Chem-X Consortium

The Material Declaration Guideline for the Chemical Industry

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For more information,
please visit www.chem-x.de

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1 Summary

Chem-X provides practical guidance for sharing material and substance information from and within the chemical industry. This resource helps companies create Digital Material Passports (DMP) which contain the material information to be implemented in Digital Product Passports (DPP).

The guideline provides clear information, showing how to structure chemical material and substance information. It explains how to handle substance declarations at different levels – from general product specifications to specific production batches and individual items.

Companies can use this framework to share required chemical information electronically throughout their supply chains while maintaining appropriate confidentiality. The guideline also illustrates how to incorporate Safety Data Sheet information when needed as an additional set of information between supply chain partners.

Developed collaboratively by chemical industry leaders, this working document represents a practical approach to meeting regulatory requirements while protecting valuable formulation knowledge. It helps ensure transparent communication about chemical products while maintaining the competitive advantages of proprietary formulations. Using these Information Models alongside the Sustainability and Circularity Information Models (see separate guidelines published in parallel), the Chem-X Digital Material Passport Models will be developed.

2 Introduction

2.1 EU regulatory landscape (Chem-X focus)

Digital Product Passports (DPP) are a central feature of the Ecodesign for Sustainable Products Regulation (EU) 2024/1781 (ESPR), which entered into force on 18 July 2024, as well as several other regulations, such as the EU Construction Products Regulation (EU) 2024/3110, the EU Detergents Regulation (EC) No 648/2004 or the Toy Safety Directive 2009/48/EC. The ESPR replaces the Ecodesign Directive 2009/125/EC and significantly broadens its scope. While the previous directive focused only on energy-related products, the ESPR will cover products that do not have a regulatory framework of their own. Examples of such existing frameworks are food and feed, medical products, marine applications, and medical products/devices. This means that the ESPR is not a standalone EU regulation. It is an addition to the existing regulatory framework for products placed on the EU market.

As in other regulatory frameworks, there is a set of general baseline requirements which apply to products placed on the EU market, irrespective of whether the product is intended for industrial users, professional users, or consumers and the public. Furthermore, they apply both to products being given away for free such as gifts or promotional items as well as products which are sold to people, businesses or as part of public procurement. Examples of such baseline requirements are the General Product Safety Regulation (EU) 2023/988 and the Market Surveillance Regulation (EU) 2019/1020. In addition to the baseline, product-specific requirements apply.

These product-specific requirements often combine EU-wide regulations with country-specific rules. They govern various aspects of a product, including the materials or chemicals used, mechanical performance, fire safety, IT security, sustainability, and user-friendliness. Their purpose is to ensure that any product with a viable business case in the EU market is both safe and sustainable.

Importantly, this principle applies not only to the product itself but also to its packaging. Packaging materials are subject to additional regulatory requirements, such as those outlined in the Packaging and Packaging Waste Regulation (EU) 2025/40. As part of these requirements, each packaging material must be documented in a dedicated packaging passport, which must be integrated into the product's Digital Product Passport. The result is a single, unified DPP that covers both the product and its packaging.

The selection of materials and chemicals plays a crucial role in the design of physical products, including packaging. However, choosing the right materials is a complex task. Products may intentionally contain certain chemicals to fulfil specific functions, while others must exclude particular substances to ensure safe usage. In both cases, it is essential to share information on the chemical content not only with customers and in response to authority requests but throughout the supply chain.

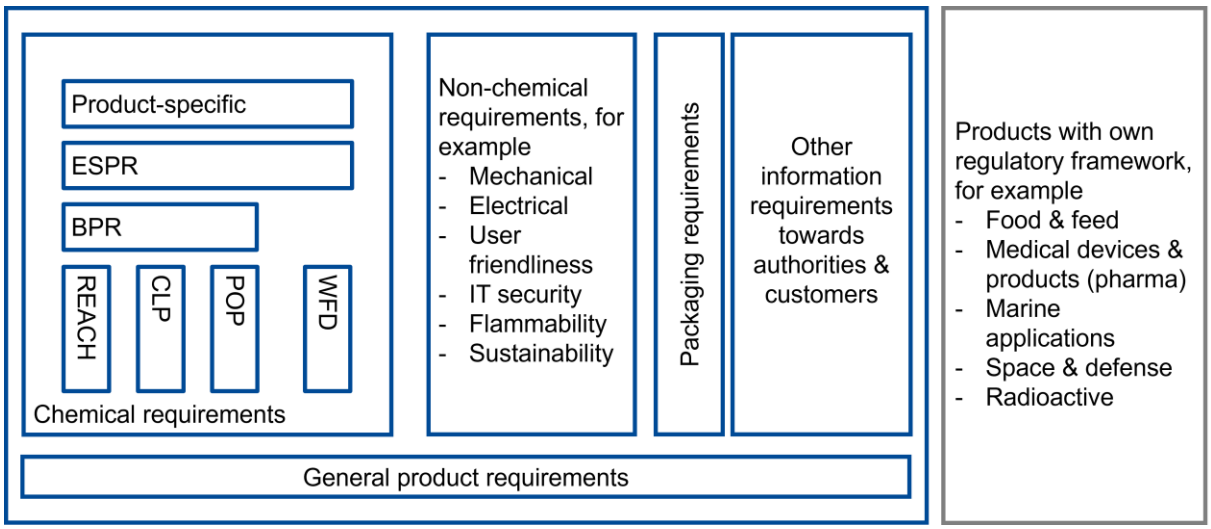

Figure 1: Simplified overview of EU product regulatory framework

Figure 1 shows a simplified overview of the EU regulatory framework for products placed on the EU market. Every product shall comply with a unique combination of these requirements; wherein chemical requirements represent only one of many complex subsets of legal requirements.

2.2 Information requirements on chemicals for the EU market

Given the considerations outlined above, it becomes clear that today's information flow is not seamless. There are several contributing factors to this, but we will refrain from elaborating on them at this stage. In practice, information is frequently shared either in printed form or through static formats such as PDFs, which are typically not machine-readable. This is precisely where the regulatory push for Digital Product Passports comes in: they are intended to enhance the flow of information across the entire value chain. Chem-X represents one such solution tailored to the needs of customers of the European chemical industry. However, to fully understand the Information Model presented in the subsequent sections of this guideline, it is first necessary to review the current information requirements for chemical products.

Similar to the regulatory framework for products in general, there is a complementary framework that outlines chemical requirements, including specific information requirements for materials and individual substances. For the sake of simplicity, we will refer to all materials as "chemicals", since every material is chemically composed of either a single substance or a mixture of substances.

Unsurprisingly, the chemical regulatory framework includes a baseline of legal information requirements that apply to all chemicals used in products, covered by the broader product regulation framework. Packaging materials are also subject to these requirements. However, these information obligations do not necessarily extend to products outside that scope, such as food or animal feed.

The baseline for chemical information requirements (e.g. for ESPR) in the EU is established by three key regulations:

- EU REACH Regulation (EC) No 1907/2006
- EU CLP Regulation (EC) No 1272/2008
- EU POP Regulation (EU) 2019/1021

In addition, the Waste Framework Directive 2008/98/EC introduces specific obligations for Substances of Very High Concern (SVHC). These obligations complement the three core regulations and collectively form the legal basis for communicating chemical information (see Annex I).

The EU REACH Regulation not only requires information sharing within the supply chain but also distinguishes between chemical products (substances/mixtures) and other products primarily defined by their non-chemical functions (articles). More importantly, most product-specific regulations base their chemical requirements on this distinction. This implies that there is one set of product-specific regulations for chemical products, and another set covering products which are typically articles according to EU REACH.

Examples for chemical product regulations are:

- Biocidal Products Regulation (EU) No 528/2012
- Detergents Regulation (EC) No 648/2004
- Cosmetic Products Regulation (EC) No 1223/2009
- Paints Directive 2004/42/CE
- Industrial Emissions Directive 2010/75/EU

For non-chemical product-specific regulations, requirements on chemicals are either found in EU regulations or European standards cited therein. Examples for legal requirements are:

- Battery Regulation (EU) 2023/1542
- Construction Products Regulation (EU) 2024/3110
- Food Contact Material Regulation (EC) No 1935/2004 and accompanying regulations on certain materials and Good Manufacturing Practice (GMP) (EC) No 2023/2006
- Machinery Regulation (EU) 2023/1230
- Pressure Equipment Directive 2014/68/EU
- Restriction of the Use of certain hazardous Substances in electrical and electronic Equipment Directive 2011/65/EU (RoHS2)
- Toy Safety Directive 2009/48/EC

Nevertheless, if an article contains one or more substances, chemical product requirements may apply to this specific part of the otherwise “non-chemical” product.

2.3 Information requirements on chemicals under EU ESPR

Besides the information requirements, the baseline regulations and existing product-specific legislation also include “performance requirements” on chemical content. Those either restrict chemicals that may harm human health or the environment, or they permit only chemicals listed on a positive list.

As previously mentioned, the EU ESPR adds to the regulatory framework for products placed on the EU market. In principle, its primary focus on sustainability enables the introduction of further performance requirements and information requirements on chemicals. However, performance requirements such as substance restrictions should not be based primarily on chemical safety, as this aspect is already addressed by baseline legislation. Consequently, the EU ESPR does not impose chemical-related performance requirements across all product categories, nor are such requirements expected in the upcoming product-specific delegated acts outlined in the first ESPR workplan adopted in April 2025.

For information requirements on chemicals, the situation differs. According to Article 7(2)(a), each delegated act shall at least include information requirements concerning Substances of Concern (SoCs). Importantly, the specific obligations under Article 7(5) build upon existing requirements from the three core EU chemical regulations: EU REACH, EU CLP, and the EU POP Regulation. However, the EU ESPR significantly expands the scope of information distribution. It ensures that stakeholders who currently do not receive such chemical information, or who must actively request it, will gain direct access through tools like the Digital Product Passport in the future.

The table in Annex II summarises the chemical information requirements relevant to the SoC data requested under the ESPR, excluding obligations related to substance registration under EU REACH and classification and labelling (C&L) notifications under EU CLP.

2.4 How chemical information is shared: today and tomorrow

The main purpose of sharing chemical information in the supply chain is to ensure safety, compliance, and transparency across all stages of production, distribution, use, and end-of life of products. In addition to chemical information that must be shared by law, any further disclosure is always balancing openness with the need to protect confidential business interests.

The obligation to disclose legally required information on chemicals is based on the same principles that apply to other product-related requirements within the EU regulatory framework: manufacturer responsibility and trust in the compliance of manufacturers and importers. However, this presumption of compliance is based on conditions. Market surveillance and enforcement mechanisms are in place to ensure that products are safe when placed on the EU market and remain safe throughout their lifecycle.

Although the production of chemicals is subject to audits and certification, the declaration of chemical content is typically made by the manufacturers or importers themselves. This self-declaration is based on the principle of manufacturer responsibility and presumption of compliance. This approach applies regardless of whether the information is shared with another stakeholder in the supply chain or with a market surveillance authority. It also applies to all types of information formats, whether the declaration appears in a Safety Data Sheet (SDS), on a product label, in a technical data sheet, on the company's website, or in printed marketing materials. As a result, the EU ESPR embeds the principle of self-declaration. This means that information about substances of concern will be provided through self-declaration within DPPs and in any other format required under upcoming delegated acts for specific product groups.

Given the above, we want to reiterate: the EU ESPR introduces new requirements within the existing regulatory framework, but it does not fundamentally alter the principles of information sharing in supply chains. However, the ESPR and the implementation of DPPs will significantly modernise the way how chemical information will be exchanged. Although chemical products are not included in the first EU ESPR work plan, many products manufactured by customers of the chemical industry will be affected by these new ways of sharing information. Therefore, it is in the European chemical industry's interest to ensure that relevant data is provided in a chemical declaration format that can be easily integrated into DPPs. By adopting modern, efficient electronic data submission methods as the Chem-X Digital Material Passport (DMP) approach, the chemical industry can maintain its competitiveness and continue to be seen as a reliable supplier of both chemical products and the associated information.

