

Ensure Consistency and completeness of the SDSs – new requirements from January 2023



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Introduction



EU-REACH Regulation

- **REACH:** the Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the **Registration, Evaluation, Authorization and Restriction of Chemicals**
- **Effective date:** 1 June 2007
- **Competent authority:** ECHA (European Chemicals Agency)
- **Application:** substances manufactured or imported into the EU market in quantities of 1 tonne per year or more.
- **Scope:** substances on their own, in a preparation or in an article manufactured, imported, placed on the market or used
- **Article 31:** Requirements for safety data sheets
- **Annex II.** Requirements for the Compilation of Safety Data Sheets



Source: ECHA

CLP Regulation

- **CLP:** the Regulation (EC) No 1272/2008 on the **C**lassification, **L**abelling and **P**ackaging of substances and mixtures
- **Effective date:** 20 January 2009
- **Competent authority:** ECHA (European Chemicals Agency)
- **Application:** the classification criteria and labelling rules based on the UN Globally Harmonised System of Classification and Labelling of Chemicals (GHS)
- **Scope:** classified substance or mixture that meets the classification criteria in CLP based on the relevant information



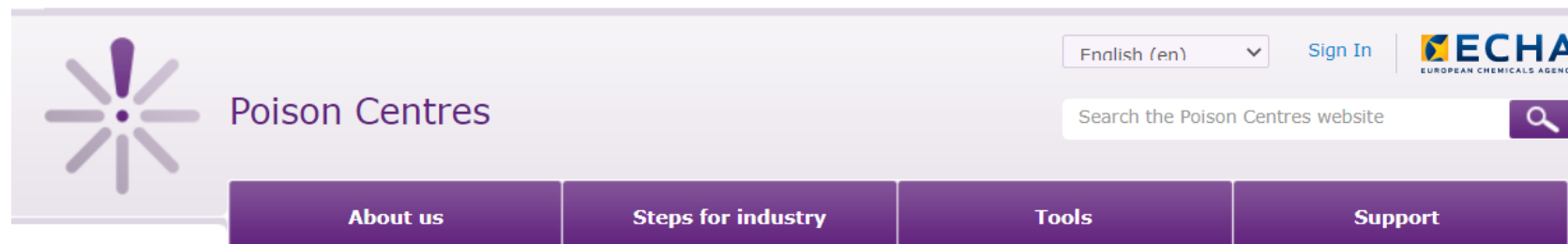
Source: ECHA

Poison Centre Notification

- **Article 45 of the CLP Regulation:**
Appointment of bodies responsible for receiving information relating to emergency health response
- **Annex VIII to the CLP Regulation:**
Harmonised Information Relating to Emergency Health Response and Preventative Measures

Companies placing hazardous mixtures on the market are obliged to provide information about certain hazardous mixtures to the relevant national bodies

Harmonised requirements for poison centre notifications (PCN) applicable as of 1 January 2021



Source: ECHA

GHS



Global Harmonization System (GHS)

- Harmonized, globally applicable
- A new uniform system for classification and labeling of chemicals
- Provides physical, environmental, and health and safety information on hazardous chemical substances and mixtures
- Defines and classifies the hazards of chemical products and communicates health and safety information on labels and safety data sheets
- Adopted by the United Nations in 2002 and is periodically updated
- GHS version 7 is adopted by EU



Source: UNECE



Why is GHS needed?

- For proper and safe handling of chemicals, all necessary information should be provided - labels, symbols and data sheets
- Variations in countries regulations provide non standardized information for the same material, leading to mishandling and/or unsafe situations
 - Promoting Regulatory Efficiency
 - Facilitating Trade
 - Providing consistent hazard information
 - Safe transport, handling and use of chemicals
 - Promoting better emergency response to chemical incidents



GHS around the world

- It is up to the country's authorities to decide how GHS will be adopted in their legislation
- Not all sections are adopted

When a country adopts GHS, the country has freedom to:

- Select one or more of the hazard classes
- Select the categories it will adopt for a particular hazard class



Argentina Armenia Australia Austria
Belarus Belgium Bolivia Brazil Bulgaria
Cambodia Canada Chile China Colombia Costa Rica Côte
d'Ivoire Croatia Cyprus Czech Republic
Democratic Republic of Congo Denmark
Ecuador Estonia
Finland France
Gambia Germany Ghana Greece Guatemala Guinea
Honduras Hungary
Iceland Indonesia Ireland Israel Italy
Japan
Kazakhstan Kyrgyzstan
Lao People's Democratic Republic Latvia Liechtenstein
Lithuania Luxembourg
Madagascar Malaysia Malta Mauritius Mexico
Montenegro Myanmar
Netherlands New Zealand Nigeria Norway
Paraguay Peru Philippines Poland Portugal
Republic of Korea Romania Russian Federation
Senegal Serbia Singapore Slovakia Slovenia South Africa
Spain Sweden Switzerland
Thailand Tunisia Turkey
Ukraine United Kingdom United States of America
Uruguay
Viet Nam
Zambia

