Guide to PCN format

November 2021

ABC

Version	Changes	
1.0	1st version	April 2018
1.1	Updated to take into account the outcome of the pilot project. Main changes: • Modification of the dossier header to include update-related information • Picklits content moved to a separate annex-file (.xls) • Inventory document removed as not part of the PCN dossier • Clarification on the use of Generic Product Identifiers, multilingual fields, additional text for labelling statements.	March 2019
1.2	Update to the version 2.0 of the PCN format	October 2019
1.3	Update to the version 3.0 of the PCN format	October 2020
1.4	Update to the version 4.0 of the PCN format	October 2021
1.5	Update to take into account the feedback on the picklists for standard formulas	November 2021

Legal notice

If you have questions or comments in relation to this document please send them (quote the reference and issue date) using the information request form. The information request form can be accessed via the Contact ECHA page at:
http://echa.europa.eu/contact

European Chemicals Agency

Mailing address: P.O. Box 400, FI-00121 Helsinki, Finland
Visiting address: Telakkakatu 6, Helsinki, Finland

contained in this document.

Reproduction is authorised provided the source is acknowledged.

Table of Contents

Table of Figures

1 Introduction

This document provides a technical background and offers a practical guide to Industry on how to encode, prepare and complete a dossier compliant with the poison centres notification format (hereafter PCN format[1]). The XML content and the inner structure of the PCN format is explained in a simple manner avoiding technical details or jargons.

The PCN format defines the data requirements and structure for the submission of information to the Member States appointed bodies. The format has been structured and organised based on the information and data requirements laid out in Annex VIII to CLP Regulation (EC) No 1272/2008. Additionally, it was adjusted and adapted in order to satisfy the stakeholder's requirements with the support of a dedicated working group consisting of experts from industry, Member State appointed bodies and their poison centres.

Among several other design principles, the format was developed taking into account the processing requirements, both in the context of a centralised PCN portal provided by ECHA and especially considering the national Member State systems as final receivers of the information submitted electronically. For this reason, the document should also be seen as a valid support tool for the appointed bodies in the Member States as ultimate recipients of the PCN dossiers in order to understand how the data is organized and structured in the PCN format.

1.1 Conventions used in this manual

This section explains the conventions used in this document in order to make it easier to read.

The following text conventions are used to identify terms and other elements of the format:

- *<Intense Emphasis>* - PCN format Data fields enclosed in angle brackets

- *Italic* - PCN format documents or root entities (e.g. *Substances*, *Mixtures*)

- **PATH:** *- Document xml path*

The document contains cross-references, designed as links, which redirect the reader either to public web pages or to other locations of this document in order to provide supplemental information on the topics. Cross-references are underlined as common links in web pages and normally indicated as follows: See chapter X.X for additional information.

---

[1] The PCN format is maintained by ECHA and made publicly available free of charge. For additional information, visit the following ECHA web page: https://poisoncentres.echa.europa.eu/poison-centres-notification-format.

1.2 Data types

The PCN format supports numerous data types listed and explained in this paragraph.

1.2.1 Text

It enables the user to enter free text (with no formatting). For *single-line*, *multi-line text*, *text area* and *text template* components, a user is allowed to enter only plain text including letters, numbers and symbols in the selected character set (UTF-8). For *rich text area* the user is allowed to specify formatting options such as font family, size and color, bullets and other text attributes.

1.2.2 Single-line text (255 chars)

It is referred in all IUCLID documents simply as Text (255 Char). Its default maximum length is 255 characters with no line breaks. If the text field contents should be limited to fewer characters, this will be clearly defined.

1.2.3 Multi-line text (2,000 chars)

It is a text field allowing default maximum length of 2,000 characters.

1.2.4 Text area (32,768 chars)

It is a text field allowing a maximum of 32,768 characters. It has the same functionality as the *multi-line text*, differing only in its capacity.

1.2.5 Rich text area

The Rich text area is a large text area where the user can specify fonts, colors, bullets, and other text attributes. The user can also insert and edit (predefined) tables. The content of this field has to be provided in HTML format.

1.2.6 Picklist (single)

Picklists contain a collection of pre-defined values from which the user can provide only a single value. Only the corresponding identifiers must be provided in the format and not the actual label or description of the value. The list of all picklists and picklist elements identifiers is available as an annex.

1.2.7 List multi.(multi-select list)

This data-type provides a list of items from which the user can select either one or more values. The list of all picklists and picklist elements identifiers is available as an annex.

1.2.8 Check box

A check box is a simple boolean flag stored as text field that can accept the following values: <true> or <false>. The absence of this field is considered the same as a <false> value for the checkbox.

1.2.9 Numeric

This data-type allows entering numeric values only.

1.2.10   Decimal

This data-type allows entering decimal values only. Decimals must separated with a dot ".".

1.2.11   Numeric range (decimal with picklist)

This data-type allows entering decimal ranges (e.g. concentration levels). It also comes with additional qualifiers as follows:

1. **Qualifier (lower value)**: It provides a list with the following two operators: >, >=. For exact concentration values no "equal to" sign (=) is provided from the list since this must be indicated by no operator selection (i.e. the qualifier field is left empty).

2. **Numeric field (lower value)**: It allows entering a single numeric value (in most of the cases a decimal value).

3. **Qualifier (upper value)**: It provides a list with following operators: <, <=. No "equal to" sign (=) is provided.

4. **Numeric field (upper value)**: It allows entering a single numeric value (in most of the cases a decimal value).

5. **Unit field**: The Unit field is a Picklist (single) field containing the unit of measurement. The unit field must be specified and can either be "w/w %" or "v/v %". It must be used consistently for all the concentrations provided in the dossier.

1.2.12   Numeric range (decimal) [No Unit field picklist]

This data-type allows entering decimal ranges (e.g. pH ranges). The structure is similar to the previous data-type namely Numeric range (decimal with picklist) however without the <Unit field>.

1.2.13   Attachment

This data-type allows encoding a file attachment (e.g. Safety data sheet).

1.2.14   Multilingual text fields

IUCLID 6 supports multilingual content (since version 6.3). All fields that include any kind of textual information have been modified to accept content in multiple languages. In the rest of the document, input possibly requiring multilingual values will be highlighted.

1.3 Icons, abbreviations and terminology

This manual uses various icons and specific abbreviations throughout. The icons are displayed to highlight useful or important information. The following icons are used:

⚠️ Very important note

❗ Useful information, guidance, assistance

Term or Abbreviation	Explanation
(International) Chemical name	The name given to a chemical in the nomenclature system developed by the International Union of Pure and Applied Chemistry (IUPAC) or the Chemical Abstracts Service (CAS) or a name that will clearly identify the chemical for hazard classification purposes.
(IUCLID) Document	A document is the generic designation of a set of information that can be entered in the PCN Format. A document is also the standard set of data that exists in a substance dataset and compose the nodes of the table of contents. Documents are discriminated between *records* and *summaries*, which in turn are separated in *fixed records*, *flexible records*, *endpoint study records*, *flexible summaries* and *endpoint summaries* respectively.
Block	A block or repeatable block is a set of fields grouped because of common business behaviour or database dependency. They are grouped and commonly identified in order to be reused throughout the application. When a block is repeatable it means that all the fields in the same group can be provided multiple times (in the same set).
BPR	Biocidal Products Regulation (EU) No 528/2012.
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.
Concentration	The mixture concentration (in chemistry) is the abundance of a constituent divided by the total volume or mass of a mixture. Several types of mathematical description can be distinguished however in the context of Annex VIII, the concentrations in a mixture can be expressed as exact percentages, in descending order either by mass or by volume.
Dataset	A dataset (or data set) is a collection of related sets of information (e.g. a Substance/Mixture dataset) that is composed of separate documents.
Dossier	A dossier or IUCLID dossier represents the collection of all the scientific and administrative information at any given time (snapshot) fulfilling the legal data requirements (CLP Article 45 and Annex VIII) needed in order to notify and place the mixture in a specific market.

Term or Abbreviation	Explanation
ECHA	European Chemicals Agency
ECHA Submission portal	Online tool provided free of charge by ECHA that supports both industry and authority users in fulfilling their obligations related to the notification of hazardous mixtures as required under Article 45 of the CLP Regulation.
EEA	European Economic Area
Endpoint study record	In Substance or Mixture/Product datasets, an endpoint is an information requirement or data point with regard to the physico-chemical properties of the substance, environmental fate and behaviour, ecotoxicological information, toxicological information and specific information (e.g. effectiveness against target organisms or residues in food and feeding stuffs) according to a given chemical regulatory programme. In a wider sense, also additional information related to endpoints is included, i.e. guidance on safe use, information on literature search and a container section for attaching assessment reports. The specific PCN information requirements are described later in this document.
Endpoint summary	Endpoint summary records can be added throughout the section hierarchy for summarising the most critical results and conclusions of a given Endpoint section.
EU	European Union
EuPCS	European Product Categorisation System
Flexible records	Similar to the endpoint study records or to the endpoint summary, this name was used for different sections in IUCLID where the information stored in the record is not a study.
Hazard classification	Hazard classification is the process of evaluating the full range of available scientific evidence to determine if a chemical is hazardous, as well as to identify the level of severity of the hazardous effect. When complete, the evaluation identifies the hazard class(es) and associated hazard category of the chemical. [Source: "Hazard Classification Guidance for Manufacturers, Importers, and Employers" – OSHA 3844-02 2016]
IUCLID	International Uniform ChemicaL Information Database, is a software application system for managing data on intrinsic and hazard properties of chemical substances and mixtures for accurate reporting to the regulatory authorities.
IUPAC	International Union of Pure and Applied Chemistry (IUPAC)

Term or Abbreviation	Explanation
Legal entity	A legal entity may represent anything between a complex business structure and a simple organized business (e.g. corporation, company, organization) or a single natural person capable and having the right to engage into contracts or commercial transactions.
MiM	When a mixture is used in the composition of a second mixture, the first mixture is referred to as a Mixture in mixture (or MiM).
Mixture	A mixture or solution composed of two or more substances (Article 2(8) of CLP).
MSCA	Member State Competent Authority
OECD	Organisation for Economic Co-operation and Development. The OECD is an intergovernmental economic organisation with 35 member countries, founded in 1961 to stimulate economic progress and world trade.
PCN	In the context of CLP Art.45 and Annex VIII, a notification or PCN (Poison Centre Notification) is the outcome of a valid and successful electronic submission (i.e. resulting in a positive outcome after processing) of the information required in a dossier fulfilling the technical data requirements.
PCN number	The PCN number is a unique identifier (UUID), generated by Industry for each initial submission and retained across updates. It is used as the correlation identifier of different submissions related to the same mixture. In case of significant change of composition, a new PCN number must be generated to identify the new series of submissions. The PCN number can be created by using a Universally Unique Identifier (UUID) generator. This solution is suitable especially for those using IUCLID standalone or the System-to-System service.
REACH	Registration, Evaluation, Authorisation of Chemicals. Regulation (EC) No 1907/2006.
Reference substance	A Reference substance is a single document used (in IUCLID) to define the identity of a Substance, in such a way that the definition may be re-used in more than one location. This provides consistency and avoids duplication of work. A Reference substance contains both the chemical identifiers and the structural information.
	Note: new reference substances can be created (with new data from the beginning), but in case the substance is well-known and already exists, it would be more efficient to take a ready-made one from the public collection published on the IUCLID website (https://iuclid6.echa.europa.eu/web/iuclid/get-reference-substances).
SDS	Safety data sheet

Term or Abbreviation	Explanation
Submission	A submission is an event resulting from the transmission of a Dossier prepared and submitted electronically.
Submission number	The submission number is the unique identifier given by the ECHA Submission portal to every submission event produced by industry. The submission number can then be used to search submissions and check their status in the ECHA Submission portal.
Substance	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 (Article 2(7) of CLP).
Synonym	Another name or names by which a material is known (e.g. Methyl alcohol is also known as 'methanol' or 'wood alcohol').
TOC	Table of content for a specific dataset
UFI	Unique Formula Identifier – The UFI is a 16-character alphanumeric code required on the product's label and an information requirement for PCN dossier, in which the submitter links this code to the mixture composition.
UUID	A universally unique identifier (UUID) is a 128-bit number used to identify data and information in computer systems.
v/v %	Volume/volume percent concentration.
w/w %	Weight by weight percent concentration.
XML	eXtensible Markup Language

1.4 IUCLID format compatibility

The PCN format is compatible with IUCLID and is based on the same format. During the feasibility study performed in 2017 it was identified that reusing an existing format, already harmonised at the OECD level, and used for submission of chemical information to ECHA according to the REACH (art. 111), CLP (art. 40) and BPR (art. 79) regulations, would bring benefits such as the possibility to reuse existing tools developed by ECHA.

The information is organised in *IUCLID Documents* that gather all relevant data fields for a specific type of information (e.g. pH results, classification and labelling, packaging). These documents are grouped in so-called '*definitions providers'* in order to indicate whether they are meant to be reused (all documents part of the 'IUCLID CORE' or the 'OECD definitions provider') or if they are specific to a single regulation/context (e.g. 'EU CLP' or 'EU REACH').

All the data is entered and stored in logical 'datasets' containing documents. When all the data have been prepared and encoded, all the datasets should then be assembled together in a final

compressed file called 'dossier' (.i6z extension file). A dossier containing all the required information can then be submitted or transmitted electronically to the Member States appointed bodies.

In order to ensure the data referential integrity and maintain the correct relationship between the various documents contained in the final dossier, a numeric identifier called a Universal Unique Identifier (UUID) must be generated and associated to each and every document contained in the dossier, acting as an unequivocal identifier. Additionally also the dossier itself must be identified with a different UUID (also known as Snapshot UUID) each time is created or exported in order to be submitted.

Each *definitions provider* comes with its own valid set of *documents*. The PCN format is part of the CLP *definitions provider*.

The term entity in this document refers to a set of data that form an object with common characteristics. Entities are documents that can exist on their own (vs records and summaries that can exist only as linked to an entity (substance or mixture). They are the entry point documents for a set of documents (datasets). Substance and Mixtures are an example of root entities.

The term *document* is going to be used throughout this document in order to indicate entities, *records* and *summaries documents as illustrated in the diagram below:*
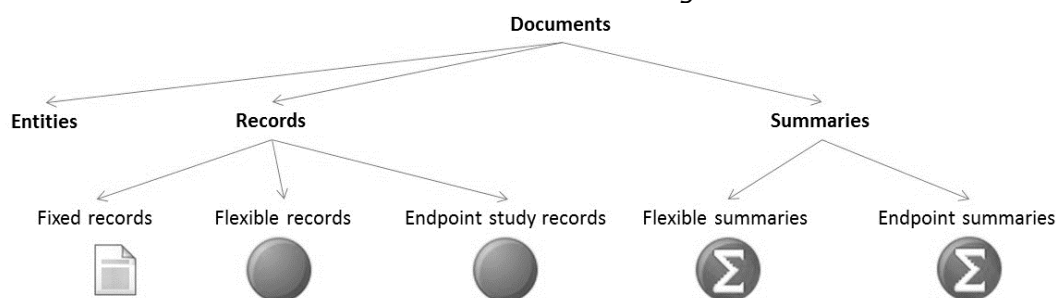
The latest version of IUCLID can be downloaded free of charge from the IUCLID website at the following address: https://iuclid6.echa.europa.eu/home.

