SDS Template Guide

Introduction

This guide includes a template based on guidance covering Annex II of REACH. A lot of emphasis is put on the template by industry and regulators and although open to legal interpretation whether certain headings and sub-headings need to be written in such a precise way, it is strongly recommended to follow guidance closely in this matter – inspecting agencies across Europe are certainly interpreting guidance as mandated.

However, the SDS template is not a form to be filled in and simply entering text into a field without thought is not acceptable. Within the confines of this rigid template, the challenge is to provide concise, easy-to-read and relevant information to help the recipient act safely when handling your product. They want to know what to do in their working environment when receiving product in the types and sizes of containers you sell.

What practical action should the user take to minimize exposure and what should they do if it goes wrong ?

Timing for changes

All new SDS and revisions should now be following the attached template and as products get labeled to CLP, it is essential that the labelling details in Section 2 are changed to reflect the labels. After 2017, the old Dangerous Substances Directive labeling details can be phased out.

Revisions are needed if the incoming SDS from your supplier gives new information, or if you have found out about other newly identified hazards, restrictions on use, new classifications etc (ie from public sources, such as the ECHA web-site), you are obliged to act on these 'without delay'. The action is to limit uses and applications, change your SDS / labelling or provide the details in an Annex to the SDS as an exposure scenario.

At no point is the term 'without delay' or as soon as possible defined and nor does the legal text tell you what is 'significant new information'. Guidance provides some help (significant means worse or tougher controls). As soon as possible needs to be considered in the context of having to explain to a judge why you failed to warn workers or customers of information you knew about at the time of someone being harmed through lack of control, but had not got around to warning them. How you warn them (ES or simply an enhanced, more detailed, SDS) is your decision.

Until 2018, there is going to be a lot of examples where some suppliers have extended SDS and others are still working on limited data as registrations have not yet been put in place.

However, to put it simply, if you have been informed of something by a supplier, a potential supplier (ie competitor to your actual supplier) or could be reasonably expected to find out (eg looking on ECHA web-site), and you need to tighten the warnings or improve RMM, then you should do something about it without delay.

The vagueness of the legal text might appear to give industry flexibility, but it also gives regulators flexibility in their enforcement.

SAFETY DATA SHEET

Issue Date: [this is not the 'printing date' (as seen on some SDSs), but is the date that the current version was issued]
Version number:
Revision / Cancels: [this needs to identify the previous version to enable version control. Old versions need to be retained on file and revisions given to customers who had previously received the hazardous substance/ mixture. Changes need identifying in Section 16]

SECTION 1 IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product Identifier
[Must be consistent with the label. One SDS can be used to cover a range of similar mixtures that have the same low hazard and same risk management, but in this case, all names of these mixtures must be included.

For substances, the full name and identifiers must be given, including REACH registration number of the manufacturer or import of this specific material if registered]

1.2 Relevant identified uses of the substance or mixture and uses advised against
[Generic details of use (eg 'detergent', 'industrial solvent' etc) and precise details are not needed. ECHA discourages the use of the Registration codes found in Chapter R-12 of ECHA guidance, but many suppliers still add them here, citing 'customer pressure']

1.3 Details of the supplier of the substance or mixture
[Address of responsible EU supplier and/or local address in Member State if being placed on the market in other member states. Note, that this may also require translation to the appropriate local language. This includes importers, even if an Only Rep has made the registration.
The non-EU supplier may be identified for information, but responsible EU legal entity must be given.]

1.4 Emergency Telephone (office hours):

For Technical Queries contact: [include e mail that will be checked by competent people, but does not have to give name of person]

SECTION 2 HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture [CLP classification]

2.2 Label elements [Consistent with the label. Pictograms may be used (in black and white if necessary), but this is not obligatory. It is recommended.]

[Note: until 2017, the old Dangerous Substances/Preparation Directive labeling must also appear here]

2.3 Other hazard information: [overview of key hazards]

- Ingestion
- Skin Contact
- Eye Contact
- Inhalation
- Environment (vPvB / PBT)

Additional Information [anything else likely to cause a problem]

SECTION 3 INFORMATION ON THE INGREDIENTS

3. 1 Substances [For substances, indicate the purity and any other substance present such as additives. Should be consistent with REACH registration where appropriate]

3.2 Mixtures [For mixtures, components considered hazardous need to be listed if above their relevant thresholds of concern. These are 1% for lower classes of hazard or 0.1% for sensitisers, Cat. 1 acute toxic, CMR, PBT, vPvB and Cat. Acute of chronic aquatic toxicity. Annex II gives the full details. Annex I of CLP provides the generic thresholds of concern, but Annex VI of CLP may contain specific limits.
The classification of these components must be identified (CLP and DSD/DPD until 2017)
The concentrations of these components needs to be given and each correctly named with correct identifiers (eg EC number, Registration number if registered under REACH); ranges of concentrations can be given, but the classification of the mixture needs to relate to the highest concentration levels in the range.
Confidentiality can be sought for components and application can be made to use generic names for 'generic' hazards such as irritant or harmful and for physical hazards. It may be necessary to make a formal application to use a masked name.]