Source: UNECE



Three Parts of GHS

Harmonized definitions of hazards (**hazard groups**)

- Physical
- Health
- Environmental

Label criteria

- Pictograms
- Signal words
- Hazard and precautionary statements

Harmonized safety data sheets (SDS) format

16 sections

Hazardous Chemical Name

UN No. 1234

CAS No. 12-23-3

DANGER

Flammable gas. Heating may cause a fire.
Causes eye irritation.



Store in a dry place. Protect from sunlight.
Keep away from heat/open flames/hot surfaces.
In case of fire: Evacuate area. Fight fire remotely
due to risk of explosion. Read label before use.

Company Name - 123 Chemical Blvd - Sanford, FL 32773 USA - www.123chemicalcompany.com - 555-123-4321

SDS

Overview of Safety Data Sheets

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Substance name: ECHA Substance

EC No.: 11111-11-1

REACH Registration No.: XX-XXXXXXXXXX-XX-XXXX

CAS No.: 77777-77-1

1.2. Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses:

- Formulation or re-packing (F): Formulation of preparations (mixtures) - PC9a, PC18, PC24, PC31
- Widespread use by professional workers (PW): Lubricant and lubricant additive (PC24), Coatings and paints, thinners, paint removers (PC9a), Polishing agent (PC31), Ink and toners (PC18)

Uses advised against:

Consumer uses (C); Coatings and paints, thinners, paint removers (PC9a).

Reason why uses advised against:

- Use on large surface area would potentially give excessive exposure to vapour

1.3. Details of the Supplier of the Safety Data Sheet

Supplier: Fictitious Business Name

Street/P.O. Box: Address 1

Postcode / City: 00120, City

Country: Country

Telephone (Telefax): +XX-XXXXXXXXXX, +XX-XXXXXXXXXX

E-mail (competent person): SDS@companyX.com

National contact: National.Contact@email.com

1.4 Emergency telephone number

Please contact: +XX-XXXXXXXX, National Chemicals Information Service, Country

Opening hours: 24 hours-a-day, 365 days-a-year

Other comments (e.g. language(s) of the phone service): English

- Essential 16-part documents with the sole purpose of conveying detailed information about hazardous chemicals
- Identifying and managing the risks associated with the use and handling of hazardous substances by providing recommendations for proper handling, storage, transport, disposal, and emergency procedure information
- Both for the workers who handle the chemicals and for those responsible for safety

16 Sections of SDS

Section 1	Identification of the substance/mixture and of the company/undertaking	Section 9	Physical and chemical properties
Section 2	Hazard identification	Section 10	Stability and reactivity
Section 3	Composition/information on ingredients	Section 11	Toxicological information
Section 4	First-aid measures	Section 12	Ecological information
Section 5	Fire-fighting measures	Section 13	Disposal consideration
Section 6	Accidental release measures	Section 14	Transport information
Section 7	Handling and storage	Section 15	Regulatory information
Section 8	Exposure controls/personal protection	Section 16	Other information

Scope

Scope

- New substances
- For a substance or mixture that is classified as hazardous according to CLP
- A substance that is Persistent, Bioaccumulative and Toxic (PBT) or very Persistent and very Bioaccumulative (vPvB)
- A substance that is included in the Candidate List of substances of very high concern (SVHCs)

Exemption

- Medicinal products
- Cosmetic products
- Food or feeding stuffs
- Food additive in foodstuffs
- Flavouring in foodstuffs
- Additive in feeding stuffs
- Animal nutrition



Relevant stakeholders

Who needs SDS?

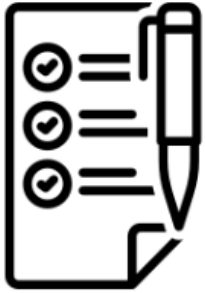
- Suppliers of chemicals that are companies or individuals within the European Union/European Economic Area who use a substance, either on its own or in a mixture, in their industrial or professional activities

Who should compile SDS?

