by his recipient, or, if the full registration number is not*

available to him, this supplier shall forward the request to his supplier within 7 days upon request and at the same time inform the enforcement authority thereof.

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

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

Other means of identification

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

According to the CLP Regulation Article 18.2, the product identifier for a substance shall consist of at least the following:

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

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

(c) if the substance is not included in Part 3 of Annex VI nor in the classification and labelling inventory, the number provided by the CAS (hereinafter referred to as 'the CAS number'), together with the name set out in the nomenclature provided by the IUPAC (hereinafter referred to as 'the IUPAC Nomenclature'), or the CAS number together with another international chemical name(s); or

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

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

If the substance has been registered, the **registration number** must be provided in this section. 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 this supplier assumes the responsibility to provide the full registration number upon request for enforcement purposes.

If the full registration number is not available to him, he must forward the request to his supplier within 7 days, and inform the enforcement authorities accordingly.

If there is no registration number, it is recommended to add explanation why this is the case. It is recommended to use standard phrases e.g.

The transition time according to REACH Regulation, Article 23 is still not expired.
The substance must not be registered according to REACH, Annex IV and V.

An example of how the structure of this section may look like is given below.

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier:
1.1.1 Substances
Substance name:
EC No.:
REACH Registration No.: XX-XXXXXXXXXX-XX-XXXX[11]
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 uses[12] 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.

A comprehensive list of use descriptors[13] should *not* be included in this section of the SDS. It could be a lengthy block of text on the front page of the SDS. An alternative is to have a rather generic list of applications and a reference to the ES. An index or table of contents could be added to section 16 with a reference in this section for the ES details e.g. generic list of applications + '*see section 16 for a complete list of uses for which an ES is provided as an annex*'

The **uses advised against** also need to be included in this section. This does not need to be an exhaustive list. This section needs to be consistent with the

[12] Identified use is defined in REACH, article 3, 26
[13] More information on use descriptors is available at: http://guidance.echa.europa.eu/guidance4_en.htm

information in section 3.6 of IUCLID (Used Advised Against). The reason why a use is not advised may also be included.

Uses advised against may be reported also using elements of the Use Descriptor system, and/or with a generic description of the use(s). Some examples of how this could look like are given below:

Do not use for injecting or spraying.

Do not use as substitution to air pressure/or to enrich the breathing air.

Do not use for inflating balloons.

Do not use for medical-clinical purposes.

Do not use for products which come into direct contact with the skin.

Do not use for products which come into contact with the food stuffs.

Not recommended for interior use on large surface areas.

Do not use for private purposes (household).

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

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

1.2.1 Relevant identified uses

Uses advised against[14]:

Do not use for injecting or spraying.

See chapter 16 for a general overview.

1.3. Details of the supplier of the SDS

Text Annex II
The supplier, whether it is the manufacturer, importer, only representative, downstream user or distributor, shall be identified. The full address and telephone number of the supplier shall be given as well as an e-mail address for a competent person responsible for the safety data sheet. *In addition, if the supplier is not located in the Member State where the substance or mixture is placed on the market and he has nominated a responsible person for that Member State, a full address and telephone number for that responsible person shall be given.* *For registrants, the information shall be consistent with the information on the identity of the manufacturer or importer provided in the registration.* *Where an only representative has been appointed, details of the non-Community manufacturer or formulator may also be provided.*

The identification of the person established within the Community who is responsible for placing the substance or mixture on the market whether it be the manufacturer,

[14] Please note that these are just examples

importer or distributor, as well as the complete address and telephone number of such person shall be provided.

Where this person is not established in the Member State in which the substance or mixture is placed on the market, a full address and telephone number of the person responsible in that Member State should be indicated, if possible.

If the manufacturer/distributor is established outside the European Union, the name and address of the person importing it into the European Union or placing it on the market there shall be indicated.

An additional department/contact person (including telephone number at minimum) responsible for the contents of the Safety Data Sheet may be indicated under heading "16. Other data"

The information can be structured as follows:
- 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 requirement to mention the name of a physical person in an SDS.

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

In some cases it can be challenging for an Only Representative (OR) to supply the SDS e.g. imported mixtures with different OR(s) for different ingredient(s). Practical solutions are still in discussion in industry.

1.4. Emergency telephone number

Text Annex II
References to emergency information services shall be provided. If an official advisory body exists in the Member State where the substance or mixture is placed on the market (this may be the body responsible for receiving information relating to health referred to in Article 45 of Regulation (EC) No 1272/2008 and Article 17 of Directive 1999/45/EC), its telephone number shall be given and can suffice. If availability of such services is limited for any reasons, such as hours of operation, or if there are limits on specific types of information provided, this shall be clearly stated

This section should include, when it exists, the references to the (or one of the) official national advisory body(ies) in the Member State where the substance or the

mixture is placed on the market. This may be a body responsible for receiving information relating to health referred to in Article 45 of CLP regulation.

Additionally, when available, references to emergency information services belonging to the supplier may be indicated, along with any limitation of such services ('opening hours or types of information that may be provided). E.g.

(1) Only available during office hours.

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

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.

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

1.3 Details of the supplier of the safety data sheet:

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

Street address/P.O. Box

Country ID/Postcode/Place

Telephone number

e-mail

National contact:

1.4 Emergency telephone number

Opening hours:

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

5.2. 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.

This section includes the description of the hazards of the substance or mixture and of the appropriate warning information associated with those hazards.

2.1. Classification of the substance or mixture

Text Annex II
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 Council Directive 67/548/EEC shall also be given.* *In the case of a mixture, the classification which arises from the application of the classification rules in Directive 1999/45/EC shall be given. If the mixture does not meet the criteria for classification in accordance with Directive 1999/45/EC, this shall be clearly stated. Information on the substances in the mixture is provided under Subsection 3.2.* *If the classification, including the hazard statements and R phrases, is not written out in full, reference shall be made to Section 16 where the full text of each classification, including each hazard statement and R phrase, shall be given.* *The most important adverse physicochemical, human health and environmental effects shall be listed consistent with Sections 9 to 12 of the safety data sheet, in a way as to allow non-experts to identify the hazards of the substance or mixture.*
Text Annex II (after 1st of June 2015)
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.*

- **<u>Substance</u>**

When the supplier has notified the classification information of the substance to the classification and labelling inventory, the classification given in the safety data sheet shall be the same than the one provided in the notification.

The classification is to be given according to the rules in the CLP regulation: indication of hazard classes and categories and hazard statements.

Until May 31st, 2015, the classification according to directive 67/548/EEC shall be given too: categories of danger symbol letters, and R phrases[15], and, for CMR effects, danger categories.

It is advised to clearly identify both classifications (i.e. with sub headings) in the safety data sheet.

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

2. Hazards identification

2.1 Classification of the substance

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

Flam. Liq. 2, H225
Acute Tox. 3, H301
Acute Tox. 3, H311
Acute Tox. 3, H331
STOT SE 1, H370

2.1.2. Classification according to Directive 67/548/EEC
F; R11
T; R23/24/25
T; R39/23/24/25

2.1.3 Additional information:
Full text of R- and H-phrases And EUH-phrases.: see section 16

- **Mixture**

If the mixture is labelled according to the DPD Directive [allowed until May 31st, 2015], the classification must be indicated according to that directive: symbol letter(s) and categories 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.

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

Note; If a supplier of a mixture chooses to identify and inform about the classification according to regulation (EC) n°1272/2008 in advance of using it for classification and labelling on the package, this classification may be included in section 16.

When the safety data sheet is provided for a non classified mixture, this should be stated. Example of industry standard phrase:

[15] Full text or reference to section 16

'This product does not meet the classification requirements of the current European legislation on classification and labelling'

The full text of classification and R-phrases/ Hazard statements may be provided here, or a reference to section 16 where this information will be provided.

Please note that additional information may be available after the first registration deadline (1st of December 2010) as result of the SIEF activity, e.g. new information that becomes available results of tests, etc. This may happen until 2018 and beyond.

An example of how the structure of this section could look like *during the transitional period* is given below:

2. Hazards identification

2.1 Classification of the mixture

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

see section 16

2.1.2. Classification according to Directive 1999/45/EC

F; R11
T; R23/24/25
T; R39/23/24/25

2.1.3 Additional information:
For full text of R- phrases: see section 16.

2.2. Label elements

Text Annex II
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.*
Text Annex II (after 1st of June 2015)

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

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

For substances, the label elements are to be indicated according to the CLP regulation.

For mixtures, the label elements indicated in this section must be consistent with the label affixed to the product: DPD Directive or CLP Regulation until May, 31st 2015, and CLP Regulation after the 1st of June 2015.

Label elements according to the CLP regulation include at least:

- Hazard pictogram(s), including graphical reproduction of the symbol or the full pictogram(s), in black and white or in colour.
- Signal word
- Hazard statement(s), H and EUH,, in full
- Precautionary statement(s), P,, in full
- The applicable label elements in accordance with Articles 25 (i.e. annex II) and 32(6) of the CLP regulation.
- The precautionary statements shall be selected in accordance with the criteria laid down in Part 1 of Annex IV taking into account the hazard statements and the intended or identified use or uses of the substance or the mixture. The precautionary statements shall be worded in accordance with Part 2 of Annex IV.
- In selecting the precautionary statements in accordance with Articles 22 and 28(3), suppliers may combine the Precautionary Statements, having regard to clarity and comprehensibility of the precautionary advice.
- It may be useful for industrial and professional use (not for consumer because they do not receive an SDS) to include special P-phrases into appropriate chapters of the SDS main body in order to reduce P-phrases on the label.
- Examples of those P-phrases are:

P 202 Do not handle until all safety precautions have been read and understood. (section 7)

P264 Wash hands thoroughly after handling. (section 8)

P270 Do not eat, drink or smoke when using this product (section 8)

P272 Contaminated work clothing should not be allowed out of the workplace (section 8)

P407 Maintain air gap between stacks/pallets. (section 7 - storage)

P406 Store in corrosive resistant container with a resistant inner liner. (section 7)

P391 Collect spillage. (section 6)

Label elements according to the DPD directive include at least:

- Symbol(s), including graphical reproduction, in black and white or in colour
- Indication(s) of danger
- Risk phrase(s) (R), in full
- Safety advice (S), in full
- The applicable label elements in accordance with sections A and B of annex V to directive 1999/45/EC.

According to REACH Article 65, holders of an authorisation, as well as downstream users referred to in Article 56(2) including the substances in a mixture, shall include the authorisation number on the label. It is therefore recommended to include the full authorisation number in this section.

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

2.2:Label elements

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

Product identifier:
Substance A
Index No xxx-xxx-xx-X
Authorisation number:

Hazard pictograms

GHS02 GHS06 GHS08

Signal word:
Danger

Hazard statements:
H225 Highly flammable liquid and vapour.
H301 Toxic if swallowed.
H311 Toxic in contact with skin.
H331 Toxic if inhaled.
H370 Causes damage to organs.

Precautionary statements[16]:
P210 Keep away from heat/sparks/open flames/hot surfaces. – No smoking.

[16] Number of P-phrases has been reduced

P233 Keep container tightly closed.
P241 Use explosion-proof electrical/ventilating/lighting/equipment.
P243 Take precautionary measures against static discharge.
P260 Do not breathe mist/vapours/spray.
P271 Use only outdoors or in a well-ventilated area.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P301 + P310 IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician.
P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
P303 + P361 + P353 IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.
P304 + P340 IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing.
P307 + P311 IF exposed: Call a POISON CENTER or doctor/physician.
P330 Rinse mouth.
P363 Wash contaminated clothing before reuse.
P403 + P235 Store in a well-ventilated place. Keep cool.
P405 Store locked up.
P501 Dispose of contents/container to special waste combustion plant.

Supplemental Hazard information (EU)[17]

Special rules for supplemental label elements for certain mixtures[5]

If the P-phrases relate to firs aid measures, the information needs to be consistent with the section 5.4 of the SDS.

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

2.2:Label elements
Labelling according to Regulation (EC) No 1272/2008 [CLP/GHS]
Product identifier[18]*:*
Hazard components for labelling:

NOTE: the reference number of pictograms and R, S, H and P phrases (i.e. H225) do not need to appear on the label and in section 2.2 of the SDS; only their full text is required. In order to be able to check and/or compare, it is recommended to add these numbers in the 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*

[17] If applicable
[18] Trade name or the designation of the mixture

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.

