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NOTE

from :	General Secretariat of the Council
to :	Ad-hoc Working Party on Chemicals
No. Cion. prop. :	15409/03 COMPET 75 ENV 651 CHIMIE 3 CODEC 1692 + ADD 1 + ADD 2 + ADD 3 + ADD 4 + ADD 5 + ADD 6
Subject :	Proposal for a Regulation of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency and amending Directive 1999/45/EC and Regulation (EC) {on Persistent Organic Pollutants} Proposal for a Directive of the European Parliament and of the Council amending Council Directive 67/548/EEC in order to adapt it to Regulation (EC) of the European Parliament and of the Council concerning the registration, evaluation, authorisation and restriction of chemicals

Introduction

Annex Ia – Guide to the Compilation of Safety Data Sheets

On 14-15 February 2005, the Ad-hoc Working Party on Chemicals examined Annex Ia (Guide to the Compilation of Safety Data Sheets) to the REACH Proposal.

In addition the Luxembourg and United Kingdom Presidencies invited delegations to send in written contributions before 29 April 2005.

During the debate, the following key issues were identified:

- Registration numbers (section 1)
- Communication of exposure scenarios in SDS annex (section 1)
- Safety Data Sheet (Annex Ia) (Section 2/3)
- Consideration of substances of very high concern (PBTs and vPvBs) (section 3)
- Further issues
    - Supply chain

Based on the interventions during the examination and written remarks received, the present document with delegations' positions set out in footnotes has been elaborated (remarks received until 13 June 2005 have been taken into consideration).

At this stage, all delegations have scrutiny reservations on the whole Proposal.

ANNEX Ia[1] [2]

GUIDE TO THE COMPILATION OF SAFETY DATA SHEETS

This Annex sets out the requirements for a Safety Data Sheet that is provided for a substance or a preparation in accordance with Article 29. The Safety Data Sheet provides a mechanism for transmitting appropriate information from the relevant Chemical Safety Report(s) down the supply chain to the immediate downstream user(s). The information provided in the Safety Data Sheet shall be consistent with the information in the chemical safety report, where one is required. Where a chemical safety report has been performed, the relevant exposure scenario(s)[3] shall be placed into an annex of the safety data sheet[4], to make reference to them under the relevant headings of the safety data sheet easier.

The purpose of this Annex is to ensure consistency and accuracy in the content of each of the mandatory headings listed in Article 29, so that the resulting safety data sheets will enable users to take the necessary measures relating to protection of health and safety at the workplace, and protection of the environment.

The information provided by safety data sheets shall also meet the requirements set out in Council Directive 98/24/EC **(footnote 2)** on the protection of the health and safety of workers from the risks related to chemical agents at work. In particular, the safety data sheet shall enable the employer to determine whether any hazardous chemical agents are present in the workplace, and to assess any risk to the health and safety of workers arising from their use.

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1 **IT**: Considering that producers and importers of articles are responsible for their articles, is the chemical safety report required also for articles that meet the conditions indicated in art. 6, paragraph 1 and 2? It should be clarified if the CSR has to be performed also for substances contained in articles. As a consequence, possible competitiveness disadvantages for enterprises based in Europe should be considered.
It is preferable to introduce a clear distinction between preparations, regulated according to directive 1999/45/EC, and substances regulated according to REACH. The provisions of the regulation shall apply to substances on their own, in preparations or in articles, in coherence with the wording of art.1, paragraph 1 of the proposal. Therefore, IT proposes to maintain Annexes I, Ia and XI only with regard to substances and, consequently, IT proposes to delete Annex Ib (and the second part of the paragraph 2 of art.29 referring to the Annex Ib).

2 **FR**: comment: FR proposes to add to this Annex the information that are required to be transferred into safety data sheets according to the provisions foreseen in sections 0.9 and 0.10 of the introduction to Annex I.

3 **DE**: insert: "... and/or use and exposure categories ..."

4 **DE**: insert: "... if they are too extensive to be given under heading 1.2, ..."

The information in the Safety Data Sheet shall be written in a clear and concise manner. The safety data sheet shall be prepared by a competent person[5] [6] who shall take into account the specific needs of the user audience, as far as it is known. Persons placing substances and preparations on the market shall ensure that competent persons have received appropriate training, including refresher training.

For preparations not classified as dangerous, but for which a safety data sheet is required according to Article [7]30, proportionate information shall be provided under each heading.