- “The safety data sheet shall be prepared by a competent person who shall take into account the specific needs and knowledge of the user audience, as far as they are known”



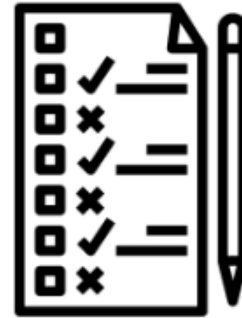
Obligations



Prepare
SDS



Share SDS within
supply chain



Update SDS



Communicate
changes in SDS



Recent updates

Updates (1): Sections

Section 1	Identification of the substance/ mixture and of the company/ undertaking
Section 2	Hazard identification
Section 3	Composition/information on ingredients
Section 9	Physical and chemical properties
Section 11	Toxicological information
Section 12	Ecological information

Updates (2): Requirements

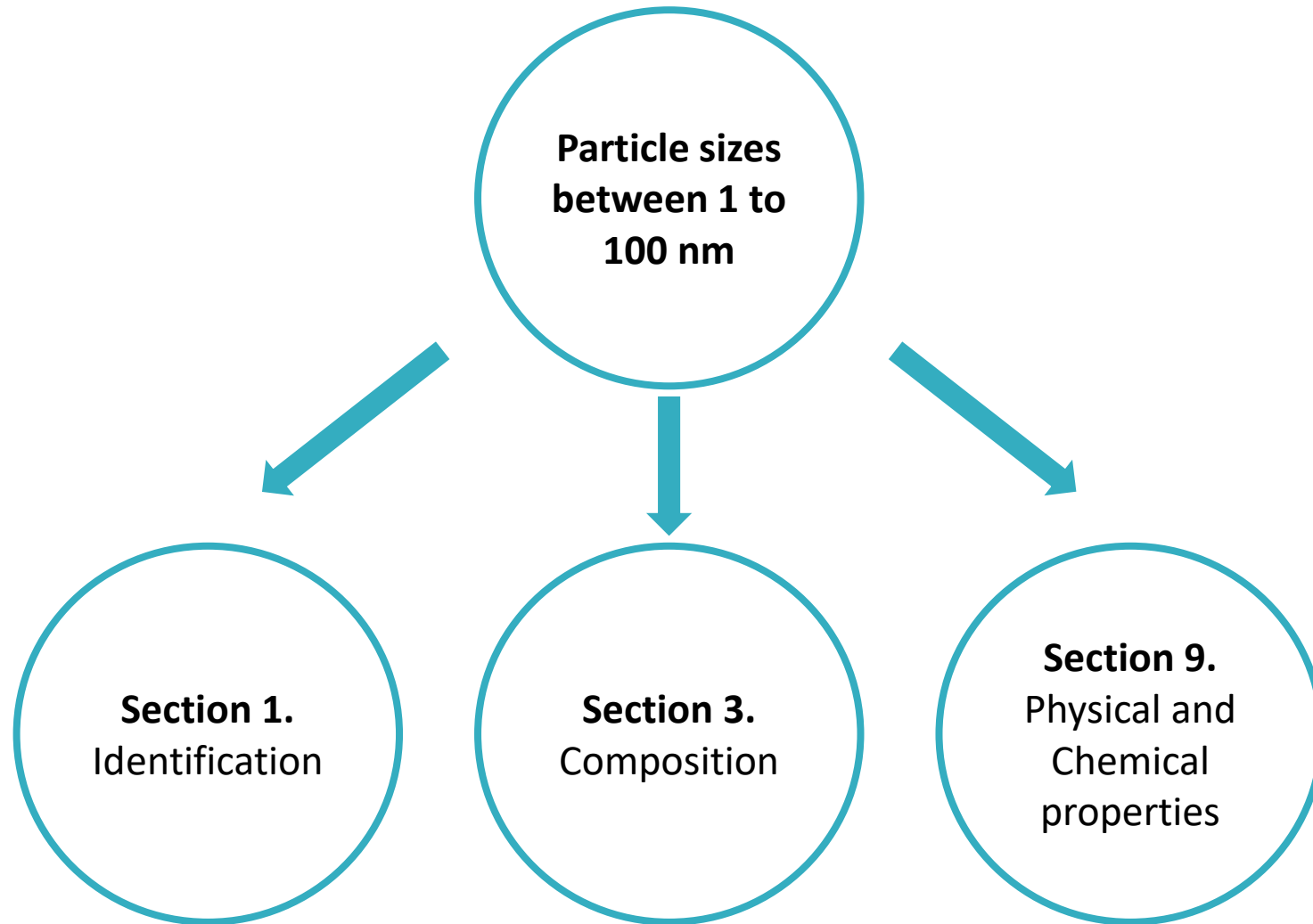
- Specific requirements regarding nanoforms of substances

- Adding requirements regarding the Unique Formula Identifier (UFI) (as set by Annex VIII to Regulation (EC) 1272/2008)

- Endocrine disrupting properties

- Specific concentration limits, M-factors and acute toxicity estimates

Updates (2-1): Nanoforms of substances



Nanomaterials are chemical substances or materials with **particle sizes between 1 to 100 nanometres** in at least one dimension.