The objective of this guideline is to provide harmonised terminology, descriptions, and selection criteria for the key material declaration metrics relevant for chemical materials. It ensures transparency and clarity in communication while enabling interoperability in the provision of circularity data via Digital Material Passports throughout the complexity of chemical supply chains. This approach facilitates compliance with regulatory requirements for DPPs. In addition to material declaration metrics, Chem-X will integrate supplementary sustainability and circularity metrics into its Digital Material Passport Models (see Figure 2).

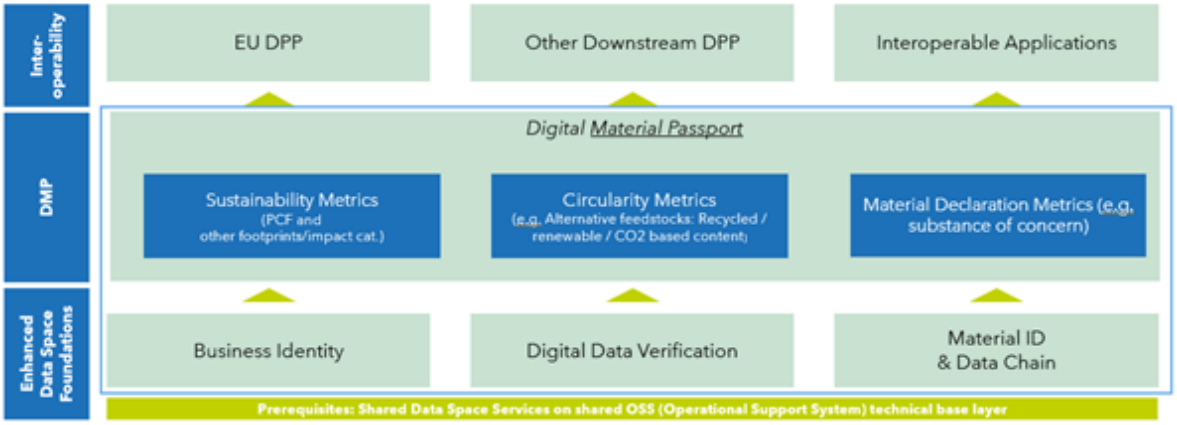

Figure 2: Chem-X DMP/DPP relations

Let's take a closer look at the types of information currently shared within the chemical industry, the methods used to share it, and what will be expected in the future under evolving regulatory requirements.

Like the mining industry, the chemical industry often operates at the beginning of supply chains. However, unlike mining, chemical production typically does not follow a linear chain of stakeholders. Instead, each chemical product is manufactured from raw materials supplied by companies that may simultaneously be competitors or customers of the same manufacturer. This complex and interconnected structure helps to explain why the mining industry tends to have a high level of transparency in product information sharing, while the chemical industry places strong emphasis on protecting confidential business information.

As illustrated in Figure 3, the manufacturer of a chemical product typically receives a Safety Data Sheet and other relevant chemical information from its supplier. In turn, the manufacturer provides an SDS and related chemical information to its industrial or professional customers. Upon request, the same information may also be shared with market surveillance authorities. Importantly, legal requirements for Safety Data Sheets do not oblige manufacturers to disclose their full product formulations. Instead, the information provided in SDSs and on labels is legally restricted to safety-relevant content. Full ingredient (material and substance) disclosure is only performed when a Non-Disclosure Agreement (NDA) has been signed.

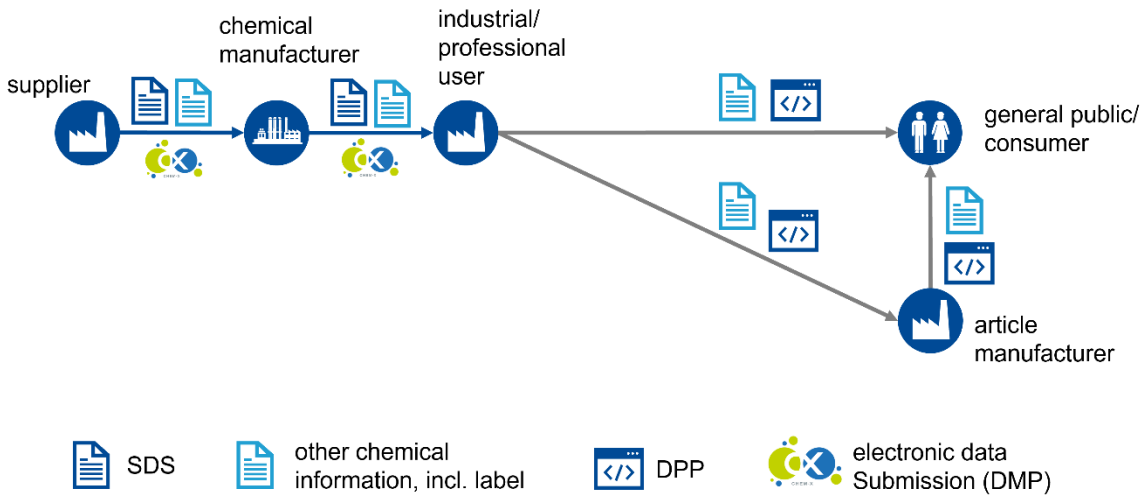

Figure 3: Simplified model for the data exchange of chemical information in supply chains

As the term “Safety Data Sheet” implies, the current flow of chemical information is primarily handled through traditional channels such as postal mail, email, uploads to customer portals, downloads from supplier platforms, or product labels. However, none of these methods offer a seamless exchange of information, nor do they support the creation of a structured material declaration that can be easily integrated into a customer’s DPP. Moreover, the flow of chemical information becomes disrupted once a product leaves the closed ecosystem of the chemical industry and enters the domain of article manufacturers, consumers, or the public. This disruption occurs because Safety Data Sheets are not legally required for articles, and products sold to the general public such as shampoos, adhesives, or ballpoint pens.

Currently, under EU REACH Articles 31 and 33, manufacturers are required to provide information about Substances of Very High Concern (SVHC). To improve transparency throughout the entire supply chain, including non-chemical end uses in articles and including the product’s end-of-life stage, ESPR extended the SVHC concept to the broader defined substances of concern (SoC) and strengthened communication by the DPP requirements.

In conclusion, the transition from document submission to fully machine-readable digital data transmission represents a major step forward. Nevertheless, some aspects will remain unchanged. For instance, if a product does not contain any hazardous substances above the thresholds and concentration limits, the Substances of Concern (SoC) section will remain empty. In such cases, no additional chemical or ingredient information will be shared with customers, consumers, or authorities.

Now that we have outlined how Chem-X contributes to compliance with chemical information requirements under the EU ESPR, we would like to conclude with a brief look at additional opportunities. These features, while not explicitly required by current regulations, can be easily implemented within Chem-X to further enhance transparency and value.

The EU ESPR allows for the electronic submission of safety-relevant data, although specific data points from Safety Data Sheets are not explicitly mentioned. To address this gap, Chem-X enables the electronic submission of key SDS data points, allowing recipients to compile SDSs for their own products using the provided information. While the primary focus of the ESPR is on legally required data, the Digital Material Passport can also support the electronic submission of voluntary chemical information, such as:

- Full ingredient disclosure provided a non-disclosure agreement is in place.
- Information demonstrating compliance with the EU Ecolabel or equivalent ecolabels.

While printed materials such as labels and Safety Data Sheets will continue to play an important role, especially in communicating occupational safety information, the data model developed by Chem-X offers a forward-looking solution. It enables customers of the chemical industry to modernise and standardise their chemical management practices and align with future requirements under the EU ESPR and DPPs under other products specific regulations.

2.5 Benefits of harmonised and standardised material and substance Information in a DMP/DPP

As supply chains evolve into complex, multi-tiered ecosystems, the ability to exchange data electronically — across organisational and system boundaries — becomes a foundational capability.

To address this, the industry is converging on standardised data models and interoperable exchange protocols, with the Digital Product and Material Passport (DPP/DMP) emerging as a central enabler. The DMP/DPP provides a structured, machine-readable format for product-related data, aligned with regulatory requirements and industry best practices. However, data exchange without harmonisation could lead to fragmentation, inefficiency, and mistrust.

By adopting a standardised and harmonised data format, supply chain actors can:

- Automate data ingestion and validation through predefined schemas (e.g. JSON-LD, XML, or RDF), reducing manual effort and error rates,
- Ensure semantic consistency via shared ontologies and controlled vocabularies, enabling systems to interpret data uniformly (see Chapter 8),
- Integrate across platforms using standardised APIs and exchange protocols (e.g. REST, AS4, or EDI), supporting scalable and secure data flows,
- Enable traceability and auditability through persistent identifiers and version-controlled data structures.

For the receiving party, this translates into:

- Reduced integration complexity: Systems can consume data without custom mapping or transformation layers,
- Higher data quality: Validation against shared schemas ensures completeness, accuracy, and consistency,
- Improved compliance readiness: Structured data supports automated reporting and regulatory alignment,
- Faster onboarding of partners: Standardised interfaces reduce time-to-integration for new suppliers or customers,
- Future-proof architecture: Alignment with evolving EU digital product regulations and circular economy goals.

In summary, standardised and harmonised electronic data exchange — finalised by the DMP/DPP — is a critical infrastructure layer for digital supply networks. It enables trusted, scalable, and efficient collaboration across the value chain, unlocking both operational and strategic benefits.

3 Information Models

The Information Model, short IM, is a knowledge representation and the Single Point of Definitions (SPoD) using the Crow's Foot notation, using collections, entities, attributes and relationships.

Collections are groups of entities referring to the same topic. Entities represent both abstract and real things. They are described by their name and definition in natural language, including a telling example. Attributes describe the properties of the entities and are represented by a unique name, a description and, if possible, by a set of values. Relationships describe the context and interaction between the entities and are described by a verb and their cardinality. Cardinality characterises the number of entities involved (one or many) and whether it is mandatory or optional.

3.1 Information Model structure

The Information Model (IM) has multiple levels to facilitate its understanding, implementation and maintenance. Its foundation is described by the "Information Reference Model", defining values that are permitted for attributes as a List of Values (LoV), e.g. a set of regions that are not defined by standards or hazard statements. The "Information Domain Model" describes the value types that shall be used in the knowledge representation, e.g. chemical identifiers. The "List of Sources" specifies the type of source used for the lineage, e.g. organisation, regulation. Based on these three pillars, "Information Reference Model", "Information Domain Model" and "List of Sources", Information Models representing the Chem-X knowledge can be seen as a Single Point of Definition.

This information guideline essentially builds on three IMs:

- The Chem-X fundamental IM that describes what a chemical or a material is.
- The DMP IM is an application of the Chem-X fundamental IM that describes what information represents the Digital Material Passport.
- The optional SDS IM is an application of the Chem-X fundamental IM that describes what information represents the minimal digital Safety Data Sheet.

This version of the Material Declaration Guideline presents initial content on Material and Substance Declaration information. Both internal and external consultation processes will refine these Information Models. After the official external feedback, updated models will be published along with Json export capabilities.

3.2 Information Model export (JSON file)

This section will be published after integration of content chapter feedback from external consultation. The information model uses data entities and attributes described in the Guideline and are modelled in dataspot® to allow an export in a machine-readable format.

3.3 SDS-Model export (JSON file)

This section will be published after integration of content chapter feedback from external consultation. The information model uses data entities and attributes described in the Guideline and are modelled in dataspot® to allow an export in a machine-readable format.

4 Scope

This guideline provides a harmonised approach for declaring materials and substances and exchanging information across the supply chain. The DMP/DPP described in this guideline does not replace a Safety Data Sheet. The producer's legal liability to provide SDSs remains intact.