Additional information may be necessary in some cases in view of the wide range of properties of the substances and preparations. If in other cases it emerges that information on certain properties is of no significance or that it is technically impossible to provide, the reasons for this shall be clearly stated under each heading. Information shall be provided for each hazardous property. If it is stated that a particular hazard does not apply, clearly differentiate between cases where no information is available to the classifier, and cases where negative test results are available.

Give the date of issue of the safety data sheet on the first page. When a safety data sheet has been revised, the changes shall be brought to the attention of the recipient.

Note

Safety data sheets are also required for certain special substances and preparations (e.g. metals in massive form, alloys, compressed gases etc.) listed in chapters 8 and 9 of Annex VI to Directive 67/548/EEC, for which there are labelling derogations.

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

1.1. Identification of the substance or preparation

The term used for identification shall be identical to that provided on the label as set out in Annex VI to Directive 67/548/EEC.

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[5] **BE, DE, HU**: Definition or clarification of "competent person" is required. Why is this competence required here and not for the CSR? For information, in the GHS, it is specified: "The SDS shall be prepared by a competent person who shall take into account the specific needs of the user audience, as far as it is known. Persons placing substances and mixtures on the market shall ensure that refresher courses and training on the preparation of SDS be regularly attended by the competent persons." **HU**: In Cion. Dir. 2001/58/EC the manufacturer/importer is as a legal entity responsible for the content of the SDS, as well as for compiling the Data Sheet. HU proposes that Title IV Article 29 should clarify the tasks of the "competent person". HU proposes furthermore a definition of "competent person" be included in Article 3.

[6] **BE**: Include after "competent person": "<u>independent from the hierarchy or to any business unit of the producer</u>" (not reporting). Opposed by: **DK**

[7] **DK** change: Article ~~30~~29 (3), ~~proportionate~~ information ...

For substances subject to registration**,** the term shall be consistent with that provided under registration [8] [9]and the registration number assigned under Article 18(1) of this Regulation shall also be indicated.

Other means of identification available may also be indicated.

1.2. Use of the substance/preparation

Indicate the [10]uses of the substance or preparation as far as they are known. Where there are many possible uses, only the most important or common [11]uses need [12]be listed. [13]This shall include a brief description of what it actually does, e.g. flame retardant, anti-oxidant, etc.

Where a chemical safety report is required, the safety data sheet shall contain information on all the identified [14]uses relevant to the recipient of the safety data sheet. This information shall be consistent with the identified [15]uses and exposure scenarios set out in the annex to the safety data sheet .

1.3. Company/undertaking identification

Identify the person responsible for placing the substance or preparation on the market within the Community, whether it be the manufacturer, importer or distributor. Give the full address and telephone number of this person[16].

In addition, where this person is not located in the Member State where the substance or preparation is placed on the market, give a full address and telephone number for the person responsible in that Member State, if possible.

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

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[8] **DK** change as follows: registration ~~and the registration number assigned under Article 18(1) of this Regulation shall also be indicated~~. For each substance it shall be clearly indicated whether the substance is registered..

[9] **AT**: change as follows: For substances subject to registration, the term shall be consistent with that provided under registration ~~and the registration number assigned under Article 18(1) of this Regulation shall also be indicated.~~

[10] **DE**: change as follows: use~~s~~ and exposure categories

[11] **DE**: change as follows: use~~s~~ and exposure categories

[12] **DE**: add to be listed

[13] **DE**: delete ~~This shall include a brief description of what it actually does, e.g. flame retardant, anti-oxidant, etc.~~

[14] **DE**: change as follows: use~~s~~ and exposure categories

[15] **DE**: change as follows: use~~s~~ and exposure categories ~~and exposure scenarios~~

[16] **BE**: add: as well as an e-mail address of the competent person responsible for the SDS/CSR content.

1.4. Emergency telephone

In addition to the above mentioned information, supply the emergency telephone number of the company and/or relevant official advisory body (this may be the body responsible for receiving information relating to health, which is referred to in Article 17 of Directive 1999/45/EC).[17]

2. HAZARDS IDENTIFICATION

Give here the classification of the substance or preparation which arises from application of the classification rules in Directives 67/548/EEC or 1999/45/EC. Indicate clearly and briefly the hazards the substance or preparation presents to man and the environment.