2 Information required for a PCN notification

⚠️ The data and information to be included in a PCN are described in the CLP Regulation Annex VIII to the CLP Regulation[2] on the classification, labelling and packaging of substances and mixtures. ECHA provides the regulatory guidance to facilitate the implementation of Annex VIII to the CLP Regulation. The regulatory guidance clarifies the interpretation of the requirements and give recommendations on how to best fulfil the obligations. The regulatory guidance document has been developed with the participation of stakeholders from Member States authorities, poison centres and industry associations. The regulatory guidance has been published by ECHA and will be updated when need arises. The information below refers to technical practicalities of complying with Annex VIII to CLP.

2.1 Standard submission information requirements

Technically, the requested information in a standard submission comprises the following documents (the corresponding name of the documents are indicated in brackets):

- The Mixture identification (*MIXTURE*) containing a single link to:

    o The Legal Submitter document, including the name, full address, telephone number and email address (*LEGAL_ENTITY* - Submitter);

- The Mixture composition (*FLEXIBLE_RECORD.MixtureComposition*), including the components concentrations, linked either to individual Substance datasets and/or MiM datasets (*SUBSTANCE* and/or MiM *MIXTURE* datasets);

Note: this document may also contain generic components identified as Generic Component Identifiers (GCIs) with the field <function>.

- The Mixture pH where applicable (*FLEXIBLE_SUMMARY.pH*);

Note: if the pH is not available, the document must be provided with the check box (flag) <pH is not available> set to <true> along with a justification (a list of predefined reasons is provided).

- Mixture Classification and labelling elements, including hazard classes, hazard categories, hazard statements, hazard pictograms, signal words and precautionary statements (*FLEXIBLE_RECORD.Ghs*);

Note: this document is always needed even in case the mixture is non-hazardous or not classified according to CLP criteria. In this cases, the field <Not classified> of the document must be set to <true>.

- The Mixture Physical state, colour, intensity and form (ENPOINT_SUMMARY.GeneralInformation). Note that intensity and form are optional.

- The Mixture toxicological information as required in Section 11 of the Safety Data Sheet of the mixture (*FLEXIBLE_RECORD.SDSInfoMixture*)

- The product information, including the product trade names and/or synonyms, the product use category, the use types and the applicable countries where the mixture will be placed. The document should contain links when applicable to the following documents that should also be part of the dossier:

    o The Unique formula identifiers (UFI) (*FLEXIBLE_RECORD.Identifiers*);

---

[2] Regulation (EC) No 1272/2008 of the European Parliament and Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC and amending Regulation (EC) No 1907/2006 [OJ L 353, 31.12.2008, p. 1].

- o The Packaging information, including packaging type and size of the product (*FLEXIBLE_RECORD.Packaging*);

- o The Colour and physical state, including information on physical state, form and colour (*ENDPOINT_SUMMARY.GeneralInformation*).

2.2 Group submission information requirements

The requested information in a group submission[3] comprises the following documents (the corresponding documents of the format are indicated in brackets):

- The Mixture identification (*MIXTURE*) containing a single link to:

  - o The Legal Submitter document, including the name, full address, telephone number and email address (*LEGAL_ENTITY* - Submitter);

- The different mixture compositions for each individual mixture of the group, where each document includes all components, both the common ones across the different mixtures of the group and the variants being mixture specific (*FLEXIBLE_RECORD.MixtureComposition*);

- In a group submission, the same classification for Health and Physical hazards is shared across the different mixtures of the group *(FLEXIBLE_RECORD.Ghs)*. In case of differences in Environmental hazards or Labelling information, it is possible that the dossier includes more than one GHS document, each one to be linked with the relevant mixture composition document(s);

- The pH, either one document that applies to all mixtures of the group, or different documents in case of differences (*FLEXIBLE_SUMMARY.pH*) each one pointing to the relevant mixture composition document(s);

- The Mixture toxicological information as required in Section 11 of the Safety Data Sheet of the mixture (*FLEXIBLE_RECORD.SDSInfoMixture*), either one document that applies to all mixtures of the group, or different documents in case of differences each one pointing to the relevant mixture composition document(s);

- The product information (*FLEXIBLE_RECORD.ProductInfo*) should contain additionally (to the Standard submission case) links to the following documents establishing a correct relationship with the different mixtures of the group:

  - o Link to exactly one Mixture composition (*FLEXIBLE_RECORD.MixtureComposition*);

⚠️ When the dossier contains a group submission it is mandatory to set also the check box of the field *<GroupSubmission>* of the Dossier Header to <true> (See Encoding the Dossier Header section for additional information).

The possibility to prepare and submit a group submission has become available in October 2021.

---

[3] The general conditions under which a 'group submission' is allowed are specified in Section 4, part A of Annex VIII to the CLP regulation.

2.3 Limited submission information

In a limited submission[4] (i.e. optional alternative to the standard and group submissions for mixtures intended for industrial use only), the list of mixture components and concentrations to be provided may be limited to that included in the Safety Data Sheet (SDS Section 3.2).

Practically the information provided in case of limited submission will just be less detailed than a standard submission and the final PCN may not contain the full composition of the mixture.

Besides the information on the composition, all the remaining information requirements for a standard submission apply to limited submissions.

The requested information in a limited submission comprises in addition the following documents (the corresponding documents of the format are indicated in brackets):

- Contact details for rapid access to additional product information (*Contact person*);

When the dossier contains a limited submission it is mandatory to set also the check box of the field *<LimitedSubmission>* of the Dossier Header to <true>. For additional information see section 9 Dossier Header (the notification 'cover letter').

2.4 Submission of notifications in bulk

ECHA provides the possibility to submit notifications using a system to system (S2S) service. However, the same format will apply to all notifications whether they are submitted one by one using the portal or using the S2S service.

2.5 Substance information

The requested information in a substance dataset comprises the following documents (the corresponding name of the documents are indicated in brackets):

- The substance identity (*Substance*), including all the substance identifiers, linked to the following documents that shall also be part of the substance dataset:
- The corresponding reference substance (*REFERENCE_SUBSTANCE*) linked to an EC entry whenever applicable:
- EC Inventory entry (*EC Inventory*);
- Substance Classification if applicable, according to the criteria set in the CLP Regulation (FLEXIBLE_RECORD.Ghs);

---

[4] The general conditions under which a 'limited submission' is allowed are specified in Section 2.3., part A of Annex VIII to the CLP regulation.

2.6 Mixture in Mixture information

2.6.1 MiM - Known components

When all components of a Mixture in Mixture are known, the components should be added and reported in the main mixture composition, as indicated under section 2.1.

2.6.2 MiM - Unknown or partially known composition

The requested information in a MiM dataset, when the mixture composition is not known, or only partially known (e.g. not communicated by the MiM supplier), comprises the following documents (the corresponding name of the documents are indicated in brackets), as also indicated in 3.4.1:

- The MiM identification (*MIXTURE*) containing a single link to:

  …either

    o An identifier document (*FLEXIBLE_RECORD.Identifiers*) containing the MiM UFI if available

    o MiM composition from the SDS and supplier details

  … or, if the MiM UFI is not available,

    o The MiM composition from the SDS required for hazardous MiMs (including at least one *SUBSTANCE* dataset);

    o The MiM Supplier details (*Legal entity* – MiM Supplier).

- The MiM CLP Classification and labelling whenever applicable and according to the criteria set in the CLP Regulation (*FLEXIBLE_RECORD.Ghs)* shall be provided in any case.

- MiM's components CLP Classification and labelling record shall provided as well

2.7 Interchangeable Component Group (ICG)

When a MiM component is indicated as ICG, then its information requirements are different to the "standard" MiM component, as indicated under section 3.4.2.

2.8 Standard Formula (SF) component

When the main mixture is compliant with a SF (fully or partially), its components may be indicated as SF components, thus, having different information requirements from the "standard" MiM components (as indicated under section 3.4.3).

3 Datasets, Table of Contents (TOC) and Dossier

A dataset is a central core of information, containing information on the intrinsic properties of a specific substance, mixture or mixture in mixture, and its constituents. It is thus the repository of technical and scientific data related to all the mixture components and the mixture itself.

In order to assist the users with the data entry, the documents are logically organised in datasets using a specific table of content (TOC). This also allows re-using the individual datasets in different notifications if needed.

The PCN format can be organized in three different types with their corresponding TOCs:

- a 'Mixture CLP PCN (Poison Centre Notification)' main dataset

- a 'Substance (information)' dataset

- a 'MiM (Mixture in Mixture)' dataset, which is further divided into three categories due to the different information requirements:

    o the "standard" MiM component

    o the Interchangeable Component Group (ICG)

    o the Standard Formula Component (SFC)

Different '*Substance (information)*' datasets can be created for each component of the mixture, along with one single main '*Mixture CLP Poison Centre Notification*' dataset. This approach must be followed in both standard, limited and group submissions. However, in a group submission, the individual mixtures of the group should be declared in different *Mixture composition* documents (for additional information see section Mixture composition).

All these individual datasets for all components should then be linked and referenced from the *Mixture composition* document of the main mixture in order to create a valid dossier (see Figure 1).

Figure 1: Standard submission – Datasets link
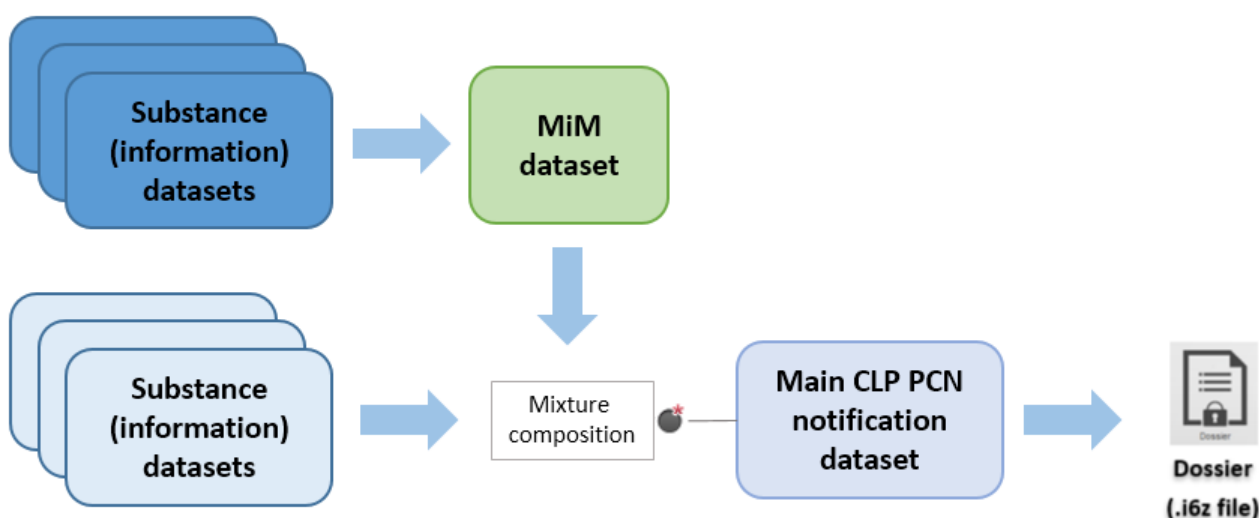
3.1 Dossier

A dossier should be seen as the final snapshot file (XML-based formatted – file extension ".i6z") based on the existing datasets and raw data entered during the dossier preparation. The dossier must contain all the relevant information in single XML files (file extension ".i6d") representing and corresponding to the various documents. The dossier must also contain a manifest file ("manifest.xml") containing a table of contents with all the data files (including file attachments e.g. SDS) and documents that are available in the dossier. For more information on the i6z IUCLID files, please refer to 'Part B – Developers' guide to the IUCLID format'.

Figure 2: Dossier file and Manifest
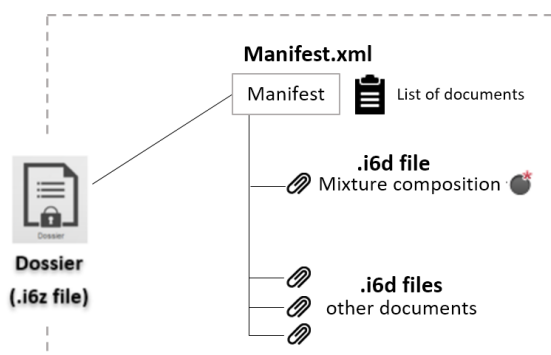
3.2 Mixture CLP PCN (Poison Centre Notification) dataset

The main Mixture dataset contains the following documents:

Document	Document name	Links to other documents
Mixture identification	*MIXTURE*	• [single] Link to: Legal submitter *LEGAL_ENTITY* • [multiple] Link to: Emergency contact* or other contacts information *CONTACT* *Mandatory in case of Limited submission; optional in other cases.
Mixture unique formula identifiers (UFI)	*FLEXIBLE_RECORD.Identifiers*	
Mixture composition	*FLEXIBLE_RECORD.MixtureComposition*	• [multiple] Links to: Substance dataset *SUBSTANCE* and/or MiM dataset *MIXTURE*

Document	Document name	Links to other documents
Physical state, colour, intensity and form	*ENPOINT_SUMMARY.GeneralInformation*	
Product information	*FLEXIBLE_RECORD.ProductInfo*	• [multiple] Links to: Mixture composition *FLEXIBLE_ RECORD.MixtureComposition** *Applicable in case of Group submission only • [multiple] Link to: Mixture unique formula identifiers (UFI) *FLEXIBLE_RECORD.Identifiers* • [multiple] Link to: Packaging *FLEXIBLE_RECORD.Packaging* • [multiple] Link to: Physical state, colour, intensity and form *FLEXIBLE_RECORD.GeneralInformation* • [multiple] Link to: Mixture Safety data sheet *FLEXIBLE_RECORD.SDSInfoMixture*
pH	*ENPOINT_SUMMARY.pH*	
Mixture Classification & Labelling	*FLEXIBLE_RECORD.Ghs*	• Optional [multiple] Links to: Mixture composition *FLEXIBLE_ RECORD.MixtureComposition** *Group submission only
Packaging	*FLEXIBLE_RECORD.Packaging*	
Mixture Safety data sheet & Toxicological information	*FLEXIBLE_RECORD.SDSInfoMixture*	

3.3 Substance (information) dataset

⚠️ The substance classification document must always be provided in a dossier even in cases when the substance is not considered as hazardous for emergency health response under Annex VIII CLP. In this case the field *<Not classified>* of the document *FLEXIBLE_RECORD.Ghs* must be set to *<true>* or only environmental classification should be provided.