SECTION 4 FIRST AID MEASURES

4.1 Description of first aid measures [make sure these are sensible, appropriate and achievable by the skill of the anticipated user. Do not suggest 'medical attention' all the time for low hazard materials].

Ingestion
Skin
Eyes
Inhalation

4.2 Most important symptoms and effects, both acute and delayed

Ingestion
Skin
Eyes
Inhalation

4.3 Indication of immediate medical attention and special treatment needed

[Consider specific instructions that relate to the hazardous properties, and can help first aid to be directed at the most important symptoms. Especially important for STOT (systemic toxic) materials]

SECTION 5 FIRE-FIGHTING MEASURES

5.1 Extinguishing media
Small fires [define 'large and small, perhaps relating to the sizes of containers you sell]
Large fires
[Select extinguishing media appropriate to surrounding area.
Extinguishing media considered incompatible with product]

5.2 Special hazards arising from the substance or mixture
[Specific chemical hazards, such as oxidising or if the material produces hazardous gases or by-products from combustion]

5.3 Special protective actions for fire-fighters
[Specific procedures or requirements, bearing in mind professional fire-fighters will have their own agenda for tackling major incidents]

SECTION 6 ACCIDENTAL RELEASE OF MATERIAL

6.1 Personal precautions, protective equipment and emergency procedures
[Consider appropriate action for professional emergency services or for user to clean up. This may relate to large or small spills (define, for example < 5 litres) and to the type of use and users. If used by professionals outside chemical factories, the skill of the user at cleaning hazardous chemicals need to be considered]

1.2 Environmental Precautions
[Again, relate to the size and nature of spill in relation to exposures defined in the ES.]

1.3 Methods and material for containment and cleaning up
[Needs to be practical for users identified in the ES and may differ between identified users and size of containers. Specify if special cleaning methods are needed or neutralising agents are needed. Any special training?]

SECTION 7 HANDLING AND STORAGE

[Section must be consistent with Exposure Scenarios and CSR (where needed for substances) and relate to the uses identified in Section 1. Note that Section 7 provides an overview to safe handling, where-as Section 8 goes into more detail for control measures and exposure limits. There is some overlap but general statements can go into Section 7 and details in Section 8]

7.1 Precautions for safe handling
[Include precautions such as prevention of dust, loss to the environment, and if specific handling controls are needed.
Consider general hygiene such as washing hands, clothing and equipment]

7.2 Conditions for safe storage, including any incompatibilities
[Consider physical (flammable) hazards as well as safety and the environment. May need to consider storage away from general public depending on the type of use (specified in Exposure Scenarios).
If oxidising or reducing agent, special storage conditions are needed]

7.3 Specific end uses
[May be sufficient to refer to attached Exposure Scenarios; chance to add any specific comments on specific uses]

SECTION 8 EXPOSURE CONTROLS / PERSONAL PROTECTION

[Consistent with Exposure Scenarios]

8.1 Control parameters
[Enter workplace exposure limits and for registered substances with agreed Derived No Effect Levels (DNEL or DMEL) and environmental Predicted No Effect Concentrations (PNEC). EC occupational

exposure limit values are defined in Article 2(d) of Directive 98/24/EC and need to be checked for current figures. National limits may be added here or in Section 15 'Regulatory Information'.
For mixtures, the limits and DNEL / PNEC must be reported for each hazardous substance present that contribute to the hazard of the mixture.
Biological limit values need to be considered to determine if the components are above or below any such limits.]

8.2 Exposure controls
[Typically, reference to attached Exposure Scenarios will be sufficient for detailed information, but add key details in this section – it is likely that many readers will quickly get bored and fail to wade through Exposure Scenarios.
If area needs to be 'well ventilated', specify conditions for ventilation (air exchanges etc) that is consistent with DNELs for inhalation for workplace use.