Distinguish clearly between preparations which are classified as dangerous and preparations which are not classified as dangerous according to Directive 1999/45/EC.

Describe the most important adverse physicochemical, human health and environmental effects and symptoms relating to the uses and possible misuses of the substance or preparation that can reasonably be foreseen.

It may be necessary to mention other hazards, such as dustiness, [18]suffocation, freezing [19] or environmental effects such as hazards to soil-dwelling organisms, [20]etc., which do not result in classification but which may contribute to the overall hazards of the material.

The information shown on the label shall be given under heading 15.

The classification of the substance shall be consistent with the classification provided to the classification and labelling inventory according to Title X.

3. COMPOSITION/INFORMATION ON INGREDIENTS

The information given shall enable the recipient to identify readily the hazards of the components of the preparation. The hazards of the preparation itself shall be given under heading 3.[21]

3.1. It is not necessary to give the full composition (nature of the ingredients and their concentration), although a general description of the components and their concentrations can be helpful.

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17 **DK**, **BE**: Specify if this phone number is available only during office hours.
18 **DK, BE**: add: "cross-sensitisation,"
19 **DK**: add: , high potency for odour or taste or environmental effects
20 **DK**: add ozone depletion, photochemical ozone creation potential, etc
21 **BE, NL** Proposal (editorial): 'heading 2'?

3.2. For a preparation classified as dangerous according to Directive 1999/45/EC, the following substances shall be indicated, together with their concentration or concentration range[22]:

(i) [23]substances presenting a health or environmental hazard within the meaning of Directive 67/548/EEC, [24]if they are present in concentrations equal to or greater than the lowest of:

– the applicable concentrations defined in the table of Article 3 (3) of European Parliament and Council Directive 1999/45/EC, or
– the concentration limits given in Annex I to Council Directive 67/548/EEC, or [25]
– the concentration limits given in Part B of Annex II to European Parliament and Council Directive 1999/45/EC, or
– the concentration limits given in Part B of Annex III to European Parliament and Council Directive 1999/45/EC, or
[26]– the concentration limits given in an agreed[27] entry in the classification and labelling inventory established under Title X,

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22 **NL** : Experience from the Netherlands shows there is confusion on how to interpret 'concentration' and 'concentration range'. This should therefore be clarified and specified with 'in the preparation'. The sentence should therefore read: '..., together with their concentration or concentration range in the preparation:'

23 **SE** (**FR** shares the concerns expressed): In paragraph 3.2(i) a number of currently used conditions for indicating the presence of a substance in a preparation in the SDS is given. However, according to the present provisions in Directive 2001/58/EC some substances with special labelling rules in Annex V of the preparations directive shall be indicated in the SDS at concentrations below the cut off level for classification. These special cases, applying for e.g. isocyanates and allergens, have been omitted in the present proposal and should be inserted. **DK**: See footnote 21.

24 **DE** (**FR** shares the concerns expressed): "..., if they are present in concentrations equal to or greater than those laid down in the table set out in Article 3(3) of Directive 1999/45/EC (unless lower limits are given in Annex I to Directive 67/548/EEC or in Annexes II, III or V to Directive 1999/45/EEC).

25 **NL** (**FR** shares the concerns expressed): The possible co-existence of both the C&L inventory according to Title X and Annex I to Directive 67/548/EEC is not clear. From article 109 of the REACH proposal it can be concluded that all substances meeting the classification criteria of Directive 67/548/EEC must be notified for the C&L inventory. Therefore, the second bullet point of paragraph 3.2. (i) can be deleted.
Proposal: delete '– the concentration limits given in Annex I to Council Directive 67/548/EEC, or'

26 **DK** (**FR** shares the concerns expressed) add new fifth bullet: – <u>the concentration limits given in Annex V to European Parliament and Council Directive 1999/45/EC, or</u> ...

27 **NL**: a registrant/notifier proposing specific concentration limits for a substance using the procedure according to Title X must be able to use these specific concentration limits even if the entry is not agreed.
Proposal: Annex Ia, Section 3 should be discussed in relation to the discussion on Title X.

(ii) and substances for which there are Community [28]workplace exposure limits[29], which are not already included under (i).[30] [31]

3.3. For a preparation not classified as dangerous according to Directive 1999/45/EC, the following substances shall be indicated, together with their concentration or concentration range, [32]if they are present in an individual concentration of ≥ 1% by weight for non-gaseous preparations and ≥ 0,2% by volume for gaseous preparations:

– substances presenting a health or environmental hazard within the meaning of Directive 67/548/EEC (footnote 3);

– and substances for which there are Community[33] workplace exposure limits[34].