The substance dataset contains the following documents:

Document	Document name	Links to other documents
Substance identification	*SUBSTANCE*	• [single] Link to one Reference substance (*REFERENCE_SUBSTANCE*) o [single] Link to EC entry (*EC inventory*)
Substance Classification	*FLEXIBLE_RECORD.Ghs*	

The diagram in Figure 3 here below illustrates the inner links and relationships in a substance (information) dataset.

Figure 3: Substance (information) dataset
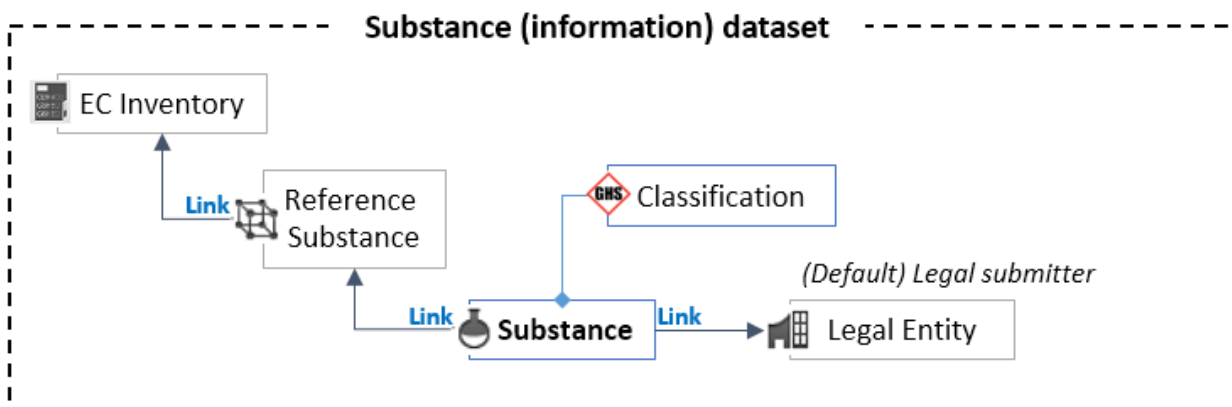
3.4 MiM datasets

The latest amendment of Annex VIII has resulted in the support for the Standard formula (SF) components, the Interchangeable Component Groups (ICG) along with the "standard" MiM components. Their information requirements are detailed in the following sub-sections.

3.4.1 MiM (Mixture in Mixture)

The MiM dataset may contain different documents. Not all documents are required at the same time, as this depends on the different cases explained in section 2.6.1 MiM - Known components. For additional information on the links between a MiM dataset and a Substance dataset see diagram in Figure 4.

Document	Document name	Links to other documents
MiM identification	*MIXTURE*	
MiM unique formula identifiers(UFI)	*FLEXIBLE_RECORD.Identifiers*	
MiM composition	*FLEXIBLE_RECORD.MixtureComposition*	• [multiple] Links to: Substance dataset *SUBSTANCE*
MiM Suppliers	*FLEXIBLE_RECORD.Suppliers*	• [single] Link to MiM Supplier (*LEGAL_ENTITY*)
MiM Classification & Labelling	*FLEXIBLE_RECORD.Ghs*	
MiM Safety data sheet & Toxicological information	*FLEXIBLE_RECORD.SDSInfoMixture*	

Figure 4: Links between a Substance dataset and a MiM dataset
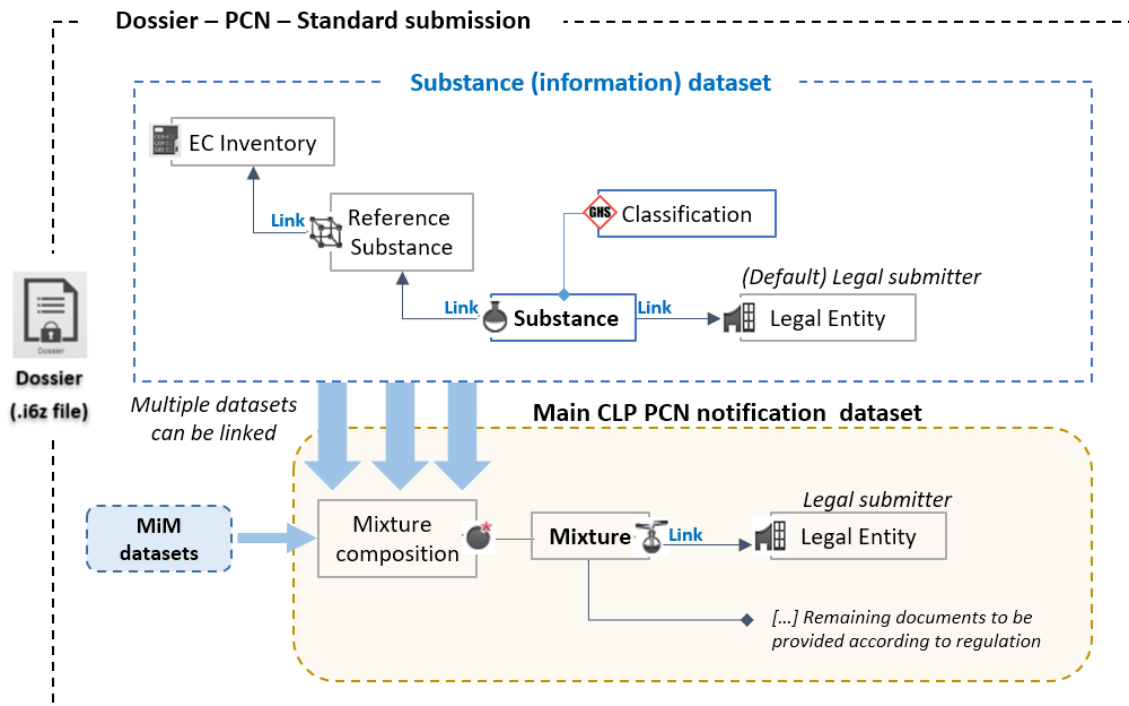
3.4.2 Interchangeable Component Group (ICG) dataset

The ICG dataset may contain the following documents.

Document	Document name	Links to other documents
MiM identification	*MIXTURE*	
MiM composition	*FLEXIBLE_RECORD.MixtureComposition*	• [multiple] Links to: Substance dataset *SUBSTANCE* and/or MiM dataset *MIXTURE*
MiM Classification & Labelling	*FLEXIBLE_RECORD.Ghs*	
MiM Safety data sheet & Toxicological information	*FLEXIBLE_RECORD.SDSInfoMixture*	
pH	*ENPOINT_SUMMARY.pH*	

3.4.3 Standard Formula (SF) component

The SF component dataset may contain the following documents.

Document	Document name	Links to other documents
MiM identification	*MIXTURE*	
MiM composition	*FLEXIBLE_RECORD.MixtureComposition*	• [multiple] Links to: Substance dataset *SUBSTANCE* and/or MiM dataset *MIXTURE*
MiM Classification & Labelling	*FLEXIBLE_RECORD.Ghs*	

4 Mixture main dataset

In order to organise the data in a PCN dossier, the submission type 'CLP Poison centres notification' should be used in order to organise the information recorded for the main mixture dataset.

4.1 Legal submitter

In the context of CLP Article 45, the Legal Submitter has the responsibility as duty holder or legal owner for submitting information on hazardous mixtures placed on the market in the different EU Member States for consumer, professional and industrial use.

The Legal submitter is also responsible for the creation and management of the *Legal Entity* details contained in the final dossier using the PCN format. A *Legal Entity* must contain all the administrative information on the Legal Entity submitter, such as the name, address, phone and email address. In addition, the details provided are used by the Member State appointed bodies to clearly identify the Legal submitter.

⚠️   A numeric identifier namely a Universal Unique Identifier (UUID) must be generated and assigned to each *Legal Entity*, acting as an unequivocal identifier (See also section IUCLID format compatibility). A Legal submitter must be represented by one single UUID. Duplicates are not allowed and must be avoided in order to ensure data consistency.

❗   It should be reminded that it is also possible to create a *Legal Entity* document containing the details of the Legal submitter using IUCLID or *ECHA accounts*. If not yet registered the Legal submitter could also optionally register the details using the sign-up procedure offered in ECHA Accounts where is also possible to encode, administer and export the Legal Entity information. The exported file (LEO)[5] can then be easily imported in the dossier for submission. For more information on the ECHA account management refer to the ECHA accounts manual available at http://echa.europa.eu/support/helpdesks/echa-helpdesk/echa-accounts.

The *LEGAL_ENTITY* document structure can be used in the PCN format to describe either the Legal submitter or the MiM supplier whenever applicable for Mixture in Mixtures (MiM). In some cases, two or more *LEGAL_ENTITY* documents (identified with different UUIDs) can be present at the same time in different datasets in the final dossier. For this reason, it is mandatory to establish the correct links between:

- The *DOSSIER* document and the correct *LEGAL_ENTITY* document representing the Legal submitter;

- the *MIXTURE* document and the correct *LEGAL_ENTITY* document representing the Legal submitter and

---

[5] The Legal Entity contact details of the company can be imported, stored and exported from ECHA Accounts as a LEO namely a Legal Entity Object.

- the *MiM Supplier* document (*FLEXIBLE_RECORD.Suppliers*) whenever relevant and applicable, and the correct *LEGAL_ENTITY* document[6].

⚠ It is only possible to link a single *LEGAL_ENTITY* document representing the Legal submitter from the MIXTURE document. This is also valid in case of group submissions, the grouped mixtures all have to be placed on the market by the same importer or downstream user. A group submission can only refer to one 'legal submitter' encoded in the *LEGAL_ENTITY* document. It is not possible to group mixtures that are placed on the market by different companies.

4.1.1 LEGAL_ENTITY - Field definitions

Field	Path and Description
Legal entity name	**LEGAL_ENTITY.GeneralInfo.LegalEntityName** Mandatory - Text (255 char.) – Company name
Legal entity type	**LEGAL_ENTITY.GeneralInfo.LegalEntityType** Optional - Picklist (single) N01 – Type of Legal entity
Address 1	**LEGAL_ENTITY.ContactInfo.ContactAddress.ContactAddress.street1** Mandatory - Text (255 char.) – Company address
Address 2	**LEGAL_ENTITY.ContactInfo.ContactAddress.ContactAddress.street2** Optional - Text (255 char.) – Company address
Postal code	**LEGAL_ENTITY.ContactInfo.ContactAddress.ContactAddress.zipcode** Mandatory - Text (255 char.) – Company postal code
Town	**LEGAL_ENTITY.ContactInfo.ContactAddress.ContactAddress.city** Mandatory - Text (255 char.) – Company town or city
Country	**LEGAL_ENTITY.ContactInfo.ContactAddress.ContactAddress.country** Mandatory – Picklist (single) A31 – Company country

---

[6] The requirements to keep the UUIDs consistent across notifications is particularly important for the submitter's information as this has to be in line with the ECHA account used for the submission of the notification. Maintaining consistent UUID and Legal Entities for suppliers is recommended but not mandatory.

Field	Path and Description
Phone	**LEGAL_ENTITY.ContactInfo.ContactAddress.ContactAddress.phone** Mandatory - Text (255 char.) – Company phone number
Email	**LEGAL_ENTITY.ContactInfo.ContactAddress.ContactAddress.email** Mandatory - Text (255 char.) – Company email address

4.2 Emergency contact

The Emergency contact (*CONTACT*) document contains the contact details for rapid access to additional product information (24 hours/7 days). The document must be provided in case of a limited submission and is optional in other cases.

One single document must be provided for each country (where the mixture is placed) even if the same number and email are applicable for all the countries.

If the mixture is placed on the market in one single country, only one *CONTACT* document must be provided containing the applicable country.

Other *CONTACT* information can be provided as optional information.

4.2.1 CONTACT - Field definitions

Field	Path and Description
Contact type	**CONTACT.GeneralInfo.ContactType** Mandatory – Picklist (single value) Mandatory Value (in case of Limited submission): "Emergency contact"
First name	**CONTACT.GeneralInfo.FirstName** Optional - Text (255 char.)
Last name	**CONTACT.GeneralInfo.LastName** Mandatory - Text (255 char.) When a last name is not available or not relevant, a more generic name can be used instead (e.g. Helpdesk, Support).

Field	Path and Description
Organisation	**CONTACT.GeneralInfo.Organisation** Mandatory - Text (255 char.) Organisation / Legal entity name to be contacted by Appointed bodies for rapid access to additional product information (24x7).
Phone	**CONTACT.GeneralInfo.Phone** Mandatory - Text (255 char.) Telephone number accessible 24 hours per day and 7 days per week, where 'additional detailed product information', which are not included in the SDS but would be requested by Annex VIII, can be obtained by a responsible authority and/or [any] medical personnel, dealing with a poisoning/ health incident
Email	**CONTACT.GeneralInfo.Email** Mandatory - Text (255 char.) E-mail address for follow-up exchange of information between the Legal submitter and the responsible authority or medical personnel as required by regulation 2017/542 Annex VIII - PART C par. 1.2.
Country	**CONTACT.GeneralInfo.Country** Mandatory - Picklist (single value) – A31 This field represents the country where the emergency contact is applicable depending on the where the Mixture will be placed on the market.

4.3 Mixture identification

The Mixture identification document should be considered as the starting point or the core document in a dossier containing a PCN notification.

4.3.1 MIXTURE - Field definitions

Field	Path and Description
Mixture/Product name	**MIXTURE.MixtureName** Mandatory - Text (2,000 char.) This can be used internally and for reference purposes in order to easily identify the mixture (or the product) if needed. Any name or chemical identifier for the Mixture (or product) can be used. It is however recommended to provide an internal identifier which is commonly used for that mixture within the company. Possibly this will allow an easier identification in a very large chemical portfolio.
Other identifiers – Start of Repeatable block	
Name type	**MIXTURE.OtherNames.NameType** Optional - Picklist (single value) – PG6-60585 Mandatory for mixtures that fully conform with a Standard Formula or specific Fuels. In such cases, the value "standard formula (SF)" or "fuels" has to be selected. If the main mixture does not fully conform with a SF (because there are additional components or only part of the SF is actually used), then the "standard formula (SF)" value should not be selected. The field may be also used to provide another identifier of the main mixture, such as the "trade name" or the "common name".

Field	Path and Description

Name	**MIXTURE.OtherNames.Name**
	
	Text (2,000 char.)
	
	Mandatory for mixtures which conform with a Standard formula or specific Fuels (when the value of 'Name type' is "standard formula (SF)" or "fuels"). In such cases, the name of the SF or Fuel must be provided according to the list provided in Annex VIII to CLP Regulation, e.g.:
	   - Cement Standard Formula – 1 [Portland cement with one main constituent: clinker]
	   - Gasoline EN228 [Automotive fuels - Unleaded petrol]
	
	A complete list of Standard Formulas and Fuels names is also available in the PCN format documentation package, in the list of picklists (cf. phrase group ID PCN_SF61036).
	
	For other Name types, the free-text description should be provided.