4.1 Material and Substance Declaration Model in Chem-X (EU focus) for a safe and circular economy

This document specifies requirements and gives guidance to economic operators and authorities for the declaration of materials and substances in a digital material and product passport (DMP/DPP) in accordance with existing EU regulations.

The Material and Substance Declaration Model (see Chapter 3) provides information entities and attributes of a chemical composition, material instances and material types for DPP integration. The data entities and attributes are designed with future-readiness in mind. They support current regulatory requirements and anticipate future needs. This applies to Material Declarations and information exchange in Digital Material Passports.

The Material and Substance Declaration Model allows the exchange of information to maintain compliance on DMP/DPP level. Current lists, maintained by the European Chemical Agency (ECHA) or defined in accordance with substances registration requirements under EU REACH, and potential substance lists expected via future ESPR delegated acts, can be integrated.

Especially for substances that potentially hinder recycling or circular economy solutions, the existing Chem-X Information Model delivers data attributes for information exchange, despite of the fact that such substance lists are currently not yet available.

A substance's main function related information is mandatory (in accordance with detergent and biocide product regulation) in the Material and Substance Declaration, while in the SDS further information like hazard identification, exposure control, and personal protection is provided.

This document and guideline with the described information will be transferred after external consultation into a Chem-X Material and Substance Declaration Model and shall be the basis for a chemical DMP/DPP standard.

4.2 Optional Safety Data Sheet Model in Chem-X (EU focus)

In addition to the mandatory material and substance declaration in a DMP/DPP, the Chem-X consortium developed an optional Information Model (see Chapter 3) to provide Safety Data Sheet related information that can be attached to a DMP/DPP.

Therefore, the Chem-X consortium decided to model requirements defined by the EU REACH Safety Data Sheet specific sections and the CLP Regulation. This approach enables automated data transfer from supplier to customer and allows this information to be optionally transported via a DMP/DPP.

The current SDS Information Model described in this document focuses on EU REACH SDS:

- Section 1. Identification: Chemical product identifier, recommended use, and supplier information

Scope

- Section 2. Hazard(s) Identification: Hazards of the chemical, including signal words, pictograms, hazard statements
- Section 3. Composition/Information on Ingredients
- Section 8. Exposure Controls/Personal Protection: Recommended exposure limits, and additional compositional information (e.g. PNEC, DNEL)
- Section 9. Physical and Chemical Properties: Key properties like appearance, odour, pH, melting/boiling point, and flammability
- Section 15. Regulatory Information: Information on relevant safety, health, and environmental regulations for the chemical

5 Material and Substance Declaration

5.1 General declaration principle

Material and Substance Declarations can range from Full Material Declarations (FMD) and Full Substance Declarations (FSD) to more limited declarations that focus on specific substances and keep the full material composition confidential.

For the chemical industry and their innovation capacity and international competitivity, the material composition is the core of intellectual property. This guideline therefore describes two distinct levels of the Material and Substance Declaration:

- Public Material Declaration (in accordance with current SDS practice)
- Confidential Material Declaration

The Information Model described in this guideline can manage both levels of confidentiality. Process-wise, the digital architecture for automated access for business partner/authority identification is out of scope of this guideline. Instead, it focuses solely on the Material and Substance Declaration. The digital architecture will be organised and proposed in upcoming Chem-X communications.

5.2 Public Material Declaration

The Public Material Declaration, as described in the Chem-X Material Declaration Information Model, is aligned with the current European regulations while being able to handle the exchange of material information in accordance with international material declaration and reporting requirements (see Annex II). In the following sections the data model entities (information carrier) will be described. Those entities with the related attributes (meta-information) will allow the combination of information in a Digital Material and Product Passport (DMP/DPP).

5.2.1 EU REACH information requirement (declaration)

Information on substance and mixture level has been modelled related to EU REACH requirements and will be described in the following sections.

5.2.1.1 Substance information

A substance is defined in Regulation (EC) No 1907/2006 (EU REACH) as a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition. The REACH and CLP guidance introduces further distinctions:

a. *Mono-constituent substance (REACH)*
   As a general rule, a substance, defined by its composition, in which one main constituent is present to at least 80% (w/w)
b. *More-than-one-constituent substance (CLP)*
   As a general rule, a substance, defined by its composition, in which more than one main constituent is present in a concentration ≥ 10% (w/w) and < 80% (w/w)

Chem-X analysed different regulatory and industry information requirements at substance level. A set of attributes was integrated into the substance information container (data entity).

These attributes will be necessary for checking and delivering future Digital Material and Product Passports (DMP/DPP). This ensures compliance with different EU regulations regarding Substance Declaration throughout the supply chain.

The following attributes will describe the substance information set as currently described in the Chem-X Information Model.

5.2.1.2 Substance identifier

Substance identifiers are the set of existing labels for a unique substance identification such as:

- CAS name and number
- EC Number
- EU REACH registration number
- INCI (International Nomenclature of Cosmetic Ingredients)
- IUPAC name
- Trivial Name

and others.

The substance identifiers have been modelled in the Information Domain Model in the section of chemical identifiers. International registries guarantee a unique substance identification. Trivial names instead are local or company specific identifiers with a possible risk of multiple substance definitions (no one-to-one relation).

5.2.1.3 Substance hazardous information

If the substance is listed in table 3 EU CLP Annex VI, it has a set of classifications and identifiers in the EU that need to be provided. Therefore, the following information could/should be delivered as substance information in a DMP/DPP:

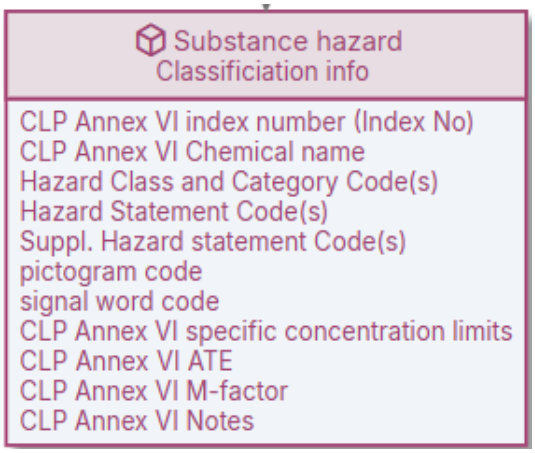

Figure 4: EU CLP-related substance information

In addition to the EU CLP Annex VI Table 3 information, further information on hazardous statements (form part of the Globally Harmonized System of Classification and Labelling of Chemicals (GHS)) could be included into the substance information carrier (data entity).

If a substance is not listed in Table 3 EU CLP Annex VI self-classification shall be used. Substance declaration information

Substance information to indicate and declare if the substance alone or the substance in a mixture and EU REACH article is:

a. An active biocidal substance in the EU in accordance with EU BPR
b. A critical raw material (CRMA) type substance in accordance with the European Critical Raw Materials Act
c. A substance listed in Annex VI of EU CLP Regulation (see Chapter 5.2.1.6)
d. A substance listed in the ECHA database subject to EU POP Regulation
e. A substance listed in the candidate list of Substances of Very High Concern for authorisation
f. A substance declared as nanomaterial in accordance with EU definition (nanosubstance)
g. A substance with European Union or national workplace exposure limits (EU OEL, national OEL) published via EU or national directives (e.g. TRGS900)

Further information carriers (data entities and attributes) for physical/chemical properties (e.g. flammability, boiling point, etc.) of a substance could be used in a DMP/DPP but also in the SDS model (see Chapter 6). This supports automated data interoperability.

The previous substance information has been modelled in the Chem-X Information Model as Boolean, so that a unique substance declaration on Digital Material and Product Passport level can directly be managed and exchanged.

Further information on substance level will be described in the following sections for:

a. A constituent substance in accordance with EU REACH (see Chapter 5.2.1.5)
b. A substance that is defined as substance of concern (see Chapter 5.2.1.6)

5.2.1.4 Constituent substance (EU REACH)

A substance may contain one or more main constituents, impurities, stabilisers or may be from unknown or variable composition (UVCB). The constituent substance describes more specifically the single constituents in a substance (MOCS – More than one constituent substance). The constituent substance entity in the Chem-X Information Model will deliver information on the concentration of the constituent substance and the constituent substance category (category name and constituent substance category). Based on a constituent substance information eventual registration or declaration or labelling requirements could be checked (e.g. BPR requirements).

5.2.1.5 Constituent substance category

The main constituent should be significantly different from the following two constituent categories:

a. Impurity: any unintentional constituents resulting from the manufacturing process or originating from the raw material(s). These impurities may be the result of secondary or incomplete reactions during production and may be present in the final material even if the manufacturer did not intend their occurrence.
b. Additive: all ingredients that have been added intentionally to maintain the stability of the substance and only for this purpose.

5.2.1.6 Substances of Concern (SoC) in ESPR

Chem-X modelled a SoC specific information carrier in close alignment with current ESPR Regulation with close connection to EU REACH, EU CLP and EU POP Regulation. Substances of Concern (SoC) are defined in Article 2 (27) of the Ecodesign for Sustainable Products Regulation (ESPR). A Substance of Concern is defined as a substance that:

a. Meets the criteria laid down in Article 57 of Regulation (EC) No 1907/2006 and is identified in accordance with Article 59(1) of that regulation
b. Is classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 in one of the following hazard classes or hazard categories:
    1. Carcinogenicity categories 1 and 2
    2. Germ cell mutagenicity categories 1 and 2
    3. Reproductive toxicity categories 1 and 2
    4. Endocrine disruption for human health categories 1 and 2
    5. Endocrine disruption for the environment categories 1 and 2
    6. Persistent, mobile and toxic or very persistent, very mobile properties
    7. Persistent, bioaccumulative and toxic or very persistent, very bioaccumulative properties
    8. Respiratory sensitisation category 1
    9. Skin sensitisation category 1
    10. Hazardous to the aquatic environment — categories chronic 1 to 4
    11. Hazardous to the ozone layer
    12. Specific target organ toxicity — repeated exposure categories 1 and 2
    13. Specific target organ toxicity — single exposure categories 1 and 2
c. Is regulated under Regulation (EU) 2019/1021
d. Negatively affects the reuse and recycling of materials in the product in which it is present.

Substances under article 2(27)(a) are Substances of Very High Concern (SVHC) in the EU REACH Regulation and modelled in Chem-X as SoC A. Substances under article 2(27)(b) are substances with a harmonised classification under the EU CLP Regulation and modelled in Chem-X as SoC B, while self-classified substances are not included. Substances with a harmonised classification are listed in Annex VI to EU CLP. Substances under article 2(27)(c) are Persistent Organic Pollutants (EU POP) regulated under the legislation on persistent organic pollutants and modelled as SoC C. Substances under article 2(27)(d) refer to substances that will be product-specific and be defined in product-specific delegated acts adopted under the ESPR listing substance hindering recyclability of products or having an adverse impact to recycling technologies of the related product modelled in Chem-X as SoC D.

Each product-specific delegated act can define thresholds and exemptions for SoCs. As the chemical industry is serving different industries and applications, potential SoCs under article 2 (27)(a)-(c) will be indicated, if they exceed the cut-off values of Safety Data Sheets. Chem-X Material Declaration shall be aligned with SDS information, while complying with the new regulation.

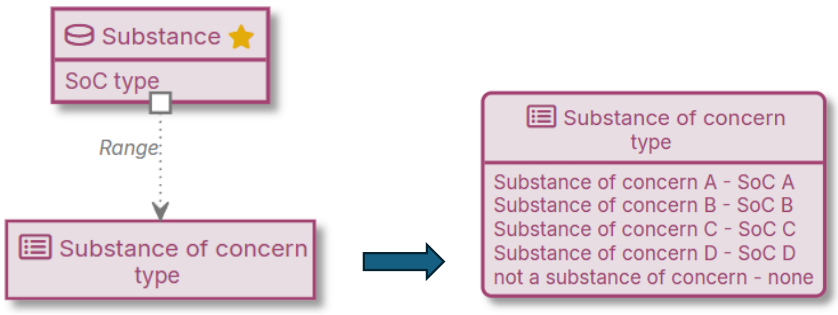

Figure 5: Chem-X model of SoC type reference data

5.2.2 Substance group

The information entity of substance group has been modelled outside of the substance entity to cover the opportunity of safety information under bundled substances in a substance group.

