



REVISION 1
March 30th, 2011

Downstream Users of Chemicals Co-ordination group

Revision Management of Safety Data Sheets for preparations/mixtures complying with REACH and CLP Regulations

Revision 1 (Annex II requirements)

This document is providing guidance for creation and keeping up-to-date Safety Data Sheets (SDS) and Communication for preparations/mixtures in the supply chain according to the

- **REACH Regulation (EC N° 1907/2006)**
- **Amendment REACH Regulation (EU N° 453/2010)**
- **Classification, Labeling & Packaging of substances & mixtures (CLP) EC N°1272/2008**

DUCC proposal to keep information and communication Of Safety data Sheet (SDS) up-to-date and complete in a practical, workable and clear way, avoiding confusion in the supply chain¹

Recommendations²:

- Any downstream user should update the SDS for his preparation/mixture within a period of **6 months**, when new information (SDS) is available which affects Risk Management Measures (RMM), classification or any other major change (as defined below) for the classified substance or hazards is to be communicated.
- Any downstream user should update the SDS for his preparation/mixture within a period of **18 months**, for minor changes and when a complete set of all Exposure Scenarios for the classified substances of the preparation/mixture is available and no change in information - which may affect Risk Management Measures, Exposure Controls or hazards - needs to be communicated.
- Any downstream user should update the SDS for his preparation/mixture containing substances identified as Substances of Very High Concern (SVHC) within a period of **2 months** after receiving from its supplier a SDS for a Substance of Very High Concern either on its own or in one preparation/mixture or official addition of the substance to the candidate list
- Once Authorisation is **granted** for a substance, the SDS for the preparation/mixture containing this substance has to be updated within a time period of **3 months**³.
- Once Authorisation is **refused** (date of publication in the Official Journal of the European Union) for a substance, the substance has to be withdrawn immediately from the market or to be replaced in the preparation/mixture. The SDS for the preparation/mixture containing this substance has to be withdrawn / updated within a time period of **1 month**³.
- Once there is **restriction** for a substance (to be included in Annex XVII of REACH Regulation), the SDS for the preparation/mixture containing this substance (specific use restricted) has to be updated within a time period of **2 months**³.

**To facilitate full compliance, we generally recommend
an internal check of each SDS of a preparation/mixture at least every 24 months**

Note: label must be changed accordingly, when applicable.

Legal context: Art 31.9 - Suppliers shall update the safety data sheet without delay on the following occasions:

(a) as soon as new information which may affect the risk management measures, or new information on hazards becomes available; (b) once an authorisation has been granted or refused

¹ Information on substance is made available by the supplier SDS.

² This recommendation is based on legal requirements and industry agreed standards.

³ The time period starts at entry into force date (sunset date).

Definition “major” / “minor” change in SDS for Preparations/Mixtures

Due to the implementation of REACH and the CLP Regulation, a lot more information on substances will become available and needs to be implemented in the documentation for preparations/mixtures provided towards the downstream users.

Definition of a major change:

- Section 1: change in emergency telephone number(s) (only for the affected countries)
- Section 2: change in user classification of preparation/mixture, product identifier, additional warning phrases
- Section 2&15: change in authorisation (granting/refusal) or restriction of substances⁴
- Section 3: change/adding of a CMR 1 or 2 (CLP: CMR 1A or 1B) or PBT, vPvB, R50/53 (CLP: Aquatic acute cat 1- H400 / Aquatic chronic cat 1 - H410) or new SVHC
- Section 8: change in Personal Protective Equipment or Exposure engineering controls or Emission controls
- Section 14: change in transport classification of preparation/mixture (excl. tech. name(s) after PSN)
- Section 16 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, imposing more severe risk management measures

Definition of a minor change:

- All changes excluding major change
- Lay out change
- Section 2, 3 and 15: deletion of DSD or DPD-classification after addition of CLP-classification
- Section 8: change in OEL values of a substance, change in DNEL, PNEC, etc.
- Section 15: change/ addition in Detergent Regulation ranges
- Section 16: availability of Exposure Scenario(s) for the classified substances of the preparation/mixture with no effect on the PPE or Exposure engineering controls or Emission controls.