Country	**MIXTURE.OtherNames.Country** Optional - Picklist (single value) – A31
Remarks	**MIXTURE.OtherNames.Remarks** Optional – Text (32,768 char.) This is meant to be used for any additional information on the SF or Fuels. *Multilingual information: this information should be provided in all relevant languages*

Other identifiers – End of Repeatable block

Field	Path and Description
Legal entity owner	**MIXTURE.OwnerLegalEntity** Mandatory • Link to Legal submitter *(LEGAL_ENTITY)* This field must always contain an association with the Legal submitter of the PCN notification. This is achieved by creating a link to the LEGAL_ENTITY document. For additional information see also section Legal submitter.

Contact persons – Start of Repeatable block

Field	Path and Description
Person	**MIXTURE.ContactPersons.ContactPerson** Mandatory for Limited submission, optional for other submission types - Entity reference field • Link to <u>Emergency contact</u> *(CONTACT)* Note: the PCN format allows to specify multiple emergency contacts per country if needed.

Contact persons – End of Repeatable block

4.4 Mixture Unique Formula Identifiers (UFI) and other identifiers

The unique formula identifier, known by its acronym UFI, is a 16-character alphanumeric code that will be required on the product's label. One UFI should be linked to only one mixture composition, to allow unique link between the UFI on the label and composition declared in the dossier. The same UFI can never be associated with mixtures of different composition. For data management or commercial reasons, more than one UFI can be assigned to the same mixture. The same UFI can be used in notifications submitted by different submittters, as long as the mixture composition is the same. In this case, each product would have its own UFI, even if it contains the same mixture.

The PCN format allows to encode one or more documents as follows:

- One single UFI per single document: this is recommended when each product record has a different UFI
- Several UFI encoded in a group per single document (using the repeatable block): this is recommended when all product records have the same UFIs

How identifiers are organized and/or encoded depends entirely on how the UFI will be associated with the relevant products in a standard submission and products/mixtures in a group submission.

For additional information on how to associate a UFI or group of UFIs to a product see section Product information.

4.4.1 FLEXIBLE_RECORD.Identifiers - Field definitions

Field	Description
Regulatory programme identifiers – Start of Repeatable block	
Regulatory programme	**FLEXIBLE_RECORD.Identifiers.RegulatoryProgrammeIdentifiers.RegulatoryProgrammeIdentifiers.RegulatoryProgramme** Mandatory – Picklist – N12
ID	**FLEXIBLE_RECORD.Identifiers.RegulatoryProgrammeIdentifiers.RegulatoryProgrammeIdentifiers.Id** Mandatory - Text (255 char.) This field allows encoding a single **Unique Formula Identifier** (16-character alphanumeric code). If additional UFI are needed to identify the Mixture another repeatable block can be added to the document. It also allows the entry of a '**CLP related PCN number**' in case a notification is sent for a product which composition has been modified significantly. This PCN number is a UUID. The UUID is a universally unique identifier (UUID) being a 128-bit number. In its canonical textual representation, the UUID is represented as 32 hexadecimal (base 16) digits, displayed in five groups separated by hyphens, in the form `8-4-4-4-12` for a total of 36 characters (32 alphanumeric characters and four hyphens). ☞ For additional information, please check Universally unique identifier - wikipedia and RFC 4122: A Universally Unique IDentifier (UUID) URN Namespace. In case of **multi-component products** (consisting of components, each one having a different mixture/mixture composition), it allows encoding a free-text value called "CLP multi-component product identifier", acting as the correlation identifier between different products. Such products may be part of the same dossier (in case of Group submissions) or different dossiers (in case of Standard submissions, or combination of Standard and Group submissions)
Regulatory programme identifiers – End of Repeatable block	
Other IT system identifiers – Start of Repeatable block	
IT system	**FLEXIBLE_RECORD.Identifiers.ExternalSystemIdentifiers. ExternalSystemIdentifiers. ExternalSystemDesignator** Optional – Text (255 char.) This field allows specifying a IT system relevant to the notification.

Field	Description
ID	**FLEXIBLE_RECORD.Identifiers.ExternalSystemIdentifiers. ExternalSystemIdentifiers. ExternalSystemDesignator.Id**
	Optional - Text (255 char.)
	This field allows specifying an identifier from any othe IT system relevant to the notification.

Other IT system identifiers – End of Repeatable block

4.5 Mixture composition

The Mixture composition document contains the relevant information concerning the components (or ingredients) of the Mixture.

4.5.1 Standard submission

In a standard submission, only one mixture composition document must be provided. The mixture composition must contain all the mixture components with the relevant concentrations or concentration ranges linked to the corresponding datasets (Substances or MiMs). In case of generic components, the function and concentrations should be provided, as well as a link to a substance dataset in order to report the corresponding classification.

Figure 5: Mixture composition links with datasets
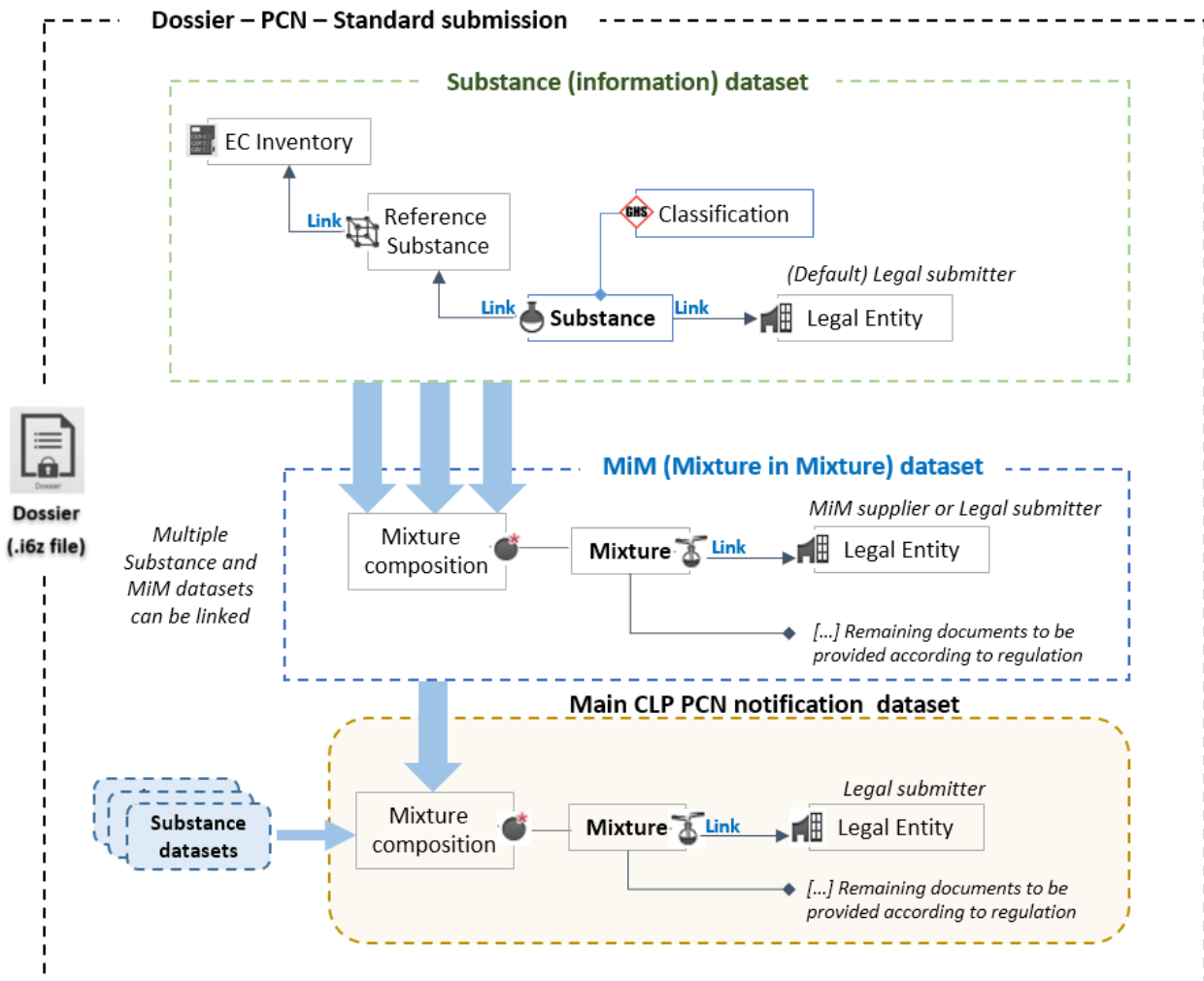
4.5.2 Limited submission

In a limited submission at least the components stated in the SDS have to be provided.

4.5.3 Group submission

In a group submission, several mixture compositions documents can be provided, each one representing the different compositions of the specific mixture in the group.

⚠️ For each individual mixture of the group, the mixture composition should include all its components, i.e. both the common ingredients of the Mixtures in the group and the differences of each mixture.

In a group submission, it is also possible to reference this document from one or more products in the dossier in order to establish the correct relationships with other documents of the notification (e.g. UFI, packaging). For additional information see section Product information.

Figure 6: Group submission – Datasets link

4.5.4 FLEXIBLE_RECORD.MixtureComposition - Field definitions

Field	Description
Mixture/product name	**FLEXIBLE_RECORD.MixtureComposition.GeneralInformation.Name** Optional - Text (255 char.) This field is not required from a regulatory perspective and it is also not mandatory for IUCLID compatibility reasons, however, it can be used internally and for reference purposes in order to easily identify the mixture composition. For example in a group submission when several mixture compositions are encoded it may be useful to assign an internal identifier to distinguish the mixtures of the group (e.g. product/mixture name). In case of standard submissions, there is only one mixture composition document, and the name of the mixture/product can also be left empty.

Components – Start of Repeatable block

Field	Description
Name	**FLEXIBLE_RECORD.MixtureComposition.Components.Components. Reference** Mandatory - Entity reference field: • Link (single) to <u>Substance dataset</u> (*SUBSTANCE); or* • Link (single) to <u>MiM dataset</u> (*MIXTURE)* This field allows linking either a substance or a mixture in mixture (dataset) for fully identifying the mixture component under consideration. This is done by creating a single link with the desired dataset created previously. For additional information on how to provide the information for each Mixture component see Sections: <u>Substance (information</u>) dataset and Mixture in Mixture (MiM) dataset.
Function	**FLEXIBLE_RECORD.MixtureComposition.Components.Components. Function** Mandatory only in case of a generic component identified as with a generic component identifier (GCI). Picklist (single) - N28A For a Generic Component Identifier, the allowed options are: • Perfume • Colourant
Typical concentration	**FLEXIBLE_RECORD.MixtureComposition.Components.Components. TypicalConcentration** Mandatory (except when a concentration range is provided) - Numeric (decimal), half-bounded, with Picklist (single) N24. This field allows encoding the component exact concentration percentages. Concentrations can be expressed using the following mandatory Picklist (single) values: • 2505 - "% (w/w)"; or • 2506 - "% (v/v)" The selected picklist (single) value must be consistent for all the components provided in the mixture composition.

Field	Description
Concentration range	**FLEXIBLE_RECORD.MixtureComposition.Components.Components. ConcentrationRange** Mandatory[7] (except when a typical concentration is provided) - Numeric range (decimal) with Picklist (single) N24 This field allows encoding the component concentration either as exact or range percentages. Concentrations can be expressed using the following mandatory Picklist (single) values: • 2505 - "% (w/w)"; or • 2506 - "% (v/v)" The selected picklist (single) value must be consistent for all the components provided in the mixture composition. When encoding concentration ranges it is also possible to specify the upper and lower limits percentages for each of the component using the following qualifiers: • ">" or ">=" for the lower numeric value; and • "<" or "<=" for the upper numeric value
Standard Formula (SF) component	**FLEXIBLE_RECORD.MixtureComposition.Components.Components. Sfc** Mandatory (for Standard formula component) – Checkbox This field is used to indicate that a mixture component is a SF component.
Interchangeable Component Group (ICG)	**FLEXIBLE_RECORD.MixtureComposition.Components.Components. Icg** Mandatory (for Interchangeable Component Groups) – Checkbox This field is used to indicate that a mixture component is an ICG.
Generic Component Identifier (GCI)	**FLEXIBLE_RECORD.MixtureComposition.Components.Components. Gci** Mandatory (for components identified via a generic component identifier) – Checkbox This field is used to indicate that a mixture component is a GCI.
Components – End of Repeatable block	

---

[7] For perfume or fragrance components that are not classified or only classified for skin sensitisation Category 1, 1A or 1B or aspiration toxicity, submitters are not required to provide information on their concentration, provided that the total concentration does not exceed 5%.

4.6 Physical state, colour, intensity and form

This document must always be provided as part of the additional Mixture information in a dossier. It is also possible to reference this document from one or more products in the dossier. For additional information see section Product information.

4.6.1 ENPOINT_SUMMARY.GeneralInformation – Field definitions

Field	Description
Physical state at 20°C and 1013 hPa	**ENDPOINT_SUMMARY.GeneralInformation.KeyValueForChemicalSafetyAssessment.PhysicalState** Mandatory – Picklist (single) A19 This field represents the Mixture physical state and must always be provided.
Form	**ENDPOINT_SUMMARY.GeneralInformation.KeyValueForChemicalSafetyAssessment.Form** Optional – Picklist (single) A101 This field represents the Mixture form. As this field is optional, it is suggested, in case the field is not applicable or relevant, to select the value "not specified". *Multilingual information: if 'other:' is selected, the other value entered should be provided in all relevant languages.*
Colour	**ENDPOINT_SUMMARY.GeneralInformation.KeyValueForChemicalSafetyAssessment.Colour** Mandatory – Picklist (multi-select list) PG6-60569 This field represents the colour of the Mixture and must always be provided.
Colour intensity	**ENDPOINT_SUMMARY.GeneralInformation.KeyValueForChemicalSafetyAssessment.ColourIntensity** Optional – Picklist (single) PG6-60568 This field represents the colour intensity of the Mixture.

4.7 Product information

This document must always be provided and represents the product information related with the only Mixture in the case of a Standard submission, or the relevant mixture in the case of a Group submission. At least one document must be present in the final dossier, however it is possible to provide multiple product information documents depending on the business needs e.g. multiple products to be associated to the Mixture. All the mandatory fields must be provided as depicted in the field definitions table below.

4.7.1 Standard submission

In a standard submission there's no need to establish a link between the product information and the mixture composition since only one mixture composition document must be provided.

4.7.2 Group submission

In a group submission a link must be established between the product information and the related mixture composition representing one of the mixtures of the group. Each product information document must be associated to exactly one mixture of the group since it is not possible to have one product having different mixture compositions, which is a case of a multi-component product described in Mixture Unique Formula Identifiers (UFI) and other identifiers).