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28 **FR**: add. "... Community or national workplace exposure limits..."

29 **NL** (support in principle: **DK**) : Community should be replaced by 'national'. This is in line with Council declaration 90/99 and the previously proposed revision of REACH article 29(3) (see also the NL proposal in WD11.05).

30 **BE** (**FR** shares the concerns expressed): See problem reported under FAQ 22 of CLEEN Report: Is there no concentration limit for substances with workplace exposure limits for preparations classified as dangerous in Heading 3?
Proposal 1: If the established TLV cannot be reached under normal circumstances for the composition described, then the producer could avoid mentioning the substance.
or proposal 2: consider the same concentrations as used under next § 3.3.

31 **FI** add (**FR** shares the concerns expressed): if the concentration is equal to or greater than 1 % (iii) substances meeting the criteria specified by Article 54 e-f, if the concentration of an individual substance is equal to or greater than 0,1 %.

32 **FI** change text and layout as follows: ...together with their concentration or concentration range,
(a) if they are present in an individual concentration of ≥ 1% by weight for non-gaseous preparations and ≥ 0,2% by volume for gaseous preparations:
– substances presenting a health or environmental hazard within the meaning of Directive 67/548/EEC(3);
– and substances for which there are Community workplace exposure limits.
(b) if they are present in an individual concentration of > 0,1 % by weight in preparations and
– substances meet the criteria specified by Article 54 e-f.
FI also proposes that 1 % concentration limit would be introduced in 3.2 when a substance is to be declared on the basis of an OEL-value. This cut-off value is missing in the present SDS Directive for those preparations that are classified. However, this cut-off limit is specified for those preparations which are not classified. This is a non-deliberate omission in the present legislation and should be corrected. **DK** supports in principle the suggestion. However, DK believes that the references to Art. 54 should be to Art. 54 (d)-(f) and not 54 (e)-(f). Furthermore, in regard to the proposed limit value for substances with an OEL we would like to add a concentration limit of 0.2% by volume for gaseous preparations. **FR** shares the concerns expressed by FI.

33 **FR**: add "... Community or national workplace ..."

34 **NL** (support in principle: **DK**): Community should be replaced by 'national'. This is in line with Council declaration 90/99 and the previously proposed revision of REACH article 29(3) (see also the NL proposal in WD11.05).

3.4. The classification (derived either from Articles 4 and 6 of Directive 67/548/EEC or from Annex I to Directive 67/548/EEC[35]) of the above substances shall be given, including the symbol letters[36] and R phrases which are assigned in accordance with their physicochemical, health and environmental hazards. The R phrases do not need to be written out in full here: reference shall be made to heading 16, where the full text of each relevant R phrase shall be listed. [37]

3.5. The name and the Einecs or Elincs number[38] [39] [40][41]of the above substances shall be given in accordance with Directive 67/548/EEC. The CAS number and IUPAC name (if available) may also be helpful. For substances listed by a generic name, according to Article 15 of Directive 1999/45/EC or the footnote to point 3.3 of this Annex, a precise chemical identifier is not necessary. The registration number assigned under Article 18(1) of this Regulation shall also be given for each substance that is subject to registration.[42]

3.6. If, in accordance with the provisions of Article 15 of Directive 1999/45/EC or the footnote to point 3.3 of this Annex, the identity of certain substances is to be kept confidential, their chemical nature shall be described in order to ensure safe handling.[43] The name used shall be the same as that which derives from the above procedures[44].

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35 **NL**: why is the classification and labelling inventory according to Title X not mentioned? Proposal: add 'the classification and labelling inventory according to Title X'.

36 **BE**: under this heading, labelling is often confused with classification; add an example for clarification: (ex.: Carc. Cat 2, T; R48; or Sensitizing, Xi; R43)

37 **FI, FR** add: <u>If the substance does not meet the classification criteria, information on hazards referred to in Article 54 e-f or when the substance is declared on the basis of an OEL, the reason for declaring the substance in section 3 shall be described otherwise, like "PBT-substance" or "substance with an OEL-value.</u>

38 **NL**: non-phase-in substances will not have an EINECS or ELINCS number, only a registration number. Proposal: 'The name and the Registration number, EINECS or ELINCS number.' Delete last sentence of paragraph 3.5. Share the views expressed: **DK**.

