

Safety Data Sheets

Amendment to Annex II of REACH Regulation

[COMMISSION REGULATION \(EU\) 2020/878 of 18 June 2020](#)

Annex II to Regulation (EC) No 1907/2006 lays down requirements for the compilation of safety data sheets, used to provide information on chemical substances and mixtures placed on the EU market. It was amended by Regulation (EU) 2020/878 which was published in the official journal on 18th June 2020.

Overview

- Regulation (EU) 2020/878 implements changes to the format and content of the SDS
- Includes changes to Sections 1,2,3, 9, 11,12 and 14
- Enters into force on 1st January 2021
- Applies to all SDSs authored from 31st December 2022
- All SDSs, including new and updated SDSs, authored after 1st January 2021 can continue to use the previous format (EC) 2015/830 and can continue to be provided to recipients until 31st December 2022.
- The new Annex II format, as amended by (EU) 2020/878 can be applied voluntarily since 8th July 2020

A summary of the main changes are:

- Aligns SDS with the 6th and 7th edition of the United Nations Globally Harmonised System ([GHS](#)) of Classification and Labelling of Chemicals (GHS)
- Introduces requirements associated with [Annex VIII](#) to CLP and is to include the Unique Formula Identifier (UFI) for hazardous mixtures supplied for use at industrial sites and for certain mixtures which are not packaged
- Updates information on the [nanofoms](#) of substances to align with those introduced by Regulation (EU) 2018/1881
- Includes information on [endocrine disruptors](#) (ED) based on the scientific criteria set out in the Delegated Regulation (EU) 2017/2100 or (EU) 2018/605 to improve the communication of ED through the supply chain.

The main changes to the relevant sections of the SDS are:

Section 1.1 Product identifier

- Indicates if the product is in a nanoform by using the word 'nanoform'
- Unique Formula Identifier (UFI) to be listed under '*Other means of identification*', when required

Section 2.3 Other hazards

- To include substances listed on ECHA [Candidate List](#) having endocrine disruptor properties
- To include any substance identified as an endocrine disruptor using criteria in the Delegated Regulations (EC) 2017/2100 or (EC) 2018/605

Section 3: Compositional information on ingredients

- Introduces lower concentration limits for substances classified as skin sensitisers 1A, respiratory sensitisers 1A and aspiration hazards, and now includes endocrine disruptors with Table 1.1 in Section 3.2.1 updated to reflect this.
- Introduces the requirement to include the specific concentration limit, M-factor and acute toxicity estimate (ATE) for any substance listed in Annex VI (with a harmonised classification) or any substance classified in accordance with Annex I criteria (self-classified), if available.
- If the substance is registered and it covers a nanoform, the particle characteristics that specify the nanoform, as described in Annex VI, shall be indicated. If the substance is not registered, but the safety data sheet covers nanoforms, the particle characteristics of which have impact on the safety of the substance, those characteristics shall be indicated.

Section 9: Physical and Chemical Properties

- New improved wording regarding information requirements and clarification on the measurement units to be used
- Reasons for omissions of data to be clearly indicated
- Additional information is provided for each property
- In section 9.1 the order and wording of physical properties changed e.g. 'physical state' instead of 'appearance', with separate point for 'colour' with odour and odour threshold merged
- Partition coefficient n-octanol/water (log value) for nanoforms the dispersion stability in different shall be indicated
- New 'particle characteristics' property including indication of nanoform characteristics.
- A new sub section 9.2.1 included with additional information on the physical hazard classes including properties, safety characteristics and test results which may be included in the SDS.
- A new section 9.2.2 'Other safety characteristics' added including mechanical sensitivity, acid/alkaline reserve, conductivity and redox potential.

Section 11: Toxicological information

- Two new sub-sections added: 11.1 'Information on hazard classes as defined in Regulation (EC) No 1272/2008' and 11.2 'Information on other hazard classes which relates to endocrine disrupting properties' as determined by the aforementioned regulations.

Section 12: Ecological information

- Changes to the subsection 12.6 which now requires info on endocrine disruptor properties with 12.7 now requiring information on 'other adverse effects'.

Section 14: Transport information

- Changes to 14.7 relating to the wording of the title and paragraph relating to IMO instrument. There are now additional requirements for information on maritime transport in bulk according to IMO instruments. This information now reflects what is required on the transport document and will help companies in preparing transport documents.
- The insertion of transport information is compulsory in Section 14 and includes: UN number or ID number; UN proper shipping name; transport hazard class(es); packing group; environmental hazards, and also special precautions for the user in connection with transport, for all relevant modes of transport.

The ECHA guidance document on the compilation of safety data sheets is being updated to reflect these changes and will be available at the following [link](#).