The substance group name is another identifier or a generic substance category under which common safety information in the optional SDS model could be attached.

5.2.3 Mixture

A mixture is defined in Regulation (EC) No 1907/2006 (EU REACH). Mixture means a mixture or solution composed of two or more intentionally added mixture substances. In the Chem-X Material Declaration Model the mixture data entity (data carrier) enables information exchange if the mixture is “as manufactured”, so before application (e.g. unreacted which could indicate not polymerised, not hardened). The mixture is assigned a name and can have an EU UFI-number or national UFI-numbers (e.g. Swiss BAG) and a mixture trade name.

The information of the “mixture substance(s)” and substances with the related information will be described in the “mixture substance” data entity (see Chapter 5).

5.2.4 Mixture substance

The mixture substance connects the substance with the mixture and is an artificial entity of the Information Model This allows to give substances a concentration or concentration range in the mixture and to indicate the substance related main function in the mixture. This main function in the mixture is added to provide the information in accordance with EU regulations like the biocidal product or/and detergent regulation.

The "mixture substance" entity describes the connections between individual substances in a mixture. This entity combines all substance information with mixture-specific details to fully describe the mixture's composition (see Figure 6).

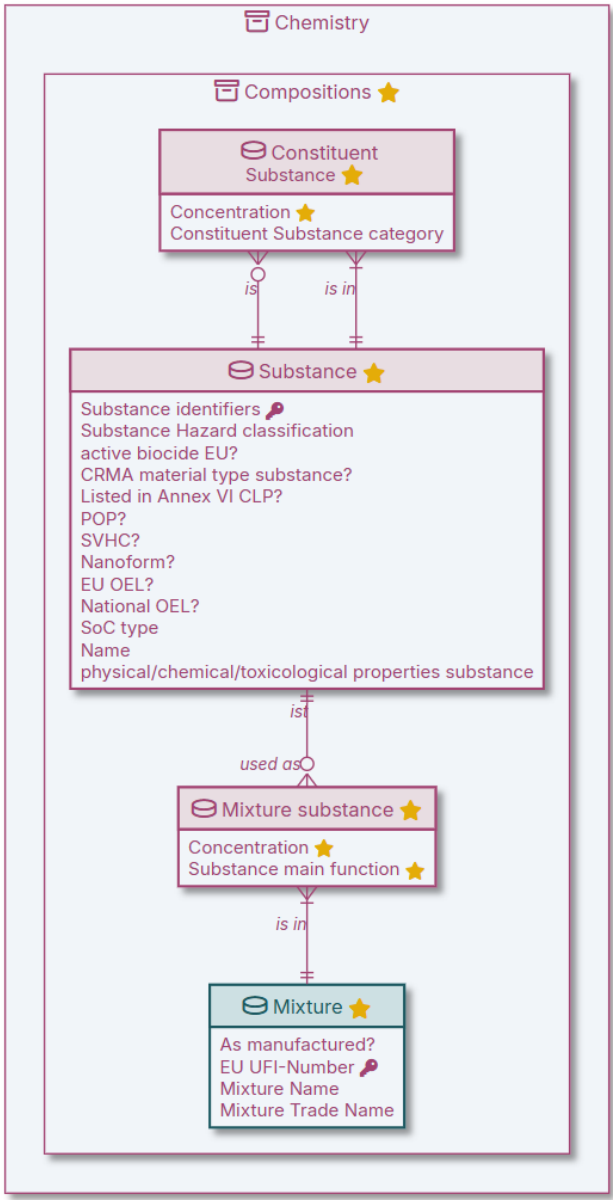

Figure 6: Mixture information (Remark: question marks indicate Boolean function)

5.2.5 EU REACH Article information

EU REACH Article has been modelled as data carrier for an unpackaged good to add information like the trivial name: “EU REACH Article” and an optional SCIP registration number listed in the ECHA database.

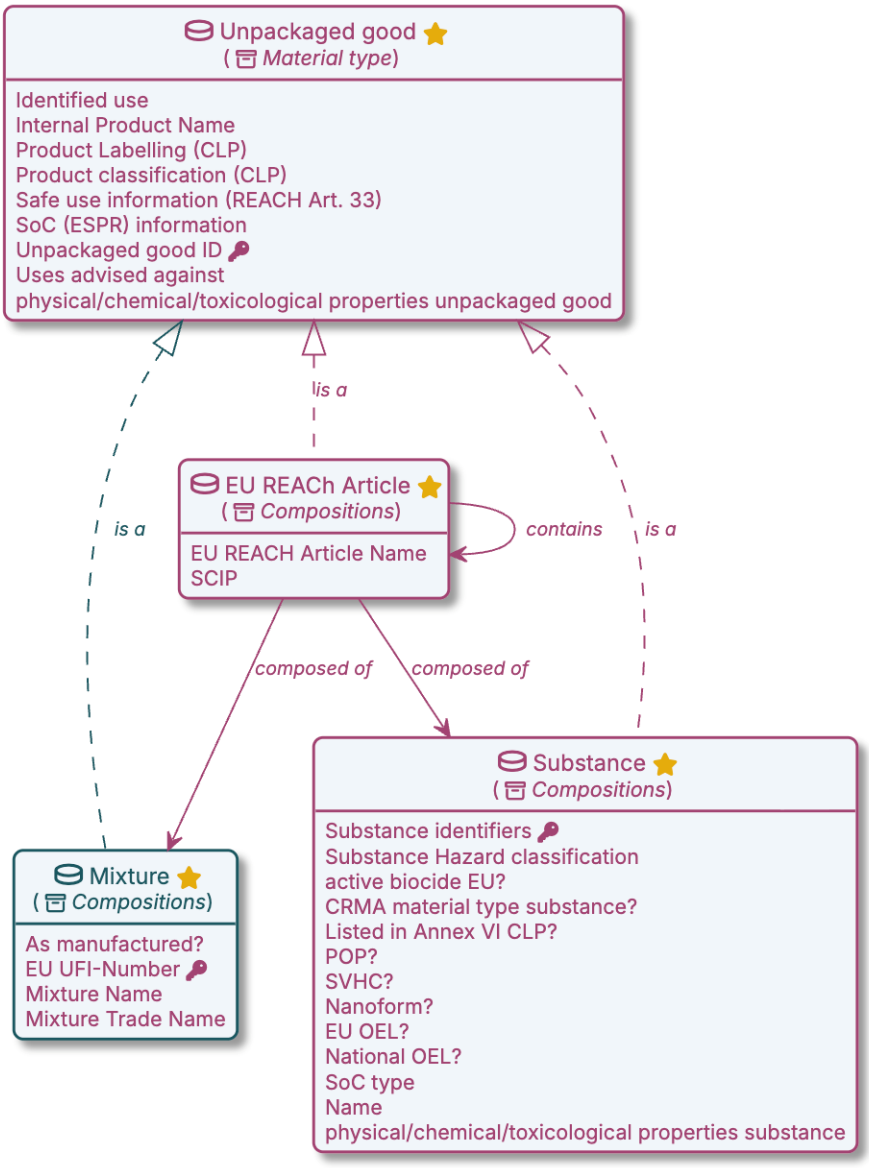

Figure 7: Information connection of EU REACH Article (Remark: question marks indicate Boolean function)

This information carrier (modelled entity of EU REACH Article) supports compliance with Article 33 of the EU REACH Regulation governing the information requirements in the supply chain. Article 33 requires information to be provided on Substances of Very High Concern (SVHC) in articles and will be transported via the substance information to indicate the presence of SVHC and provide information for safe use (see Chapter 6).

Upstream communication (back to supplier) in accordance with Article 34 is not covered by the information. It needs to be organised between supply chain actors separately (currently not modelled in the Information Model).

5.2.6 Material Type Model

The material type model describes the connectivity of different materials and related information from an unpackaged good to a packaged good.

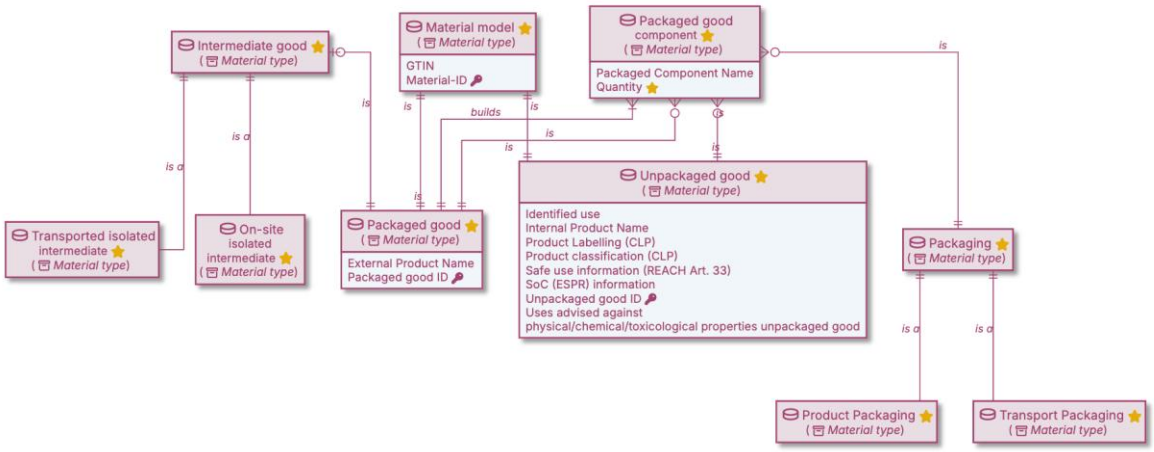

Figure 8: Material Type Model

The material type collection (grouping of multiple entities) bridges the composition collection with the Digital Material and Product Passport collection. It helps to define the material model, the packaging and how the packaged good is handled. Is it a single Stock Keeping Unit (SKU), as set or assortment or palletised goods for storage or transport.

5.2.6.1 Unpackaged good

Unpackaged good can be understood as the physical representation of a material before it gets filled into any containment (packaging). In some areas this is called “BULK”.

Unpackaged good is a “bulk material” in its natural state or as manufactured, without specified packaging or packaging size. It is identified by its unpackaged good ID and an internal product name and carries the mandatory information for safe use, i.e. physical, chemical, toxicological properties.