Figure 7: Group submission – Product links with Mixture compositions
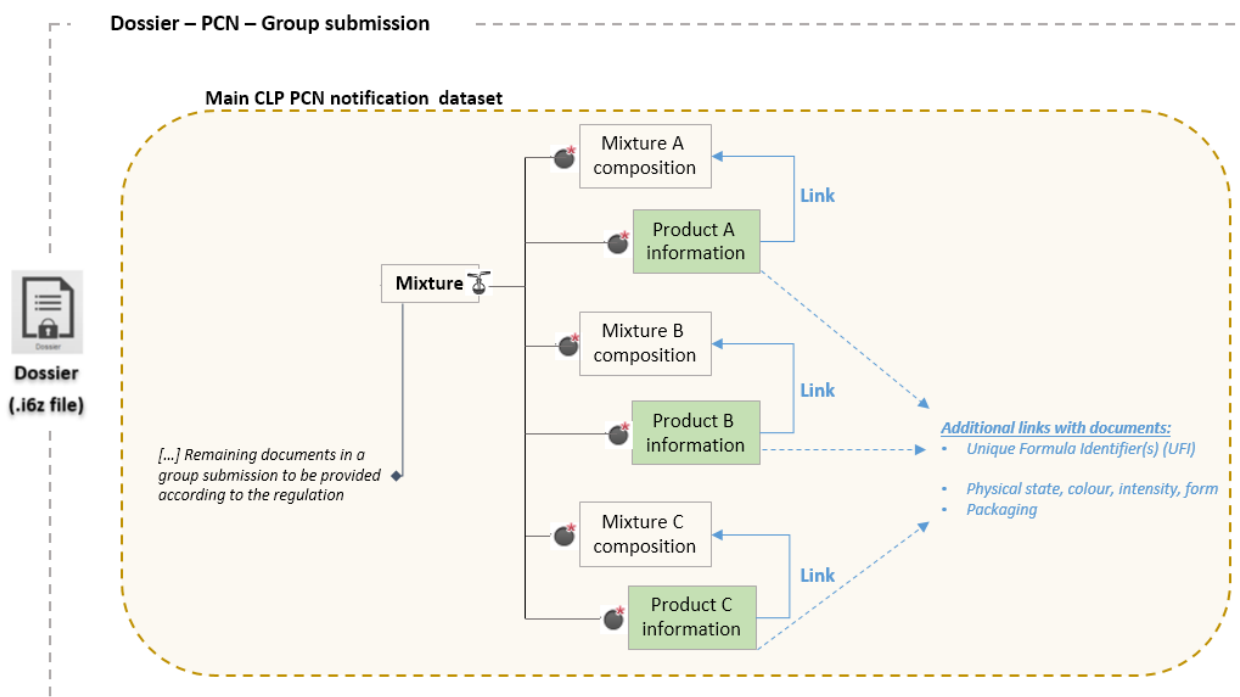
4.7.3 Multimarket notification

A multimarket notification can be encoded by providing the <*Country*> field in the product information document. As depicted in the diagram below either a single or multiple countries, to which the specific product is placed, can be provided per product. At least one country must be provided for each product information document.

It is also possible to indicate the countries the product is no longer marketed (ceased). Such countries will still receive updates related to the notified mixture and associated products since

they may include up-to-date information.

Figure 8: Multimarket notification - Product information
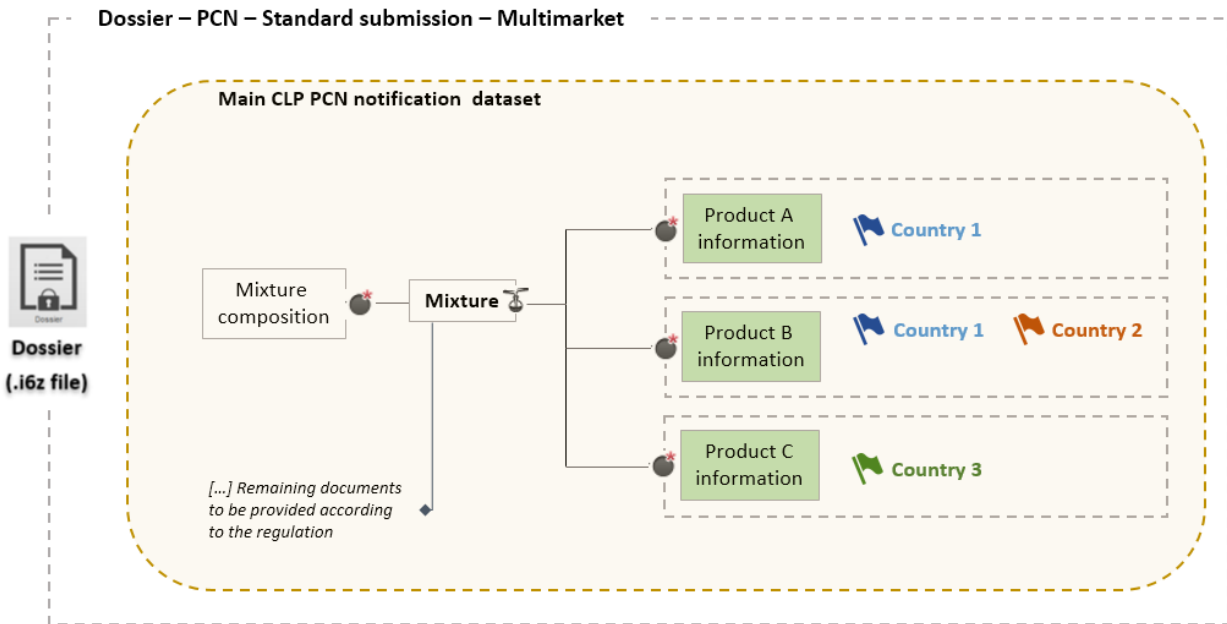
The *Product information* document allows a very flexible configuration of the links between the products and the related documents.

The example shown in the diagram below illustrates a standard submission containing 3 different products linked with existing documents in the dossier. Two *Product information* documents may also be linked to the same *Packaging* document. The same approach is valid for all the links contained in the document. For example depending on the business needs it is also possible to link two or more products to the same *Mixture Unique Formula Identifiers (UFI)* document.

Figure 9: Multiple products – Standard submission Example
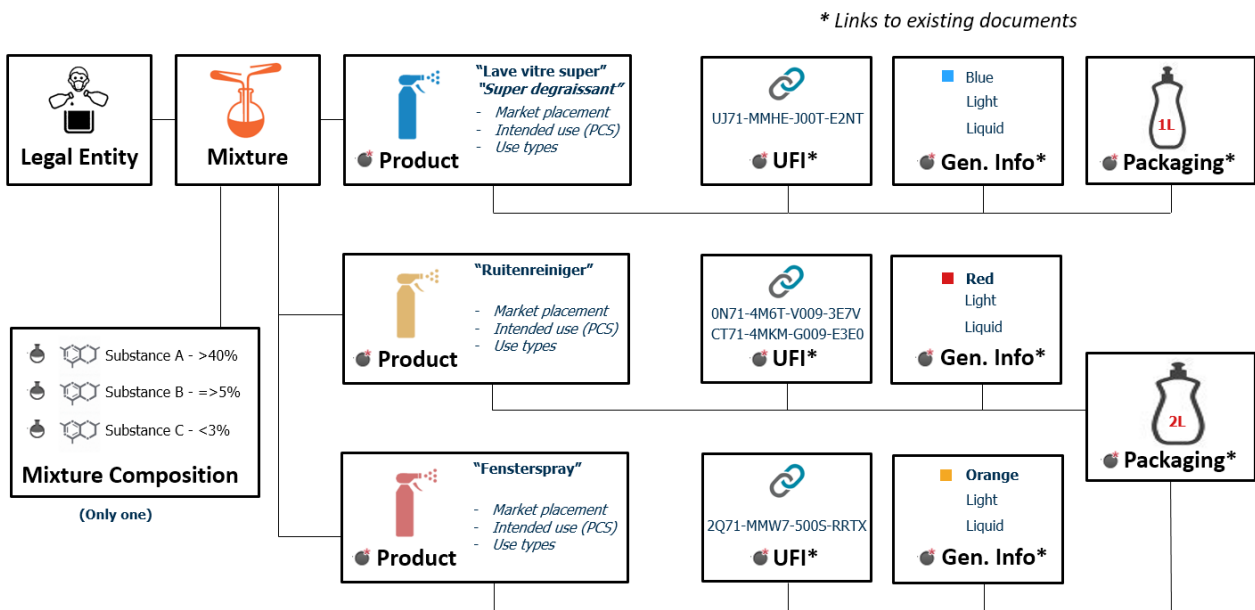
4.7.4 FLEXIBLE_RECORD.ProductInfo – Field definitions

Field	Description
For a group submission, specify to which mixture it applies:	**FLEXIBLE_RECORD.ProductInfo.GroupSubmission.MixtureLink** Mandatory in case of Group submission Link to Mixture composition *(FLEXIBLE_ RECORD.MixtureComposition)* Single link to the relevant Mixture composition in case of a Group submission.
Product identifiers	Repeatable blocks – (Each individual field can be provided multiple times)
Trade name	**FLEXIBLE_RECORD.ProductInfo.ProductIdentifiers.TradeNames.TradeName** Mandatory - Text (2,000 char.) Multiple trade names can be provided.
Other name	**FLEXIBLE_RECORD.ProductInfo.ProductIdentifiers.OtherNames.OtherName** Optional - Text (2,000 char.) Additional brand names or synonyms can be provided.

Field	Description
Unique Formula Identifier (UFI) and other identifiers	**FLEXIBLE_RECORD.ProductInfo.ProductIdentifiers.UFI** Mandatory Link to Mixture unique formula identifiers (UFI) and other identifiers document (*FLEXIBLE_RECORD.Identifiers)* Single or multiple links to Mixture unique formula identifiers (UFI) and other identifiers can be provided.
Active market (country) **Country**	**FLEXIBLE_RECORD.ProductInfo.MarketPlacement.Country** Mandatory - List multi. (multi-select list) - EU-EEA This field represents the country where the product will be placed.
Ceased market (country) **Country**	**FLEXIBLE_RECORD.ProductInfo.MarketPlacement.CeasedMarket** Mandatory - List multi. (multi-select list) - EU-EEA This field represents the country where the product is no longer placed.
Link to the information about colour and physical state	**FLEXIBLE_RECORD.ProductInfo.AdditionalInformation.ColourAndPhysicalState.LinkToColourAndPhysicalState** Mandatory Link to Physical state, colour, intensity and form document *(FLEXIBLE_RECORD.GeneralInformation)* Single or multiple links to Physical state, colour, intensity and form.
Product not packaged	**FLEXIBLE_RECORD.ProductInfo.AdditionalInformation.Packaging.ProductNotPackaged** Mandatory Checkbox

Field	Description
Link to the packaging information	**FLEXIBLE_RECORD.ProductInfo.AdditionalInformation.Packaging.LinkToPackaging** Mandatory – either a link to the packaging information needs to be provided (see below) or an indication that the product is not packaged. Link to Packaging *(FLEXIBLE_RECORD.Packaging)* Single or multiple links to Packaging document can be provided. One product can use several types of packaging, therefore the same product can be linked to several packaging documents.
Main intended use	**FLEXIBLE_RECORD.ProductInfo.AdditionalInformation.ProductUseCategory.MainIntendedUse** Mandatory - List (picklist) - EuPCS - PG6-60567 (hierarchical) This field must contain one single identifier corresponding to one product category according to the EuPCS. The European product categorisation system (EuPCS) is used to describe 'the intended use of a mixture'. The EuPCS for mixtures in the scope of Article 45 is maintained by ECHA and subject to change – the latest version is currently available (in English) at the following web page: EuPCS for mixtures within the scope of Article 45 of CLP Regulation. Additionally, more information on selecting the main intended use can be found in the EuPCS practical guidance[8].
Secondary uses	**FLEXIBLE_RECORD.ProductInfo.AdditionalInformation.ProductUseCategory.SecondaryUses** Optional - List multi. (multi-select list) EuPCS - PG6-60567 (hierarchical)

---

[8] https://poisoncentres.echa.europa.eu/eu-product-categorisation-system

Field	Description
Use type	**FLEXIBLE_RECORD.ProductInfo.AdditionalInformation.ProductUseCategory.UseType** Mandatory - List multi. (multi-select list with remarks - 2,000 char.) - PG6-60565 This field must contain one or more identifiers from a pre-defined list of values: • Consumer • Professional • Industrial

4.8 pH

This document collects information about the mixture pH. The document must always be provided even when the pH is not available.

4.8.1 ENPOINT_SUMMARY.pH

Field	Description
pH is not available	**ENDPOINT_SUMMARY.pH.KeyValueForChemicalSafetyAssessment. pHNotRelevant** Mandatory (except when a pH value is provided) – Check box (True/False) When the pH is not available, the field must be set to *<true>*.
Justification	**ENDPOINT_SUMMARY.pH.KeyValueForChemicalSafetyAssessment. Justification** Mandatory when pH is not available - List (picklist) – PH-1 This field must contain one identifier from a pre-defined list of values indicating the reason why pH is not available.

Field	Description
pH value	**ENDPOINT_SUMMARY.pH.KeyValueForChemicalSafetyAssessment. pH** Mandatory – Numeric range (decimal) The field is mandatory when field pH is not available is set to *<false>*. The pH value can be expressed using an exact value or range numeric values. When encoding the pH value it is also possible to specify the upper and lower limits using the following qualifiers: • ">" or ">=" for the lower numeric value; and • "<" or "<=" for the upper numeric value
Solution concentration (%)	**ENDPOINT_SUMMARY.pH.KeyValueForChemicalSafetyAssessment. SolutionConcentration** Mandatory when pH value is provided Solution concentration to be provided for aqueous solution – Numeric value, percentage
Related composition	**ENDPOINT_SUMMARY.pH.Discussion.RelatedComposition** Mandatory in case of Group submission Link to Mixture composition (FLEXIBLE_ RECORD.MixtureComposition) Single or multiple links to the relevant Mixture composition(s) in case of a Group submission.

4.9 Mixture Classification and labelling

The information that must be provided for the classification and labelling of the mixture contains the following elements (as relevant and in accordance with Annex VIII and the CLP regulation criteria):

- Hazard classes, categories/subcategories and statements (Health and Physical hazards)
- Hazard pictogram codes (Annex V)
- Signal word
- Supplemental hazard information codes (Annex III)
- Precautionary statement codes (Annex IV)
- M-factors
- Specific concentration limits

⚠️ This document is always needed even in case the Mixture is non-hazardous or not classified for health and physical hazards according to CLP criteria. In this case the field <*Not classified*> of the document must be set to <true> and the remaining fields must not be provided, or the environmental classification can be reported instead, if available. The document is needed also when the mixture is classified for hazard classes excluded by the scope of Annex VIII[9].

4.9.1 FLEXIBLE_RECORD.Ghs – Field definitions

Field	Description
Not classified	**FLEXIBLE_RECORD.Ghs.GeneralInformation.NotClassified** Mandatory (except when classification is provided) – Check box (True/False) When the Mixture classification and labelling is regarded as not classified the field must be set to <true>.
Related composition	**FLEXIBLE_RECORD.Ghs.GeneralInformation.RelatedCompositions.Composition** Mandatory in case of Group submission Link to Mixture composition (FLEXIBLE_ RECORD.MixtureComposition) Single or multiple links to the relevant Mixture composition in case of a Group submission.

