The Easy HANDBOOK
of European SDSs

SECTION 12:
ecological information

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What information do I need to provide in section 12 of the SDS?

12.1 Toxicity

12.2 Persistence and degradability

12.3 Bioaccumulative potential

12.4 Mobility in soil

12.5 Results of PBT and vPvB assessment

12.6 Endocrine disrupting properties

12.7 Other adverse effects

The content of section 12 provides the basis for classification and possible risk management measures for the environmental sector.
This section summarizes information on:

• environmental impact, if the product is released into the environment;
• test results for toxicity, persistence and biodegradability, accumulation potential and mobility in soil;
• the results of a PBT and vPvB assessment, if carried out as part of a chemical safety assessment.

When drafting this section, it shall be specified whether the data mentioned are derived from testing or bridging principles.
Where reliable and relevant experimental data are available, these data shall take precedence over information obtained from models.

12.1 subsection

FIRST STEP
Toxicity

Where available, toxicity information shall be provided using test data from aquatic and/or terrestrial organisms, including available relevant data on **acute and chronic aquatic toxicity to fish, crustaceans, algae and other aquatic plants.**

Historically, the data used to classify for **acute toxicity** to the aquatic environment concern three "trophic levels": fish, crustaceans and aquatic plants.
Normally the following data are reported:

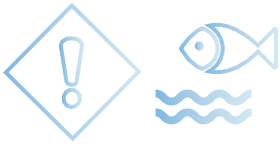
- LC50 for fish in 96 hours;
- EC50 for crustaceans in 48 hours;
- EC50 or ErC50 for aquatic plants or algae in 72 or 96 hours.

Definitions

LC50 = median lethal concentration, i.e., the concentration causing death of 50% of the organisms used in the test after a specified period.
EC50 = concentration causing a sub-lethal effect in 50% of test organisms after a specified period.
ErC50 = concentration that reduces biomass growth by 50% after a specified period.

These data are generally derived from these OECD tests:

OECD Guidelines	Regulation 440/2008	Type of test
OECD 201 EC50 72h or 96h on algae	C.3	Acute/chronic effect
OECD 202 EC50 48h on crustaceans	C.2	Acute effect
OECD 203 LC50 96h on fish	C.1	Acute effect
OECD 236 Fish Embryo Acute Toxicity test (FET)	-	Acute effect
OECD 212 (toxicity on embryonic and larval stages in fish)	C.15	Acute effect



For **chronic toxicity** to the aquatic environment, the data normally used are:

- NOEC for fish;
- NOEC for crustaceans;
- NOEC for algae or aquatic plants.

Sometimes the LOEC value is reported.

Definitions

NOEC = *No Observed Effect Concentration*, i.e., the highest concentration for which no effects are observed on the organisms used in the test.
LOEC = *Lowest Observed Effect Concentration*, i.e., the lowest concentration for which a significant effect is observed on the test organisms.

These data are generally derived from these OECD tests:

OECD Guidelines	Regulation 440/2008	Type of test
OECD 210 (fish early life stage)	-	Chronic effect
OECD 215 (toxicity to fish growth)	C.13	Chronic effect
OECD 211 (*Daphnia*, reproduction test)	C.20	Chronic effect

Where available, toxicity data for soil micro- and macro-organisms and other environmentally relevant organisms, such as birds, bees and plants, shall also be included.
If the substance or mixture has inhibitory effects on the activity of micro-organisms, the possible impact on sewage treatment plants must be mentioned.

For substances subject to registration, summaries of the information derived from the application of Annexes VII to XI of the REACH Regulation must be provided.

12.2
subsection

SECOND STEP

Persistence and degradability

Degradability is the potential of the substance or the substances in a mixture to degrade in the environment, either through biodegradation or other processes, such as oxidation or hydrolysis. **Where available, test results relevant for the assessment of persistence and degradability shall be reported.**

Normally, the data used for the assessment of persistence is the time required for the halving of the initial amount of this substance ("half-life") or for the disappearance of measurable concentrations of the substance.

If degradation half-lives are indicated, it shall be specified whether they refer to mineralisation or to primary degradation.

If available, report the following data:

- solubility;
- BOD, COD and BOD/COD;
- ready degradability.

For inorganic substances, the hydrolysis test result is also included.

Definitions

BOD = Biochemical Oxygen Demand, i.e., the amount of oxygen used in 5 days by aerobic microorganisms to decompose the organic substances present in a litre of water or aqueous solution in the dark and at 20 °C.

COD = Chemical Oxygen Demand, i.e., the amount of oxygen required for the complete chemical oxidation of organic and inorganic compounds present in a water sample.