39 **BE**: Replace Einecs or Elincs number into EC-number (Einecs, Elincs, NLP, ...). Share the views expressed: **DK**

40 **UK**: see general comments on SDS

41 **DE**: Scrutiny reservation on the necessity of the use of a registration number.

42 **BE**: Downstream users switch frequently from producer/or retrieve their products form different producers at the same time according to the market prizes or availability in a specific region of Europe/World. What to do in this situation? (? Should all numbers be mentioned on the SDS?)

43 **BE**: What about the registration number (see point 3.5)? Not needed ? How can a downstream user trust that the substance is registered correctly ?

44 **NL**: See general comment at Safety Data Sheet.

4.[45] FIRST AID MEASURES

Describe the first-aid measures.[46]

Specify first whether immediate medical attention is required.

The information on first aid shall be brief and easy to understand by the victim, bystanders and first-aiders. The symptoms and effects shall be briefly summarised. The instructions shall indicate what is to be done on the spot in the case of an accident and whether delayed effects can be expected after exposure.

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

Indicate whether professional assistance by a doctor is needed or advisable.

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

5. FIRE-FIGHTING MEASURES

Refer to requirements for fighting a fire caused by the substance or preparation, or arising in its vicinity by indicating:

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

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[45] **DK** Potential conflict between the use of DNELs and the Occupational Exposure Limit values OEL's in the SDS. Most properly the values will differ from each other due to different methodology on how to calculate and set up the values. Furthermore binding OELs most often has incorporated technically and economically factors. The consequences of indicating both values should be analysed e.g. in regard to communication, legal aspects etc. (**FR** shares concern, however, suggests to refer this comment to paragraph 8.1 (exposure limit values) (unofficial translation)

[46] **BE**: Why do we need this first phrase ? Start directly with the second phrase

6. ACCIDENTAL RELEASE MEASURES

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

– personal precautions such as:

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 indications such as: "never use, neutralise with ...".

Note

If appropriate refer to headings 8 and 13.

7. HANDLING AND STORAGE

Note

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

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

7.1. Handling

Specify precautions for safe handling including advice on 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 bounded area, measures for collection and disposal of spillages, etc.) and any specific requirements or rules relating to the substance or preparation (e.g. procedures or equipment which are prohibited or recommended) and if possible give a brief description.

7.2. Storage

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 (temperature and humidity limit/range, light, inert gas, etc.) special electrical equipment and prevention of static electricity.

Give 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 preparation.

7.3. Specific use(s)

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 industry – or sector – specific approved guidance.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Exposure limit values

Specify 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 preparation is placed on the market. Give information on currently recommended monitoring procedures.

Where a chemical safety report is required, the relevant DNELs and PNECs for the substance shall be given for the exposure scenarios set out in the annex to the safety data sheet.

For preparations, it is useful to provide values for those constituent substances which are required to be listed in the safety data sheet according to heading 3.

8.2. Exposure controls

For the purposes of this document exposure control means the full range of specific protection and prevention[47] measures to be taken [48]during use in order to minimise worker and environmental exposure.

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[47] **UK**: "For the purposes of this document exposure control means the full range of ~~specific protection and prevention~~ risk management measures to be taken during use in order to minimise worker and environmental exposure. Where a chemical safety report is required, a summary of the risk management measures shall be given in section 8 of the safety data sheet for the identified uses set out in the safety data sheet."

[48] **DE**: change as follows: ~~during use~~ for all identified use and exposure categories in order ...

8.2.1. Occupational exposure controls

This information will be taken into account by the employer in carrying out an assessment of risk to the health and safety of workers for the substance or preparation under Article 4 of Directive 98/24/EC, which requires [49]the design of appropriate work processes and engineering controls, the use of adequate equipment and materials, the application of collective protection measures at source, and finally the use of individual protection measures, such as personal protection equipment. Therefore provide suitable and adequate information on these measures to enable a proper risk assessment to be carried out under Article 4 of Directive 98/24/EC. This information shall complement that already given under heading 7.1.

