

European Photo and Imaging Association¹

EPIA REACH Information document SDS Requirements

Requirements for Safety Data Sheets under REACH²

- ⇒ **Overview of REACH requirements for Safety Data Sheets (article 31 and Annex II)**
- ⇒ **Changes in the SDS content with respect to DIR 2001/58/EC**
- ⇒ **Guidance regarding the practical implementation problems in relation to the immediate application on 1 June 2007**

I. Overview of REACH requirements for Safety Data Sheets

Obligations under REACH regarding Requirements for Safety Data Sheets are laid down in Article 31. Safety Data Sheets have to be compiled in accordance with Annex II.

When (in which cases)

The supplier of a substance or preparation has the **legal obligation to deliver a SDS** (article 31.1):

- for dangerous substances and preparations
- for PBT- and vPvB-substances (new)
- for other substances in the Candidate List (new)

The supplier of a **preparation that is not dangerous** must deliver a **SDS at the request** of his customer **if it contains at least one** (article 31.3):

- dangerous substance ≥ 1 % w/w for non-gases or ≥ 0.2 % vol/vol for gases
- PBT- , vPvB- or Candidate List substance ≥ 0.1 % w/w (new)
- substance for which there are Community workplace exposure limits

The supplier of a dangerous substance or preparation **sold to the general public** must provide sufficient information to enable safe use and must deliver a **SDS to a downstream user or distributor at their request** (article 31.4).

How

The SDS must be **compiled in accordance with Annex II** (article 31.1), **dated** (article 31.6) and written in an **official language of the Member State of the customer** (article 31.5).

It must be supplied **free of charge**, on **paper or electronically** (article 31.8).

¹ EPIA represents photo imaging companies and European national associations of photo imaging companies. The membership includes the major manufacturers of photographic products and the major national associations CIPHO (Chemieverband Imaging und Photo e.V.), PIC (Photo Imaging Council) and Federchimica.

² 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).

Updates

The supplier must **update** the SDS (article 31.9):

- when significant new information is available
- once authorisation has been granted or refused (new)
- once a restriction has been imposed (new)

The updated SDS must be dated and identified as "Revision: (date)". The supplier must provide it free of charge on paper or electronically to all former customers to whom he has supplied the substance or preparation within the preceding 12 months.

Any updates following registration shall **include the registration number**.

Extended SDS (new)

The supplier of a **substance**, on its own or in a preparation, that is **subject to performing a chemical safety assessment and completing a chemical safety report** (article 14 or 37), has the legal obligation to deliver an **extended SDS** and must **add the relevant exposure scenarios** (including use and exposure categories where appropriate) **in an annex to the SDS** (article 31.7).

The information in the SDS must be consistent with the information of the chemical safety assessment (article 31.2).

The information given in the extended SDS must be used by actors down the supply chain when compiling their own SDS for identified uses (downstream user, distributor) (article 31.7).

More details regarding the issue of carrying out a chemical safety assessment and completing a chemical safety report, will be subject to a future dedicated EPIA Guidance Document.

The full text of the relevant sub-articles is given below:

When (in which cases)

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).*
3. *The supplier shall provide the recipient at his request with a safety data sheet compiled in accordance with Annex II, where a preparation does not meet the criteria for classification as dangerous in accordance with Articles 5, 6 and 7 of Directive 1999/45/EC, but contains:*
 - (a) *in an individual concentration of ≥ 1 % by weight for non-gaseous preparations and $\geq 0,2$ % by volume for gaseous preparations at least one substance posing human health or environmental hazards; or*
 - (b) *in an individual concentration of $\geq 0,1$ % by weight for non-gaseous preparations 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.*

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

How

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:*

5. *The safety data sheet shall be supplied in an official language of the Member State(s) where the substance or preparation is placed on the market, unless the Member State(s) concerned provide otherwise.*

6. *The safety data sheet shall be dated and shall contain the following headings: (+ 16 section headings)*
note: section 2 and 3 are interchanged as compared to DIR 2001/58/EC

8. *A safety data sheet shall be provided free of charge on paper or electronically.*

Updates

Article 31: Requirements for Safety Data Sheets

9. *Suppliers shall update the safety data sheet without delay on the following occasions:*

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

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

Extended SDS (new)

Article 31: Requirements for Safety Data Sheets

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).

II. Changes in the SDS content with respect to DIR 2001/58/EC

As previously stated the SDS must be **compiled in accordance with Annex II** (article 31.1). In this Annex the full text of guidance to the compilation of SDSs under REACH is given.

Overview of main changes

- **Section 1: addition of e-mail address of the competent person responsible for the SDS**
- **Section 2 and Section 3 have to be interchanged** (adoption of the order in GHS)
- **Section 3: the presence of PBT and vPVB substances $\geq 0.1\%$ w/w must be mentioned in the SDS of all preparations, dangerous and non-dangerous**
- **extended Safety Data Sheet: for substances subject to performing a chemical safety assessment and completing a chemical safety report: an annex of the Safety Data Sheet must be made to describe the relevant exposure scenario(s)**

Detailed changes per Section

- **Section 1: Identification of the substance/preparation and of the company/undertaking**

Annex II, 1.1. Identification of the substance or preparation

... For substances subject to registration, the term shall be consistent with that provided under registration and the registration number assigned under Article 20(1) of this Regulation shall also be indicated.

Annex II, 1.2. Use of the substance/preparation

... Where a Chemical Safety Report is required, the Safety Data Sheet shall contain information on all the identified uses relevant to the recipient of the Safety Data Sheet. This information shall be consistent with the identified uses and exposure scenarios set out in the annex to the Safety Data Sheet.