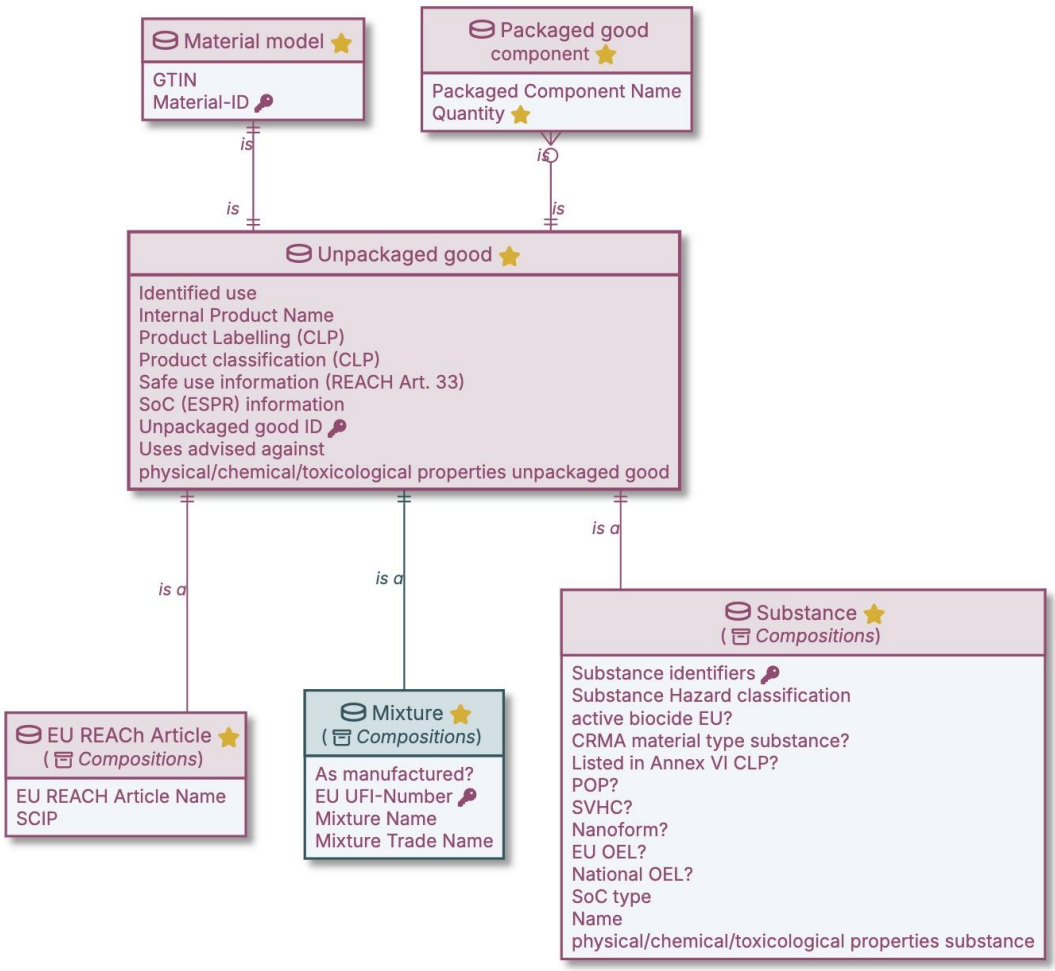

Figure 9: Unpackaged good composition (Information model without a hierarchical view)

As unpackaged good is a representation of a material type that is being manufactured at a later stage as a physical product, its material and product information granularity will be on “model”-level only. Unpackaged good consists of either substances, mixtures or EU REACH Articles or of the combination of these three entities. Hence unpackaged good inherits the information of these entities (see Figure 7).

5.2.6.2 Packaged good

A packaged good is derived from an unpackaged good by filling it into packaging. This can be either product packaging (also called primary packaging) or transport packaging (also called secondary packaging). It is characterised as unpackaged or packaged goods in a packaging that serves safety, identification, logistic (transportability, storage), and declaration (information) purposes. A packaged good must consist of at least one unpackaged or packaged good and at least one packaging component.

It represents the description of an article and its packaging. Some may refer to it as a Stock Keeping Unit (SKU). Packaged goods can exist at various levels of granularity, ranging from a single packaged good (a drum, container, or bag filled with unpackaged good) to an assortment (a specific selection of packaged goods). Chem-X defines "product" as a synonym for "packaged good."

A set, kit, or Multi-Component Product (MCP) is a packaged product containing several components, which can themselves be packaged products (such as assortments or gift packs with several goods inside). Sets, kits, and MCPs may have their own identifiers and can be integrated into a DMP/DPP as information.

5.2.7 Packaging

Packaging (type) refers to materials used to enclose or protect unpackaged goods for distribution, storage, sale, and use. It serves multiple functions including protection, preservation, information, marketing, and convenience. The packaging material will be handled as a material and could be declared with the same attributes and entities provided in this guideline.

We distinguish between two packaging types and entities:

5.2.7.1 Product packaging

Product packaging is a packaging (also known as primary packaging) is an integral part of the product that is necessary to deliver unpackaged goods to the customer. It comes in direct contact with the product (e.g. paint bucket, plastic bottle, cardboard box).

Example: A carton box secured with adhesive tape represents two product packaging components: the carton box and the adhesive tape.

5.2.7.2 Transport packaging

Transport packaging assembles multiple unpackaged goods for transportation purposes. It is typically used multiple times throughout the product life cycle (e.g. EU pallet, silo tank, Intermediate Bulk Container (IBC)).

5.3 Confidential Material Declaration

The exchange of confidential material information may be necessary depending on the use of a material (e.g. in a specific industry sector like medical or aviation) or may be required by an authority for disclosure. This data often extends beyond the usual scope of information required in the supply chain (e.g. data from the safety data sheet) and may be classified as confidential business information by the supplier. In the private sector, confidentiality is typically established through contractual agreements before data exchange occurs. Access to confidential material information is organised by business partner or authority identifiers. The Chem-X Material and Substance Declaration Model is designed to deliver detailed confidential information.

5.3.1 Sector- and regulatory-specific Material Declaration

Certain uses of substances and mixtures may be linked to special information obligations in the supply chain due to specific chemicals legislation. As soon as this information exceeds generally mandatory content (such as BoM/recipes, which is the intellectual property of chemical producers/companies), it is shared only with selected supply chain participants (e.g. in medical, aviation, or military sectors). Additional industry- or use-specific data is transferred only after the conclusion of a non-disclosure agreement.

5.3.2 Authority-specific Material Declaration

Based on legal requirements, public authorities (e.g. market surveillance, customs) can demand the disclosure of additional information, which is often classified as confidential data.

Unlike the exchange of product information and data in the private sector, non-disclosure agreements are not common in these regulatory contexts.

5.4 Material Instances Model (Model/Batch/Item Information)

In Chem-X we distinguish between three different Instance Information Levels with their specific information carrier which could be combined in a Digital Material and Product Passport (DMP/DPP)

Material Instance Information Levels:

1. Model Level Information
2. Batch Level Information
3. Item Level Information

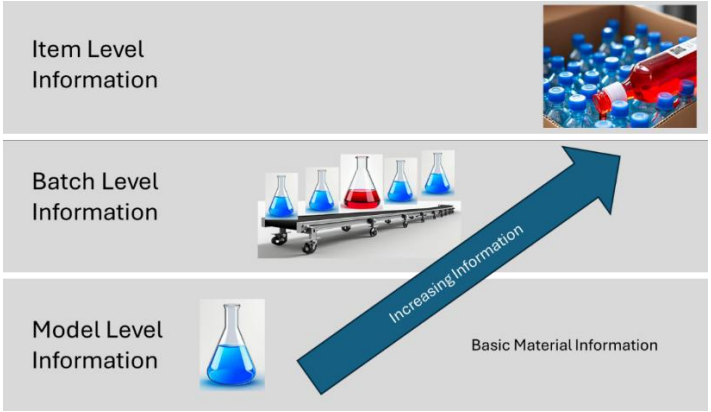

Figure 10: Material Instance Level of information

Only for specific Industry requirements and regulations Item or Batch Level Information may be required to be delivered in a DMP/DPP. These requirements originate from sectors such as pharmaceutical and aviation industries for specific traceability purposes.

Those items – including Batch Information – are mostly combined with required confidentiality agreements between the supply chain partners. This Batch and Item Level Information will be saved in digital product data bases (enterprise resource planning systems) of the supply chain partner for use in cases involving safety, specification, traceability, or warranty issues.

5.4.1 Model Level Information

The Chem-X general instance level of information is the Model Level Information that is directly linked to the physical material and product/manufactured product with the respective composition of the material, used in a Digital Material and Product Passport.

5.4.2 Batch Level Information (optional)

Batch Information could be particularly valuable because it:

- Enables precise product recalls if quality issues arise
- Facilitates material traceability throughout the value chain
- Supports quality investigations when performance issues occur
- Helps with regulatory compliance documentation
- Enables tracking of sustainability metrics across different production runs
- Supports circular economy initiatives by providing data on material composition

As a product steward, explaining Batch Information is a critical part of ensuring product traceability, quality control, and regulatory compliance while delivering the following key attributes of Batch Information

- Batch/Lot Number: A unique identifier for a specific production run
- Production Date: When the material was manufactured
- Expiration Date: When the product should no longer be used
- Manufacturing Location: Where the batch was produced
- Quantity: Amount produced in that specific batch
- Raw Material Information: Traceability to input materials (which is connected to the composition entity)
- Optional Process Parameters: Key production conditions that may affect quality

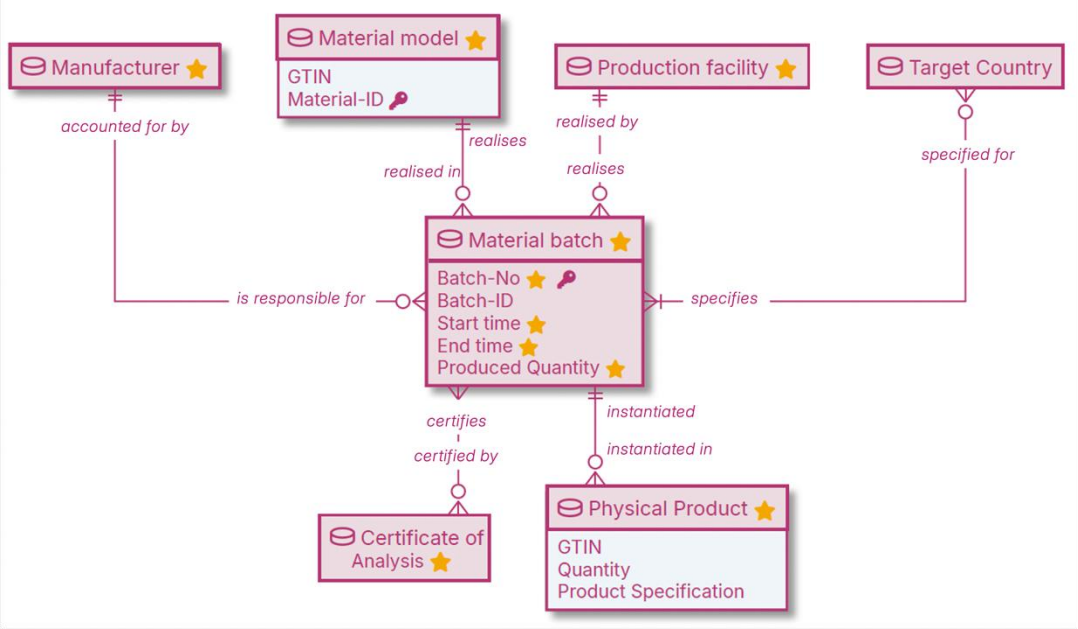

Figure 11: Material Batch Information

5.4.3 Item Level Information (optional)

Material Item Information refers to the comprehensive data set that identifies and characterises a specific material or physical product within your inventory or supply chain. This is particularly relevant for quality managers.

Item Level Information is connected to Batch Level Information and the related physical product information with links to the material composition information. While Batch Information tracks specific production runs, Material Item Information provides the baseline data about the material itself, independent of production timing. Together, they form a complete picture of materials throughout their lifecycle.