Where personal[50] protection is needed, specify in detail which equipment will provide adequate and suitable protection. Take into account Council Directive 89/686/EEC(footnote 4) and make reference to the appropriate CEN standards.[51]

[52]Where a chemical safety report is required, a summary of the risk management measures that adequately control exposure of workers to the substance shall be given for the exposure scenarios set out in the annex to the safety data sheet.[53]
[54]

8.2.1.1. Respiratory protection

For dangerous gases, vapours or dust, specify the type of protective equipment to be used, such as self contained breathing apparatus, adequate masks and filters.

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[49] **DK, UK** (**FR** support in principle) insert additional text and change layout as follows which requires, in order of priority:

- ~~the~~ design of appropriate work processes and engineering controls, the use of adequate equipment and materials;
- ~~the~~ application of collective protection measures at source; such as adequate ventilation and appropriate organisational measures; and,
- where exposure cannot be prevented by other means, the use of individual protection measures, such as personal protective equipment.

~~finally the use of individual protection measures, such as personal protection equipment.~~

[50] **DK, UK** (**FR** support in principle): "Where ~~personal~~ individual protection measures ..."

[51] **DK, UK** (**FR** support in principle): Add "such as adequate ventilation and appropriate organisational measures" at the end of the second bullet.

[52] **DK, UK** (**FR** support in principle): Delete last paragraph.

[53] **DE**: suggestion: "Where a chemical safety report is required, ~~a summery~~ of the risk management measures that adequately control exposure of workers to the substance shall be given for the exposure scenarios and/or use and exposure categories set out in the ~~annex to the~~ safety data sheet."

[54] **DK, UK** (**FR** support in principle): Add new 3rd bullet "where exposure cannot be prevented by other means, the use of individual protection measures, such as personal protective equipment.

8.2.1.2. Hand protection

Specify clearly the type of gloves to be worn when handling the substance or preparation, including:

– the type of material,
– the breakthrough time of the glove material, with regard to the amount and duration of dermal exposure.

If necessary indicate any additional hand protection measures.

8.2.1.3. Eye protection

Specify the type of eye protection equipment required such as: safety glasses, safety goggles, face shield.

8.2.1.4. Skin protection

If 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: apron, boots and full protective suit. If necessary, indicate any additional skin protection measures and specific hygiene measures.

8.2.2. Environmental exposure controls

Specify the information required by the employer to fulfil his commitments under Community environmental protection legislation.

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.[55]

9. PHYSICAL AND CHEMICAL PROPERTIES

To enable proper control measures to be taken, provide all relevant information on the substance or preparation, particularly the information listed under heading 9.2. The information in this section shall be consistent with the information provided in a registration where one is required.

[55] **DE**: suggestion: "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 and/or use and exposure categories set out in the ~~annex to the~~ safety data sheet.

9.1. General information

Appearance

Indicate the physical state (solid, liquid, gas) and the colour of the substance or preparation as supplied.

Odour

If odour is perceptible, give a brief description of it.

9.2. Important health, safety and environmental information

pH

Indicate the pH of the substance or preparation as supplied or of an aqueous solution; in the latter case, indicate the concentration.

Boiling point/boiling range:

Flash point:

Flammability (solid, gas):

Explosive properties:

Oxidising properties:

Vapour pressure:

Relative density:

Solubility:

Water solubility:

Fat solubility (solvent – oil to be specified):[56]

Partition coefficient: n-octanol/water:

Viscosity:

Vapour density:

Evaporation rate:

[56] **UK**: This is not currently a data requirement under REACH (see general comments on SDS).

9.3. Other information

Indicate other important safety parameters, such as, miscibility, conductivity, melting point/melting range, gas group (useful for European Parliament and Council Directive 94/9/EC)[(footnote 5)], auto-ignition temperature etc.

Note 1

The above properties shall be determined in accordance with the specifications of Part A of Annex X or any other comparable method.

Note 2

For preparations, information shall normally be given on the properties of the preparation itself. However, if it is stated that a particular hazard does not apply, clearly differentiate between cases where no information is available to the classifier, and cases where negative test results are available. If it is considered necessary to give information about the properties of individual components, please indicate clearly what the data refers to.

10. STABILITY AND REACTIVITY

State the stability of the substance or preparation and the possibility of hazardous reactions occurring under certain conditions of use and also if released into the environment.

10.1. Conditions to avoid

List those conditions such as temperature, pressure, light, shock, etc., which may cause a dangerous reaction and if possible give a brief description.