This section includes hazards which may not lead to classification but that should be known as they may contribute to the overall hazards of the substance or mixture, e.g. 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 etc

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

2.3 Other hazards
Poisonings effect on central nervous system and cause convulsions, difficulty in breathing and unconsciousness.
Risk of blindness after swallowing the product
Substance is an endocrine disruptor
Substance meets the criteria for PBT or vPvB according to Regulation (EC) No 1207/2006, Annex XIII
Substance is phototoxic

5.3. 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 (substance / mixture).

3.1. Substances

Text Annex II
The chemical identity of the main constituent of the substance shall be provided by providing at least the product identifier or one of the other means of identification given in Subsection 1.1. *The chemical identity of any impurity, stabilising additive, or individual constituent other than the main constituent, which is itself classified and which contributes to the*

classification of the substance shall be provided as follows:

(a) the product identifier in accordance with Article 18(2) of Regulation (EC) No 1272/2008;

(b) if the product identifier is not available, one of the other names (usual name, trade name, abbreviation) or identification numbers.

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

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

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

An example of how the structure of this section could look like for a formaldehyde solution is given below:

CAS #	**Chemical name**	**%**	**EINECS#**
50-00-0	Formaldehyde	4.0	200-001-8
7647-14-5	Sodium chloride	0.9	231-598-3
7732-18-5	Water	balance	231-791-2

3.2. Mixtures

Text Annex II

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

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

(a) exact percentages in descending order by mass or volume, if technically possible;

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

When using a range of percentages, the health and environmental hazards shall describe the effects of the highest concentration of each ingredient.

If the effects of the mixture as a whole are available, this information shall be included under Section 2.

Where the use of an alternative chemical name has been allowed under Article 15 of

Directive 1999/45/EC or under Article 24 of Regulation (EC) No 1272/2008, that name can be used.

3.2.1. For a mixture meeting the criteria for classification in accordance with Directive 1999/45/EC, the following substances shall be indicated, together with their concentration or concentration range in the mixture:

(a) substances presenting a health or environmental hazard within the meaning of 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.

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

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

3.2.2. For a mixture not meeting the criteria for classification in accordance with Directive 1999/45/EC, substances present in an individual concentration equal to or greater than the following concentrations shall be indicated, together with their concentration or concentration range:

(a) 1% by weight in non-gaseous mixtures and 0,2% by volume in gaseous mixtures for

(i) substances which present a health or environmental hazard within the meaning of 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

(ii) substances which are assigned Community workplace exposure limits;

(b) 0,1% by weight for substances which are persistent, bioaccumulative and

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

3.2.3. For the substances indicated in Subsection 3.2, the classification of the substance according to 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. 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.

Text Annex II (after 1st of 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.

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

(a) substances presenting a health or environmental hazard within the meaning of Regulation (EC) No 1272/2008, if those substances are present in concentrations equal to or greater than the lowest of any of the following:

(ia) the generic cut-off values set out in Table 1.1 of Regulation (EC) No 1272/2008;

(ib) the generic concentration limits given in parts 3 to 5 of Annex I to Regulation (EC) No 1272/2008 and for aspiration hazard (Section 3.10 of Annex I to Regulation (EC) No 1272/2008) ≥ 10%;

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

1.1 Hazard class and category	*Concentration limit %*
Acute toxicity, category 1, 2 and 3	*≥ 0,1*
Acute toxicity, category 4	*≥ 1*
Skin corrosion/irritation, category 1A, 1B, 1C and 2	*≥ 1*
Serious damage to eyes/eye irritation, category 1 and 2	*≥ 1*
Respiratory/skin sensitisation	*≥ 0,1*
Germ cell mutagenicity category 1A and 1B *Germ cell mutagenicity category 2*	*≥ 0,1* *≥ 1*
Carcinogenicity category 1A, 1B and 2	*≥ 0,1*
Reproductive toxicity, category 1A, 1B, 2 and	*≥ 0,1*

effects on or via lactation	
Specific target organ toxicity (STOT) - single exposure, category 1 and 2	*≥ 1*
Specific target organ toxicity (STOT) – repeated exposure, category 1 and 2	*≥ 1*
Aspiration hazard	*≥ 1*
Hazardous to the aquatic environment – Acute, category 1	*≥ 0.1*
Hazardous to the aquatic environment – Chronic, category 1	*≥ 0.1*
Hazardous to the aquatic environment – Chronic, category 2, 3 and 4	*≥ 1*
Hazardous for the ozone layer	*≥ 0.1*

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

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

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

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

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

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

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

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

(a) 1% by weight in non-gaseous mixtures and 0,2% by volume in gaseous mixtures for

(i) substances which present a health or environmental hazard within the meaning of Regulation (EC) No 1272/2008; or

(ii) substances which are assigned Community workplace exposure limits;

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

3.2.3. For the substances indicated in Subsection 3.2, the classification of the substance according to Regulation (EC) No 1272/2008, including the hazard class(es) and category code(s) as provided in Table 1.1 of Annex VI to that Regulation as well as the hazard statements which are assigned in accordance with their physical, human health and environmental hazards, shall be provided. The hazard statements do not need to be written out in full in this section; their codes shall be sufficient. In cases where they are not written out in full, reference shall be made to Section 16, where the full text of each relevant hazard statement shall be listed. If the substance does not meet the classification criteria, the reason for indicating the substance in Subsection 3.2 shall be described, such as "non-classified vPvB substance" or "substance with a Community workplace exposure limit".

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

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

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

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

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

For substances indicated in this subsection by means of an alternative chemical name in accordance with Article 15 of Directive 1999/45/EC or Article 24 of Regulation (EC) No 1272/2008, the registration number, EC number and other precise chemical identifiers are not necessary.

The identifiers of the hazardous components have to be included here with the same identifiers as above: EC No, Index No., REACH registration No. and/or d CAS number, percentage in the mixture, range etc.

In the case of mixtures, the last four digits of the REACH Registration number can be omitted by any supplier, except for imported mixtures.

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

3: Composition/information on ingredients

Description of the mixture:
Aqueous solution of Substance A. No further substances with acute toxicity.

Hazardous ingredients

CAS No	***EC No***	***Index No.***	***REACH Registration No.***	***% [weight][19]***	***Name***	***Classification according to 67/548/EEC***
xx-xx-x	*xxx-xxx-x*	*603-001-00-X*	*XX-XXXXXXXXXX-XX-…*	*50*	*substance A*	*F; R11 T; R23/24/25 T; R39/23/24/25*

CAS No	***EC No***	***Index No***	***REACH Registration No***	***% [weight]***	***Name***	***Classification according to Regulation (EC) No 1272/2008 [CLP]***
xx-xx-x	*xxx-xxx-x*	*603-001-00-X*	*XX-XXXXXXXXXX-XX-…*	*50*	*substance A*	*Flam. Liq. 2, H225 Acute Tox. 3, H301 Acute Tox. 3, H311 Acute Tox. 3, H331 STOT SE 1, H370*

Additional information:
For full text of R- and H-phrases: see section 16.

Table 3 below shows the general cut-off limits for SDSs of mixtures classified to be hazardous. The differences are highlighted in **bold (new items)** and plain text (existing items). Please note that these values do not have to be included in the SDS. The reference to these cut-off values is only in the context of the determining the threshold for when a substance is required to be disclosed in this section

Table 3: General cut-off limits for hazardous mixtures

Hazard class and categories of the substance	**CLP cut-off limit**	**1999/45/EC cut-off for liquid mixtures***	**Special provisions[20]**
Acute toxicity Cat. 3 or 4	**≥1.0%**	**≥ 0.1% for all T+, T ≥ 1.0% for all Xn**	
Skin irritation Skin	≥ 1.0%	≥ 1.0%	

[19] The % weight can be indicated as ranges. If ranges are used, the hazard assessment should be based in the highest concentration.
[20] For example Annex V of 1999/45/EC and others

corrosion			
Eye irritation Eye corrosion	≥ 1.0%	≥ 1.0%	
Sensitization (skin and respiratory tract)	**≥ 0.1%**	**≥ 1.0%**	
Muta. 1A/1B Mut. Cat. 1, 2	≥ 0.1%	≥ 0.1%	
Muta. 2 Mut. Cat. 3	**≥ 0.1 %**	**≥ 1.0%**	
Carc. 1A/1B Carc. Cat. 1,2	≥ 0.1%	≥ 0.1%	
Repr. 2 (Repr. Cat. 3) Lactation	≥ **0.1%** ≥ **0.3%**	≥**1.0%** ≥ **1.0%**	
STOT SE and RE	**≥ 1.0%**	**≥ 0.1% for all T+, T** ≥ 1.0% for all Xn	
Aqu. acute 1	≥**0.1%**	**≥ 0.1%**	**"N; R50"** **"N; R50/53"**
Other aquatic toxicity Ozone layer	≥**1,0%**	**≥ 1.0%**	**"N; R51/53"** **"R52/53"** **"N; R59" and others without symbol "N"**

* For gaseous mixtures limits are 5 times lower (except in the case of "N").

5.4. 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.

The information on first aid must be brief and easy to understand by the victim, bystanders and first-aiders.

The symptoms and effects shall be briefly summarised.

The instructions should indicate what is to be done on the spot in the case of an accident and whether delayed effects can be expected after exposure.

4.1. Description of first aid measures

Text Annex II
4.1.1. First aid instructions shall be provided by relevant routes of exposure.

Subdivisions shall be used to indicate the procedure for each route, such as inhalation, skin, eye and ingestion. *4.1.2. Advice shall be provided as to whether:* *(a) immediate medical attention is required and if delayed effects can be expected after exposure;* *(b) movement of the exposed individual from the area to fresh air is recommended;* *(c) removal and handling of clothing and shoes from the individual is recommended; and* *(d) personal protective equipment for first aid responders is recommended.*

It is recommended to subdivide the information according to the different routes of exposure, i.e. inhalation, skin and eye contact and ingestion, under different subheadings.

This section also needs to specify whether medical attention is required or advisable. For some substances or mixtures it may be important to emphasize that special means to provide specific and immediate treatment must be available at the workplace.

The information should be structured as follows:
- *general notes*
- *following inhalation*
- *following skin contact*
- *following eye contact*
- *following ingestion*
- *notes for the doctor*

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.

The measures shall be described in a readily understandable manner so that they can be implemented by non-expert first-aiders. Indicate:

- if no first-aid measures can or may be carried out by untrained personnel.

- If a specific danger caused by the product if taken up through a defined route of exposure, detailed first-aid measures shall be indicated with respect to this route of exposure.

- Where it appears to be necessary to provide specific information for the doctor (e.g. specific antidote treatment, positive airway pressure, prohibition of certain drugs, eating, drinking or smoking, etc.) this information shall be given under the heading “Notes for the doctor” (symptoms, hazards, treatment). The information provided under this heading may contain special medical terms and may be difficult to understand for non-medical personnel.

4.3. Indication of 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.*

In summary:

- The first aid measures should be brief and easy to understand.
- The symptoms and effects should be described concisely.
- Possible / delayed effects should be stated.
- For some substances or mixtures attention must be drawn to the providing of special means/medicinal products for immediate treatment at the workplace (for example poisoning by alkyl phosphates the antidote is atropine).
- When stating the measures, it should be considered that they can be performed by non-experts. Otherwise it is essential to emphasize **only** qualified medical help
- In special cases it could be necessary to point to specific hazards due to a certain route of exposure

5.5. SDS Section 5: Fire-fighting measures

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

This section should include the requirements for fighting a fire caused by the substance or mixture, or arising in its vicinity by indicating:

- suitable extinguishing media
- extinguishing media which must not be used for safety reasons,
- special exposure hazards arising from the substance or mixture itself,
- combustion products, resulting gases,
- special protective equipment for fire-fighters.

5.1. Extinguishing media

Text Annex II
Suitable extinguishing media: *Information shall be provided on the appropriate extinguishing media.* *Unsuitable extinguishing media:*

Indications shall be given whether any extinguishing media are inappropriate for a particular situation involving the substance or mixture.

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

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

A useful source of information about suitable or unsuitable extinguishing media is the **Cefic Emergency Response Intervention Cards** (ERICards or ERIC's). This database provides guidance on initial actions for fire crews when they first arrive at the scene of a chemical transport accident without having appropriate and reliable product specific emergency information at hand (http://www.ericards.net). ERICards are intended for fire crews, trained in chemical emergency response, and contain information and procedures that may require specialised equipment.