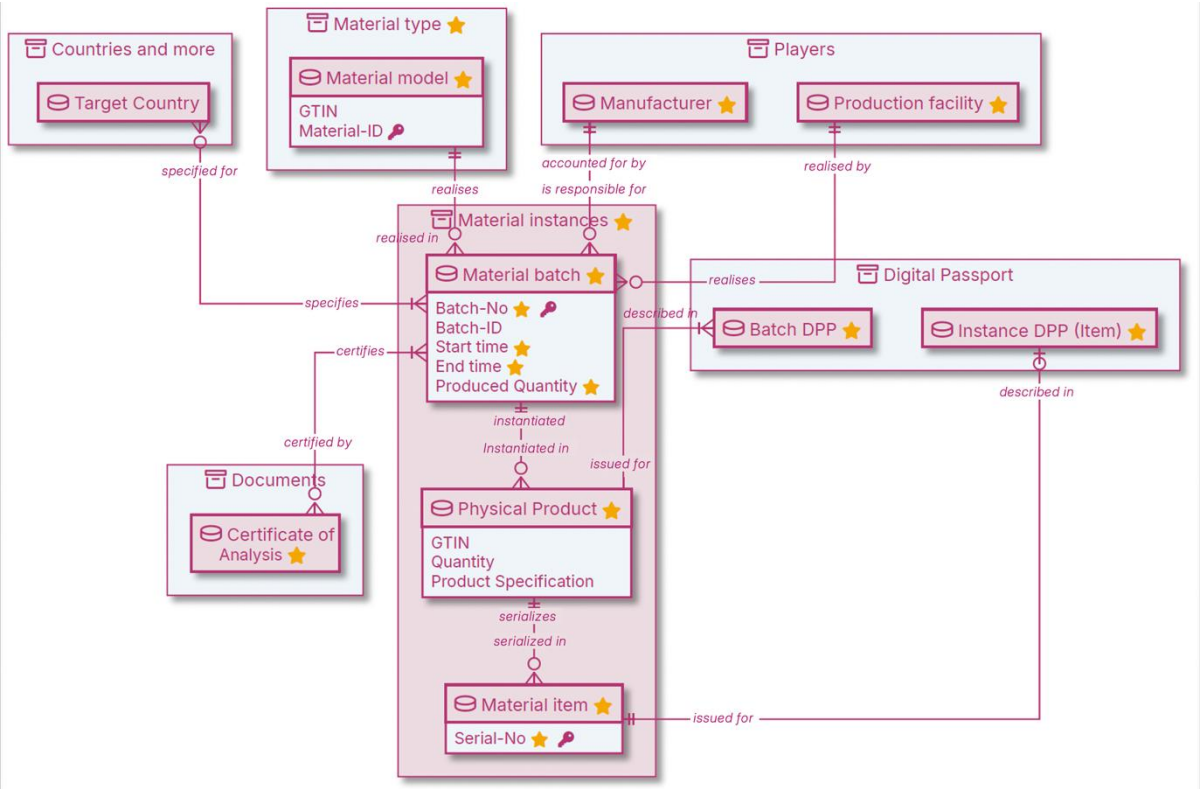

Figure 12: Material Item Information Set

Figure 13 explains the Instance Model from the content (product information depth) perspective to the information contained in the different levels while having the Model Information as core of information set useable in an DMP/DPP.

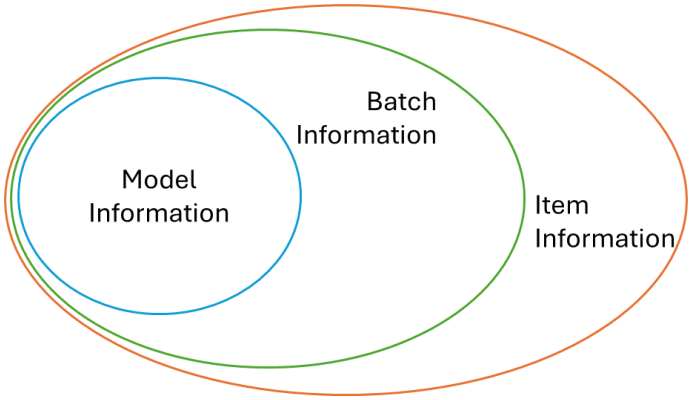

Figure 13: Model/Batch/Item onion model

6 Safety Data Sheet Information (in DMP/DPP – optional)

6.1 Rational SDS information in DMP/DPP

This section addresses data specified in safety data sheets that may also be relevant for digital product passport records. This applies particularly to technical, physicochemical, and regulatory information on substances and mixtures. The section headings referenced here correspond to those in the EU REACH Regulation (EC) No 1907/2006) (see Annex II).

Horizontal information like geographic (country), language, versioning, and authoring date will be provided on DMP/DPP level. SDS information will be modelled as optional information in a DMP/DPP model. An SDS data life cycle management is not part of this guideline.

6.2 Section 1: Identification of the substance/mixture and of the company

In this section of the safety data sheet, EU REACH requires how the substance or mixture should be identified. A brief description of the intended uses like “adhesive”, “surface cleaner”, “lubricant” is given. If relevant, uses advised against for safety or environmental protection reasons must be indicated. Additionally, the supplier's name and contact information, including an emergency contact, must be provided.

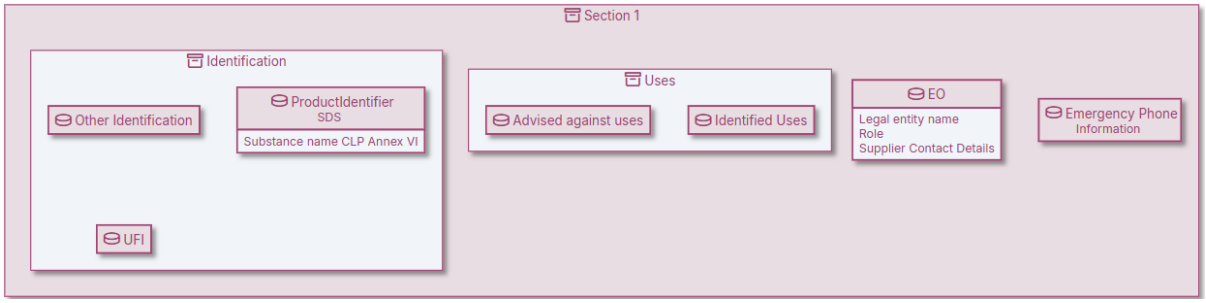

Figure 14: SDS Section 1 data entities and attributes

6.3 Section 2: Hazards identification

This section describes the hazards of the substance or mixture, and the appropriate warnings related to these hazards.

The classification of the substance or mixture must be provided in accordance with the EU CLP Regulation (EC) No 1272/2008. If the substance or mixture does not meet the classification criteria according to the EU CLP Regulation, this must be clearly stated.

Based on the classification, at least the following elements must be provided on the label in accordance with the EU CLP Regulation: hazard pictogram(s), signal word, hazard statement(s), and precautionary statement(s).

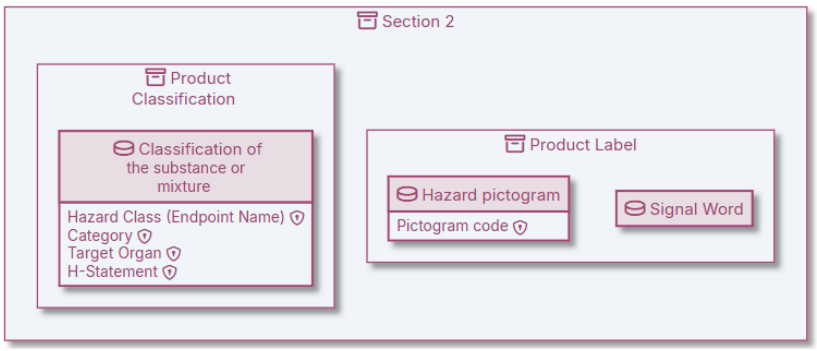

Figure 15: SDS Section 2 data entities and attributes

6.4 Section 3: Composition/information on ingredients

This section describes the chemical identity of components in the substance or mixture classified as hazardous under EU CLP that meet or exceed minimum concentration thresholds for disclosure. Appropriate and available information on surface chemistry must also be provided.

The chemical identity of the main component(s) shall be indicated at least by providing appropriate identifiers.

Suppliers of substances may voluntarily choose to list additional or all components, including non-classified components.

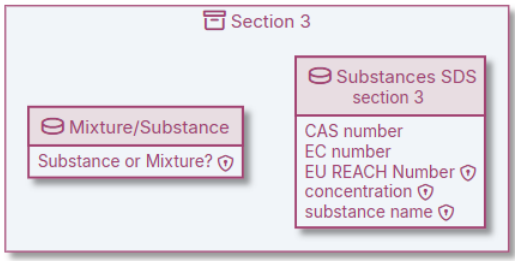

Figure 16: SDS Section 3 data entities and attributes

6.5 Section 8: Exposure controls/personal protection

Under Regulation (EC) No 1907/2006 (EU REACH) (see Annex II) occupational exposure limits for respective substances must be listed in accordance with both national and Union legislation. If only national exposure limits apply, the relevant substance may be referenced solely in Section 8. In such cases, this information may serve as a complement to the compositional data provided in Section 3.

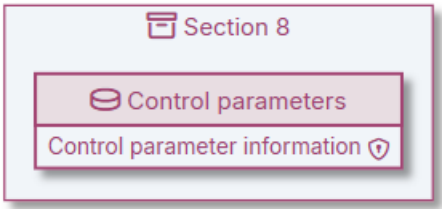

Figure 17: SDS Section 8 data entity and attribute

6.6 Section 9: Physical and chemical properties

The properties listed in Section 9 of a Safety Data Sheet are essential for product handling, transport, and hazard assessment. As this section allows the display of a manifold of information, our model focuses on section 9.1 as specified in EU REACH, Part A, 9.1, and selective characteristics from Section 9.2 to cover the most relevant data. For the section 9.2 flammability and oxidising properties consolidated across all three aggregate states.

Figure 18: SDS Section 9 data entities and attributes

6.7 Section 15: Regulatory information

Information in Section 15 includes information on applicable Union and national laws for the product. Our model focusses on EU REACH-relevant content such as the availability of chemical safety assessment and applicable authorisations or restrictions according to Title VII and Title VIII of EU REACH.

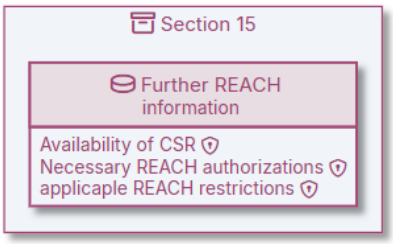

Figure 19: Selection of SDS Section 15 data attributes

7 Outlook

The Chem-X project supports the chemical industry, a key enabler for economic growth, resilience, and transition to a sustainable future. The industry faces challenges including rising costs, regulatory pressure, and international competition, which require a shift towards digitalisation and sustainability. Chem-X aims to support this transformation by creating an interoperable data space for chemicals and materials. This includes defining chemistry-specific data points, improving supply chain interoperability and efficiency, and promoting sustainable practices and circular economy principles. Material Declaration forms the core of any Digital Material Passport, while a full Material and Substance Declaration balances transparency requirements with the critical need to protect intellectual property of material and chemical producers.

The chemical industry needs to be prepared to support customer (OEM, B2C) requirements in accordance with ESPR and existing chemical regulations. Therefore, Chem-X started to develop a Material Declaration Information Model for efficient data exchange within Digital Material and Product Passports. To harmonise requirements across different EU chemical regulation, Chem-X will publish guidelines featuring the Information Model with specific material instance and material types. The consortium will collect feedback and improve these models throughout 2026 for implementation in DMP/DPP semantic models across supply chains.

Chem-X strives to align the Information Model with ongoing manufacturing X sector related projects and intends to advance the developed Information Model and related architecture toward EU and international standardisation.

8 Terminology (Glossary)

This guideline uses precise terminology to indicate which provisions are required in material and substance declarations within a potential Chem-X DPP. All abbreviations are explained, and references to current regulations have been incorporated.