10.2. Materials to avoid

List materials such as water, air, acids, bases, oxidising agents or any other specific substance which may cause a dangerous reaction and if possible give a brief description.

10.3. Hazardous decomposition products

List hazardous materials produced in dangerous amounts upon decomposition.

Note

Address specifically:

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

11. TOXICOLOGICAL INFORMATION[57]

This section deals with the need for a concise but complete and comprehensible description of the various toxicological (health) effects, which can arise if the user comes into contact with the substance or preparation.

The information shall include dangerous-to-health effects from exposure to the substance or preparation, based on[58], for example, test data and experience. The information shall also include, where appropriate, delayed, immediate and chronic effects from short- and long-term exposure: for example sensitisation, narcosis, carcinogenicity, mutagenicity and reproductive toxicity (developmental toxicity and fertility). It shall also include information on the different routes of exposure inhalation, ingestion, skin and eye contact), and describe the symptoms related to the physical, chemical and toxicological characteristics.

Taking account of the information already provided under heading 3, composition/information on ingredients, it may be necessary to make reference to specific health effects of certain substances in the preparation.

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[57] **BE**: The guidance given here should be more clearly detailed : effects, likely routes of exposure, related symptoms. Distinguish clearly information asked for a substance and for a preparation. (see also new chapter developed under GHS) This section should give an overview of the different toxicological effects of the substance(s), even if no registration is require:

- acute toxicity (numerical measures of toxicity should be provided)
- skin, respiratory, eyes irritation/corrosivity
- respiratory or skin sensitisation
- repeated dose toxicity
- CMR effects:
  - carcinogenicity
  - mutagenicity
  - toxicity for reproduction (developmental toxicity and fertility)

If delayed effects are expected : report it.
When human data are not available, animal data should be summarised and the species clearly identified. Provide information on the likely routes of exposure and the effects of the substance or mixture via each possible route of exposure. Symptoms related to the physical, chemical and toxicological characteristics are then summarised. If the data are missing for some effects: it should be clearly stated.

[58] **DK**: "The information shall include dangerous-to-health form exposure to the substance or preparation, based on the conclusion from, for example, test data and experience ..."

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 and shall give information on the following groups of potential effects:

– toxicokinetics, metabolism and distribution,

– acute effects (acute toxicity, irritation and corrosivity),

– sensitisation,

– repeated dose toxicity, and

– CMR effects (carcinogenity, mutagenicity and toxicity for reproduction).

For substances subject to registration, summaries of the information derived from the application of Annexes V to IX of this Regulation shall be given. The information shall also include the result of the comparison of the available data with the criteria given in Directive 67/548 [59] for CMR, categories 1 and 2, following Paragraph 1.3.1 of Annex I.

12. ECOLOGICAL INFORMATION

Describe the possible effects, behaviour and environmental fate of the substance or preparation in air, water and/or soil. Where available, give relevant test data (e.g. LC50 fish ≤ 1 mg/l)**.**

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.

Describe the most important characteristics likely to have an effect on the environment owing to the nature of the substance or preparation and likely [60]methods of use. Information of the same kind shall be supplied for dangerous products arising from the degradation of substances and preparations. This may include the following:

12.1. Ecotoxicity

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 preparation 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 V to IX of this Regulation shall be included.

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[59] **NL** Proposal (editorial): Directive 67/548/EEC

[60] **DE**: change as follows: ~~methods of~~ use and exposure categories

12.2. Mobility

The potential of the substance or the appropriate constituents of a preparation [(footnote 6)], if released to the environment, to transport to groundwater or far from the site of release.

Relevant data might include:

– known or predicted distribution to environmental compartments,

– surface tension,

– absorption/desorption.

For other physicochemical properties see heading 9.

12.3. Persistence and degradability

The potential of the substance or the appropriate constituents of a preparation (6) to degrade in relevant environmental media, either through biodegradation or other processes such as oxidation or hydrolysis. Degradation half lives shall be quoted where available. The potential of the substance or appropriate constituents of a preparation(6) to degrade in sewage treatment plants shall also be mentioned.

12.4. Bioaccumulative potential

The potential of the substance or the appropriate constituents of a preparation (6) to accumulate in biota and, eventually, to pass through the food chain, with reference to the octanol-water partition coefficient (Kow) and bioconcentration factor (BCF), if available.