ERICards are intended to deal with chemical accidents involving a substantial amount of product, occurring during land transport only and may therefore not be appropriate for accidents in other situations.

ERICards apply to a group of products, and hence can never be a substitute for the specific product information obtained from a reliable source (e.g. safety data sheet, reference databases or industry experts). Using ERICards therefore always requires sound judgment, taking into account the particular circumstances of each accident.

5.2. Special hazards arising from the substance or mixture

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

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

When writing this section, it should be considered that spillage and fire water can cause pollution of watercourses. Guidance should be given to minimize their impact on the environment.

5.3. Advice for fire-fighters

Text Annex II
Advice shall be provided on any protective actions to be taken during fire-fighting, such as "keep containers cool with water spray", and on special protective equipment

for fire-fighters, such as boots, overalls, gloves, eye and face protection and breathing apparatus.

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

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

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

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

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

PVC protective clothing is not suitable for many chemicals being transported.

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

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing media:
Suitable extinguishing media:

Unsuitable extinguishing media:

5.2 Special hazards arising from the substance or mixture
Hazardous combustion products:
5.3 Advice for fire-fighters
5.4 Additional information:

5.6. 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.

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").*

This section includes information such as removal of ignition sources, provision for sufficient ventilation/respiratory protection, control of dust, prevention of skin and eye contact,

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.

This section includes information such as: keeping away from drains, surface- and ground-water and soil, possible need to alert the neighbourhood.

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 …'.*

This section includes information such as: use of absorbent material (e.g. sand, diatomaceous earth, acid binder, universal binder, sawdust, etc.), reduction of gases/fumes with water, dilution.

6.4 Reference to other sections

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

Depending on the substance or mixture involved, information may be needed on:

- personal precautions: e.g. removal of ignition sources, provision for sufficient ventilation/respiratory protection, control of dust, prevention of skin and eye contact

- environmental precautions such as: keeping away from drains, surface- and ground-water and soil, possible need to alert the neighbourhood,

- methods for cleaning up such as: use of absorbent material (e.g. sand, diatomaceous earth, acid binder, universal binder, sawdust, etc.), reduction of gases/fumes with water, dilution.

Also consider the need for references to materials that must not be used under any circumstances or to appropriate neutralizers by including indications such as: 'Never use ……..", Neutralize with …".

If appropriate refer to sections 8 and 13 of the Safety Data Sheet.

General measures, like ventilation, removal of ignition sources and control of dust should be stated.

Measures to prevent damage to human health are stated, e.g. prevention of skin contact and warning and evacuating people in the neighbourhood if needed

Personal protective equipment for persons cleaning up spills is stated. If this is the same as for normal handling of the product a reference can be given to chapter 8

Unsuitable cleaning methods and unsuitable absorbing agents are stated

Method for disposal of collected and contained spill, absorbent or similar is stated

Suitable methods and media for neutralizing or inactivating spilled product are stated

Advice is given to contact the fire brigade, waterworks, sewage treatment plant or the community's environmental administration if relevant.

In some cases, it can be useful to refer to advice included in other relevant sections such as sections 8 (exposure controls and personal protection) and 13 (Disposal considerations) of the Safety Data Sheet.

6.5 Additional information

Some examples of what kind of recommendations can 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.*

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

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

6.1.1 For non-emergency personnel

Protective equipment:
Emergency procedures:

6.1.2 For emergency responders

6.2 Environmental precautions:

6.3 Methods and material for containment and cleaning up

6.3.1 For containment:

6.3.2 For cleaning up:

6.3.3 Other information:

6.4 Reference to other sections

6.5 Additional information:

5.7. 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.*

This section shall contain important health, safety and environmental information. It shall assist the employer in devising suitable working procedures and organisational measures according to Article 5 of Directive 98/24/EC.

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, local and general ventilation, 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.

The information should be structured as follows:
- Information on safe handling
- Information on fire and explosion protection
- Other information

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

7. HANDLING AND STORAGE

7.1 Precautions for safe handling

7.1.1 Protective measures:
Measures to prevent fire:
Measures to prevent aerosol and dust generation:
Measures to protect the environment:

7.1.2 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 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. In particular indicate any special requirements such as the type of material used in the packaging/containers of the substance or mixture.

Some companies may decide to indicate the storage class according to the VCI storage concept (only available in German) [21]

The storage class is derived from the classification of the pure substance or mixture, the packaging shall not be considered 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 like 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:

Hints on storage assembly:

Storage class:

Further information on storage conditions:

7.3 Specific end use(s)

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

For end products designed for specific use(s), recommendations shall refer to the identified use(s) and be detailed and operational. If possible, reference shall be made to applicable industry- or sector-specific available guidance.

21 http://www.vci.de/default2~rub~739~tma~882~cmd~shd~docnr~121802~nd~,n18,umw,~ond~n135~snd~n135~shmode~.htm
(to be repealed in summer 2010 by a Technical Rule of the German Ausschuss für Gefahrstoffe).

For biocidal products, 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.

For paint and varnish products, the product category of the ready-to-use product should be indicated in accordance with Directive 2004/42/EC (Deco Paint Directive)

If the SDS has the corresponding ES attached, there is no need to use this section for specific recommendations for end uses. The industry specific guidance can be included in any case.

For substances with no ES e.g. substances < 10 t/a, this section may be used to include equivalent information as the ES. This section can also be of potential use for mixtures for which no ES is attached.

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

7.3 Specific end use(s):
Recommendations:

Industrial sector specific solutions:

5.8. SDS Section 8: Exposure controls/personal protection

Note: If you are preparing an SDS for a "special mixture"*, how to adapt section 8 is explained in Annex 3.

** 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.*

Text Annex II
This section of the safety data sheet shall describe the applicable occupational exposure limits and necessary risk management measures. *Where a chemical safety report is required, the information in this section of the safety data sheet shall be consistent with the information given for the identified uses in the chemical safety report and the exposure scenarios showing control of risk from the chemical safety report set out in the annex to the safety data sheet.*

8.1 Control parameters

Text Annex II
8.1.1. Where available, the following national limit values, including the legal basis of each of them, which are currently applicable in the Member State in which the safety data sheet is being provided shall be listed for the substance or for each of the substances in the mixture. When listing occupational exposure limit values, the

chemical identity as specified in Section 3 shall be used.
8.1.1.1. the national occupational exposure limit values that correspond to Community occupational exposure limit values in accordance with Directive 98/24/EC, including any notations as referred to in Article 2(1) of Commission Decision 95/320/EC ;
8.1.1.2. the national occupational exposure limit values that correspond to Community limit values in accordance with Directive 2004/37/EC, including any notations as referred to in Article 2(1) of Commission Decision 95/320/EC;
8.1.1.3. any other national occupational exposure limit values;
8.1.1.4. the national biological limit values that correspond to Community biological limit values in accordance with Directive 98/24/EC, including any notations as referred to in 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 shall be given for the Member State where the substance or mixture is placed on the market.

If a Community limit value has been defined with respect to the workplace exposure to a specific substance, this limit value shall be indicated if it has not yet been transformed into national law.

An example of how this information can be displayed is given below:

Substance	Acetone			
CAS No.	67-64-1			
	Limit value - Eight hours		Limit value - Short term	
	ppm	mg/m³	ppm	mg/m³
Austria	500	1200	2000	4800
Belgium	500	1210	1000	2420
Denmark	250	600	500	1200
European Union	**500**	**1210**		
France	**500**	**1210**	**1000**	**2420**
Germany	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 :

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 (DFG)	*STV 15 minutes average value*

Source: http://bgia-online.hvbg.de/LIMITVALUE/WebForm_ueliste.aspx

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

The information in this section shall also include the currently recommended monitoring or observation methods. For mixtures, it is useful to provide values for those constituent substances which are required to be listed in the Safety Data Sheet according to section 3.

If a mixture contains substances whose limit values are below the limit to be taken into consideration, and if exposure at the workplace cannot be excluded when applying the processing methods recommended by the distributor, it is advisable to include these substances and their limit values under this heading. For example, as regards isocyanate-containing mixtures refer to section 3 (3).

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

Substance name:												
EC number:	CAS number:											
Exposure route of relevance	**DNELs, DMELs, PNECs**											
	Industrial				**Professional**				**Consumer**			
	Long term, local effects	Long term, systemic effects	Short term, local effects	Short term, systemic effects	Long term, local effects	Long term, systemic effects	Short term, local effects	Short term, systemic effects	Long term, local effects	Long term, systemic effects	Short term, local effects	Short term, systemic effects
Human oral												
Human inhalation												
Human dermal												
Environment: water												
Environment: air												
Environment: soil												
Environment: sediment												
Environment STP												
Critical physical parameters: solubility, flammability, corrosivity**:**												

1
2 **8.2 Exposure controls**
3

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.* *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 means all protective measures and precautions to be taken during use of the substance or mixture in order to minimise worker and environmental exposure.

Any information available concerning workplace exposure shall be indicated in this section. This information may be derived from sources such as product codes, industry- and sector-specific regulations or may be obtained from the state occupational safety and health authorities, the employers' liability insurance associations, the guilds, etc.

Where design regulations concerning technical facilities are required for exposure control in addition to the guidance provided in section 7." Handling and storage" they shall 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 the section 5.7 "Handling and storage" if appropriate.

8.2.1 Appropriate engineering controls

The employer has complied with this information requirement by assessing the workers' health and safety risks posed by the substance or mixture in accordance with Article 4 of Directive 98/24/EC. This Directive contains stipulations concerning the design of appropriate **working methods and technical control facilities** as well as the use of **suitable work equipment and materials**, the performance of collective means of protection at the hazard source, and the performance of individual protective measures including the provision of personal protective equipment.

Suitable information on these measures shall be provided to enable a proper risk assessment to be carried out under Article 4 of Directive 98/24/EC. This information should concur with section 7.1.

Detailed information shall be provided with respect to the **possible exposure route.** This is of particular importance if one of the Hazard Statements: 300 to 373 with respect to 370 to 373 or the equivalent R phrases - R 20, 21, 23, 24, 26, 27, 34 to 43, 45, 46, 48, 49, 60 to 68, has been indicated alone or in any combination in section15 (Regulatory information).
With respect to R phrases 39, 48 and 68 (R68 only as a combined R phrase) this only applies to inhalation and dermal exposure.

This section includes also information concerning **general occupational safety and health measures** and industrial hygiene under the "Industrial hygiene" heading, in particular, if the author of the Safety Data Sheet believes that no specific information has to be provided concerning personal protective equipment.

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

8.2.2 Personal Protection

Where personal protection is needed, this section should precisely specify the type of equipment to provide adequate and suitable protection. Such specification shall take Directive 89/686/EEC into account and refer to the relevant CEN norms.

The equipment shall be specified in terms of kind, type and class, if necessary, with due regard to handling the product for known uses.

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

Eye/face protection

Specify the type of eye protection equipment required such as: safety glass, safety goggles, face shields or screens and the material to be used for the glasses, if applicable. Include the EN standard where applicable.

Skin protection

Specify the type of gloves to be worn when handling the substance or mixture to address splash and immersion protection. Include the following where available:

- the EN standard recommended.
- glove material,
- penetration time (equivalent to the maximum duration it may be worn) of the glove material subject to the intensity and duration of skin exposure.

In some cases, reference to gauntlets may be included (gloves with an extended cuff covering part of the forearm).

Helpful information may also include e.g.
- the maximum duration they may be worn under practical conditions, or
- the glove material and the minimum material thickness necessary as well as the maximum time the glove may be worn under practical conditions.

No brand name or commercial reference of equipment may be included in an SDS.

If necessary indicate any additional skin protection measures.

Body protection

Where it is necessary to protect a part of the body other than the hands, specify the type and quality of protection equipment required, such as: full protective suit, apron, boots.

If necessary, indicate any additional skin protection measures (skin products) and specific hygiene measures (preferable under a specific sub-heading).

Respiratory protection

In the case of hazardous gases, vapours or dust, consider the need for appropriate protective equipment, such as self-contained breathing apparatus, adequate masks and filters (e.g. half/quarter mask with P1 filter, half mask FFP1).
Reference shall be made to the EN standard for the mask and cartridge recommended and the maximum time respirators may be worn in accordance with the rules for wearing respirators.