As far as degradability is concerned, it is normally evaluated with specific tests:

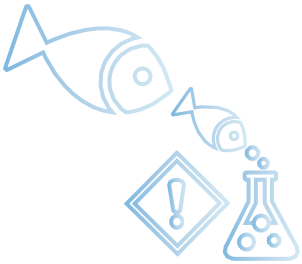
OECD Guidelines	Regulation 440/2008	Type of test
OECD 301 A-F (ready biodegradability)	C.4 A-F	Biodegradability
OECD 306 (marine biodegradability)	C.4	Biodegradability
-	C.5 (BOD)	Degradation
-	C.6 (COD)	Degradation
OECD 111 (hydrolysis as a function of pH)	C.7 (abiotic hydrolysis)	Degradation

The degradation potential of the substance or substances in a mixture in wastewater treatment plants must also be reported.

For detergents, specific biodegradability requirements are imposed by sector legislation (Reg. (EC) no. 648/2004).

12.3 subsection

THIRD STEP
Bioaccumulative potential



Bioaccumulative potential is the potential of the substance or substances in a mixture to accumulate in living organisms and, ultimately, to pass through the food chain.

Tests results relevant to assess bioaccumulative potential shall be reported.

They shall include, where available, references to the octanol-water partition coefficient (K_{ow}) and the bioconcentration factor (BCF).

Octanol-water partition is often reported as the logarithm of K_{ow}: Log K_{ow}. When reporting this data, it is useful to indicate which of the two values (Kow or Log K_{ow}) is reported.

Both the K_{ow} and the BCF are dimensionless values, without units of measurement.

Definitions

K_{ow} = n-octanol/water partition coefficient, i.e., the ratio between the concentration of the substance in an octanol solution and the concentration of the substance in an aqueous solution.

BCF = bioconcentration factor, i.e., the ratio between the concentration of the substance in an organism and the concentration of the substance in water.

For mixtures, this information shall be provided where available and appropriate for each substance listed in Section 3 of the SDS.

12.4 subsection

FOURTH STEP
Mobility in soil

Mobility in soil is the potential of the substance or components of a mixture, when released in the environment, to move by natural forces to groundwater or to move away from the site of release.

The potential for mobility in soil shall be indicated, if available.

Information on mobility in soil can be derived from relevant mobility data, such as adsorption or leaching studies, known or predicted distribution to environmental compartments or surface tension. For example, K_{oc} (organic carbon-water partition coefficient) values can be predicted from octanol/water partition coefficients (K_{ow}). Leaching and mobility can be predicted from models.

Definitions

K_{oc} = organic carbon/water partition coefficient, i.e., the ratio between the concentration of the substance bound organic carbon in soil and the concentration of the substance in water. The higher the K_{oc} value, the more likely it is that a chemical compound is bound to soil rather than dissolved in water.

For mixtures, this information shall be provided where available and appropriate for each substance listed in Section 3 of the SDS.

12.5
subsection

FIFTH STEP

Results of PBT and vPvB assessment

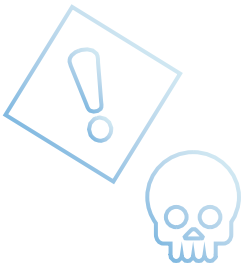
When a chemical safety report is required, the results of the PBT and vPvB assessment, as set out in the chemical safety report, shall be given.

It is not necessary to provide detailed information on the data used to reach the conclusion regarding PBT or vPvB properties, especially if the conclusion is that the product does not have such properties.
A simple statement is sufficient, for example:
"According to the results of its assessment, this substance is not a PBT or vPvB"
"This mixture does not contain substances that are assessed to be a PBT or a vPvB"

However, if the criteria for PBT or vPvB are met, it is recommended to briefly indicate in this section the reasons why they are met as part of the results of the assessment that must in any case be given.

12.6 subsection

SIXTH STEP
Endocrine disrupting properties



In this subsection, information shall be provided on adverse effects on the environment caused by substances identified as having endocrine-disrupting properties in subsection 2.3.
This information must consist of brief summaries of the information derived from the application of the assessment criteria set out in the REACH Regulation and Regulations 2017/2100 and 2018/605.

Guidance on endocrine disruptors and their identification is available at:
https://echa.europa.eu/hot-topics/endocrine-disruptors

For substances that have no endocrine-disrupting properties for the environment, a simple statement is sufficient, for example:
"This substance does not have endocrine disrupting properties with respect to non-target organisms as it does not meet the criteria set out in Section B of Regulation (EU) No 2017/2100."

12.7 subsection

SEVENTH STEP
Other adverse effects

All available information on any other adverse effects on the environment shall be included, such as environmental fate (exposure), photochemical ozone creation potential, ozone depletion potential, or global warming potential.

Focus on… consistency with other sections of the safety data sheet

An assessment of the consistency of this section is necessary, particularly with respect to the following sections:

- **SECTION 2:** hazards identification
- **SECTION 3:** composition/information on ingredients
- **SECTION 6:** accidental release measures (i.e., environmental protection precautions)
- **SECTION 7:** handling and storage (i.e., measures to prevent emissions)
- **SECTION 9:** physical and chemical properties (i.e., log K_{ow}, miscibility)
- **SECTION 13:** disposal considerations
- **SECTION 14:** transport information
- **SECTION 15:** regulatory information