12.5. Results of PBT assessment

Where a chemical safety report is required, the results of the PBT assessment as set in the Chemical Safety Report shall be given.

12.6. Other adverse effects

If available, include information on any other adverse effects on the environment, e.g. ozone depletion potential, photochemical ozone creation potential, endocrine disrupting potential and/or global warming potential.

Remarks

Ensure that information relevant to the environment is provided under other headings of the safety data sheet, especially advice for controlled release, accidental release measures, transport and disposal considerations under headings 6, 7, 13, 14 and 15.

13. DISPOSAL CONSIDERATIONS[61]

If the disposal of the substance or preparation (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.

Specify the appropriate methods of disposal of both the substance or preparation and any contaminated packaging (incineration, recycling, landfilling, etc.)

Where a chemical safety report is required, the information on the waste management measures that adequately control exposure of humans and the environment to the substance shall be consistent with the exposure scenarios set out in the annex to the safety data sheet.

Note

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.

14. TRANSPORT INFORMATION

Indicate any special precautions which a user needs to be aware of or needs to comply with in connection with transport or conveyance either within or outside his premises. Where relevant, provide information on the transport classification for each of the modal regulations: IMDG (sea), ADR (road, Council Directive 94/55/EC(9)), RID (rail, Council Directive 96/49/EC(10)), ICAO/IATA (air). This might include inter alia:

– UN number,

– class,

– proper shipping name,

– packing group,

– marine pollutant,

– other applicable information.

[61] **DE**: Against the background of existing national disposal legislation, further considerations and clarifications would be needed.

15. REGULATORY INFORMATION

Give the health, safety and environmental information shown on the label according to Directives 67/548/EEC and 1999/45/EC.

If the substance or preparation covered by this safety data sheet is the subject of specific provisions in relation to protection of man or the environment at Community level (e.g. authorisations given under Title VII or restrictions under Title VIII) these provisions shall, as far as is possible, be stated.

Also mention, where possible, the national laws which implement these provisions and any other national measures that may be relevant.[62]

16. OTHER INFORMATION

Indicate any other information which the supplier assesses as being of importance for the health and safety of the user and for the protection of the environment, for example:

– list of relevant R phrases. Write out the full text of any R phrases referred to under headings 2 and 3 of the safety data sheet,

– training advice,

– recommended restrictions on use (i.e. non-statutory recommendations by supplier),

– further information (written references and/or technical contact point),

– sources of key data used to compile the data sheet,

For a revised safety data sheet, indicate clearly the information, which has been added, deleted or revised (unless this has been indicated elsewhere).[63]

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[62] **HU**: Delete last sentence. 15. Reasons: the SDS has to be provided to users in various countries. Therefore it is uncertain who has to provide the translation in the language requested. Reference to national legislation might complicate the situation. Opposed by **DK**.

[63] **NL**: the date of the last revision of the Safety Data Sheet should also be mentioned. Proposal: Include 'data of the last revision of the Safety Data Sheet' as a requirement.

Footnote 2: OJ L131, 5.5.1998, p. 11.

Footnote 3: Where the person responsible for placing the preparation on the market can demonstrate that the disclosure in the safety data sheet of the chemical identity of a substance which is exclusively classified as:

– irritant with the exception of those assigned R41 or irritant in combination with one or more of the properties mentioned in point 2.3.4 of Article 10 of Directive 1999/ 45/EC, or

– harmful in combination with one or more of the properties mentioned in point 2.3.4 of Article 10 of Directive 1999/45/EC presenting acute lethal effects alone, will put at risk the confidential nature of his intellectual property, he may, in accordance with the provisions of Part B of Annex VI to Directive 1999/45/EC, refer to that substance either by means of a name that identifies the most important functional chemical groups, or by means of an alternative name.[64]

Footnote 4: OJ L399 30.12.1989 p. 18.

Footnote 5: OJ L100 19.4.1994 p. 1

Footnote 6: This information cannot be given for the preparation because it is substance specific. It should therefore be given, where available and appropriate, for each constituent substance in the preparation which is required to be listed in the safety data sheet according to the rules under heading 2[65] of this Annex.

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[64] **NL**: See general comment; Footnote 3 is not consistent with the option provided in Directive 1999/45/EC. Support to Cion Proposal: **DK**.

[65] **BE**: It should be heading 3 instead of heading 2 (order of these headings is reversed)