8.2.3 Environmental Exposure Controls

This section includes the information required by the employer to fulfil his commitments 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 section could look like is given below:

8.2 Exposure controls

8.2.1 Appropriate engineering controls:
Product related measures to prevent exposure:
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:

8.2.2.2 Skin protection:
Hand protection:
Body protection:
Other 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:

5.9. SDS Section 9: Physical and chemical properties

Text Annex II
This section of the safety data sheet shall describe the empirical data relating to the substance or mixture, if relevant. The information in this section shall be consistent

with the information provided in the registration and/or in the chemical safety report where required, and with the classification of the substance or mixture.

This section of the SDS shall describe the empirical data of the substance or mixture, if relevant. The properties shall be determined in accordance with the testing methods laid down in Regulation (EC) No 440/2008, referred to Regulation (EC) No 1272/2008 or any other comparable method.

Critical information such as test temperature and methods used, which affect the value of physical-chemical properties and safety characteristics, shall be provided for all testing results and, when available, for data acquired from the literature. However, if it is stated that a particular property or hazard does not apply, clearly differentiate between cases where no information is available to the classifier, and cases where negative test results are available.

For mixtures, information shall normally be given on the properties of the mixture itself. If it is considered necessary to give information about the properties of individual components, please indicate clearly what the data refers to.

The information in this section shall be consistent with the information provided in the registration dossier and in the chemical safety report where required, and with the classification of the substance or mixture and should support transport classification given in section 14.

9.1. Information on basic physical and chemical properties

Text Annex II

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

(a) Appearance:

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

(b) Odour:

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

(c) Odour threshold;

(d) pH:

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

(e) Melting point / freezing point;

(f) Initial boiling point and boiling range;

(g) Flash point;

(h) Evaporation rate;

(i) Flammability (solid, gas);

(j) Upper/lower flammability or explosive limits;

(k) Vapour pressure;

(l) Vapour density;

(m) Relative density;

(n) Solubility(ies);

(o) Partition coefficient: n-octanol/water;

(p) Auto-ignition temperature;

(q) Decomposition temperature;

(r) Viscosity;

(s) Explosive properties;

(t) Oxidising properties.

If it is stated that a particular property does not apply or if information on a particular property is not available, the reasons shall be given.
To enable proper control measures to be taken, all relevant information on the substance or mixture shall be provided. The information in this section shall be consistent with the information provided in a registration where one is required.
In the case of a mixture, the entries shall clearly indicate to which substance in the mixture the data apply, unless it is valid for the whole mixture.

9.1. Information on basic physical and chemical properties

a) Appearance

The physical state (solid (including, if appropriate, information on granulometry), liquid, gas) shall be indicated.

The colour of the substance or mixture as supplied shall be indicated. The term “various” or “diverse” is permissible if stated on a group of products which are all covered by the same SDS; for example, in the case of varnishes with different colours.

If the substance is supplied as nanomaterial, this should be indicated in this section. E.g. Physical state: solid (nanomaterial)

b) Odour

If odour is perceptible, a brief description of it shall be given; no phrases like “characteristic” or “typical” shall be used here.

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, indicate the concentration and temperature, preferably for room temperature (…g/l water, at …°C).

Where the pH can be properly measured, it shall be determined from the original product. Otherwise, the pH of the dissolved substance shall be indicated. Also specify if the alkali or acid reserve has been considered.

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, with indication of the temperature (at … °C);

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

l) Vapour density;

m) Relative density, with indication of the temperature (at … °C);

For gases: Relative density (air = 1).

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

n) Solubility(ies)

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

o) Partition coefficient: n-octanol/water;

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

p) Auto-ignition temperature

q) Decomposition temperature

r) Viscosity

For certain product groups, data concerning the viscosity (dynamic viscosity in mPas or kinematic viscosity in mm²/s) or the flow times (in s) including the measuring temperature shall be provided for the solvent separation test and the solvent content.

For mixtures containing hydrocarbons in an overall concentration of 10% or more, the flow time or the kinematic viscosity at 40 °C shall be specified subject to No 3.10 of Annex I to Regulation (EC) No 1272/2008.

s) Explosive properties;

t) Oxidising properties

Physical hazards

For substances and mixtures, the relevant hazard classes, for which data shall be provided, are:

(a) Explosives
(b) Flammable gases
(c) Flammable aerosols
(d) Oxidising gases
(e) Gases under pressure
(f) Flammable liquids
(g) Flammable solids
(h) Self-reactive substances and mixtures
(i) Pyrophoric liquids
(j) Pyrophoric solids
(k) Self-heating substances and mixtures
(l) Substances and mixtures which, in contact with water, emit flammable gases
(m) Oxidising liquids
(n) Oxidising solids
(o) Organic peroxides
(p) Corrosive to metals

If data for any of these hazard classes is not available, these hazard classes shall still be listed in the safety data sheet with a statement that data is not available or not applicable.

Examples of standard phrases that can be used in this section are:

- *Not applicable*
- *Not determined*
- *Calculated*
- *Literature value*
- *No data available*
- *This information is not available.*
- *Not relevant*
- *Literature information*
- *Data obtained by analogy, e.g. (Q)SAR.*

9.2 Other safety 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.

This part shall be used to include other data that may be relevant for the completion of the initial hazard assessment of the substance/mixture. Details such as those outlined below may be supplied.

- properties of explosive atmospheres (mixtures) as a basis for all explosion prevention and protection measures:

  Gases and vapours:

  - upper and lower explosion limit and/or
  - upper and lower explosion point
  - auto-ignition temperature
  - explosion group (maximum experimental safe gap)
  - minimum ignition energy
  - maximum rate of explosion pressure rise
  - maximum explosion pressure

  Dusts:

  - lower explosion limit of dust clouds
  - dust explosion class (VDI)
  - particle size distribution (median value)
  - moisture content (quantitative determination of water content)
  - minimum ignition temperature of a dust cloud
  - minimum ignition energy of dust/air mixtures
  - maximum explosion pressure of dust clouds
  - maximum rate of explosion pressure rise of dust clouds
- Limiting oxygen concentration
- Bulk density
- Solubility in different media
- Stability in organic solvents and identity of relevant degradation products
- Evaporation rate
- Conductivity
- Surface tension
- Dissociation constant in water (pKa)
- Oxidation-reduction Potential
- Fat solubility (solvent – oil to be specified) etc.

Specific information for nanomaterial can be added to this section e.g. specific surface area, agglomeration/aggregation state, size distribution, structure including crystallinity and solubility.

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

5.10. 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.

This section of the SDS shall describe the stability of the substance or mixture and the possibility of hazardous reactions occurring under certain conditions of use, including if applicable release into the environment. Where appropriate, a reference to the test methods used can be included.

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.

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 needs to be included in this section.

Stability and reactivity are included into certain hazard classes (see section 9), or this information is already given under section 7. Additionally, information on protection measures is given under section 8.2.1. Appropriate engineering controls. Therefore all information in section 10 is generally given in other sections (see table 4 at the end of the 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.*

The reactivity hazards of the substance or mixture, which are not included under the other sub-headings (the other sub-headings are chemical stability, possibility of hazardous reactions, conditions to avoid, incompatible materials and hazardous decomposition products), shall be described here.

Specific test data shall be provided for the substance or mixture as a whole, where available.

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.

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

10.2. Chemical stability

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.

It shall be indicated if the substance or mixture is stable or unstable under normal ambient and anticipated storage and handling conditions of temperature and pressure.

Any stabilisers which are, or may need to be, used to maintain the chemical stability of the substance or mixture shall be described.

The safety significance of any change in the physical appearance of the substance or mixture shall be indicated.

10.3. Possibility of hazardous reactions

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.

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.

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.

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.

This section needs to specifically address:

- the need for and the presence of stabilizers,
- the possibility of a hazardous exothermic reaction,
- safety significance, if any, of a change in physical appearance of the substance or mixture,
- hazardous decomposition products, if any, formed upon contact with water,
- possibility of degradation to unstable products.

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

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 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

Table 4: Overview of information required for section 10 already covered by other sections

Safety data sheet	Remarks
10.1. Reactivity	
10.1 (1) The reactivity hazards of the substance or mixture shall be described. Specific test data shall be provided for the substance or mixture as a whole, where available. However, the information may also be based on general data for the class or family of substance or mixture if such data adequately represent the anticipated hazard of the substance or mixture.	These data are specified in section 9: - the possibility of a hazardous exothermic reaction, - hazardous decomposition products, if any, formed upon contact with water,
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.	Not covered elsewhere
10.2. Chemical stability It shall be indicated if the substance or mixture is stable or unstable under normal ambient and anticipated storage and handling conditions of temperature and pressure. Any stabilisers which are, or may need to be, used to maintain the 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: - Under normal conditions, the product is stable. - No hazardous reaction when handled and stored according to provisions. - Hazardous reactions are not known.
10.3. Possibility of hazardous reactions If relevant, it shall be stated if the substance or mixture will react or polymerise, releasing excess pressure or heat, or creating other hazardous conditions. The conditions under which the hazardous reactions may occur shall be described.	Information e.g. on dust explosion hazard is given in section 2 and 9
10.4. Conditions to avoid	see 7.2 Conditions for safe storage, including

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.	any incompatibilities The advice provided shall be consistent with the physical and chemical properties described in Section 9 of the safety data sheet. If relevant, advice shall be provided on specific storage requirements including: (a) How to manage risks associated with: (i) explosive atmospheres; (ii) corrosive conditions; (iii) flammability hazards; (iv) incompatible substances or mixtures; conditions; and potential ignition sources (including electrical equipments). (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 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.	see 7.1. Precautions for safe handling (b) prevent handling of incompatible substances or mixtures; and
10.6. Hazardous decomposition products	Examples of common standard phrases: - Does not decompose when used for intended uses.

Known and reasonably anticipated hazardous decomposition products produced as a result of use, storage and heating shall be listed. Hazardous combustion products shall be included in Section 5 of the safety data sheet.	- Hazardous decomposition products are not known.

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5.11. 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. *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.

This section is of great importance in the creation of an SDS as it forms the basis for the human health C&L of the substance or mixture as they are placed on the market.

For substances registered under REACH it is of great importance to ensure that the data used in the SDS are consistent with those used to establish the REACH registration.

For mixtures containing such substances the references to substance toxicity data should also be consistent with the applicable registration dossiers.

A large quantity of information has to be provided under this toxicology part and therefore, all efforts should be made to arrange the layout of this section in a way that a clear separation is established between the data on mixtures and those on substances and the different endpoints should be reported distinctly.

The key information and critical studies provided should be presented in a clear and concise way without duplication. This can be achieved by using text boxes or tables.

If no data are available for certain endpoints, it needs to be specified if this is due to lack of data, data not applicable, technical impossibility to obtain the data, inconclusive data or data which are conclusive although insufficient for classification; in the latter case the SDS shall specify "*based on available data, the classification criteria are not met.*"

If relevant negative data are included supportive evidence should be provided.

SUBSTANCES

Information shall be provided, for the following relevant hazard classes or differentiations, separated according to the route of exposure, species (rat, mouse, human), study duration and study method.

(a) acute toxicity;

- oral

-dermal

-inhalation

(b) skin corrosion/irritation;

(c) serious eye damage/irritation;

(d) respiratory or skin sensitization;

(e) germ cell mutagenicity;

- in vitro

- in vivo

(f) carcinogenicity;

(g) reproductive toxicity;

- impairment of fertility

- reproductive toxicity

-developmental toxicity

(h) STOT-single exposure;

(i) STOT-repeated exposure;

(j) aspiration hazard.

If data are not available for a specific substance and read-across or QSAR's are applied this should be clearly mentioned.

For the registration substances, the significant key study results from the registration dossiers shall be given with short reference to the test methods used.

The listed information should reflect the C&L presented in Section 2 of the SDS

MIXTURES

For mixtures, the relevant effects for which information shall be provided are the same as for substances except for STOT-single exposure; STOT-repeated exposure and aspiration hazard which are determined only via the calculation method using general and specific concentration limits.

Important to note is that according to Article 6 of the CLP, where information is available for the mixture itself, and the manufacturer, importer or downstream user has ascertained that information to be adequate and reliable, that manufacturer, importer or downstream user shall use that information for the evaluation where applicable and scientifically valid (Article 6.2 of CLP).

This is *not* applicable for the following endpoints: carcinogenicity, mutagenicity and toxicity for reproduction, for which classification of mixtures shall be based on the available test data for the individual ingredients of the mixture using concentration limits for the ingredients of the mixture (Article 6.3 of CLP).

On a case-by-case basis, test data on mixtures may be used for classification when demonstrating effects that have not been established from the evaluation based on the individual components (section 3.7.3.2.1 of CLP).