Classification – Physical and Health Hazards – Start of repeatable blocks

(Environmental hazards can be provided optionally)

See the annex for the content of the relevant picklists.

Hazard category/class	Mandatory – Picklist (single) This field must contain the correct and relevant hazard class from a predefined list of existing values (according to the CLP regulation criteria). If at least one 'Hazard category' and/or 'Hazard statement' is encoded, then the check box <*Not classified*> should be set to <false>.
Hazard statements	Mandatory – Picklist (single) This field must contain the correct and relevant hazard statements from a

---

[9] Mixtures classified only for the hazards "gases under pressure" and/or "explosives" are excluded by the application of Annex VIII. A submission can be made on voluntary basis though.

Field	Description

predefined list of existing values (according to the CLP regulation criteria).

Classification – Physical and Health Hazards – End of repeatable blocks

Labelling – Start of repeatable blocks

Signal word	**FLEXIBLE_RECORD.Ghs.Labelling.SignalWord** Mandatory – Picklist (single) - GHS29 This single field represents the signal word used to indicate the relative level of severity of hazard and alert of a potential hazard on the product's label. The signal words used in this picklist are 'Danger' and 'Warning.' whereby 'Danger' is used for the more severe hazards, and 'Warning' is used for the less severe. If no signal word is present the field must contain the corresponding identifier for 'No signal word'.
Hazard pictograms **Code**	**FLEXIBLE_RECORD.Ghs.Labelling.HazardPictogramBlock.HazardPictogram.Code** Mandatory – Picklist (single) - DM02 This section represents a repeatable block namely *<Hazard pictograms>* containing one single field *<code>*. The hazard pictograms are a graphical composition, intended to convey specific information on the hazard concerned on the product's label. It should be provided depending on the hazard classes and categories. Each field *<code>* should contain a valid identifier from the list of available values (whenever applicable) that represents a single hazard pictogram. It is possible to provide up to 9 different GHS codes according to the CLP regulation (Annex V – Hazard pictograms).
Hazard statements	**FLEXIBLE_RECORD.Ghs.Labelling.HazardStatementsBlock.HazardStatements.HazardStatement** **FLEXIBLE_RECORD.Ghs.Labelling.HazardStatementsBlock.HazardStatements.AdditionalText** This mandatory section represents a repeatable block namely *<Hazard statements>* containing two fields: • *<Hazard statements>* Picklist (single) - GHS65 • *<Additional text>* Text This section must contain all the correct and relevant (labelling) hazard statements from a predefined list of existing values (according to the CLP

Field	Description
	regulation criteria). ⚠️ The field *<Additional text>* must only be used whenever the hazard statement contains editable parts that must be explicitly stated. In this case the text of the field must contain only the editable parts (e.g. route of exposure, organs) separated with the following character '|'. For example: doctor|inhalation *Multilingual information: if an 'Additional text' is provided, it should be made available in all relevant languages.*
Precaution ary statements	**FLEXIBLE_RECORD.Ghs.Labelling.PrecautionaryStatementsBlock.PrecautionaryStatements.PrecautionaryStatement** **FLEXIBLE_RECORD.Ghs.Labelling.PrecautionaryStatementsBlock.PrecautionaryStatements.AdditionalText** This mandatory section represents a repeatable block namely <Precautionary statements> containing two fields: • <*Precautionary statement*> Picklist (single) - GHS66 • <Additional text> Text This section must contain all the correct and relevant (labelling) precautionary statements from a predefined list of existing values (according to the CLP regulation criteria). ⚠️ The field *<Additional text>* must only be used whenever the hazard statement contains editable parts that must be explicitly stated. In this case the text of the field must contain only the editable parts (e.g. route of exposure, organs) separated with the following character '|'. For example: doctor|inhalation *Multilingual information: if an 'Additional text' is provided, it should be made available in all relevant languages.*
Additional non- GHS hazard statements	**FLEXIBLE_RECORD.Ghs.Labelling.LabelingRequirementsBlock.LabelingRequirements.SupplHazardStatement** **FLEXIBLE_RECORD.Ghs.Labelling.LabelingRequirementsBlock.LabelingRequirements.AdditionalText** This section refers to the supplemental hazard information namely EUH-Statements (CLP Regulation – Annex III – Part 2 – Table 2.1). This section (to be filled in if relevant) represents a repeatable block namely <Additional non GHS hazards statements> containing two fields: • <*Additional non-GHS statement*> Picklist (single) - EUGHS1 • <Additional text> Text

Field	Description
	This section must contain all the correct and relevant (labelling) supplementary statements from a predefined list of existing values (according to the Annex III part 2 of the CLP regulation). ⚠️ The field *<Additional text>* must only be used whenever the hazard statement contains editable parts that must be explicitly stated. In this case the text of the field must contain only the editable parts (e.g. route of exposure, organs) separated with the following character '|'. For example: doctor|inhalation *Multilingual information: if an 'Additional text' is provided, it should be made available in all relevant languages.*

Labelling – End of repeatable blocks

4.10   Packaging

This document must be encoded in order to provide information about the product packaging. It is mandatory when the mixture is placed on the market for consumer or professional use. It is optional in case of limited submission. Multiple documents can be encoded depending on the packaging type and size. The documents can then be linked from the product information document depending on the business needs. For additional information see Product information.

4.10.1   FLEXIBLE_RECORD.Packaging – Field definitions

Field	Description
Type of packaging in contact with the product (container type)	**FLEXIBLE_RECORD.Packaging.Packaging.TypeOfPackaging** Mandatory (for consumer or professional use) – Picklist (single) - B05 This field is used to indicate the material of container that is in contact with a product.
Size of packaging in contact with the product (container size) – Start of repeatable block	

Size of packaging in contact with the product (container size)	**FLEXIBLE_RECORD.Packaging.Packaging. SizeOfPackagingInContactWithTheProductContainerSize. SizeOfPackaging** Mandatory (for consumer or professional use) – Numeric value (decimal with picklist) Picklist (single) - B06 This field is used to indicate the size of the container that is in contact with a product. In case the product is sold in different sizes under the same product identifiers (e.g. product name and UFI) all available sizes should be indicated.

Size of packaging in contact with the product (container size) – End of repeatable block

Packaging related attachments – Start of repeatable block

Type of attachment	**FLEXIBLE_RECORD.Packaging.Packaging. PackagingRelatedAttachments.TypeOfAttachment** Optional – Picklist (single) – phrase code 9300 'example label(s)'
Attached document	**FLEXIBLE_RECORD.Packaging.Packaging. PackagingRelatedAttachments.AttachedDocument** Optional - Single file attachment This field is used to upload an optional label picture or document.

Packaging related attachments – End of repeatable block

4.11   Mixture Safety data sheet and Toxicological information

This document is mandatory as it is required in order to provide the Mixture toxicological information although the SDS section is optional and not required by the regulation.

4.11.1   FLEXIBLE_RECORD.SDSInfoMixture – Field definitions

Field	Description
Name or trade name of mixture / product	**FLEXIBLE_RECORD.SDSInfoMixtures.InformationOnMixtures.MixtureProductName** Optional – Text (2,000 char.) This field is not required from a regulatory perspective and it is also not mandatory, however, it can be used internally and for reference purposes in order to easily identify the SDS provided.

Field	Description
Related composition	**FLEXIBLE_RECORD.SDSInfoMixtures.InformationOnMixtures.RelatedComposition** Mandatory in case of Group submission Link to Mixture composition (FLEXIBLE_ RECORD.MixtureComposition) Single or multiple links to the relevant Mixture composition in case of a Group submission.

Safety data sheets of mixture / product – Start of repeatable block

Field	Description
Safety data sheet	**FLEXIBLE_RECORD.SDSInfoMixtures.InformationOnMixtures.TradeNamesAndSafetyDataSheetsOfTheMixture.TradeNamesAndSafetyDataSheets.Attachment** Optional – Attachment (single) Note: Attaching the SDS does not release the duty holder from provision of information in the required format, even if that information is contained in the SDS.
Country	**FLEXIBLE_RECORD.SDSInfoMixtures.InformationOnMixtures.TradeNamesAndSafetyDataSheetsOfTheMixture.TradeNamesAndSafetyDataSheets.Country** Optional – Picklist (single) - EU-EEA This field represent the country where the SDS is applicable.
Language	**FLEXIBLE_RECORD.SDSInfoMixtures.InformationOnMixtures.TradeNamesAndSafetyDataSheetsOfTheMixture.TradeNamesAndSafetyDataSheets.Language** Optional – Picklist (single) - PG6-60564 This field represents the language used in the SDS.

Safety data sheets of mixture / product – End of repeatable block

Field	Description
Toxicological information (section 11 of SDS)	**FLEXIBLE_RECORD.SDSInfoMixtures.InformationOnMixtures.TradeNamesAndSafetyDataSheetsOfTheMixture.SDSsection11** Mandatory – Rich text area This field can contain formatted text with special formatting such as font size, font colour, bold, italic, tables, etc. The content of a Rich text field is expected to be standard HTML. ⬤ When copying text from SDS Section 11 the formatted text keeps its settings from where it is copied. Note: In case of 'copying' pay attention that the text does not cross-references to other SDS sections or documents. The text must be stand alone. *Multilingual information: this information should be provided in all relevant languages.*

5 Substance (information) dataset

The chemical identity of all the substances listed as Mixture components should be carefully prepared and completed with all known information.

There are three important parts and documents (highlighted in brackets) related to the identification of a Substance in the PCN format:

- The Substance identity (*SUBSTANCE* entity);
- The Reference substance (*REFERENCE_SUBSTANCE* document);
- The EC Inventory (*EC Inventory*)

The aforesaid documents should be linked in cascade manner as highlighted in the diagram in Figure 10 here below. However, it should be noted that the EC inventory document is available by default in IUCLID installations. Hence, it does not need to be transported together with the reference substance in a IUCLID dossier. It is only necessary to provide the Inventory number in the relevant field of the reference substance.

Figure 10: Substance identity documents relationships
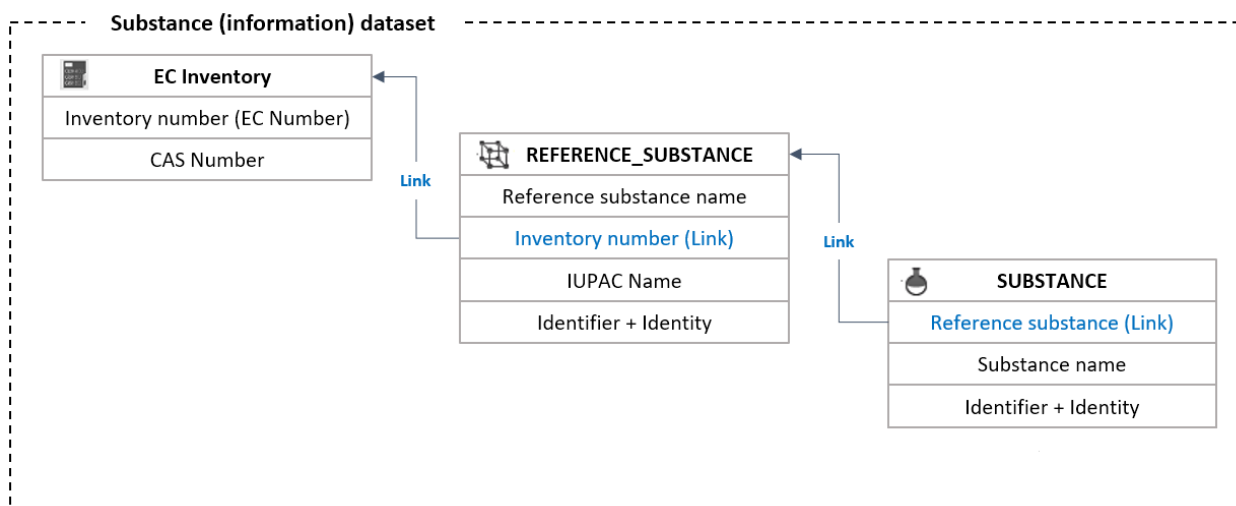
Both the EC Inventory and the existing (well-known) Reference substance inventory are managed by ECHA and contains catalogues that can be re-used and downloaded free of charge from IUCLID public web site: https://iuclid6.echa.europa.eu/web/iuclid/iuclid-inventories

All the known substance identifiers should be provided as described in section 3.2.1 Mixture components – Substance of Annex VIII to the CLP regulation and in accordance with CLP regulation Art. 18(2).

The following simplified stepwise approach can be used in order to encode the substance identifiers information (corresponding documents in brackets):

Steps	Identification process	Substance identifiers
a)	if the substance is included in Part 3 of Annex VI, a name and an identification number as given therein can be used	Annex VI Index name – *<Substance name>* (SUBSTANCE)
		EC Number – *<Inventory number> (EC Inventory)*
		CAS Number – *<CAS number> (EC Inventory)*
		Annex VI Index Number [Other substance identifiers – Rep. block] *<Identifier: CLP index number - harmonised C&L> <Identity>* (SUBSTANCE)
b)	if the substance is not included in Part 3 of Annex VI, but appears in the classification and labelling inventory, a name and an identification number as given therein;	EC Name – *<Substance name>* (SUBSTANCE)
		IUPAC Name – *<IUPAC name> (REFERENCE_SUBSTANCE)*
		EC Number – *<Inventory number> (EC Inventory)*
		CAS Number – *<CAS number> (EC Inventory)*
c)	if the substance is not included in Part 3 of Annex VI nor in the classification and labelling inventory, the number provided by the CAS (hereinafter referred to as 'the CAS number'), together with the name set out in the nomenclature provided by the IUPAC (hereinafter referred to as 'the IUPAC Nomenclature'), or the CAS number together with another international chemical name(s);	CAS Number *<CAS number> (EC Inventory)*
		IUPAC Name *<IUPAC name>* (REFERENCE_SUBSTANCE)
		International Chemical Name *<Substance name>* (SUBSTANCE)
d)	if the CAS number is not available, the name set out in the IUPAC Nomenclature or another international chemical name(s).	IUPAC Name *<IUPAC name>* (REFERENCE_SUBSTANCE)
		International Chemical Name *<Substance name>* (SUBSTANCE)
		Other/additional international chemical names *(REFERENCE_SUBSTANCE)*
e)	Alternatively an INCI name, a colour index name or another international chemical name may also be used, provided the chemical name is well-known and unambiguously defines the substance identity.	INCI Name [Other substance identifiers – Rep. block] *<Identifier:INCI name> <Identity>* (SUBSTANCE)
		Colour Index Name [Other substance identifiers – Rep. block] *<Identifier:Colour index> <Identity>* (SUBSTANCE)

Substances must always be identified by linking a reference substance and whenever applicable an EC Inventory number should also be indicated in the reference substance document.

⚠ However, in some cases an EC inventory entry may not be available from the existing chemical inventory. In this case, the known identifiers should be encoded in the corresponding fields of the substance and reference substance linked to it.