⁴ Section 2-15: Section 2 or 15 change in authorisation (granting-refusal) or restriction of substances (of very high concern), since according to Commission Regulation 453/2010 and Guidance on compilation of safety data sheets (draft October 2010)
Downstream users who include the substance subject to authorisation in a mixture, must include the authorisation number on the label according to article 65 of REACH, so If any component substance(s) is in the mixture is/are subject to authorisation, the authorisation number(s) must be included in section 2.2 of SDS on label elements (pages 10 and 44 of Guidance on compilation of safety data sheets - draft October 2010).
The section 15.1 of SDS refers that: "If the substance or mixture covered by this safety data sheet is the subject of specific provision 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."

Table: Major/minor changes with non-exhaustive examples

Section	Major change	Minor change
1	Emergency Telephone number(s)	Address / Product use
2 & 3	Addition of CLP-classification	Deletion of DSD, DPD-classification after addition of CLP-classification
2	Classification: Hazard symbol / Danger pictogram, product identifier, Risk phrases/Hazard statement, Signal word, Additional warning phrase	Safety phrases/Precautionary statements.
3	Change/add of CMR 1 & 2 (CLP: CMR 1A & 1B) or R50/53 (CLP: Aquatic acute cat 1- H400 / Aquatic chronic cat 1 - H410) or PBT, vPvB, and SVHC in the Hazardous Ingredients disclosure table	
2 & 15	Change in Authorisation or Restriction of substances	
8	Change in PPE or Exposure engineering controls or Emissions controls, OEL ⁵ (local)	OEL (EU)
14	Change of UN number, PSN, Class, PG or MP	Technical name after PSN
15		Other Additional warning phrase Detergent Declaration table Local data
16 Annex Extended SDS	Availability of exposure scenario for a risk determining substance which indicates a change in Risk Management Measures ⁶ (more stringent) Complete set of exposure scenarios available for all risk determining substances	Availability of Exposure Scenario(s) for the classified substances of the preparation/mixture with no effect on the PPE or Exposure controls
		REACH lay out change

⁵OEL changes: an OEL change is considered as a major change when this triggers a change in Classification and Labelling or Risk Management Measures.

From a legal point of view, when the national OEL is modified, then the local SDS preferably should be changed.

⁶The DPD+ method is currently the preferred method for the identification of substances in preparations/mixtures that rise to the highest risk level (per endpoint). Selection of ES information and its communication will therefore focus on those Lead substances. For more information on DPD+ see CEFIC practical guidance on Exposure Assessment and Communication in the Supply Chains -Part III: Mixtures under REACH. http://www.cefic.org/Documents/PolicyCentre/REACH_Practical_Guide_Part_III_Mixtures_FINAL_CEFIC.pdf

The relevant Exposure Scenario information of the lead substance(s) will be included into the Annex of the preparation/mixture SDS in order to ensure that the risks of these substances are adequately controlled. It is not applicable to preparations/mixtures containing substances which are classified as category 1A or 1B, mutagenic or reprotoxic or as respiratory sensitizers, and PBT- or vPvB-substances. Other possible options: Forward the substance ES without any changes; or consolidate the substance ES into a new Exposure Assessment for the preparation/mixture; or extract the relevant information to include in the main body (sections) of the SDS.

Back-Up information /Legal text

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
(Official Journal of the European Union L 396 of 30 December 2006)

TITLE IV **INFORMATION IN THE SUPPLY CHAIN**

Article 31 **Requirements for Safety Data Sheets**

1. The supplier of a substance or a preparation shall provide the recipient of the substance or preparation with a safety data sheet compiled in accordance with Annex II:
 - (a) Where a substance or preparation 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).
2. Any actor in the supply chain who is required, under Articles 14 or 37, to carry out a chemical safety assessment for a substance shall ensure that the information in the safety data sheet is consistent with the information in this assessment. If the safety data sheet is developed for a preparation and the actor in the supply chain has prepared a chemical safety assessment for that preparation, it is sufficient if the information in the safety data sheet is consistent with the chemical safety report for the preparation instead of with the chemical safety report for each substance in the preparation.
7. *Any actor in the supply chain who is required to prepare a chemical safety report according to Articles 14 or 37 shall place the relevant exposure scenarios (including use and exposure categories where appropriate) in an annex to the safety data sheet covering identified uses and including specific conditions resulting from the application of Section 3 of Annex XI.*