Term	Definition	Chem-X Model Category	Source
Battery Regulation	EU rules on batteries aim to make batteries sustainable throughout their entire life cycle – from the sourcing of materials to their collection, recycling and repurposing	DMP / DPP Model	Regulation (EU) 2023/1542
Biocidal Active substance (EU)	If a substance is an active biocidal substance according to Regulation (EU) No 528/2012, an indication on DPP substance level is mandatory	Substance	Regulation (EU) No 528/2012
BoM	Bill of Materials Presentation of the constituents in a product structure with the possibility to adopt the level of decomposition to actual need		ISO 29845:2011(en) Technical product documentation — Document types
CAS Name	CAS Name is the substance name associated to the CAS Number	Composition / Substance Identifier	CAS REGISTRY
CAS Number	A CAS Registry Number (CAS RN®) is an identifier for a substance that allows communication and, with the help of CAS scientists, links together all available data and research about that substance. Governmental agencies rely on CAS Registry Numbers for substance identification in regulatory applications because they are unique, easily validated, and internationally recognised.	Composition / Substance Identifier	CAS REGISTRY
CLP Annex VI	European Chemical Agency Table of harmonised entries	Composition / Substance	Table of harmonised entries in Annex VI to EU CLP - ECHA

Term	Definition	Chem-X Model Category	Source
Concentration	Proportion [%] of a substance in a mixture. The proportion of all substances in a mixture cannot add up to a concentration of 100% if all substances are declared. Units: mass or volume percentage, ppm, ppb	Mixture Substance & Constituent Substance	
Constituent	Any single species present in a substance can be characterised by its unique chemical identity. Constituents of substances are atoms and molecules.	Substance / Constituent Substance	See ECHA Q&A
Constituent Substance	Parts list entry for a substance in a combination of substances in accordance with EU REACH. The EU REACH definition includes MOCS (More than one constituent Substance). A constituent substance could be 1. **Main constituent** A constituent, not being an additive or impurity, in a substance that makes a significant part of that substance and is therefore used in substance naming and detailed substance identification. 2. **Impurity** An unintended constituent present in a substance as manufactured. It may originate from the starting materials or be the result of secondary or incomplete reactions during the manufacturing process. While it is present in the final substance it was not intentionally added. 3. **Constituent** Any single species present in a substance can be characterised by its unique chemical identity.	Substance / Constituent Substance	BAuA - Reflections on the definition of the term 'substance' in the European Law on Substances - Federal Institute for Occupational Safety and Health

Term	Definition	Chem-X Model Category	Source
Constituent Substance Category	In our Material Declaration Model, we defined three substance categories: 1. Main Constituent 2. Additive 3. Impurity	Composition / Constituent Substance	
Cosmetic Products Regulation	Legal framework for cosmetic products on the EU market, establishing rules for product safety and free movement		Regulation (EC) No 1223/2009
CRMA material-type substance	Strategic substances (raw materials) in accordance with Annex I Section 1 and critical substances (raw materials) in accordance with Annes II Section 1 of EU Regulation (EU) 2024/1252	Composition / Substances	Regulation (EU) 2024/1252
Crow's notation	Also described as crow's foot notation is a notation for semantic data modelling that allows the visualisation of simplified "entity"-relationship modelling		Gordon Everest, Basic Data Structure Models, Computing Systems 1976, Proceedings Fifth Texas Conference on Computing System
Detergents Regulation	EU framework for detergents and cleaning products, designed to protect human health and the environment by harmonising rules on biodegradability, ingredient disclosure, and labelling to ensure free movement of these products within EU's internal market.		Regulation (EC) No 648/2004

Term	Definition	Chem-X Model Category	Source
DMP **Digital Material Passport**	A structured digital record for a material that contains detailed information about sustainability and circularity, as well as required and potentially optional declarations, certificates, and additional material information. It focuses on intermediate materials in the value chain which may not be subject to regulation, but whose data are required to enable the issue of regulated Digital Product Passports (DPPs). DMPs are designed to interoperate with one or more DPPs.	DMP Model Level	Chem-X Definition
DPP **Digital Product Passport**	A structured digital record for a product that contains detailed information about sustainability and circularity, as well as required and potentially optional declarations, certificates, and additional product information. It focuses on a regulated end product in the value chain. Both its information content and technical requirements follow regulatory requirements and/or standards delegated by the legislator to designated standardization bodies.	DPP Model Level	Chem-X Definition *Note 1: based on DPP definition in ESPR*
ECHA	European Chemical Agency		echa.europa.eu
EC-Number	An EC-number, i.e. the EINECS, ELINCS or NLP number, is the official number of a substance within the European Union. An EC-number can be obtained from the official publications of EINECS, ELINCS and NLP and of the European Chemicals Agency (list numbers).	Composition / Substance Identifier	About EC and list numbers - ECHA
ESPR	Ecodesign for Sustainable Products Regulation		Regulation (EU) 2024/1781
EU BPR	European Biocidal Product Regulation (EU) No 528/2012	Composition / Substances	Regulation (EU) No 528/2012
EU CLP Regulation	Regulation (EC) No 1272/2008 on the Classification, Labelling and Packaging of substances and mixtures		Regulation (EC) No 1272/2008

Term	Definition	Chem-X Model Category	Source
EU CPR	European Construction Products Regulation (EU CPR) lays down harmonised rules for the marketing of construction products in the EU. The regulation provides a common technical language to assess the performance of construction products. It ensures that reliable information is available to professionals, public authorities, and consumers, so they can compare the performance of products from different manufacturers in different countries.		Regulation (EU) 2024/3110
EU OEL	European Occupational Exposure Limits (OELs) are indicative or binding limits for the concentration of a chemical substance in the air of a workplace. OELs is a key component of workplace safety and risk management.	Composition / Substances	
EU POP	European Persistent organic pollutants (EU POPs) - organic substances that persist in the environment, accumulate in living organisms and pose a risk to our health and the environment.	Composition / Substances	Regulation (EU) 2019/1021
EU REACH	EU REACH Regulation ("Registration, Evaluation, Authorisation and Restriction of Chemicals") is the main EU law governing chemicals, requiring companies to identify and manage the risks of chemicals to protect human health and the environment.		Regulation (EC) No 1907/2006
EU REACH Article	An object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition. Examples: bolt, adhesive tape, bicycle, empty paint can, steel pipe, jewellery diamond, diamond drill, cut diamond, battery, car, polymer film, polymerised foam, shaped mattress, cardboard box, printed plastic film, milk carton, spoon		

Term	Definition	Chem-X Model Category	Source
EU REACH Registration number	A REACH Registration Number is a unique, 18-digit identifier assigned by the European Chemicals Agency (ECHA) after a company successfully registers a chemical substance under the EU's REACH regulation (Registration, Evaluation, Authorisation, and Restriction of Chemicals).	Composition / Substance Identifier	[registration] EU REACH - Registration, Evaluation, Authorisation and Restriction of Chemicals
Full Material Declarations (FMD)	Composition declaration whereby all materials and substances are declared Note 1 to entry: Substances anonymously identified can be proprietary substances the responder retains as confidential business information (CBI). The mass of all substances including those that are identified as anonymous adds up to 100% of the mass of the product.		IEC 82474-1:2025
Full Substance Declarations (FSD)	Composition declaration whereby all substances are declared Note 1 to entry: FSD is an FMD that does not include any anonymous identification of substances in the declaration.		IEC 82474-1:2025
FCM	Food Contact Material (FCM) Regulation (EC) No 1935/2004 is the EU framework regulation establishing general safety and inertness requirements for all food contact materials		Regulation (EC) No 1935/2004
Hazard classes		SDS / Substance	Regulation - 1272/2008 - EN - clp regulation - EUR-Lex

Term	Definition	Chem-X Model Category	Source
Hazard Statement	EU CLP hazard statements (H-phrases) are standardised phrases describing the nature and degree of hazards posed by a hazardous substance or mixture, as defined by the European Union's CLP Regulation (Classification, Labelling and Packaging). They are part of the mandatory labelling for chemicals, consisting of a letter 'H' followed by a three-digit code (e.g. H315: "Causes skin irritation") that specifies the hazard. These statements communicate physical, health, and environmental risks to users, providing crucial information for safe handling and use.	Composition / Substance	http://data.europa.eu/eli/reg/2008/1272/oj
Hazards and identifiers according to EU CLP Annex VI tab 3	If the substance(s) are listed in the table 3 EU CLP Annex VI, it has or have a set of classifications and identifiers in the EU	Composition / Substance	ECHA CHEM | Obligation list
IM	Information Model		
Impurity	An unintended constituent present in a substance as manufactured. It may originate from the starting materials or be the result of secondary or incomplete reactions during the manufacturing process. While it is present in the final substance it was not intentionally added. NIAS (non-intentionally added substances) are impurities in accordance with (EU) No 10/2011 (18)		See “Constituent Substance”
INCI	INCI names (International Nomenclature Cosmetic Ingredient) are systematic names internationally recognised to identify cosmetic ingredients.	Composition / Substance Identifier	INCI - International Nomenclature Cosmetic Ingredient
IUPAC Name	IUPAC Nomenclature ensures that each compound (and its various isomers) has only one formally accepted name known as the systematic IUPAC name.	Composition / Substance Identifier	Nomenclature - IUPAC

Term	Definition	Chem-X Model Category	Source
Main Constituent	A constituent, not being an additive or impurity, in a substance that makes a significant part of that substance and is therefore used in substance naming and detailed substance identification.		See “Constituent Substance”
Mixture	Mixture or solution composed of two or more substances. Examples: Salt solution, petrol, windshield wiper washer fluid. Remark: MOCS (More than one constituent substance or Multi constituent substance) are excluded.	Composition / Mixture	
Mixture substance	Parts list entry for a substance in a mixture. The proportions of all substances in a mixture must add up to 100%. Synonyms: Mixture-BoM, Mixture Part List	Composition / Mixture Substance	
MOCS	More than one constituent substance A substance, defined by its composition, in which more than one main constituent is present in a concentration ≥ 10% (w/w) and < 80% (w/w).	Composition / Substances	
Nanoform	A “nanoform” is a form of a natural or manufactured substance containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm-100 nm, including also by derogation fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm.	Composition / Substances	ECHA Guidance on nanoforms

Term	Definition	Chem-X Model Category	Source
National OEL	Occupational Exposure Limits (OELs) published by national authorities e.g. via TRGS900 for Germany	Composition / Substances	BAuA - Technical Rules for Hazardous Substances (TRGS) - Federal Institute for Occupational Safety and Health
Packaged good	A product combined with its packaging, prepared in advance for sale and with a predetermined quantity that cannot be altered without opening or modifying the packaging. A packaged good is a combination of an unpackaged good and a packaging for safety, identification, logistic (transportability, storage), declaration (information) reasons.	Chemical Material / Material Type	
Packaging	Packaging (type) refers to processes and materials used to enclose or protect products for distribution, storage, sale and use. Including: Protection, preservation, information, marketing, convenience. We distinguish in the Chem-X Material model between product packaging and transport packaging.	Chemical Material / Material Type	
Product Packaging	Is a packaging that is part of the product that is needed to bring the unpackaged goods to the customer. In direct contact with the product.	Chemical Material / Material Type	

Term	Definition	Chem-X Model Category	Source
SCIP number	The SCIP number is a unique identifier assigned to a notification submitted to the SCIP database – the Substances of Concern In articles as such or in complex objects (Products) database – established under Article 9(1)(i) of the EU Waste Framework Directive (WFD). This database is managed by the European Chemicals Agency (ECHA) and is directly linked to Article 33 of the EU REACH Regulation, which mandates that suppliers of articles containing Substances of Very High Concern (SVHCs) above 0.1% w/w must communicate safe use information to downstream users and consumer	Composition / EU REACH article	ECHA SCIP database
Substance	Substance means a chemical element and its compounds in the natural state	Composition /S ubstance	Point 1 of Article 3 of Regulation (EC) No 1907/2006
Substance Function Type	Type of Substance identifying the role and function of the substance in a mixture (e.g. EU BPR Product Type in accordance with Biocidal Products Regulation (EU BPR, Regulation (EU) No 528/2012) and/or detergent regulation (EC) No 648/2004)	Composition / Mixture Substance	EU BPR, Regulation (EU) No 528/2012 and/or detergent Regulation (EC) No 648/2004
Substance group	Two or more substances, which share at least one chemical sub-structure, or chemical or physical property under a generic name	Composition / Substance group	
Substance Identifier	The product identifier for a substance shall consist of at least of one identifier (CAS name, CAS number, EC-Number, EU REACH registration number, INCI, IUPAC Name or a trivial name)	Composition / Substance	
Substance Main Function	Main function (role or effect) that a substance has in a mixture. There can only be one of these. The substance main function is listed in different regulations in so-called substance function types.	Composition / Mixture Substance	