5.1 Substance identification

5.1.1 SUBSTANCE – Field definitions

Field	Description
Substance name	**SUBSTANCE.ChemicalName** Mandatory – Text (2,000 char) This field is mandatory, and can contain one the following substance identifiers: • Annex VI Index name • EC Name • International Chemical Name
Other substance identifiers – Start of repeatable block	
Identifier	**SUBSTANCE.OtherNames.NameType** Optional – Picklist (single) - N97 The type of identifier can be selected among a list of pre-defined values. This field should be provided only when applicable, and can contain one of the following identifiers: • CLP index number - harmonised C&L – (Value 55444) • INCI name (Value 60822) • Colour index name (Value 2757) Mandatory in cases the main mixture is not fully compliant with SF, but one or more of its substance components are declared. In such cases, the relevant value should be selected, i.e. "standard formula (SF)".

Field	Description
Identity	**SUBSTANCE.OtherNames.Name** Optional - Text (2,000 char.) This field contains the identity (name, number, code) corresponding to the *<Identifier>* type selected. Mandatory in cases the main mixture is not fully compliant with SF, but one or more of its Substance components are declared. In such cases, the relevant SF name should be provided, e.g. "Cement Standard Formula – 1 [Portland cement with one main constituent: clinker]".

Other substance identifiers – End of repeatable block

Field	Description
Reference substance	**SUBSTANCE.ReferenceSubstance.ReferenceSubstance** Mandatory – Link (single) • Link to Reference substance (*REFERENCE_SUBSTANCE*) This field must always contain a link with an existing reference substance.

5.2 Reference substance (REFERENCE_SUBSTANCE)

A Reference substance can be seen as an entity in the PCN format that is used to define the identity of a Substance, in such a way that the definition may be re-used in more than one dossier if needed. This provides consistency and avoids duplication of work. A Reference substance contains both chemical identifiers and structural information.

Reference substances can be encoded or created as new documents, however, it is also possible and more efficient to re-use and import them in the PCN format as a ready-made set from the public collection available free of charge from the IUCLID public web site[10].

It may be that the reference substance has not yet been entered in the aforesaid inventory. In this case, a new reference substance can be encoded and linked to an existing entry in the EC Inventory.

⚠ The reference substance document must always be present in a dossier. As a minimum the <Reference substance name> (EC Name, chemical name etc..) along with one of the following fields must be provided:

- EC number;
- CAS number and CAS name;

---

[10] Thousands of existing and well-known reference substances are publicly available. The set is provided as an archive file with extension zip. Its content must be extracted before the .i6z files can be used and imported but it is also possible to search and download only the one needed here: https://iuclid6.echa.europa.eu/web/iuclid/iuclid-inventories.

- IUPAC name
- INCI name
- Colour Index

5.2.1 REFERENCE_SUBSTANCE – Field definitions

Field	Description
Reference substance name	**REFERENCE_SUBSTANCE.ReferenceSubstanceName** Mandatory - Text (2,000 char.) This field must always be provided and should be aligned with the main chemical identifier provided for the substance identity (e.g. EC name, International chemical name, CAS name, IUPAC name etc...).
IUPAC name	**REFERENCE_SUBSTANCE.IupacName** Optional – Text (2,000 char.) This field contains the substance IUPAC name. To be provided when applicable and available as substance identifier.
Inventory number	**REFERENCE_SUBSTANCE.Inventory.InventoryEntry** One single link if an entry exists in the Chemical inventory. EC or list number (see more explanations below) When an inventory entry is not present, the correct substance identifiers must be provided in the reference substance document.
CAS Number	**REFERENCE_SUBSTANCE.Inventory.CASNumber** Optional - Text (255 char.) When an EC inventory entry with the specific CAS number is not available to be linked from the chemical inventory, this field can be used to encode the CAS Number.
CAS Name	**REFERENCE_SUBSTANCE.Inventory.CASName** Optional – Text (2,000 char.) This field contains the optional CAS Name if applicable and available.
Synonyms – Start of repeatable block	

Field	Description
Identifier	**REFERENCE_SUBSTANCE.Synonyms.Synonyms.Identifier** Optional – Picklist (single) - PG6-60192 The picklist contains additional identifiers, that should be used only when an EC inventory entry is not available to be linked from the chemical inventory. In this case EC number / EC name or other international chemical identifiers can also be provided. If none of the pre-defined items applies, the 'other:' option can also be provided along a text field where it is possible to specify the type of identifier.
Identity	**REFERENCE_SUBSTANCE.Synonyms.Synonyms.Name** Optional - Text (2,000 char.) This field contains the identity (name, number, code) corresponding to the *<Identifier>* type selected.

Synonyms – End of repeatable block

The *EC Inventory* is a public catalogue[11] (received from the JRC in 2008 on the founding of ECHA) listing substance identities and chemicals identifiers based on a combination of following EU inventories:

- **EINECS**: European Inventory of Existing Commercial Chemical Substances, which includes substances that were on the European market between 1st January 1971 and 18th September 1981. The EINECS is based on the European COre INventory (ECOIN) to which supplementary substance reporting could be made by industry (according criteria for reporting substances for EINECS). ECOIN was composed by blending different lists of chemicals presumed to be on the European market (e.g. the TSCA list (The Toxic Substances Control Act)).

- **ELINCS**: European List of New Chemical Substances, which includes substances notified and placed on the market after 18th September 1981.

- **NLP-list**: No-Longer Polymers list, which includes substances that have been on the EU market between 18th September 1981, and 31st October 1993 and satisfy the requirement that they were considered to be polymers under the reporting rules for EINECS but are no longer considered to be polymers under the 7th amendment of Directive 67/548/EEC (Directive 92/32/EEC). The NLP-list is a non exhaustive list.

---

[11] The EC inventory is also published by ECHA here: https://echa.europa.eu/information-on-chemicals/ec-inventory and can be can be downloaded free of charge from IUCLID public web site: https://iuclid6.echa.europa.eu/web/iuclid/iuclid-inventories.

5.3 Substance Classification

The classification of each mixture component for Health and Physical hazards including hazard classes, hazard categories and hazard statements should be provided.

⚠️ This document is always needed even in case the substance is non-hazardous or not classified for health and physical hazards according to CLP criteria. In this cases the field <Not classified> of the document must be set to <true> and the remaining fields must not be provided, or the environmental classification can be reported instead if available.

For each Physical Hazards or Health Hazards repeatable block several pre-defined categories are available for selection (according to CLP regulation criteria).

5.3.1 FLEXIBLE_RECORD.Ghs – Field definitions

Field	Description
Not classified	**FLEXIBLE_RECORD.Ghs.GeneralInformation.NotClassified** Mandatory (except when classification is provided) – Check box (True/False)
Classification – Physical and Health Hazards – Start of repeatable blocks See the annex for the content of the relevant picklists.	
Hazard category/class	Mandatory – Picklist (single) This field must contain the correct and relevant hazard class from a predefined list of existing values (according to CLP regulation criteria).
Hazard statements	Mandatory – Picklist (single) This field must contain the correct and relevant hazard statements from a predefined list of existing values (according to the CLP regulation criteria).

Classification – Physical and Health Hazards – End of repeatable blocks

6 Mixture in Mixture (MiM) dataset

When a mixture is used in the composition of a second mixture, the first mixture is referred to as a mixture in mixture (or MIM). For additional information see also Figure 1 in section Datasets, Table of Contents (TOC) and Dossier.

⚠️ Important note: when the Legal submitter has access to information on the full composition of the MIM, all the MiM components must be linked (as individual datasets) along with the other main Mixture components in the *Mixture composition* document. In this case a MiM dataset **must not be used, but instead linked** to the main CLP PCN notification dataset.

When the Legal submitter does not have access to information on the full composition of the MIM, the information on known mixture components and concentrations must be provided in the MiM dataset along with the UFI of the MiM. For additional information on what documents must be provided see Section 2.6.2 MiM - Unknown or partially known composition.

The relationship between the various documents in a MiM dataset is also illustrated in the data model annex published on the Poison Centres website.

6.1 MiM Identification

6.1.1 MIXTURE - Field definitions

Field	Description
Mixture/Product name	**MIXTURE.MixtureName** Mandatory - Text (2,000 char.) According to the regulation[12] the product identifier for a MiM (mixture in mixture) shall include the trade name or the designation of the mixture that can be encoded in this field.
Other identifiers – Start of Repeatable block	
Name type	**MIXTURE.OtherNames.NameType** Optional - Picklist (single value) – PG6-60585 The type of identifier can be selected among a list of pre-defined values and should be provided only when applicable

---

[12] See CLP Regulation – Annex VIII Section 3.2.2. Mixture in Mixture

Field	Description
Name	**MIXTURE.OtherNames.Name** Optional - Text (2,000 char.) In case of multiple MiM trade names or synonyms the PCN format allows the use of this field to provide additional MiM designations.

Other identifiers – End of Repeatable block

6.2 MiM Unique Formula Identifiers (UFI)

The MiM unique formula identifier has to be provided whenever applicable and provided by the MiM supplier, even when the supplier has not notified it in the relevant Member State yet.

⚠️   Only a single document can be provided for each MiM dataset.

6.2.1 FLEXIBLE_RECORD.Identifiers - Field definitions

Field	Description
Regulatory programme identifiers – Start of Repeatable block	
Regulatory programme	**FLEXIBLE_RECORD.Identifiers.RegulatoryProgrammeIdentifiers.RegulatoryProgrammeIdentifiers.RegulatoryProgramme** Mandatory – Picklist (single value) - Picklist N12 - Mandatory field value: 64856 This picklist allows the selection of many other pre-defined identifiers type for IUCLID compatibility reasons, however, the only mandatory value in order to report a UFI is 64856 corresponding to "CLP unique formula identifier (UFI)".
ID	**FLEXIBLE_RECORD.Identifiers.RegulatoryProgrammeIdentifiers.RegulatoryProgrammeIdentifiers.Id** Mandatory - Text (255 char.) – MiM UFI 16-character alphanumeric code This field allows encoding a single MiM Unique Formula Identifier. If additional MiM UFI(s) are needed to identify the Mixture in Mixture, another repeatable block can be added to the document.
Regulatory programme identifiers – End of Repeatable block	

6.3 MiM composition

⚠️ Only a single MiM Composition document can exist in a MiM dataset.

6.3.1 FLEXIBLE_RECORD.MixtureComposition – Field definitions

Field	Description
Mixture/product name	**FLEXIBLE_RECORD.MixtureComposition.GeneralInformation.Name** Optional - Text (255 char.) This field is not required from a regulatory perspective and it is also not mandatory, however, it can be used internally and for reference purposes in order to easily identify the MiM composition.
Components – Start of Repeatable block	
Name	**FLEXIBLE_RECORD.MixtureComposition.Components.Components.Reference** Mandatory if the component is not identified with a Generic Component identifier (See Function field). • Link (single) to <u>Substance dataset</u> (*SUBSTANCE)* This field allows linking a substance (dataset) for fully identifying the mixture component under consideration. This is done by creating a single link with the desired dataset created previously.
Typical concentration	**FLEXIBLE_RECORD.MixtureComposition.Components.Components.TypicalConcentration** Mandatory[7] (except when a concentration range is provided) - Numeric (decimal), half-bounded, with Picklist (single) N24 This field allows encoding the component concentration percentages. Concentrations can be expressed using the following mandatory Picklist (single) values: • 2505 - "% (w/w)"; or • 2506 - "% (v/v)" The selected picklist (single) value must be consistent for all the components provided in the mixture composition.

Field	Description
Concentration range	**FLEXIBLE_RECORD.MixtureComposition.Components.Components.ConcentrationRange** Mandatory[7] (except when a typical concentration is provided) - Numeric range (decimal) with picklists(single) This field allows encoding the MiM component concentration either as exact or range percentages. Concentrations can be expressed using the following mandatory Picklist (single) values: • "% (w/w)"; or • "% (v/v)" The selected picklist (single) value must be consistent for all the components provided in the mixture composition. When encoding concentration ranges it is also possible to specify the upper and lower limits percentages for each of the component using the following qualifiers: • ">" or ">=" for the lower numeric value; and • "<" or "<=" for the upper numeric value
Components – End of Repeatable block	

6.4 MiM Suppliers

6.4.1 FLEXIBLE_RECORD.Suppliers – Field definitions

Field	Description
Name	**FLEXIBLE_RECORD.Suppliers.ManufacturerImportForm.LegalEntity** Mandatory - When applicable in a MiM Limited Dataset (when no UFI or not notified UFI is provided). Link to MiM Supplier – Legal entity document. For additional information on when this field is requested by the regulation see MiM - Unknown or partially known composition.

6.5 MiM Supplier – Legal entity

6.5.1 LEGAL_ENTITY - Field definitions

Field	Path and Description
Legal entity name	**LEGAL_ENTITY.GeneralInfo.LegalEntityName** Mandatory - Text (255 char.) – Company name
Address 1	**LEGAL_ENTITY.ContactInfo.ContactAddress.ContactAddress.street1** Optional - Text (255 char.) – Company address
Address 2	**LEGAL_ENTITY.ContactInfo.ContactAddress.ContactAddress.street2** Optional - Text (255 char.) – Company address
Postal code	**LEGAL_ENTITY.ContactInfo.ContactAddress.ContactAddress.zipcode** Optional - Text (255 char.) – Company postal code
Town	**LEGAL_ENTITY.ContactInfo.ContactAddress.ContactAddress.city** Optional - Text (255 char.) – Company town or city
Country	**LEGAL_ENTITY.ContactInfo.ContactAddress.ContactAddress.country** Optional – Picklist (single) A31 – Company country

Field	Path and Description
Phone	**LEGAL_ENTITY.ContactInfo.ContactAddress.ContactAddress.phone** Mandatory - Text (255 char.) – Company phone number
Email	**LEGAL_ENTITY.ContactInfo.ContactAddress.ContactAddress.email** Mandatory - Text (255 char.) – Company email address

6.6 MiM Classification and labelling

For MiM Classification, please refer to the mixture classification section (4.9).

6.7 MiM Safety data sheet

The SDS information is optional information for Mixture in Mixtures.

6.7.1 FLEXIBLE_RECORD.SDSInfoMixture – Field definitions

Field	Description
Name or trade name of mixture / product	**FLEXIBLE_RECORD.SDSInfoMixtures.InformationOnMixtures.MixtureProductName** Optional – Text (2,000 char.) This field is not required from a regulatory perspective and it is also not mandatory, however, it can be used internally and for reference purposes in order to easily identify the SDS if provided.
Safety data sheets of mixture / product – Start of repeatable block	
Safety data sheet	**FLEXIBLE_RECORD.SDSInfoMixtures.InformationOnMixtures.TradeNamesAndSafetyDataSheetsOfTheMixture.TradeNamesAndSafetyDataSheets.Attachment** Optional– Attachment (single)
Country	**FLEXIBLE_RECORD.SDSInfoMixtures.InformationOnMixtures.TradeNamesAndSafetyDataSheetsOfTheMixture.TradeNamesAndSafetyDataSheets.Country** Optional – Picklist (single) – EU-EEA

Field	Description
Language	**FLEXIBLE_RECORD.SDSInfoMixtures.InformationOnMixtures.TradeNamesAndSafetyDataSheetsOfTheMixture.TradeNamesAndSafetyDataSheets.Language** Optional

Safety data sheets of mixture / product – End of repeatable block

7 Standard Formula (SF) and Fuels component dataset

When the main mixture is compliant with a Standard Formula (SF) reported in Part D of Annex VIII, then its mixture composition should include the components of the indicated SF. In case of MiM components, the information has to be provided as described in 3.4.3 Standard Formula (SF) component.