Annex II, 1.3. Company/undertaking identification

Identify the person responsible for placing the substance or preparation on the market within the Community, whether it is the manufacturer, importer or distributor. Give the full address and telephone number of this person as well as the e-mail address of the competent person responsible for the Safety Data Sheet.

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

Annex II, 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). Specify if this phone number is available only during office hours.

- **The order of Section 2 and Section 3 has to be interchanged**

To promote broad international consensus the REACH Regulation takes account of existing and emerging international standards in the regulation of chemicals such as the Globally Harmonised System (GHS) of classification and labelling of chemicals.

As a result REACH requires to interchange Section 2 and Section 3 as compared to DIR 2001/58/EC and the REACH headings will be as follows:

Heading section 2: Hazards identification

Heading section 3: Composition/Information on ingredients

- **Section 2: Hazards identification**

Annex II, 2. Hazards identification

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

- **Section 3: Composition/information on ingredients**

Annex II, 3.2.

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 in the preparation:

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(c) substances that are persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII, if the concentration of an individual substance is equal to or greater than 0,1 %.

Annex II, 3.3.

3.3. For a preparation not classified as dangerous according to Directive 1999/45/EC, the substances shall be indicated, together with their concentration or concentration range, if they are present in an individual concentration of either:

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(b) ≥0,1 % by weight and the substances are persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII.

Annex II, 3.4.

3.4. The classification (derived either from Articles 4 and 6 of Directive 67/548/EEC, from Annex I to Directive 67/548/EEC or from an agreed entry in the classification and labelling inventory established under Title XI of this Regulation) of the above substances shall be given, including the symbol letters and R phrases which are assigned in accordance with their physicochemical, human health and environmental hazards.

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If the substance does not meet the classification criteria, the reason for indicating the substance in section 3 shall be described, such as "PBT-substance" or "substance with a Community workplace exposure limit".

Annex II, 3.5.

3.5. The name and the Registration number, assigned under Article 20(1) of this Regulation, EINECS or ELINCS number, if available, 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 Section 3.3 of this Annex, a precise chemical identifier is not necessary.

- **Section 7: Handling and storage**

Annex II, 7. Handling and storage

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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.

- **Section 8: Exposure controls/personal protection**

Annex II, 8.1. Exposure limit values

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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.

Annex II, 8.2. Exposure controls

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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.

Annex II, 8.2.2. Environmental exposure controls

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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.

- **Section 9: Physical and chemical properties**

Annex II, 9. Physical and chemical properties

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The information in this section shall be consistent with the information provided in a registration where one is required.

- **Section 11: Toxicological information**

Annex II, 11. Toxicological information

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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 (carcinogenicity, mutagenicity and toxicity for reproduction).

For substances subject to registration, summaries of the information derived from the application of Annexes VII to XI 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/EEC for CMR, categories 1 and 2, following paragraph 1.3.1 of Annex I of this Regulation.

- **Section 12: Ecological information**

Annex II, 12. Ecological information

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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.

Annex II, 12.1 Ecotoxicity

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For substances subject to registration, summaries of the information derived from the application of Annexes VII to XI shall be included.

Annex II, 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.

- **Section 13: Disposal considerations**

Annex II, 13. Disposal considerations

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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.

- **Section 15: Regulatory information**

Annex II, 15. Regulatory information

Indicate if a Chemical Safety Assessment has been carried out for the substance (or a substance in the preparation).

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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.

- **extended Safety Data Sheet**

Annex II, Guide to the compilation of Safety Data Sheets

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Where a Chemical Safety Report has been performed, the relevant exposure scenario(s) shall be placed into an annex of the Safety Data Sheet, to make reference to them under the relevant headings of the Safety Data Sheet easier.

III. Guidance regarding the practical implementation problems in relation to the immediate application on 1 June 2007

As previously stated obligations under REACH regarding requirements for Safety Data Sheets are laid down Article 31, which is part of Title IV "Information in the supply chain". Title IV of the REACH Regulation enters into force on 1 June 2007 (article 141), without any transition period.

As a result the changes listed in chapter II of this EPIA Information document should be implemented overnight which causes practical implementation problems.

Discussion in the "Commission Working Group on the Practical Preparations for REACH" (DG ENV)

The practical problems in relation to the immediate application of the REACH requirements for Safety Data Sheets on 1 June 2007 were discussed in the "Commission Working Group on the Practical Preparations for REACH" (CWG) of March 13, 2007.

All member states supported a flexible and pragmatic approach to enforcing the administrative changes, i.e. the reversed order of chapters 2 and 3 and the addition of the e-mail address of the responsible person.

The Chair concluded that there was consensus that the content, not the format, of the safety data sheet is the priority for the enforcement and that the changes required by REACH, i.e. the changed order of sections 2 and 3 and the addition of the e-mail address can be introduced when (substantial) changes/up-dates are made of the safety data sheet. A substantial change could be the classification according to GHS or the addition of exposure scenarios. The changes required by REACH should however be introduced before the first dead-line for registration on 1 December 2010.

This conclusion will be recorded in the official minutes of the Commission Working Group meeting.

Application of the REACH requirements for Safety Data Sheets on 1 June 2007: conclusion

- **REACH compliant SDSs are required from 1 June 2007 in case of new SDSs and when (substantial) changes/updates are made** (a substantial change could be a change in classification, the introduction of the classification according to GHS or the addition of an exposure scenario when it becomes available)
- **No need to revise all existing SDSs for the sole purpose of administrative changes required by REACH** (i.e. the changed order of Sections 2 and 3 and the addition of the e-mail address)
- **The changes required by REACH should however be introduced before the first dead-line for registration on 1 December 2010.**

Disclaimer

The present document was developed by experts from the photochemical industry to their best knowledge and judgement, but no liability whatsoever is accepted in respect of this document. The text of the REACH Regulation is decisive in all cases.