If no test data are available on the mixtures themselves, such data should not normally be generated by testing.

Where the mixture itself has not been tested to determine its hazardous properties, but there are sufficient data on similar tested mixtures and individual hazardous ingredient substances to adequately characterise the hazards of the mixture, these data shall be used in accordance with the following bridging rules referred to in Article 9.4 of CLP for each individual hazard class, subject to any specific provisions for mixtures in each hazard class (section 1.1.3, and Article 6.5 of CLP). The manufacturer, importer or downstream user shall have ascertained that the information is adequate and reliable.

In the SDS, for a given health effect, if a mixture has not been tested for its health effects as a whole, then the relevant information on relevant substances listed under Section 3 of the SDS shall be provided.

When a mixture has been classified according to CLP using Acute Toxicity Estimate (ATE), the value of the ATE may be included in this section:

Example

ATE_{mix} (oral) = xxx mg/kg
ATE_{mix} (dermal) = xxx mg/kg
ATE_{mix} (inhal.) = x mg/l/4 h (vapours)

HUMAN HEALTH

In this subsection of the SDS also the potential adverse health effects/symptoms after exposure to the substance, mixture and known by-products shall be described. For the intended uses (Subsection 1.2.) the symptoms caused by the physical, chemical, and toxicological characteristics of the substance or mixture shall be listed. Symptoms occurring after exposure should be arranged in a sequential order from low to high exposure levels, indicating if occurrence of the effects is immediate or delayed.

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

Without specific data available on the mixture regarding interactions between composing substances, assumptions shall not be made and instead the health effects of each substance shall be listed separately (see Annex II section 11.1.12.2)

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

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

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

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

11.TOXICOLOGICAL INFORMATION
11.1 Toxicokinetics, metabolism and distribution
Non-human toxikological data
Method:
Dosis:
Routes of administration:
Results:
Absorption:
Distribution:
Metabolism:
Excretion:

Human toxicological data:

11.2 Information on toxicological effects

11.2.1 Substances

- *Acute toxicity:*
- *Skin corrosion/irritation:*
- *Serious eye damage/irritation:*
- *Respiratory or skin sensitisation*
- *germ cell mutagenicity;*

- *carcinogenicity;*
- *reproductive toxicity;*
- *STOT-single exposure;*
- *STOT-repeated exposure;*
- *aspiration hazard:*

11.2.2 Mixtures

see above: where test data are available for the mixture itself it should be stated.

5.12. 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.*

12.1. Toxicity

Text Annex II
Information on toxicity using data from tests performed on aquatic and/or terrestrial organisms shall be provided when available. This shall include relevant available data on aquatic toxicity, both acute and chronic for fish, crustaceans, algae and other aquatic plants. In addition, toxicity data on soil micro and macro-organisms and other environmentally relevant organisms, such as birds, bees and plants, shall be included when available. Where the substance or mixture has inhibitory effects on the activity of micro-organisms, the possible impact on sewage treatment plants shall be mentioned. *For substances subject to registration, summaries of the information derived from the application of Annexes VII to XI shall be included.*

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.*

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.*

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.*

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.

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.

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

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

5.13. 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.*

If the disposal of the substance or mixture (surplus or waste resulting from the foreseeable use) presents a danger, a description of these residues and information on their safe handling shall be given.

Indicate the appropriate methods of disposal of both the substance or mixture and any contaminated packaging (incineration, recycling, landfill, etc.)

Refer to any relevant Community provisions relating to waste. In their absence, it is useful to remind the user that national or regional provisions may be in force.

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

Where the use recommended by the distributor permits predicting the origin of the waste, it is additionally recommended to specify the European Waste Catalogue Code (EWC).

In analogy to the disposal of the unused product, suitable disposal procedures shall be stated for un-cleaned and emptied packaging. Any special cleaning agents that may be suitable for cleaning the packaging shall be stated at this point.

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.*

Suitable means for neutralising or deactivating product residues and waste must be specified.

Special risks to safety, health or the environment that can arise when handling waste must be specified, e.g. risk for self ignition in combination with certain materials.

Unsuitable means of handling product waste or contaminated packaging must be stated if known.

An indication must be given of whether or not residues of unused product are regarded as hazardous waste.

Unsuitable means of handling product waste or contaminated packaging should be stated if known.

Local and national disposal methods for that particular containment must be complied with.

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

13. DISPOSAL CONSIDERATIONS
13.1 Waste treatment methods
13.1.1 Product / Packaging disposal:
Waste codes / waste designations according to EWC / AVV:

13.1.2 Waste treatment options:
13.1.3 Sewage disposal options:
13.1.5 Other disposal recommendations:
13.2 Additional information:

5.14. 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)[22], Regulations concerning the International Carriage of Dangerous Goods by Rail (RID)[23], European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways (ADN)[24], all three of which have been implemented by Directive 2008/68/EC of the European Parliament and of the Council on the inland transport of dangerous goods[25], International Maritime Dangerous Goods (IMDG Code[26]) (sea), and Technical Instructions for the Safe Transport of Dangerous Goods by Air (ICAO-TI)[27] (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*

22 UN-ECE, UN-Economic Commission for Europe, ADR effective amendment

23 OTIF RIDAnnex 1 to Appendix B (Uniform Rules concerning the Contract for International Carriage of Goods by Rail) of the Convention concerning International Carriage by Rail, effective amendment

24 UN-ECE ADN. effective amendment

25 European Parliament and Council, Directive 2008/68/EC . effective amendment

26 IMO, IMDG Code International Maritime Organisation, effective amendment

27 ICAO, ICAO-TI . effective amendment

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)[28] and the International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk (International Bulk Chemical Code) (IBC Code)[29].

The product name shall be provided (if different from that given in Subsection 1.1) as required by the shipment document and in accordance with the name used in the lists of product names given in chapters 17 or 18 of the IBC Code or the latest edition of the IMO's Marine Environment Protection Committee (MEPC).2/Circular[30]. Ship type required and pollution category shall be indicated.

This section of the SDS 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) , Regulations concerning the International Carriage of Dangerous Goods by Rail (RID) , European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways (ADN) , all three of which have been implemented by Directive 2008/68/EC of the European Parliament and of the Council on the inland transport of dangerous goods , International Maritime Dangerous Goods (IMDG) Code (sea), and Technical Instructions for the Safe Transport of Dangerous Goods by Air (ICAO-TI) (air). Reference to classification for Air transport could also be made to the IATA Dangerous Goods Regulations (IATA DGR) because all requirements of the ICAO-TI are incorporated.

Sufficient transport information shall be provided in order to ensure safe shipping of the product. In principle all classification information required for transport documentation are sufficient, but minimum

[28] IMO, MARPOL 73/78 – effective amendment
[29] IMO, IBC Code, effective amendment
[30] IMO, MEPC.2/Circular, Provisional categorization of liquid substances, effective amendment

information are inter alia:

- UN number
- Proper shipping name of the dangerous goods
- 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 marine pollutant if applicable) .
- For ICAO-TI /IATA-DGR: Class and subsidiary risk.
- Packing Group for all transport regulations if applicable.

Section 14.6 “Special precautions for user” may be deleted if this information is already provided in other sections of the SDS

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.

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 N.O.S. entry not included in the list of substances listed under this segregation group

Further information IBC-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.

Other points to consider:

In IMDG Code and in ADR there are provisions for the total exemption of viscous substances with a flashpoint above 23°C from the regulations. In these cases a hint may be given like: "Exemption for viscous substances according to ADR 2.2.3.1.5 applicable".

Other additional information may be hints of special handling labels (e.g. “keep away from heat”)

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

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:

…

5.15. SDS Section 15: Regulatory information

Text Annex II
This section of the safety data sheet shall describe the other regulatory information on the substance or mixture that is not already provided in the safety data sheet (such as whether the substance or mixture is subject to Regulation (EC) No 2037/2000 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

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.*

The following points may be included in this section:

- Information regarding relevant Community safety, health and environmental provisions (for example Seveso category/named substances in Annex I of Directive 96/82/EC).
- National information on the regulatory status of the substance or mixture (including the substances in the mixture), including advice regarding action that should be taken by the recipient as a result of these provisions
- National laws of the relevant Member States which implement these provisions
- Any other national measures that may be relevant e.g. such as (this is a non-exhaustive list):

In Germany:

i. Water hazard classes (Wassergefährdungsklassen)

ii. Technical instruction air (TA-Luft)

iii. Technical rules for dangerous substances (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)

If the substance or mixture covered by the 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 of REACH or other regulations) these provisions shall be mentioned.

This section can be one option to include this information e.g.

Authorisations:

Restrictions on use:

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.

This section should include an indication of whether the chemical safety assessment has been carried out by the supplier, for the substance or the mixture.

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

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.

5.16. 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 chapters such as:

- Indication of changes, revision of the SDS
- Key literature references and sources of data
- List of relevant hazard statements and risk phrases

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.

If companies wish to include disclaimers in the SDS, this section 16 is the place to include them. 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*

Advice on training for workers may be included here.

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

16. OTHER INFORMATION

16.1 Indication of changes

16.2 Abbreviations and acronyms:

16.3 Key literature references and sources for data

16.4 Classification and used classification procedure for mixtures labelled DPD according to regulation (EC) 1207/2009 [CLP]:

Example of an aqueous solution:

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

Classification according to Regulation (EC) Nr. 1207/2009	***Classification procedure***
Flam. Liq. 2, H225	*On basis of test data*
Acute Tox. 3, H301	*Calculation method*
Acute Tox. 3, H311	*Calculation method*
Acute Tox. 3, H331	*Calculation method*
STOT SE 1, H370	*Calculation method*

Possible other evaluation method used for classifications (reference Article 9 of CLP Regulation) are for example:
On basis of test data
Calculation method.
Bridging principle "Dilution".
Bridging principle "Batching".
Bridging principle "Concentration of highly hazardous mixtures".
Bridging principle "Interpolation within one toxicity category".
Bridging principle "Substantially similar mixtures".
Bridging principle "Aerosols".
Expert judgement
Weight of evidence

16.5 Relevant R- and H-phrases (number and full text):

16.6 Training advice:

16.3 Further information:

CHAPTER 6: EXTENDED SDS : MAIN SDS BODY vs ANNEX (EXPOSURE SCENARIO)

The table 5 below shows the different sections of the ES, and the corresponding section of the SDS that needs to be checked for consistency.

Table 5: Consistency check between ES and SDS sections

ES section[31]	SDS Chapter
Substance / User identity	
Downstream user identity and contact data	
Registration number(s)	1.1
Substance identity	1.1
Identity of M/I and other suppliers	1.3
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	
For article service life	
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
Technical conditions and measures to control dispersion from source towards the worker	7
Engineering controls:	7
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	**8**
Control of environmental exposure	**8**
Worker:	
Product characteristic	
Amounts used	
Frequency and duration of use	
Environmental factors not influenced by risk management	
Flow rate of receiving surface water:	
Other given operational conditions affecting environmental exposure	**7**

[31] The ES format is not the most up-to-date ES format which is still under discussion: http://guidance.echa.europa.eu/guidance4_en.htm

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**
Organisational measures to prevent/limit release from site	**6 + 7**
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	
Amounts used	
Frequency and duration of use	
Environmental factors not influenced by risk management	**8 + 12**
Flow rate of receiving surface water:	**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)	
Exposure assessment tool reference	
Guidance to DU to evaluate whether he works inside the boundaries set by the ES	
Service life of substances in articles	

1
2

CHAPTER 7: FORMULATORS

The safe use of chemicals is one of the main objectives of REACH. Therefore Chemical Safety Assessments (CSA) of substances are of central importance. In the CSA the whole life cycle of a substance has to be evaluated.

In many cases, substances are used in mixtures during their life cycle. Therefore this use has to be evaluated in the CSA. On the other side, the use of substances in mixtures often implies changes of the conditions of use. These changes may be relevant for the operational conditions and risk management measures.

REACH obligations for manufacturers, formulators and the final downstream user differ according to their role.

REACH documents that have to be prepared for the registration by the manufacturer/importer (M/I) related to a hazardous substance:

- Registration dossier
- Chemical safety report[32] (CSR), which documents the chemical safety assessment (CSA) of the substance. It is part of the registration dossier.
- Exposure scenarios (ES) for the identified uses of the substance (part of the CSR)
- Extended Safety data sheet (ext-SDS), with one or more exposure scenarios as annexes to the ext-SDS, only if the substance is placed on the market in the EU.