Eye / face protection
Skin protection
Respiratory protection
Other
Thermal hazards

Personal hygiene precautions such as gloves, coveralls, goggles etc. Where appropriate, consider the materials for gloves etc. and try to avoid use of trade names. Help in determining the type of glove may include help in the type of material (eg 'resistant to organic acids' etc)
Consider 'thermal' hazards if exposure scenarios predict use of heated material.]

8.3 Environmental exposure controls
[Add any specific environmental controls (eg, bunding, intercept of waste water etc) consistent with the Exposure Scenario and Section 13 covering disposal]

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties
[if not applicable, it needs to be stated why. New parameters can be added if needed.
Use correct EU units and avoid vague descriptions such as 'poorly soluble', 'high melting point', 'not very viscous']
Appearance [at temperatures of use, defined in exposure scenarios]
Odour
Odour threshold
pH [concentration in water?]
Freezing/Melting Point (degree C)
Initial boiling point and boiling range
Flash Point (degree C)
Evaporation rate
Flammability (solids and gases)
Upper/lower flammability or explosive limits
Vapour Pressure, Pa at temperature degree C [for mixtures, consider presence of solvents and water]
Relative Density (at degree C)
Solubility in water and solvents (mg/l)
Partition coefficient [for mixtures, it may be appropriate to report partition coefficients for key components]
Autoignition temperature (degree C)
Decomposition temperature (degree C)
Viscosity (at degree C)
Explosive properties

Oxidising properties

9.2 Other information
Other physical and chemical parameters such as miscibility, fat solubility (solvent – oil to be specified), conductivity, or gas group

[The data in this section needs to relate to the substance or mixture being supplied. For substances, these properties will relate to those determined for registration and used for the CSR (if appropriate). For mixtures, the properties of the mixture must be reported. For example, an aqueous solution will take on many properties of water, including vapour pressure, partition coefficient, boiling point, and special care is needed to ensure that the correct physical properties are reported]

SECTION 10 STABILITY AND REACTIVITY

[This section is less to do with shelf-life than dangerous decomposition and hazards from breakdown and reactivity. The Exposure Scenarios will need to take all this into account. The precautions need to be practical and relevant for identified uses and the skill levels of users.]

10.1 Reactivity
[Reactive with other chemicals if mixed or used at the same time?]

10.2 Chemical stability

10.3 Possibility of hazardous reactions

10.4 Conditions to Avoid
[Consider sparking for organic powders that may have a risk of explosion]

10.5 Incompatible materials

10.6 Hazardous decomposition products
[Such as flammable gases, toxic materials etc]

SECTION 11 TOXICOLOGICAL INFORMATION

[For substances, this is consistent with the data for registration (if applicable) and should agree with harmonised classification and labelling or at least consistent with industry agreed classification. For mixtures, the acute toxicity and irritation / corrosion of the mixture may be more relevant to the reader than the properties of the components, but for longer-term toxicity (including CMR effects) and systemic effects (STOT and sensitising) the properties of the specific components may be more relevant.

If there is no data on the mixture, end points must be estimated; it is not sufficient to state that ‘no data are available’.]

11.1 Information on toxicological effects
[The use of units and terminology must be precise and phases such as ‘low toxicity’ need to be avoided unless fully qualified. If the substance or mixture is not classified in relation to a specific end-point, any hazards below the threshold for classification need to be put into context; eg mild irritant to eyes, but not sufficient to cause classification’. This will avoid confusion to the reader.]

(a) acute toxicity

[Oral, dermal and inhalation or other routes as appropriate for Exposure Scenarios for the substance or mixture- note that exposure to formulated product may be different to the exposure to the substance]

(b) skin corrosion/irritation

(c) serious eye damage/irritation

(d) respiratory or skin sensitisation
[Convention is that skin sensitisers should be considered an inhalation sensitiser if there is a risk of inhalation; for mixtures, consider enhanced risk of inhalation as a result of formulation changes]

(e) germ cell mutagenicity
[Data may be limited and assumptions may need to be made according to mutagenicity endpoints or reference to class of substance]

(f) carcinogenicity
[Data may be limited and assumptions may need to be made according to mutagenicity endpoints or reference to class of substance]

(g) reproductive toxicity
[Data may be limited and assumptions may need to be made through reference to class of substance]

(h) STOT-single exposure
[Specific organ effects from acute studies]

(i) STOT-repeated exposure
[Specific organ effects from repeat exposure studies]

(j) aspiration hazard.
[Only relevant for low viscosity organic substances]

[If data is missing, justification is needed and best-estimates should be made, giving a justification for that estimate]

[Any other relevant information should be added]

SECTION 12 ECOLOGICAL INFORMATION

[This section is very much like Section 11 in that for substances, this is consistent with the data for registration (if applicable) and should be consistent with classification. However, unlike the mammalian toxicity, the impact of mixing substances is less important since mixtures will be diluted greatly when in the environment and components will not interact. Therefore, data should be reported in terms of components.]