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

Any distributor shall pass on relevant exposure scenarios, and use other relevant information, from the safety data sheet supplied to him when compiling his own safety data sheet for uses for which he has passed on information according to Article 37(2).
8. A safety data sheet shall be provided free of charge on paper or electronically.
9. **Suppliers shall update the safety data sheet without delay on the following occasions:** (See Note 1)
 - (a) **as soon as new information which may affect the risk management measures, or new information on hazards becomes available;**
 - (b) **once an Authorisation has been granted or refused;**
 - (c) **once a restriction has been imposed.**

The new, dated version of the information, identified as 'Revision: (date)', shall be provided free of charge on paper or electronically to all former recipients to whom they have supplied the substance or preparation within the preceding 12 months. Any updates following registration shall include the registration number.

Article 32

Duty to communicate information down the supply chain for substances on their own or in preparations for which a Safety Data Sheet is not required

1. Any supplier of a substance on its own or in a preparation who does not have to supply a safety data sheet in accordance with Article 31 shall provide the recipient with the following information:
 - (a) the registration number(s) referred to in Article 20(3), if available, for any substances for which information is communicated under points (b), (c) or (d) of this paragraph
 - (b) if the substance is subject to Authorisation and details of any Authorisation granted or denied under Title VII in this supply chain;
 - (c) details of any restriction imposed under Title VIII;
 - (d) 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.
2. The information referred to in paragraph 1 shall be communicated free of charge on paper or electronically at the latest at the time of the first delivery of a substance on its own or in a preparation after 1 June 2007.
3. **Suppliers shall update this information without delay on the following occasions:** ^(see note 2)
 - (a) as soon as new information which may affect the risk management measures, or new information on hazards becomes available;**
 - (b) once an Authorisation has been granted or refused;**
 - (c) once a restriction has been imposed.**

In addition, the updated information shall be provided free of charge on paper or electronically to all former recipients to whom they have supplied the substance or preparation within the preceding 12 months. Any updates following registration shall include the registration number.

Article 34

Duty to communicate information on substances and preparations up the supply chain

Any actor in the supply chain of a substance or a preparation shall communicate the following information to the next actor or distributor up the supply chain:

- (a) new information on hazardous properties, regardless of the uses concerned;
- (b) any other information that might call into question the appropriateness of the risk management measures identified in a safety data sheet supplied to him, which shall be communicated only for identified uses.

Distributors shall pass on that information to the next actor or distributor up the supply chain.

TITLE V DOWNSTREAM USERS

Article 37

Downstream user chemical safety assessments and duty to identify, apply and recommend risk reduction measures