REACH documents that may be prepared or forwarded by downstream users related to a mixture classified as hazardous:

- Extended safety data sheet for the mixture.
- Exposure scenarios for substances in the mixture, if required according to Article 31 or 37.
- Exposure scenario for the mixture as part of own assessment or ext-SDS (option)
- Downstream user notification to ECHA of uses not covered by exposure scenarios he received from his suppliers
- Downstream user Chemical safety report (DU CSR) for one or more hazardous substances in the mixture (Article 37,4 REACH) (if their use is not covered by the ES of the supplier) or (optional)
- Downstream user Chemical safety report (DU CSR) for the mixture (Article 31.2 REACH).[33]

Inclusion of information in safety data sheets (SDS) (M/I, DU)

- Any downstream user shall include relevant exposure scenarios, and use other relevant information, from the safety data sheets supplied to him when compiling his own safety data sheet for identified uses (REACH Article 31.7, 2nd sentence).
- This requirement refers to everybody who receives safety data sheets and is required to develop a safety data sheet for his substance or mixture for identified uses. This is especially the case for formulators producing mixtures and supplying them together with the corresponding safety data sheets

[32] A chemical safety report is required for substances with a production volume of 10 t/year and more per manufacturer/importer and is part of the registration dossier

[33] REACH Art. 37.4 describes in which cases a downstream user chemical safety report is not required

to the customers. Final downstream users of an end-use mixture do not prepare safety data sheets and therefore are not affected by this obligation.

Under REACH, like in the past, SDSs for mixtures are required only if mixtures are classified as hazardous according to the Dangerous Preparations Directive (REACH Article 31.1 (a)), if they contain at least one hazardous or PBT/ vPvB substance in concentrations above the limits defined in REACH Article 31.3 or if they contain a substance for which a Community workplace exposure limit exists.[34] (Note: PBT assessment is a new requirement under REACH).

New obligations for formulators under REACH

REACH defines new obligations for formulators and partly changes the conditions for existing and continuing tasks.

Throughout the guidance, provisions for the SDS of mixtures have been highlighted.

Formulators have to do a compliance check for their – and their customers' – uses

Future ext-SDS supplied to formulators will contain exposure scenarios, or exposure information in the SDS. The new task of formulators is to assess whether their uses and the uses of their customers are covered by the exposure scenarios of the substances. If the exposure scenarios described in the ext-SDS of the supplier do not match with the operational conditions of the identified uses significant differences in the exposure situations can result.

If the exposure scenarios of the substances do not cover the intended uses of the mixtures yet, the formulator has several possible follow-up tasks. For uses of a hazardous mixture not covered by an exposure scenario, at least one actor in the supply chain has to do the exposure assessment, the risk characterization and the identification of the conditions of safe use. The downstream user has the right to communicate his use to the supplier to make it an identified use (REACH Article 37.2.)[35]

Formulators will receive more information on their substances under REACH and will have to check whether classification & labelling was changed. SDS will anyway need to be modified to fit with new Annex II requirements and CLP classification.

More information on the hazardous properties of substances will become available due to the registration of substances. Classification and labelling of substances may change due to new information or change of regulation

More information on the safe use of substances will be communicated in the supply chain, especially safe limit values (DNEL, PNEC) for the substances. To an increasing degree, safety data sheets for substances will contain exposure scenarios as annexes describing the conditions of safe use. Later on, extended safety data sheets of mixtures classified as hazardous will be supplied.

Formulators must include relevant exposure scenarios and use other relevant information from the safety data sheet supplied to them when compiling the safety data sheet for their product (REACH Article 31.7).

This requirement refers to all actors of the supply chain which are compiling safety data sheets. It is of specific relevance for formulators because they have to handle information from all of the substances that they use to make their products.

[34] REACH article 31.3 refers to safety data sheets which have been requested by the customer.

[35] For reasons of protection of human health or the environment, the registrant can decide not to include it as an identified use (REACH Art. 37.3). In this case, he shall inform ECHA and the downstream user and may not supply the substance to any DU without informing on the rationale.

Recommendations for a smooth compliance with obligations under REACH

- Perform a downstream user compliance check only if concentrations of substances in a mixture are above the limit concentrations of REACH Article 14.2.
- When compiling an SDS for a mixture:

– Use limit concentrations of REACH Article 14.2 to focus on relevant substances of a mixture

! As a general rule, for substances contained in mixtures in concentrations below 0.1% or 1%, it **is not required** to perform a chemical safety assessment (Art.14.2).**!** Exemptions from this general rule: for a particular substance, specific concentration limits can be defined in the Dangerous Preparations Directive (Directive 1999/45/EC) and in the CLP Regulation (EC) No. 1272/2008 (the CLP Regulation also includes the classification and labelling inventory). In this case, if the concentration in the mixture is lower than the lowest substance-specific concentration limit (see REACH Art. 14.2), a CSA is not required.

– Concentrate on the lead substances[36] for the specific properties of the mixture (see chapter 7)

– Decide which of the different ES received are relevant for the use and the use conditions of the mixture supplied

– Decide if a new ES for the mixture is necessary or more appropriate.

– In chapter 15 of the SDS, it must be made clear whether a CSR has been made or not. In addition, information must be given if an exposure scenario has been prepared.

For mixtures, it is helpful to document for which substances in the mixture CSR and ES (or/and the CSR/ES for the mixture as such) have been prepared.

If a registrant prepares an exposure scenario for a substance used in the supply chain, it is obligatory for him to communicate this exposure scenario. For downstream users who prepare their own safety data sheets, there is no legal obligation to prepare own exposure scenarios as long as their uses are covered by the exposure scenarios of their suppliers. For them it is compulsory to **include** information which they have received into their own safety data sheets (REACH Article 31.7, see chapter 2). They can do this in several ways[37] :

1. Forwarding the exposure scenarios for each substance to the customers without consolidation.

Note: Forwarding is only possible if the pieces of information in the exposure scenarios are in line to each other and if there are no contradictions to the information in the SDS. Therefore in many cases it will be necessary to modify one or more of the received exposure scenarios of substances according to the specific conditions of use of the mixture. The modified exposure scenarios of the substances can be attached to the SDS of the mixture.

2. Consolidating the received exposure scenarios for substances into a new exposure scenario for the mixture ("mixture exposure scenario") annexed to the SDS of the mixture.

[36] For any given exposure pathway or emission route, the substance with the highest classification impact is considered to be the lead substance for that effect (Source: Cefic guidance on ES for preparations (the DPD+ approach): http://cefic.org/templates/shwPublications.asp?HID=750&T=806

[37] See ECHA Guidance on information requirements and chemical safety assessment, Chapter G, Extending the safety data sheet (in version May 2008: p. 18ff).

3. Extracting the relevant information on risk management measures and operational conditions from the received ES, summarizing and including them in the related sections of the SDS for the mixture.

If the immediate downstream user is the formulator of a product to be offered or sold to the general public, he can use another option: he can extract, summarize and include the relevant information on risk management measures and operational conditions in the information for the general public.

It depends on the specific situation of an actor in the market which option will be the most appropriate for him and his customers. It also depends on the number of hazardous substances in the mixture and the type of effects.

The first option, just forwarding received exposure scenarios, seems to be simple. Especially in cases of mixtures containing only a very limited number of hazardous substances this option might be of relevance. However, it has to be ensured that information in the exposure scenarios is consistent with the information in the safety data sheet of the mixture themselves. In addition, it is possible that the ES for the substances have to be modified in order to cover the specific properties of the mixture.

If the same route of exposure is relevant for several substances in the mixture, it is advisable to cover them in one exposure scenario for this route for a mixture. It is very unlikely that in practice downstream users will implement conditions of safe use distributed in several exposure scenarios.

It is a company decision which of these options will be most appropriate for them. It may depend on its customers. Some aspects play a role in this decision:

1. If the mixture is an end-use product which is used under different conditions (e.g. adhesives), consolidation of information into new exposure scenarios for the different uses can be the best option. Here use-specific risk management measures for each use are necessary. They might be described in use-specific ES, while the main body of the SDS contains the information which is relevant for all users.
2. For a mixture which is an end-use product with a well-defined user group, integration of information into the main body of the SDS might be the best way. Risk management measures and operational conditions can be described which are appropriate for this specific use. In such a case it is not necessary to define different RMM and OC for different conditions of use. In addition it is not necessary to describe scaling possibilities because the conditions of use are more or less fixed.
3. As long as mixtures are further “processed” in the supply chain, in particular when used in other mixtures, supplying information in form of an ES helps the following actor in his task of identifying and including the relevant information for the substances which he receives in his own safety data sheet.
4. If use of scaling possibilities plays an important role for the downstream user, at present it is easier to provide this information in the exposure scenario than in the main body of the SDS.
5. If an ES is attached, it should be ensured that information in chapter 1 – 16 of the SDS are consistent with the information given in the ES.
6. If industrial users with experience in workplace exposure control are interested primarily in the substance specific data given in the main body of the safety data sheet, inclusion of information seems more appropriate.

7. In addition, the safe use of substances and mixtures will be considered more likely if the necessary information for this is provided in a structured way. This makes it easier for a downstream user to check whether he complies with the conditions of use which have been assessed as being safe. Chances of implementation by professional users as handicraftsman increase if the advices on safe use are presented in a short annex – instead of being distributed in several pages of an SDS.

Preparing exposure scenarios and extended safety data sheets for a mixture

Mixtures often consist of many substances. The task of including the relevant information from the exposure scenarios of the substances into the extended safety data sheet (ext-SDS) of the mixture can be made easier if it is possible to concentrate on substances which determine the hazardous properties and/or the Risk Management Measures (RMM) of the mixture – and to sort out substances which are not relevant for the operational conditions and the RMM.
In this context, for substance-rich mixtures, the following points are important:

1. Information from exposure scenarios only have to be included for substances present in the mixture in concentrations above the concentration limits set in Article 14(2).

2. the decision which ES of a CSA for a specific substance in a mixture is relevant should be reflected on the question “does it require risk management measures (RMMs) and operational conditions (OCs) for the mixture itself” and on the question “are the RMM not already triggered by other substances or the mixture itself (regardless if ES for these components are available)”. Tools are being developed which help to identify the risk-determining substances (lead substances, critical components, priority substances) for specific exposure routes.

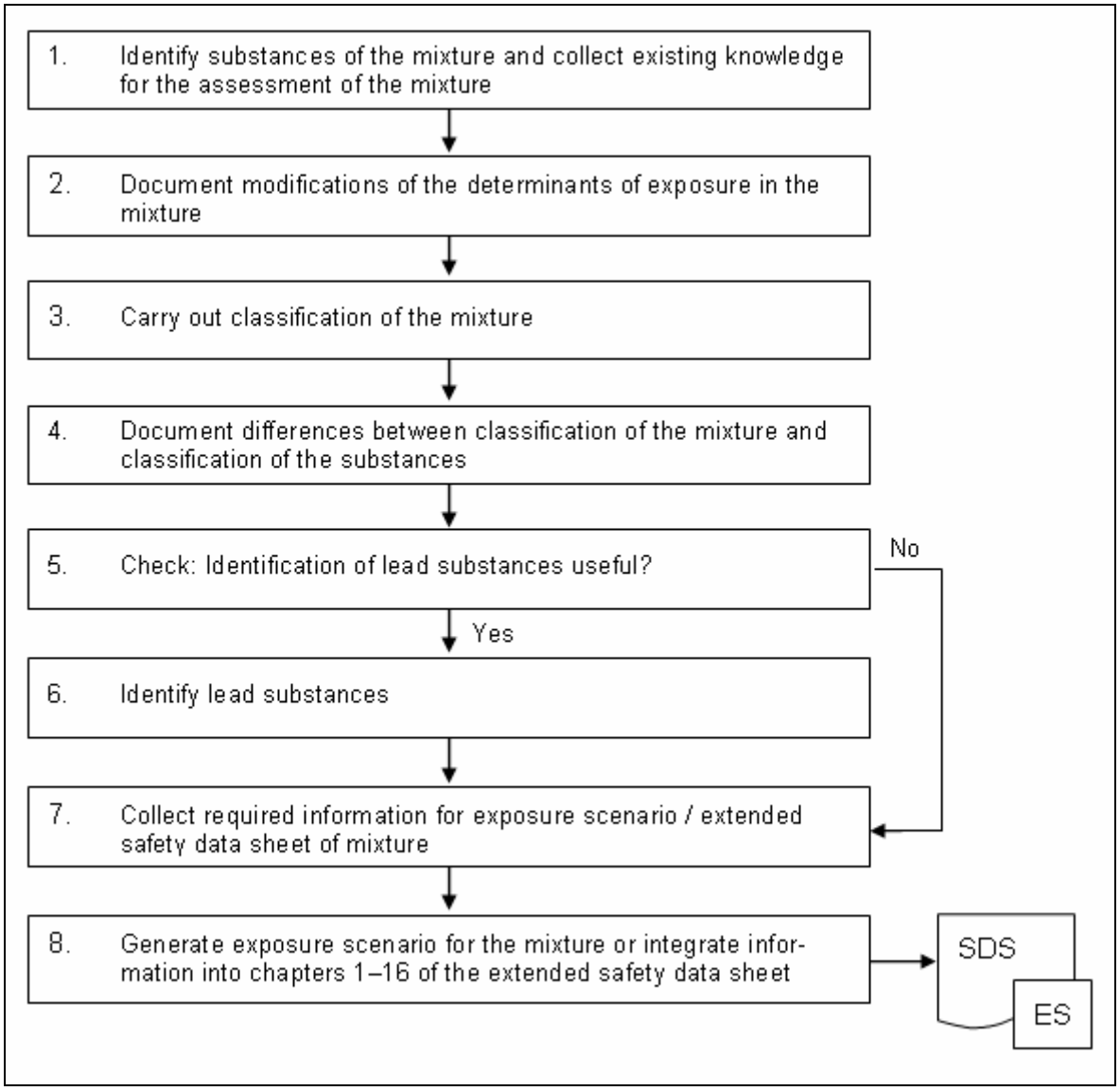
The basic assumption is that if the risk associated with the lead substance is adequately controlled for a particular endpoint, risks from other substances for the same endpoint will also be controlled adequately.