Term	Definition	Chem-X Model Category	Source
Substance of Concern (SoC)	Substance of concern (SoC) means a substance that: (a) meets the criteria laid down in Article 57 of Regulation (EC) No 1907/2006 and is identified in accordance with Article 59(1) of that Regulation; (b) is classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 in hazard classes or hazard categories.	Composition / Substances	
SVHC	Substances of very high concern, published by ECHA in accordance with Article 59(10) of the EU REACH Regulation	Composition / Substances	Candidate List of substances of very high concern for Authorisation - ECHA
Toy Safety Directive	EU Toy Safety Directive 2009/48/EC sets mandatory safety requirements for toys sold in the European Economic Area (EEA) to protect children from hazards		Directive 2009/48/EC
Transport Packaging	Is a packaging to assemble several unpackaged goods or packaged goods for transportation purposes. It is used several times in the life cycle stage.	Chemical Material / Material Type	
Trivial Name	1. Retained names are often used for the most fundamental parts of a nomenclature system: almost all the chemical elements have retained names rather than being named systematically, as do the first four alkanes, benzene and most simple heterocyclic compounds. Water and ammonia are other examples of retained names. Retained names may be either semi systematic or completely trivial; that is, they may contain certain elements of systematic nomenclature or none. 2. Non-systematic substance name which is not a formal name while describing the essential properties of the substance named	Composition / Substance Identifier	

Term	Definition	Chem-X Model Category	Source
Unpackaged good	A good (mixture, substance, EU REACH Article) ready to be packaged for further value chain steps	Chemical Material / Material Type	
WFD	The Waste Framework Directive sets out the basic concepts and definitions related to waste management, including definitions of waste, recycling, and recovery.		Directive 2008/98/EC

9 Literature / Citations

Citations and references from EU regulations have been integrated into the glossary for the related term and definition.

Gordon Everest, Basic Data Structure Models Explained with a Common Example, in Computing Systems 1976, Proceedings Fifth Texas Conference on Computing Systems

Regulation (EU) 2024/1781 of the European Parliament and of the Council of 13 June 2024 establishing a framework for the setting of ecodesign requirements for sustainable products, amending Directive (EU) 2020/1828 and Regulation (EU) 2023/1542 and repealing Directive 2009/125/EC - see recital 26

10 Disclaimer

The content presented in this guideline was developed by the Chem-X consortium of selected companies and individual experts working in collaboration in the Material Declaration sub-project of "Chem-X".

Funded by the European Union – NextGeneration EU. The views and opinions expressed are solely those of the authors and do not necessarily reflect the views of the European Union or the European Commission. Neither the European Union nor the European Commission can be held responsible for them.

Additional Information: For some text formulations in the introduction and the summary section and for the generation of selected pictures artificial intelligence programs have been used.

The data model figures are hard copies from the material declaration and SDS information model developed with dataspot® software.

Annex I Chemical information requirements in European products regulations

The following table summarises the chemical information requirements relevant to the data requested under selected EU regulations, excluding obligations related to substance registration under REACH and Classification and Labelling (C&L) notifications under EU CLP.

	Authorities (ECHA & member states)	**Customers (B2B)**	**Consumers (B2C)**	**Label**	**Safety Data Sheet (SDS)**
EU REACH Regulation (EC) No 1907/2006	Classification and labelling (if not registered) [EU CLP Art. 40] - Substance identity with analytical data [EU REACH Annex VI]	Safety Data Sheet (SDS) [EU REACH Art. 31] - Exposure scenarios (if CSR required) [EU REACH Art. 14, Annex II] - EU REACH registration number [EU REACH Art. 20(3)] - SVHC communication [EU REACH Art. 33]	SVHC communication for articles >0.1% w/w [EU REACH Art. 33(2)]	Not regulated by EU REACH directly	Section 1: Substance identity, registrant info [EU REACH Annex II] - Section 2: Hazard identification [EU REACH Annex II] - Section 3: Composition [EU REACH Annex II] - Section 8: Exposure controls [EU REACH Annex II] - Annex: Exposure scenarios (if CSR required) [EU REACH Art. 14] - EU REACH registration number [EU REACH Art. 20(3)]

	Authorities (ECHA & member states)	Customers (B2B)	Consumers (B2C)	Label	Safety Data Sheet (SDS)
EU CLP Regulation (EC) No 1272/2008	- Poison Centre Notification (PCN) for hazardous mixtures [EU CLP Art. 45, Annex VIII] - UFI code generation [Annex VIII]	SDS Section 2: EU CLP classification and label elements [EU CLP Art. 17] - UFI code (for mixtures) [EU CLP Annex VIII] - Packaging and label compliance [EU CLP Art. 35–36]	Label with pictograms, signal word, hazard and precautionary statements [EU CLP Art. 17–20] - Child-resistant packaging and tactile warnings [EU CLP Annex II] - UFI code on label [Annex VIII]	Product identifier [EU CLP Art. 17] - Hazard pictograms [EU CLP Annex V] - Signal word [EU CLP Art. 20] - Hazard statements (H) [EU CLP Annex III] - Precautionary statements (P) [EU CLP Annex IV] - Supplier contact [EU CLP Art. 17] - UFI code (mixtures) [EU CLP Annex VIII]	Section 2: EU CLP classification and label elements [EU CLP Art. 17] - Section 3: Hazardous ingredients [EU CLP Art. 18] - Section 15: Regulatory info incl. SVHC status [EU CLP Art. 17] - Section 1: UFI reference [EU CLP Annex VIII]
SCIP (Waste Framework Directive 2008/98/EC)	Notification of SVHCs in articles placed on the market [WFD Art. 9(1)(i); ECHA SCIP Guidance] - Substance identity, concentration, article category, safe use instructions	Safe use information for SVHCs in articles [WFD Art. 9(1)(i)]	Consumers may request SVHC info [EU REACH Art. 33(2)]	Not applicable	Not applicable Remark: SVHC presence may be referenced in SDS if relevant [EU REACH Art. 31, 33]

	Authorities (ECHA & member states)	Customers (B2B)	Consumers (B2C)	Label	Safety Data Sheet (SDS)
EU POP Regulation (EU) 2019/1021	Notification of EU POPs in products and waste [EU POP Reg. Art. 4, 7] - Reporting to authorities if EU POPs are present above thresholds [Annex I–IV]	EU POP content disclosure if applicable [EU POP Reg. Art. 7(2)]	EU POPs in consumer products shall not exceed limits; restrictions apply [EU POP Reg. Annex I–IV]	EU POPs must not be marketed if restricted; label must not mislead [EU POP Reg. Art. 3, 4]	EU POPs must be disclosed in SDS if present and relevant [EU POP Reg. Art. 7(2)]
EU BPR Regulation (EU) No 528/2012	Biocidal products must be registered acc. EU BPR	SDS and Label needs to disclose information acc. to EU BPR information if applicable (Biocidal Product/Treated Article)	SDS and Label needs to disclose information acc. to EU BPR information if applicable (Biocidal Product/Treated Article)	Label needs to disclose information acc. to EU BPR if applicable (Biocidal Product/Treated article) EU BPR Reg. Art. 58 and Art. 69	SDS needs to disclose information acc. to EU BPR if applicable (Biocidal Product/Treated article)

Annex II Selected Chemical information requirements for European products

Regulation	What to declare	Thresholds	Scope / Applicability	Exemptions / Notes	Sources
EU CLP (Classification, Labelling & Packaging)	Hazardous substances and mixtures- Classification (H/P statements) UFI for mixtures SDS Sections 2–3	Any hazardous substance ≥ 0.1% w/w despite of substance Specific Concentration Limits (SCL)	Substances and mixtures placed on the EU market (excludes articles directly)	Non-hazardous substances Articles (unless EU REACH applies) Waste- R&D substances Military use	Regulation (EC) No 1272/2008
EU REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals)	SVHCs (Substances of Very High Concern) Restricted substances (Annex XVII)- SDS info if hazardous SCIP notification (for articles)	≥ 0.1% w/w per article (SVHCs) Use-specific thresholds (Annex XVII)	Substances and mixtures Articles containing SVHCs	Substances not on candidate list Articles with SVHCs <0.1% w/w Waste Military exemptions R&D exemptions	Regulation (EC) No 1907/2006 candidate list of Substances of very high Concern (SVHC)
EU CPR (Construction Products Regulation)	Dangerous substances released from construction products Info per basic requirement 3 (hygiene, health, environment)		Products placed on the market for construction use	Products not covered by harmonised standard or ETA Not applicable outside construction	Regulation (EU) No 305/2011

Regulation	What to declare	Thresholds	Scope / Applicability	Exemptions / Notes	Sources
RoHS (Restriction of Hazardous Substances in Electrical & Electronic Equipment)	Presence of restricted substances (Pb, Hg, Cd, Cr(VI), PBB, PBDE, phthalates)- Declaration of Compliance or Declaration of Conformity (DoC)	0.1% by weight in homogeneous materials 0.01% for Cadmium	Electrical and Electronic Equipment (EEE) categories 1–11	Medical, military, R&D uses spare parts for equipment placed on market before cutoff dates	Directive 2011/65/EU WEEE Directive for chemicals in in EEE, especially coatings or adhesives
ESPR (Ecodesign for Sustainable Products Regulation)	Material composition Substances of concern (as defined by ESPR) Circularity-relevant substances Durability, repairability indicators Recyclability/hazard data	≥ 0.1% w/w for substances of concern (likely aligned with EU REACH/SCIP)	Products covered by delegated acts (initially: textiles, batteries, electronics, furniture)	Products outside scope of delegated act Waste Military applications Temporary exemptions likely	Regulation (EU) 2024/1781
Battery Regulation (EU) 2023/1542 *(DPP pilot)*	Material composition Critical raw materials Hazardous substances (e.g. Hg, Cd, Pb) Carbon footprint, performance	≥ 0.1% w/w for SVHCs Specific limits for Hg, Cd, Pb	Batteries placed on EU market from 2027	Military batteries Equipment designed for space/defence waste	Regulation (EU) 2023/1542
GADSL (Global Automotive Declarable Substance List)	Substances on the declarable or prohibited list Material Composition	≥ 0.1% w/w per component or substance specific threshold	Automotive sector worldwide	Voluntary in regulation but mandatory by OEM/customer requirement	https://www.gadsl.org/

Regulation	What to declare	Thresholds	Scope / Applicability	Exemptions / Notes	Sources
EU BPR (Biocidal Products Regulation (EU) No 582/2012)	Biocidal substances in treated articles (4 groups, 22 product types)	No concentration threshold (all active biocide)	Treated articles (textiles, furniture, etc.)	Required disclosure even at trace levels	Regulation (EU) No 528/2012 EU BPR Compliance - European Union - Chemicals - CIRS Group BAuA - Biocides - The Biocidal Products Regulation - Federal Institute for Occupational Safety and Health
Detergents Regulation (EC) No 648/2004	Biodegradability of surfactants; allergen/hazardous ingredients labelling	Any amount of biocidal active substance must be declared	Manufacturers/suppliers of consumer and industrial detergents	Requires ingredient list; EU often enforces stricter national limits	Regulation (EC) No 648/2004 Understanding the European Commission's Regulation on Detergents - Aropha
Regulation (EU) 2019/1148 (Explosive Precursor Regulation)	Control & documentation of listed explosive precursors in supply chain	Nitric acid > 3% H_2O_2 > 12% Sulfuric acid > 15% Other listed substances in ANNEX I (e.g. acetone, nitrates)	Producers, traders, importers, buyers and users of precursors in EU	Proof of legitimate use required suspicious transaction reporting obligatory verification	Regulation (EU) 2019/1148 Regulation (EU) 2019/1148 - new Regulation on the marketing and use of precursors for explosives - WESSLING