1. A downstream user or distributor may provide information to assist in the preparation of a registration.
2. Any downstream user shall have the right to make a use, as a minimum the brief general description of use, known in writing (on paper or electronically) to the manufacturer, importer, downstream user or distributor who supplies him with a substance on its own or in a preparation with the aim of making this an identified use. In making a use known, he shall provide sufficient information to allow the manufacturer, importer or downstream user who has supplied the substance, to prepare an exposure scenario, or if appropriate a use and exposure category, for his use in the manufacturer, importer or downstream user's chemical safety assessment. Distributors shall pass on such information to the next actor or distributor up the supply chain. Downstream users in receipt of such information may prepare an exposure scenario for the identified use(s), or pass the information to the next actor up the supply chain.
3. For registered substances, the manufacturer, importer or downstream user shall comply with the obligations laid down in Article 14 either before he next supplies the substance on its own or in a preparation to the downstream user making the request referred to in paragraph 2 of this Article, provided that the request was made at least one month before the supply, or within one month after the request, whichever is the later.
For phase-in substances, the manufacturer, importer or downstream user shall comply with this request and with the obligations laid down in Article 14 before the relevant deadline in Article 23 has expired, provided that the downstream user makes his request at least 12 months before the deadline in question.
Where the manufacturer, importer or downstream user, having assessed the use in accordance with Article 14, is unable to include it as an identified use for reasons of protection of human health or the environment, he shall provide the Agency and the downstream user with the reason(s) for that decision in writing without delay and shall not supply downstream user(s) with the substance without including these reason(s) in the information referred to under Articles 31 or 32. The manufacturer or importer shall include this use in Section 3.7 of Annex VI in his update of the registration in accordance with Article 22(1)(d).
4. A downstream user of a substance on its own or in a preparation shall prepare a chemical safety report in accordance with Annex XII for any use outside the conditions described in an exposure scenario or if appropriate a use and exposure category communicated to him in a safety data sheet or for any use his supplier advises against.
A downstream user need not prepare such a chemical safety report in any of the following cases:
a safety data sheet is not required to be communicated with the substance or preparation in accordance with Art. 31;
(a) a chemical safety report is not required to be completed by his supplier in accordance with Article 14; 29.5.2007 EN Official Journal of the European Union L 136/37;
(b) the downstream user uses the substance or preparation in a total quantity of less than one ton per year;
(c) the downstream user implements or recommends an exposure scenario which includes as a minimum the conditions described in the exposure scenario communicated to him in the safety data sheet;
(d) the substance is present in a preparation in a concentration lower than any of the concentrations set out in Art.14(2);
(e) the downstream user is using the substance for the purposes of product and process oriented research and development, provided that the risks to human health and the environment are adequately controlled in accordance with the requirements of legislation for the protection of workers and the environment.
5. Any downstream user shall identify, apply and where suitable, recommend, appropriate measures to adequately control risks identified in any of the following:
(a) the safety data sheet(s) supplied to him;
(b) his own chemical safety assessment;
(c) any information on risk management measures supplied to him in accordance with Article 32.
6. Where a downstream user does not prepare a chemical safety report in accordance with paragraph 4(c), he shall consider the use(s) of the substance and identify and apply any appropriate risk management measures needed to ensure that the risks to human health and the environment are adequately controlled. Where necessary, this information shall be included in any safety data sheet prepared by him.
7. Downstream users shall keep their chemical safety report up to date and available.
8. A chemical safety report prepared in accordance with paragraph 4 of this Article need not include consideration of the risks to human health from the end uses set out in Article 14(5).

Article 39
Application of downstream user obligations

1. Downstream users shall be required to comply with the requirements of Article 37 at the latest **12 months** after receiving a registration number communicated to them by their suppliers in a safety data sheet.

(See Note 1)

- 9 (a) Applicable for substances and / or preparations/mixtures
- 9 (b) Applicable for substances
- 9 (c) Applicable for substances and / or preparations/mixtures

(See Note 2)

- 3 (a) Applicable for substances and / or preparations/mixtures
- 3 (b) Applicable for substances
- 3 (c) Applicable for substances and / or preparations/mixtures

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
(EC) No 1272/2008

on classification, labelling and packaging of substances and mixtures,

and amending Directive 67/548/EEC and Regulation (EC) No 1907/2006

Article 30

Updating information on labels

1. The supplier shall ensure that the label is updated, without undue delay, following any change to the classification and labeling of that substance or mixture, where the new hazard is more severe or where new supplemental labeling elements are required under Article 25, taking into account the nature of the change as regards the protection of human health and the environment. Suppliers shall co-operate in accordance with Article 4(9) to complete the changes to the labeling without undue delay.
2. Where labeling changes are required other than those referred to in paragraph 1, the supplier shall ensure that the label is updated within 18 months.

(26) "Supplier" means any manufacturer, importer, downstream user or distributor placing on the market a substance, on its own or in a mixture, or a mixture;