The process and its main steps

The main steps in preparing the extended safety data sheet (ext-SDS) of a mixture are shown in figure 4 below.

It includes the use of existing knowledge, the requirements for the classification and labelling of a mixture and also the new obligations under REACH. Figure 4 below shows the whole process from the identification of the substance profile of the mixture and its hazard assessment until the preparation of the safety data sheet of the mixture.

Figure IV: Assessment of a mixture and generation of an extended SDS



Step 1–4 refer to the hazard assessment of the mixture, step 5–8 to the generation of the safety data sheet for the mixture, including the option to generate an exposure scenario for the mixture.

This refers to the case that the formulator not only forwards exposure scenarios which he has received, but consolidates or integrates the information. Some of the steps are described in the next subchapters, as indicated in the table. For the formulator these steps require more time for a new mixture than for a product which is already used in the supply chain

For more information, see industry guidance:
http://cefic.org/templates/shwPublications.asp?HID=750&T=806

APPENDIX 1 : Timetable for the application of CLP labelling and the amended versions

There are 3 versions of the annex II of REACH:

- **2006 =** present annex II, published with REACH
- **2010 I =** annex I of 2010 Regulation xx 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 Regulation xx 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 expected that, until 2017, there will be different valid formats of SDS is co-existence.

The annexed table shows the different requirements and possibilities during the transition period, both for 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.

	1/12/10	1/12/12	1/6/15	1/6/17	
Substances (general rule)	**Labelling**: DSD **SDS**: 2006 or **Labelling**: CLP **SDS**: 2006, with also DSD classification, or 2010 I [includes DSD classification in 2-1]	**Labelling:** CLP **SDS:** 2010 I [includes DSD classification 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 [includes DSD classification in 2-1]	**Labelling:** CLP **SDS:** 2010 I [includes DSD classification 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

1 ***** Possibility CLP classification in section 16

APPENDIX 2 : SDS: consistency check between sections

The ‘check-lists’ below show the consistency between sections of the SDS.

Section 9 Physical and Chemical properties should be consistent with:

- 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

Section 10 Stability and reactivity should be consistent with:

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

Section 11 Toxicological information should be consistent with:

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

Section 12 Ecological information should be consistent with:

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

Alternatively, the matrix below can also be used as a check-list for the consistency among SDS sections:

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
1	X															
2		X							X		X					
3			X													
4				X							X					
5					X				X							
6						X			X		X					
7							X		X		X					
8								X			X					
9		X			X	X	X		X		X	X	X	X		
10										X						
11		X		X		X	X	X	X		X		X	X	X	
12									X			X				
13									X		X		X			
14									X		X			X		
15											X				X	
16																X

APPENDIX 3 : SDS for Special Mixtures

Introduction: What are Special Mixtures?

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** (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.

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

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

Placeholder: work is ongoing on assessing the possibility of including bioavailability considerations when classifying the alloy as Special Mixture. This may have some impact on Section 2: Hazard identification

How to refine the proposed measures for controlling exposure/personal protection with Special Mixtures data?

- Usually, the production of a Special Mixture can involve a series of constituents. The Special Mixture producer, who has to generate an SDS for the Special Mixture, may receive a significant amount of information from which it will be difficult to identify and to extract *key and relevant information* to include in his SDS because of different properties, different exposure scenarios, etc.
- As a first step, it is suggested that the formulator responsible for preparing an SDS for an alloy should compile all relevant information about the mixture's constituents and the mixture as a whole in a spreadsheet as follows, and then extract the information required for the respective constituents SDS sections.

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

Example of a table that can be used to report data on an alloy and its constituents:

Alloy:															
Constituent 1 Substance name:															
EC number:	CAS number:								% in alloy						
Classification (specify physical form)*					Classification*				Conc.limit**						
Exposure route of relevance	**DNELs, DMELs, PNECs**												**PNECs**	**Endpoint**	**RMM**
	Industrial				**Professional**				**Consumer**						
	Long term, local effects	Long term, systemic effects	Short term, local effects	Short term, systemic effects	Long term, local effects	Long term, systemic effects	Short term, local effects	Short term, systemic effects	Long term, local effects	Long term, systemic effects	Short term, local effects	Short term, systemic effects			
Human oral															
Human inhalation															
Human dermal															
Environment: water															
Environment: air															
Environment: soil															
Environment: sediment															
Environment STP															
Critical physical parameters: solubility, flammability, corrosivity:															

Alloy:															
Constituent 2 Substance name:															
EC number:	CAS number:								% in alloy						
Classification (specify physical form)*					Classification*				Conc.limit**						
Exposure route of relevance	**DNELs, DMELs, PNECs**												**PNECs**	**Endpoint**	**RMM**
	Industrial				**Professional**				**Consumer**						
	Long term, local effects	Long term, systemic effects	Short term, local effects	Short term, systemic effects	Long term, local effects	Long term, systemic effects	Short term, local effects	Short term, systemic effects	Long term, local effects	Long term, systemic effects	Short term, local effects	Short term, systemic effects			
Human oral															
Human inhalation															
Human dermal															
Environment: water															
Environment: air															
Environment: soil															
Environment: sediment															
Environment STP															
Critical physical parameters: solubility, flammability, corrosivity:															

Alloy:			
Alloys classification, if available			
Critical physical parameters: solubility, flammability, corrosiveness			
Alloys data:			
Environment (TDp data…)		Human health data (bio-elution data, …)	
Source + reliability of the data	Outcomes	Source + reliability of the data	Outcomes

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

Exposure to alloy powders and massives

When coarser (non-respirable/inhalable) powders and massives (>20 µm) are handled, the inhalation route is not relevant. In this case, oral and dermal exposures are relevant for human health hazards. Toxicity resulting from these exposure routes depends on the availability of ions at target sites. This availability can be estimated in vitro by measuring ion release from the alloy in the gastric fluid and sweat and compared with release from the constituents. The results of availability tests on alloys can be used to refine actual exposure considerations from the “alloy” versus actual exposure from the “metals in the alloy. If exposure is reduced by inclusion in the matrix, then less stringent risk reduction measures could be applied.

APPENDIX 4 : Guidance for the provision of Information in the Supply Chain and Safety Data Sheets for Recovered Substances and Mixtures in accordance with Articles 2.7.d, 31 and 32 of REACH

CONTENTS

Note 1:
This document should be read in conjunction with the ECHA Guidance document on Waste and Recovered Substances

Note 2:
For the purposes of this document the terms recycling and recycler are used throughout, although there are references to recovery processes and to recovered substances for consistency with other documents

Introduction

1. Introduction and scope of this document

1.1. REACH recital (11) states that "*to ensure workability and to maintain the incentives for waste recycling and recovery, wastes should not be regarded as substances, mixtures or articles within the meaning of this Regulation"*.

1.2. Article 2.2 further specifies that "*waste is not to be considered as a substance, on its own, in a mixture or in an article in the context of Article 3 of the REACH Regulation*".

1.3. Recyclers are not Downstream Users in REACH and therefore will not automatically receive a Safety Data Sheet with the waste materials intended for reprocessing.

1.4. The guidance document on waste and recovered substances[38], specifies that the final recovery operation is considered as manufacturing.

1.5. It is important that the recycling industry should be able to operate within REACH because of its vital role in minimising the use of non-renewable raw materials and in meeting the requirements of producer responsibility directives (e.g. automotive, batteries, electrical & packaging waste). However, one problem recyclers are facing for meeting the above conditions is that for post consumer waste, the information chain will stop at the last downstream user.

1.6. This document provides guidance to recyclers to help them to decide:

1.7. whether a Safety Data Sheet is required and whether this should include exposure scenarios

1.8. what information is necessary to compile the Safety Data Sheet

1.9. how to obtain legitimate access to the necessary information

1.10. In the case that a Safety Data Sheet is not required, recyclers must still comply with the obligation to supply information down the supply chain in accordance with Article 32.

1.11. The recycler will also have an obligation to make safety information available to workers.

2. The issues facing some recyclers

2.1. For recovered materials composed primarily of substances which are not chemically modified by the recycling process, these substances on their own or in mixtures are known and generally will have been registered.

2.2. During original manufacture various other substances or additives may have been combined with the primary substance.

2.3. Some of the substances or additives will still be in production and will therefore be registered under REACH. However, others will have been phased out of production, either through voluntary or regulatory action, although they will continue to be present in waste materials for a number of years. They may or may not fulfil their original function.

2.4. In order to encourage recycling and to be consistent with other pieces of EU legislation that set out recycling targets, it is recommended that Manufacturers/Importers should support the recyclers efforts to compile the necessary information even though, ultimately, the responsibility for REACH compliance lies with the recyclers.

2.5. It has to be noted that some sectors carrying out recycling or recovery activities, have enough information available on the substances/mixtures they produce and place on the market in order to compile Safety Data Sheet complying with Art 31 of REACH.

3. When is a Safety Data Sheet needed?

3.1. The recycling industry produces different types of output:

[38] ECHA Guidance on Waste and Recovered Substances 2010 - Version 2.0

- The output may still have waste status in which case it is outside REACH and therefore does not require a Safety Data Sheet
- The output may be a "new" substance in which case the recycler must register that substance and carry out appropriate supporting ES and CSA evaluations[39].
- The output may be a substance (or a mixture containing substances) which is the same as the original substance(s)

3.2. Certain recovered materials may contain some impurities which are either a result of the use of the material prior to becoming a waste or which were present in the original material as additives but which are no longer produced and which will not have been registered (legacy substances)

3.3. The recovery process may remove contamination from the recovered waste or may physically transform the recovered waste (e.g. crushing or grinding)

3.4. Article 31.1 states that "*The supplier of a substance or a mixture shall provide the recipient of the substance or mixture with a safety data sheet compiled in accordance with Annex II:*

(a) where a substance or mixture meets the criteria for classification as dangerous in accordance with Directives 67/548/EEC or 1999/45/EC; or

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

(c) where a substance is included in the list established in accordance with Article 59(1) for reasons other than those referred to in points (a) and (b)."

3.5. In the above case a Safety Data Sheet is required. However, ECHA Guidance on Waste and Recovered Substances states that an exposure scenario is not required. .

3.6. Article 31.3 states that *"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 nongaseous mixtures and ≥ 0,2 % by volume for gaseous mixtures at least one substance posing human health or environmental hazards; or

(b) in an individual concentration of ≥ 0,1 % by weight for non-gaseous mixtures at least one substance that is persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII or has been included for reasons other than those referred to in point (a) in the list established in accordance with Article 59(1); or

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

3.7. The recycler must therefore satisfy himself whether his recovered substance or mixture meets any of these criteria and, if so, should follow the guidance set out in Section 5 when compiling his Safety Data Sheet.

