



DOSSIER.CLP_PCN

- Dossier name <Text>
- Limited submission <Check-box>
- Group submission <Check-box>
- Voluntary submission <Check-box>
- The submission is an update <Check-box>
- Last submission number <Text>
- Reason for updating <Block>
 - Further to a request/decision <Check-box>
 - Number <Rep-block>
 - Spontaneous update <Check-box>
 - Justification <Rep-block>

Dossier header

LEGAL_ENTITY

- Legal entity name <Text>
- Legal entity type <List>
- Address 1 <Text>
- Address 2 <Text>
- Postal code <Text>
- Town <Text>
- Country <List>
- Phone <Text>
- E-mail <Text>

Legal submitter

CONTACT

- Contact type <List>
- Organisation <Text>
- Phone <Text>
- Email <Text>
- Country

Emergency contact
Only for limited submission

Core Mixture document
Legal entity owner is the "Legal Submitter"

MIXTURE

- Mixture/Product name <Text>
- Legal entity owner <Ref LEGAL_ENTITY>
- Contact persons <Rep-block>
 - Person <Ref CONTACT>

FLEXIBLE_RECORD.Ghs

- Not classified <Check-box>
- Classification <Block>
 - ... (see field definition)
- Labelling <Block>
 - ... (see field definition)

Some statements have parameter placeholders. 'Additional text' to be used to convey such parameters.

Link to different C&L documents in case of group submission

ENDPOINT_SUMMARY.pH

- pH is not relevant <Check-box>
- pH value <Range>

ENDPOINT_SUMMARY.ProductComposition

- Product family or group name <Text>
- Composition <Rep-block>
 - Function <List>
 - Concentration range <Range>
 - Name <Ref SUBSTANCE or MIXTURE(MIM)>

Needed only to describe the common mixture composition for the group submission

FLEXIBLE_RECORD.Identifiers

- Regulatory programme ids <Rep-block>
 - Regulatory programme <List>
 - ID <Text>

Mixture UFIs

ENDPOINT_SUMMARY.GeneralInformation

- Physical state at 20 C and 1013 hPa <List>
- Form <List>
- Colour <Multi-list>
- Colour intensity <List>

FLEXIBLE_RECORD.SDSInfoMixture

- Name or trade name of mixture / product <Text>
- Safety data sheets of mixture / product <Rep-block>
 - Safety data sheet <Attachment>
 - Country <List>
 - Language <List>
- Toxicological information (section 11 of SDS) <Text>

FLEXIBLE_RECORD.Packaging

- Type of packaging <List>
- Size of packaging <Range>

FLEXIBLE_RECORD.MixtureComposition

- Mixture/Product name <Text>
- Components <Rep-block>
 - Name <Ref SUBSTANCE or MIXTURE(MIM)>
 - Function <List>
 - Concentration range <Range>

SUBSTANCE

- Substance name <Text>
- Other substance identifiers <Rep-block>
 - Identifier <List>
 - Identity <Text>
- Legal entity <Ref LEGAL_ENTITY>
- Reference substance <Ref REFERENCE_SUBSTANCE>

Core document of substance dataset representing a substance composition element

FLEXIBLE_RECORD.Ghs

- Not classified <Check box>
- Classification <Block>
 - ... (see field definition)

REFERENCE_SUBSTANCE

- Reference substance name <Text>
- Inventory number <Ref InventoryEntry>
- IUPAC name <Text>
- Synonyms <Rep-block>
 - Identifier <List>
 - Identity <Text>
- CAS number <Text>
- CAS name <Text>

Predefined EC Inventory entry

InventoryEntry

- EC Number
- CAS Number

FLEXIBLE_RECORD.ProductInfo

- Group submission – relevant mixture <Multi-ref MixtureComposition>
- Trade name <Rep-block>
- Other name <Rep-block>
- Unique Formula Identifier (UFI) <Multi-ref Identifiers>
- Country <Multi-list>
- Safety data sheet (SDS) <Multi-ref SDSInfoMixture>
- Colour and physical state <Multi-ref GeneralInformation>
- Packaging <Multi-ref Packaging>
- Use type <Multi-list>
- Main intended use <List>
- Secondary uses <Multi-list>

Product of a mixture

MIXTURE

- Mixture/Product name <Text>

Core document of mixture dataset representing a mixture in mixture composition element (MIM only)

FLEXIBLE_RECORD.Identifiers

- Regulatory programme ids <Rep-block>
 - Regulatory programme <List>
 - ID <Text>

Mixture in mixture UFIs

FLEXIBLE_RECORD.SDSInfoMixture

- Name or trade name of mixture / product <Text>
- Safety data sheets of mixture / product <Rep-block>
 - Safety data sheet <Attachment>
 - Country <List>
 - Language <List>
- Toxicological information (section 11 of SDS) <Text>

FLEXIBLE_RECORD.Ghs

- Not classified <Check box>
- Classification <Block>
 - ... (see field definition)
- Labelling <Block>
 - ... (see field definition)

Mixture in mixture classification

Mixture in mixture supplier

FLEXIBLE_RECORD.Suppliers

- Name <Ref LEGAL_ENTITY>

LEGAL_ENTITY

- Legal entity name <Text>
- Legal entity type <List>
- Address 1 <Text>
- Address 2 <Text>
- Postal code <Text>
- Town <Text>
- Country <List>
- Phone <Text>
- E-mail <Text>

FLEXIBLE_RECORD.MixtureComposition

- Mixture/Product name <Text>
- Components <Rep-block>
 - Name <Ref SUBSTANCE or MIXTURE(MIM)>
 - Function <List>
 - Concentration range <Range>

MIM composition provided if mixture in mixture ingredients are known to the Legal submitter

SUBSTANCE

- Substance name <Text>
- Other substance identifiers <Rep-block>
 - Identifier <List>
 - Identity <Text>
- Legal entity <Ref LEGAL_ENTITY>
- Reference substance <Ref REFERENCE_SUBSTANCE>

FLEXIBLE_RECORD.Ghs

- Not classified <Check-box>
- Classification <Block>
 - ... (see field definition)

REFERENCE_SUBSTANCE

- Reference substance name <Text>
- Inventory number <Ref InventoryEntry>
- IUPAC name <Text>
- Synonyms <Rep-block>
 - Identifier <List>
 - Identity <Text>
- CAS number <Text>
- CAS name <Text>

Predefined EC Inventory entry

InventoryEntry

- EC Number
- CAS Number