[It is not sufficient to state that ‘no data are available’ when components have been registered under REACH and data is available on these components. This is especially important for persistence and accumulation potentials; each component must be considered.]

[Statements such as ‘all organic components are considered biodegradable’ are acceptable, but the term ‘biodegradable’ may need to be qualified if the product is covered by the Detergents Regulation.]

12.1 Toxicity

[Key organisms such as fish, Daphnia, algae, sludge bacterial inhibition, earthworms, higher plants etc. Use correct units and check against reported water solubility. Estimate effects of mixtures or diluted materials. If solubility in water is < 100 mg/l, water accommodated fraction .
PNECs need to be added for each key component with a potential for biological impact].

12.2 Persistence and degradability
[Biodegradation data and other breakdown processes. For mixtures, each component will need separate consideration]

12.3 Bioaccumulative potential
The partition coefficient may give an indicator if now specific test data available. For mixtures, each component will need separate consideration]

12.4. Mobility in soil
The partition coefficient and adsorption coefficient may give an indicator if now specific test data available. For mixtures, each component will need separate consideration]

12.5. Results of PBT and vPvB assessment
[The PBT / vPvB potential must be assessed for substances being registered and for mixtures, each component will need separate consideration]

12.6. Other adverse effects
[For mixtures, each component will need separate consideration]

SECTION 13 DISPOSAL CONSIDERATIONS

[Consistent with Exposure Scenarios]

13.1 Waste treatment methods
[Do not simply sate 'in accordance with local regulations' but give positive suggestions in agreement with the conditions of the Exposure Scenarios. Quantify disposal in accordance with use patterns (eg. If sold in 5 litre packs, disposal of 5 litres will be of interest). Remember that sending for 'chemical waste disposal and incineration' is expensive not practical for non-industrial or domestic settings.
Consider recycling or recovery.]

SECTION 14 TRANSPORT INFORMATION

[For substances, these are identified in the Registration and may already be published in Transport legislation. For mixtures, key components may take priority for identification for transport; if multiple hazardous components, consider the properties of the mixture and classify accordingly]

14.1 UN Number
14.2 UN Proper Shipping Name
14.3 Transport hazard class(es)
14.4 Packing group
14.5 Environmental hazards
14.6 Special precautions for user
14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

[In many cases, the SDS author may wish to confirm these with qualified transport specialists and must agree with their organisation's Dangerous Goods Safety Advisor (DGSA) who will be taking legal responsibility for transport labelling]

SECTION 15 REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture
[Include national regulatory status where different Community laws exist in various Member States]

15.2 Chemical Safety Assessment
[Indicate if a full CSA / CSR is available (noting that the Exposure Scenario attached to the SDS will be an abridged easy-to-read version)]

[Note that the label elements that used to go in Section 15 are now in Section 2]

SECTION 16 OTHER INFORMATION

Date of compilation and revision details, including key changes since last revision

Literature sources and references where needed

List of abbreviations used in the SDS

Explanation of risk phrases and/or hazard statements from Sections 2 and 3
Note that these classifications relate to the pure forms of the components listed in Section 3.

ANNEX
Addition of Exposure Scenarios as applicable

Exposure Scenario 1

Exposure Scenario 2

Exposure Scenario 1:

[Note that the figures in the example are for illustration and are not correct estimations]

Product Name	Organic Solvent
Revision Date	22-06-2011
Version No.	1
ES-Ref	Internal reference ? Optional
Author	
Notes	This is the example of the exposure scenario generated by ECHA
1.Title of Exposure Scenario.	
Title	

Activities and Processes	
Product Category	
Article Category	
Main Sector	
Sector of Use	
Environmental Release Category	ERC 8d Wide dispersive outdoor use of processing aids in open systems.
Process Category	PROC8a Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non dedicated facilities.