3.8. A decision tree to help confirm the necessity for a Safety Data Sheet for recovered substances is provided at the end of this Annex.

4. Evaluating the availability of existing **Safety Data Sheet** information and the "Sameness" of recovered substances

4.1. Having determined whether the recovered material needs to be accompanied by a Safety Data Sheet and having identified the data required to prepare the Safety Data Sheet for the recovered material, Recyclers may opt to use an available Safety Data Sheet instead of preparing the Safety Data Sheet themselves in order to meet their Title IV requirement as well as the conditions of art 2(7)(d) to benefit from the conditional exemption to Titles II and VI.

[39] e.g. feedstock recycling

4.2. The recycler will need to satisfy himself that any information he relies upon to compile a Safety Data Sheet relates to substances which are the same as those in the recovered material.

4.3. Meeting the requirement to communicate information down the supply chain by just taking over the Safety Data Sheet from a primary producer, may induce certain liability issues, when for example the presence of hazardous minor constituents or impurities can change the hazard profile of the recovered substances/mixture and could hence lead to the communication of incorrect hazard information for the recovered material.

Note: For metallic or non-metallic scrap that is not waste, whether as new scrap which might be a by-product and may be accompanied by a Safety Data Sheet or whether old scrap which has been collected and sorted and if necessary processed from End-of-Life Goods and meets the conditions set in the Waste Framework Directive Art.6 and the criteria set in any related Commission Decision on "End-of-Waste", these recovered materials may be placed on the market where the next process may then make additions of substances (to alter the composition or properties) or refine to remove substances, it is then that subsequent process (for example in a metal works or in a foundry) that may be required to provide a Safety Data Sheet for the mixture they have produced.

4.4. For a "mono-constituent" substance or a "multi constituent substance" with known composition, this will be relatively simple as a substance with the same chemicals identifier (name) is in general sufficient. Additional criteria that may be used are:

- For **"**mono-constituent" substances, a substance will be considered the same if the major constituent is present in concentrations of more than 80% (the 80% rule).
- For multi-constituent substance; the >10 % to <80% rule applies, i.e. if the major constituent that are present in concentration between 10 and 80 % are the same.

For substances with a well-defined composition (i.e. mono-constituent and multi-constituents substances) the sameness of the naming is in principle sufficient to be able to share data even though certain impurities might lead to a different classification/hazard profile. Only in cases where all data is clearly not suitable for the other substance these substances can be regarded as different (e.g. in case of very different physical properties which have essential impact on the hazard properties, like water solubility)[40].

For substances of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB) the name, origin/source and/or process are considered to be sufficient to determine the sameness.

4.5. The ECHA Guidelines on waste and recovered substances41 notes that "the decision on the sameness should be based on the main constituents. Information about the impurities does not in principle change the conclusion about the sameness42. The same EINECS and CAS numbers for substances are an indicator for the sameness of the substance.

4.6. The documents recovery operators use to provide evidence for the "sameness" and for the safety information can be provided in the form of standardised information prepared by their associations. Such standard documents should cover all relevant aspects for those materials which comply with end-of-waste criteria43

5. Guidance for writing a Safety Data Sheet for recycled substances and mixtures using Generic Information

[40] guidance doc on data sharing, p. 35, point 4.5.1, 2§

[41] ECHA Guidance on Waste and Recovered Substances 2010 - Version 2.0

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

[43] The Commission representatives recommended this approach in the discussion with the metal recycling sector in October 2009. See JRC report on iron and steel scrap, pg. 41 and 43 available at http://susproc.jrc.ec.europa.eu/activities/waste/documents/Endofwastecriteriafinal.pdf .

5.1. The recycler must provide appropriate safety information on classified substances or mixtures, including information from the relevant Chemical Safety Report(s) down the supply chain to the immediate downstream user(s).

5.2. The 'appropriate information' can come from chemical and/or physical analysis, toxicological or ecotoxicological studies, from legislative sources, or from generic information built up from knowledge of the input material and verified as statistically correct by testing if required.

5.3. In case Generic Information built up from knowledge of the input material is used to produce a Safety Data Sheet, the following should be observed:

- There needs to be confidence in the reliability of generic information
- The first step is to assess what is known about the waste material that is to be recovered as accepted as best practice by the recovery sector. This includes information on the composition of the waste, and any known relevant history of the material such as where applicable:
  - the previous application,
  - handling and storage during the use, waste and transport stages
  - the treatment carried out (e.g. during reprocessing).

1.1.1. All known content should be assessed and where relevant recorded, including the original material(s) as well as anything likely to be present from additives used in the original application (e.g. alloying substances, coatings, colorants, or stabilisers).

1.1.2. Information on the substances and mixtures present in the waste and their relative quantities will enable Safety Data Sheet information on relevant materials to be obtained and used as the basis of the Safety Data Sheet for the recycled material.

1.1.3. If there are substances subject to restriction, meeting the classification criteria as dangerous, CMRn PBT, vPvB or candidate list substances in the recycled material then the chemical composition of all such content should be established. This will enable the CAS and EINECS references to be obtained as well as the Risk Phrases and Hazard Symbols for each material, which in turn will provide information on the threshold concentration for each substance.

1.1.4. The incoming raw material and the recyclate should be characterised to establish average content for each substance of concern and the likely range (maximum and minimum). Alternatively the hazard profile of the recovered mixture must be established.

5.4. The maximum levels of substances of concern established in the recyclate can be used to assess risks and set out risk management measures in the Safety Data Sheet for accepted uses.

1.1.5. Any process details that are necessary to define any risk associated with the recovered material should be documented.

5.5. For recovered substances containing impurities that are classified and contribute to the classification, the impurities have to be indicated. It is worth noting that the presence of impurities above the legal cut-of values[44] should be addressed in the communication via a SDS or safe use information communicated towards customers. Furthermore, according to Article 31(1) of REACH recovery operators are only required to provide a SDS if the substance or the mixture which they recover requires a SDS. Impurities as such cannot create the need for a SDS under Article 31(1) as this is may only be triggered by the obligations under Article 31(2) of REACH.

[44] This is based on the lowest of the concentration limits in Directive 1999/45/EC or in Annex I to Directive 67/548/EEC, so that the preparation would not have to be classified as dangerous; and the 0,1 % (weight by weight) threshold for PBTs, vPvBs and substances of equivalent concern for which classification rules do not apply.

5.6. The recovery operator that has the required information available for the same substance and therefore can rely on Article 2(7)(d) of REACH even if the use of a recovered substance is not covered by the registration of the same substance, is not required to:

- make an exposure scenario for the use of the recovered substance;
- register the recovered substance;
- notify the use of the recovered substance.

However he should take account of the existing information and has to provide appropriate risk management measures in the SDS, if needed, or to provide sufficient information on the safe use of the recovered substance in case no SDS is needed.

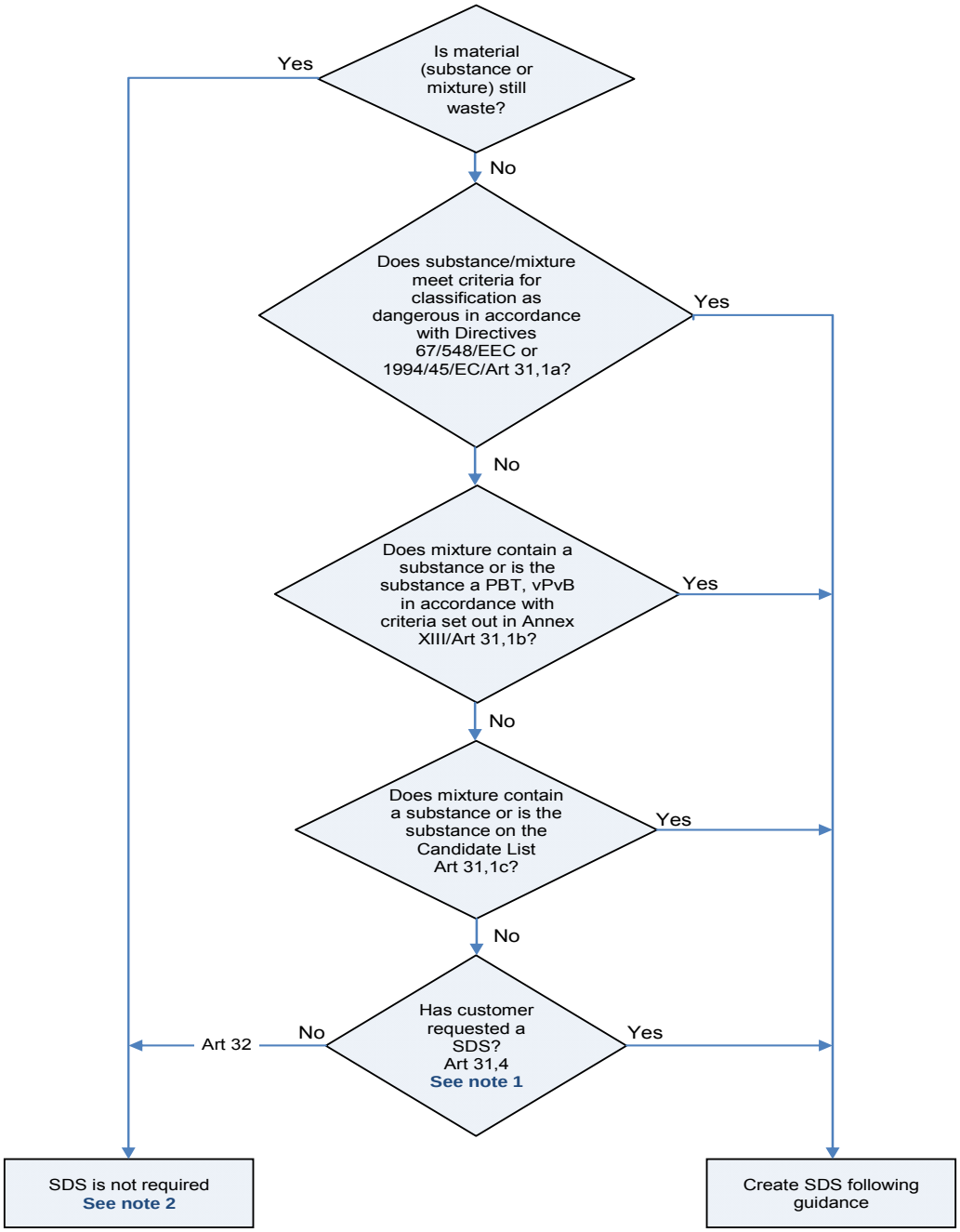
5.7. Other than for exceptions set out in this Annex the Safety Data Sheet should be compiled in accordance with the guidance set out in the main body of this document.

6. General

6.1. Recovered substances are generally not exempted from notification obligations for the classification and labelling inventory of CLP. Moreover, they are not exempted from the authorisation and restrictions under REACH.

6.2. Trade Associations representing specific material recovery sectors should provide their members with examples of how to use this guidance.

Figure 1: Decision tree to confirm the necessity for a SDS for a recovered substance under REACH



Note 1: For commercial reasons a manufacturer may choose to produce a SDS at the request of a customer, even if he is not legally obliged to do so.

Note 2: SDS need not be supplied if a dangerous substance or mixture is offered or sold to the general public and provided with sufficient information (Art 31,4) i.e. SDS are only for professional users.

1 **Note 3:** Some processes, such as metal refining, are capable of removing or destroying certain constituents.

APPENDIX 5 : Glossary / List of acronyms

LIST OF ACRONYMS

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
DMEL	Derived Minimal Effect Level
DNEL	Derived No Effect Level
DPD	Dangerous Preparation Directive 1999/45/EEC
DSD	Dangerous Substances Directive 67/548/EEC
DU	Downstream User
DUCC	Downstream Users of Chemicals Co-ordination platform
EC	European Commission
EC50	Half maximal effective concentration
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
GES	Generic Exposure Scenario
GHS	Globally Harmonized System
HH	Human Health
IC50	Half maximal inhibitory concentration
IT	Information Technology
IUCLID	International Uniform ChemicaL Information Database
IUPAC	International Union for Pure Applied Chemistry
JRC	Joint Research Centre
LC50	Lethal concentration, 50 %
LD50	Median Lethal Dose
LE	Legal Entity
LR	Lead Registrant
M/I	Manufacturer / Importer
MS	Members 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
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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