Updates (2-2): Unique Formula Identifier (UFI)

Section 1. Identification

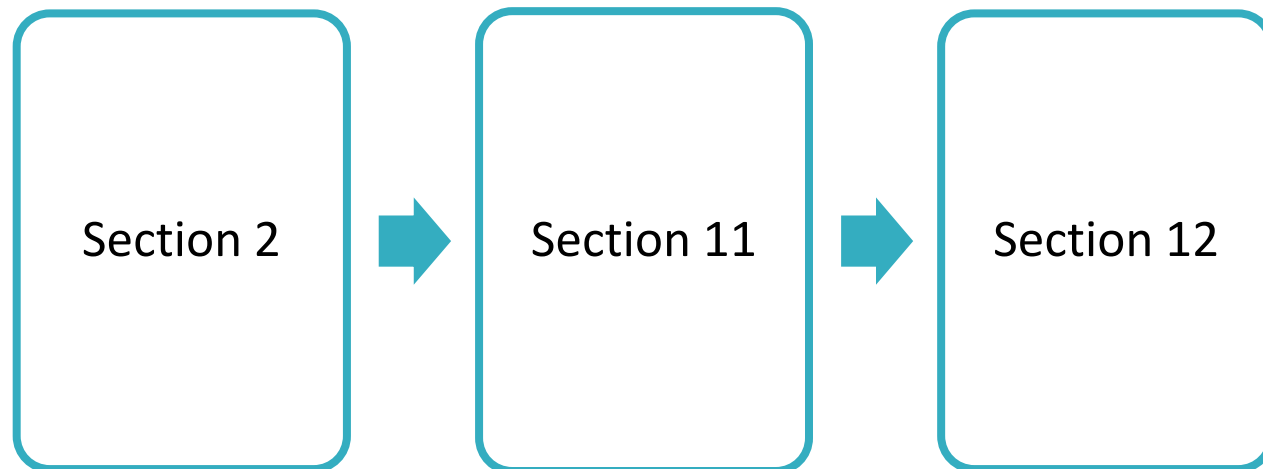
Assigning a UFI to a product comes from Annex VIII of the Classification, Labelling and Packaging of substances and mixtures (CLP) Regulation (EC) No 1272/2008 and is part of the process for poison centre notifications.

Updates (2-2): Unique Formula Identifier (UFI)

- UFI link a specific product on the market to the submitted mixture information
- The unique formula identifier (UFI) is a 16-character code to be indicated on the label of mixtures
- The UFI is an element of the submission of hazardous mixtures which has to be carried out in a **harmonized form (PCN)**
- PCN requirements started from 1 January 2021
 - The deadline for chemicals for consumer and commercial use expired on 1 January 2021
 - Chemicals for industrial use need to comply with the requirements from 1 January 2024



Updates (2-3): Endocrine disrupting properties



Endocrine disruptors are chemicals that may interfere with the hormonal system and produce harmful effects in humans and wildlife.

Updates (2-4): Specific concentration limits, M-factors and acute toxicity estimates

Section 3.1. Substance

Section 3.2. Mixture

The specific concentration limit, the M-factor and the acute toxicity estimate for substances included in Part 3 of Annex VI to Regulation (EC) No 1272/2008 or determined in accordance with Annex I to that Regulation shall be indicated, if available.

Timeline

January
2021

- Any new SDS has to be as per Regulation (EU) 2020/878

December
2022

- Transition period
- As per Regulation (EU) 2015/830 or as per Regulation (EU) 2020/878

January 1st,
2023

- Every SDS as per Regulation (EU) 2020/878

Take Home messages

Regulation

- EU REACH, Article 31: Requirements for safety data sheets
- CLP regulation

Scope

- New substances
- For a substance or mixture that is classified as hazardous according to CLP
- PBT or vPvB substances
- SVHCs substances

Relevant stakeholders

- Suppliers of chemicals that are companies or individuals within the European Union/European Economic Area who use a substance, either on its own or in a mixture, in their industrial or professional activities

Updates

- Specific requirements regarding nanoforms of substances
- Adding requirements regarding the UFI
- Endocrine disrupting properties
- Specific concentration limits, M-factors and acute toxicity estimates



Deadline



- All SDS must be updated and re-issued as given in Article 31(9) before 1st January 2023
- SDS must be updated without any delay as soon as new information which may affect the risk management measures, or new information on hazards becomes available



Thank You!

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Global Regulatory Compliance.* ”

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