For certain fuels listed in Table 3, Part B of Annex VIII, the composition (components' identity and concentration) can be reported as in the SDS. For the purposes of PCN dossier preparation, these fuels are considered a category of Standard Formulas. As such information requirements for fuels can be provided using the same working context as for Standard Formulas.

7.1 Standard Formula (SF) identity

7.1.1 MIXTURE - Field definitions

Field	Description
Mixture/Product name	**MIXTURE.MixtureName** Mandatory - Text (2,000 char.) It shall include the name of the SF mixture component.
Other identifiers – Start of Repeatable block	
Name type	**MIXTURE.OtherNames.NameType** Optional - Picklist (single value) – PG6-60585 Mandatory in cases the main mixture is not fully compliant with SF, but one or more of its MiM components are declared. In such cases, the relevant value should be selected, i.e. "standard formula (SF)" or "fuels".
Name	**MIXTURE.OtherNames.Name** Optional - Text (2,000 char.) Mandatory in cases the main mixture is not fully compliant with SF, but one or more of its MiM components are declared. In such cases, the relevant SF name should be provided, e.g. "Cement Standard Formula – 1 [Portland cement with one main constituent: clinker]" In case of multiple MiM trade names or synonyms the PCN format allows the use of this field to provide additional MiM designations.

Other identifiers – End of Repeatable block

7.2 SF composition

⚠️   Only a single SF Composition document can exist in a SF dataset.

7.2.1 FLEXIBLE_RECORD.MixtureComposition – Field definitions

Field	Description
Mixture/product name	**FLEXIBLE_RECORD.MixtureComposition.GeneralInformation.Name** Optional - Text (255 char.) This field can be used internally and for reference purposes in order to easily identify the MiM composition.
Components – Start of Repeatable block	
Name	**FLEXIBLE_RECORD.MixtureComposition.Components.Components.Reference** Mandatory if the component is not identified with a Generic Component Identifier (See Function field). • Link (single) to <u>Substance dataset</u> (*SUBSTANCE); or* • Link (single) to <u>MiM dataset</u> (*MIXTURE)* This field allows linking either a substance or a mixture in mixture (dataset) for fully identifying the mixture component under consideration. This is done by creating a single link with the desired dataset created previously.
Typical concentration	**FLEXIBLE_RECORD.MixtureComposition.Components.Components.TypicalConcentration** Mandatory[7] (except when a concentration range is provided) - Numeric (decimal), half-bounded, with Picklist (single) N24 This field allows encoding the component concentration percentages. Concentrations can be expressed using the following mandatory Picklist (single) values: • 2505 - "% (w/w)"; or • 2506 - "% (v/v)" The selected picklist (single) value must be consistent for all the components provided in the mixture composition.

Field	Description
Concentration range	**FLEXIBLE_RECORD.MixtureComposition.Components.Components.ConcentrationRange** Mandatory[7] (except when a typical concentration is provided) - Numeric range (decimal) with picklists(single) This field allows encoding the MiM component concentration either as exact or range percentages. Concentrations can be expressed using the following mandatory Picklist (single) values: • "% (w/w)"; or • "% (v/v)" The selected picklist (single) value must be consistent for all the components provided in the mixture composition. When encoding concentration ranges it is also possible to specify the upper and lower limits percentages for each of the component using the following qualifiers: • ">" or ">=" for the lower numeric value; and • "<" or "<=" for the upper numeric value

Components – End of Repeatable block

7.3 SF Classification and labelling

For SF Classification and labelling, please refer to the mixture classification section (4.9).

8 Interchangeable Component Group (ICG) dataset

In case of a MiM component, which is indicated as an ICG, the information has to be provided as described in 3.4.2 Interchangeable Component Group (ICG) dataset.

8.1 Interchangeable component group (ICG) identity

8.1.1 MIXTURE - Field definitions

Field	Description
Mixture/Product name	**MIXTURE.MixtureName** Mandatory - Text (2,000 char.) It shall include the name of the ICG mixture component.
Other identifiers – Start of Repeatable block	
Name type	**MIXTURE.OtherNames.NameType** Optional - Picklist (single value) – PG6-60585 The format allows the selection of the "interchangeable component group (ICG)" option, which gives the possibility to provide the description of the ICG component in the declared languages of the dossier.
Name	**MIXTURE.OtherNames.Name** Optional - Text (2,000 char.) In case of multiple MiM trade names or synonyms the PCN format allows the use of this field to provide additional MiM designations.
Remarks	**MIXTURE.OtherNames.Remarks** Optional - Text (32,768 char.) Mandatory in cases the "interchangeable component group (ICG)" has been selected in the Name type. In such case, the description of the ICG should be provided. *Multilingual information: this information should be provided in all relevant languages.*
Other identifiers – End of Repeatable block	

8.2 ICG composition

⚠️ Only a single ICG Composition document can exist in an ICG dataset.

8.2.1 FLEXIBLE_RECORD.MixtureComposition – Field definitions

Field	Description
Mixture/product name	**FLEXIBLE_RECORD.MixtureComposition.GeneralInformation.Name** Optional - Text (255 char.) This field can be used internally and for reference purposes in order to easily identify the MiM composition.
Components – Start of Repeatable block	
Name	**FLEXIBLE_RECORD.MixtureComposition.Components.Components.Reference** Mandatory[7] if the component is not identified with a Generic component identifier (See Function field). • Link (single) to <u>Substance dataset</u> (*SUBSTANCE); or* • Link (single) to <u>MiM dataset</u> (*MIXTURE)* ⚠️ The PCN format allows nesting multiple MiM datasets if needed. This field allows linking either a substance or a mixture in mixture (dataset) for fully identifying the mixture component under consideration. This is done by creating a single link with the desired dataset created previously.
Typical concentration	**FLEXIBLE_RECORD.MixtureComposition.Components.Components.TypicalConcentration** Optional - Numeric (decimal), half-bounded, with Picklist (single) N24 This field allows encoding the component concentration percentages. Concentrations can be expressed using the following mandatory Picklist (single) values: • 2505 - "% (w/w)"; or • 2506 - "% (v/v)" The selected picklist (single) value must be consistent for all the components provided in the mixture composition.

Field	Description
Concentration range	**FLEXIBLE_RECORD.MixtureComposition.Components.Components.ConcentrationRange** Optional - Numeric range (decimal) with picklists(single) This field allows encoding the MiM component concentration either as exact or range percentages. Concentrations can be expressed using the following mandatory Picklist (single) values: • "% (w/w)"; or • "% (v/v)" The selected picklist (single) value must be consistent for all the components provided in the mixture composition. When encoding concentration ranges it is also possible to specify the upper and lower limits percentages for each of the component using the following qualifiers: • ">" or ">=" for the lower numeric value; and • "<" or "<=" for the upper numeric value
Components – End of Repeatable block	

8.3 ICG Classification

For ICG Classification, please refer to the mixture classification section (4.9).

8.4 ICG Safety data sheets and Toxicological information

This document provides the ICG SDS and toxicological information.

8.4.1 FLEXIBLE_RECORD.SDSInfoMixture – Field definitions

Field	Description
Name or trade name of mixture / product	**FLEXIBLE_RECORD.SDSInfoMixtures.InformationOnMixtures.MixtureProductName** Optional – Text (2,000 char.) This field can be used internally and for reference purposes in order to easily identify the SDS if provided.
Safety data sheets of mixture / product – Start of repeatable block	

Field	Description
Safety data sheet	**FLEXIBLE_RECORD.SDSInfoMixtures.InformationOnMixtures.Tra deNamesAndSafetyDataSheetsOfTheMixture.TradeNamesAndSaf etyDataSheets.Attachment** Optional
Country	**FLEXIBLE_RECORD.SDSInfoMixtures.InformationOnMixtures.Tra deNamesAndSafetyDataSheetsOfTheMixture.TradeNamesAndSaf etyDataSheets.Country** Optional – Picklist (single) – EU-EEA
Language	**FLEXIBLE_RECORD.SDSInfoMixtures.InformationOnMixtures.Tra deNamesAndSafetyDataSheetsOfTheMixture.TradeNamesAndSaf etyDataSheets.Language** Mandatory – Only for MiM, when applicable – PG6-60564
Safety data sheets of mixture / product – End of repeatable block	
Toxicological information (section 11 of SDS)	**FLEXIBLE_RECORD.SDSInfoMixtures.InformationOnMixtures.Tra deNamesAndSafetyDataSheetsOfTheMixture.SDSsection11** Optional – Rich text area This field can contain formatted text with special formatting such as font size, font colour, bold, italic, tables, etc. The content of a Rich text field is expected to be standard HTML. ⓵ When copying text from SDS Section 11 the formatted text keeps its settings from where it is copied. Note: in case of 'copying', pay attention that the text does not cross-references to other SDS sections or documents. The text must be stand alone. *Multilingual information: this information should be provided in all relevant languages.*

8.5 pH

This document records information about the mixture pH.

8.5.1 ENPOINT_SUMMARY.pH

Field	Description
pH is not available	**ENDPOINT_SUMMARY.pH.KeyValueForChemicalSafetyAssessment. pHNotRelevant** Mandatory (except when a pH value is provided) – Check box (True/False) When the pH is not available, the field must be set to *<true>*.
Justification	**ENDPOINT_SUMMARY.pH.KeyValueForChemicalSafetyAssessment. Justification** Mandatory when pH is not available - List (picklist) – PH-1 This field must contain one identifier from a pre-defined list of values indicating the reason why pH is not available.
pH value	**ENDPOINT_SUMMARY.pH.KeyValueForChemicalSafetyAssessment. pH** Mandatory – Numeric range (decimal) The field is mandatory when field pH is not available is set to *<false>*. The pH value can be expressed using an exact value or range numeric values. When encoding the pH value it is also possible to specify the upper and lower limits using the following qualifiers: • ">" or ">=" for the lower numeric value; and • "<" or "<=" for the upper numeric value
Solution concentration (%)	**ENDPOINT_SUMMARY.pH.KeyValueForChemicalSafetyAssessment. SolutionConcentration** Mandatory when pH value is provided Solution concentration to be provided for aqueous solution – Numeric value, percentage

9 Dossier Header (the notification 'cover letter')

A single Dossier header document must be provided in a dossier. The Dossier header contains administrative and technical information that are required in order to process correctly the information received.

⚠️ Once the dossier has been transmitted electronically to the relevant authorities, it cannot be modified and sent again as it is. If changes are required, a new Dossier must be created, assigning a new (snapshot) UUID to the new dossier, re-using the existing documents if needed. However, the correct information should be encoded in the Dossier header document providing the indication in case of updates or corrections.

9.1 DOSSIER.CLP_PCN – Field definition

Field	Description
Dossier name (given by user)	**PlatformMetadata/name** Optional - Text (255 char.) This field is not required by the regulation however it is useful for internal reasons in order to easily identify the submitted dossier. For example internal incremental reference numbers and/or codes can be used in order to keep track and better organize the information submitted.
Dossier submission remark	**DOSSIER.CLP_PCN/remarks** Optional - Text (32,768 char.) This field is not required by the regulation however, it may be useful for internal reasons in order to keep track of additional notes and internal remarks. *Multilingual information: this value should be provided in all relevant languages.*
PCN number	**DOSSIER.CLP_PCN.SpecificSubmissions.PCNNumber** Mandatory – UUID The PCN number identifies a poison centre notification. The same PCN number is used to reference all updates of the same notification. In case of a major update (because of a major change of composition), a new number is generated and the PCN number previously used is moved to the document 'Identifiers' and stored as a 'CLP related PCN number'.

Field	Description
Country (market placement)	**DOSSIER.CLP_PCN.SpecificSubmissions.MarketPlacement** Mandatory - Picklist (multiple) - Indicate the countries in which the product is notified. This should include the full list of countries from all products including both the active and ceased market areas.
Language	**DOSSIER.CLP_PCN.SpecificSubmissions.Language** Mandatory - Picklist (multiple) – Indicate the language(s) for which the notification is provided.
Limited submission (industrial use only)	**DOSSIER.CLP_PCN.SpecificSubmissions.SubmissionType.LimitedSubmission** Check box (True/false) Must be set to <true> in case of limited submissions
Group submission	**DOSSIER.CLP_PCN.SpecificSubmissions.SubmissionType.GroupSubmission** Check box (True/false) Must be set to <true> in case of group submissions
Voluntary submission	**DOSSIER.CLP_PCN.SpecificSubmissions.SubmissionType.VoluntarySubmission** Check box (True/false) Must be set to <true> in case of voluntary submissions for mixtures non hazardous for health and physical hazards or for mixture classified only for the hazards "gases under pressure" and/or "explosives".
Initial notification	**DOSSIER.CLP_PCN.NotificationType.InitialNotif** Check box (True/false) Must be set to <true> in case the notification is an initial notification (i.e. not an update).

Field	Description
New notification after a significant change of composition	**DOSSIER.CLP_PCN.NotificationType.NewNotifChangeCompo** Check box (True/false) Must be set to <true> in case the notification is a new notification following a significant change of composition[13].
The submission is an update	**DOSSIER.CLP_PCN.NotificationType.SubmissionIsAnUpdate** Check box (True/false) Must be set to <true> in case the dossier is an update of an existing notification.

Reason for updating	

Justification - Start of repeatable block

Justification	**DOSSIER.CLP_PCN.NotificationType.ReasonForUpdating.AfterSpontaneousUpdate.Justification** Mandatory in case field <*The submission is an update*> is set to <*true*> Picklist (single) – PG6-60571 The field can contain one single identifier from a list of predefined values: • cease product from market • change in mixture composition without requiring a new UFI • change in the mixture classification • change in the product identifier • correction of error • correction/deletion of trade name • expansion of market area • new toxicological information available • re-place product on market

---

[13] Note that this refers to an update of an existing submission following changes in the compositon specified in Part B.4.1, 4th indent, of Annex VIII.

Field	Description
	DOSSIER.CLP_PCN.NotificationType.ReasonForUpdating.AfterSpontaneousUpdate.Remarks Optional - Text (255 char.) The field may be used to provide additional information on the selected justification (see previous field) *Multilingual information: this information should be provided in all relevant languages*
Justification - End of repeatable block	
Other update reason	**DOSSIER.CLP_PCN.NotificationType.ReasonForUpdating.OtherUpdateReason** Mandatory in case field <*The submission is an update*> is set to <*true*> and the Justification's predefined values do not reflect the reason for update. Text (32,768 char.) *Multilingual information: this information should be provided in all relevant languages*