2. Conditions of Use Affecting Exposure. (Industrial – Environment)

Notes	
Product characteristics	Liquid
Concentration Details	Concentration of the substance up to 100 %
Amounts Used	Annual site tonnage: 600 t/year Maximum daily site tonnage: 2000 kg/day
Frequency and duration of use	Emission Days: 300 days/year
Other given operational conditions affecting environmental exposure.	
Emission factor air	
Emission factor water	
Emission factor soil	
Environmental factors not influenced by risk management measures.	
Dilution	Receiving surface water flow: 18,000 m3/day Local marine water dilution factor: 100
Other Factors	Spent process fluid discharged to wastewater
Risk management measures	
Good Practice	See chapter 8 of the safety data sheet (Environmental exposure controls).
Technical measures	
Type of STP	
Technical onsite conditions and measures to reduce or limit discharges to air, water and soil.	
Air	Air emission controls are not applicable as there is no direct release to air.
Water	Spent process fluid discharged to wastewater.
Soil	Not applicable - no direct release to soil.
Conditions and measures related to external treatment of waste for disposal	
Sludge Treatment	
Waste Treatment	Wastewater is to be treated by a municipal STP.
Disposal Method	Dispose of this material and its container at hazardous or special waste collection.
Recovery methods	External recovery and recycling of waste should comply with local regulations.

2. Conditions of use affecting exposure. (Workers-Health)

Control of workers exposure	
PROC	PROC8a Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non dedicated facilities.
Product characteristics	Liquid
Amounts used	
Frequency and duration of use.	Application duration : < 1 hour Covers frequency up to 5 days/week, 40 week(s)/year
Human factors not influenced by risk management	
Potentially exposed body parts	Hands and forearms
Other operational conditions affecting workers exposure	

Setting	Indoor
Temperature	Assumes activities are at room temperature
Room Size	Use in a room with a volume minimum $25m^3$
Ventilation Rate	Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour)
Technical conditions and measures at process level (source) to prevent release.	
Technical Protective Measures	No specific risk management measure identified beyond those operational conditions stated
Organisational measures to prevent/limit releases, dispersion and exposure.	
Organisational Measures	Ensure operatives are trained to minimise exposures.
Risk Management Measures	
Risk Management Measures	Wear face shield, goggles or safety glasses with side shield. Wear nitrile rubber, chloroprene rubber, butyl rubber gloves. Gloves should have a breakthrough time of 480 min Efficiency of at least 90 % Gloves should comply with the requirements of EN 374
3. **Exposure Estimation (Environment)**	
Assessment Method	ECETOC TRA v2.0 Environment
Environmental Release	Water 9.9 kg/day Air Negligible Soil 0 Kg/Day
Environmental Exposure Risk Characterisation	Freshwater (pelagic): Exposure 0.07 mg/l, PNEC 1 mg/l, RCR 0.07 Freshwater (sediment): Exposure 0.361 mg/l, PNEC 5.23 mg/l, RCR 0.069 Marinewater (pelagic): Exposure 0.007 mg/l PNEC 0.1 mg/l RCR 0.07 Marinewater (sediment): Exposure 0.036 mg/l PNEC 0.53 mg/l RCR 0.068 Effluent: Exposure 0.625 mg/l PNEC 39.06 mg/l RCR 0.016 Agriculture soil: Exposure 0.023 mg/l, PNEC 0.45 mg/l, RCR 0.051
4. Guidance to check compliance with the Exposure Scenario (Environment)	
Guidance	Guidance is based on assumed operating conditions which may not be applicable to all sites; thus, scaling may be necessary to define appropriate site-specific risk management measures. Further details on scaling and control technologies are provided in SpERC factsheet (http://cefic.org/en/reach-for-industries-libraries.html).
3. **Exposure Estimation (Health)**	
Assessment Method	The ECETOC TRA tool has been used to estimate workplace exposures unless otherwise indicated
Exposure Risk Characterisation	Worker - inhalation, long-term - systemic. Exposure: 22.53 mg/m3, DNEL: 90 mg/m3 RCR: 0.25 Worker - dermal, long-term - systemic. Exposure: 1.371 mg/kg, DNEL: 9.52 mg/kg, RCR: 0.144 Worker - combined, long-term - systemic. Exposure --, DNEL --, RCR: 0.395 Worker - inhalation, short-term - systemic. Exposure: 225 mg/m3, DNEL: 450 mg/m3 RCR: 0.5 Worker - dermal, short-term - systemic. Exposure: 1.371 mg/m3, DNEL: 47.3 mg/m3 RCR: 0.029 Worker - combined, short-term - systemic. Exposure --, DNEL --, RCR: 0.53
4. Guidance to check compliance with the exposure scenario (Health)	
Guidance for user	
Guidance on scaling	