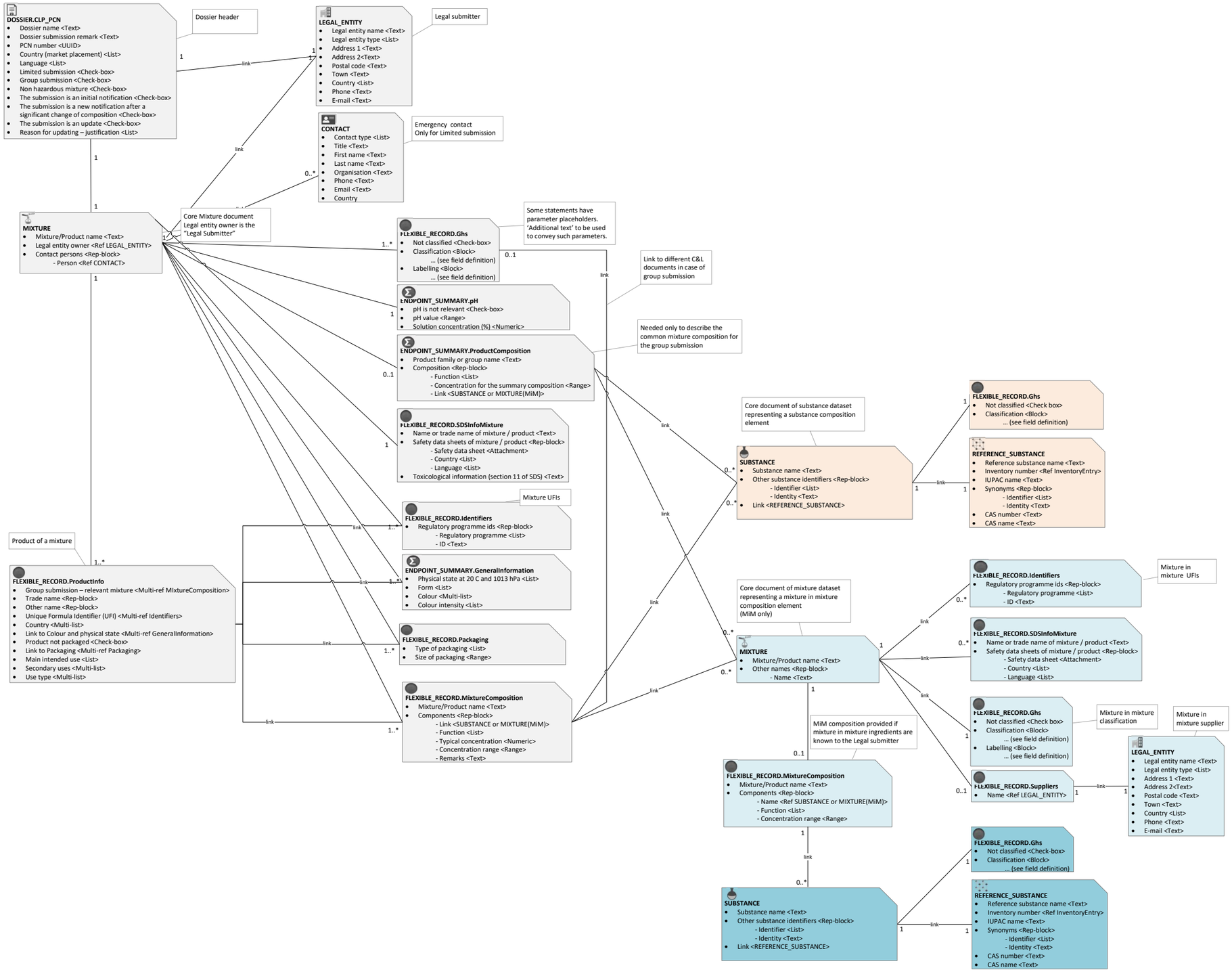
DOSSIER.CLP_PCN
Dossier name <Text>
Dossier submission remark <Text>
PCN number <UUID>
Country (market placement) <List>
Language <List>
Limited submission <Check-box>
Group submission <Check-box>
Non hazardous mixture <Check-box>
The submission is an initial notification <Check-box>
The submission is a new notification after a significant change of composition <Check-box>
The submission is an update <Check-box>
Reason for updating – justification <List>
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>
Title <Text>
First name <Text>
Last name <Text>
Organisation <Text>
Phone <Text>
Email <Text>
Country
Emergency contact
Only for Limited submission
MIXTURE
Mixture/Product name <Text>
Legal entity owner <Ref LEGAL_ENTITY>
Contact persons <Rep-block>
- Person <Ref CONTACT>
Core Mixture document
Legal entity owner is the "Legal Submitter"
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>
Solution concentration (%) <Numeric>
ENDPOINT_SUMMARY.ProductComposition
Product family or group name <Text>
Composition <Rep-block>
- Function <List>
- Concentration for the summary composition <Range>
- Link <SUBSTANCE or MIXTURE(MiM)>
Needed only to describe the common mixture composition for the group submission
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.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.Packaging
Type of packaging <List>
Size of packaging <Range>
FLEXIBLE_RECORD.MixtureComposition
Mixture/Product name <Text>
Components <Rep-block>
- Link <SUBSTANCE or MIXTURE(MiM)>
- Function <List>
- Typical concentration <Numeric>
- Concentration range <Range>
- Remarks <Text>
Product of a mixture
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>
Link to Colour and physical state <Multi-ref GeneralInformation>
Product not packaged <Check-box>
Link to Packaging <Multi-ref Packaging>
Main intended use <List>
Secondary uses <Multi-list>
Use type <Multi-list>
Core document of substance dataset representing a substance composition element
SUBSTANCE
Substance name <Text>
Other substance identifiers <Rep-block>
- Identifier <List>
- Identity <Text>
Link <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>
Core document of mixture dataset representing a mixture in mixture composition element (MiM only)
MIXTURE
Mixture/Product name <Text>
Other names <Rep-block>
- Name <Text>
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>
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>
MiM composition provided if mixture in mixture ingredients are known to the Legal submitter
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>
Link <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>
link
1
0..*
1..*
0..1