

Substance identity - screening of the registration dossiers

Missing and unclear information

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Substance identity IT screening campaign

Scope defined by 10 Issue types:

1. Missing concentration ranges
2. Typical concentration outside of concentration range
3. Composition reported with no constituents
4. Low or ambiguous degree of purity for well-defined substances
5. Unidentified constituent or impurity present at significant concentration
6. Well-defined substance with inconsistency between degree of purity and constituent concentrations
7. Well-defined substance with inconsistency between degree of purity and impurity concentrations
8. No spectral and analytical information provided
9. Additives without stabilising function
10. Inconsistent identifiers of constituents, impurities and additives

Issue types observed during the IT screening

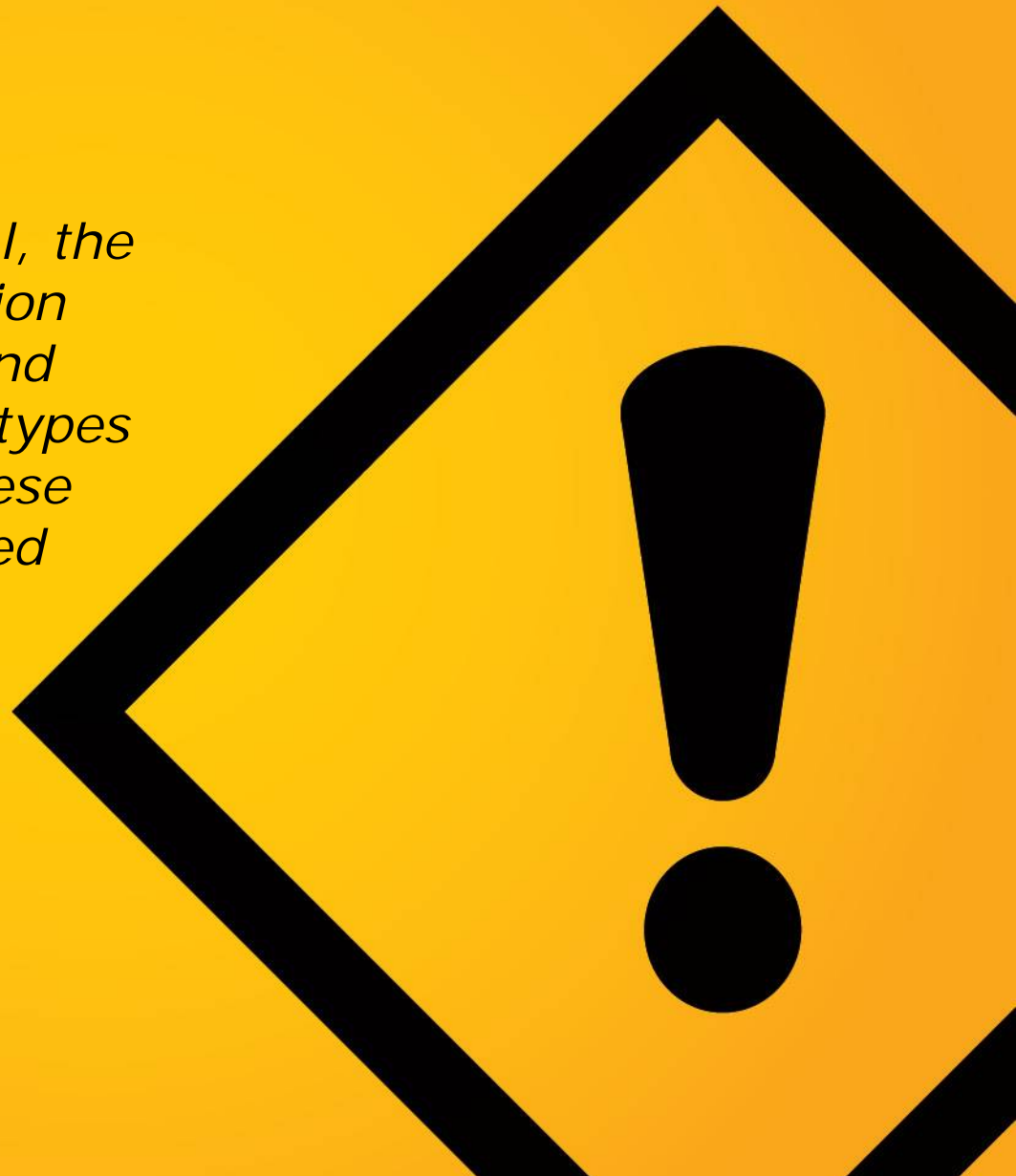
Missing information

- Issue type 1: Missing concentration ranges
- Issue type 3: Composition reported with no constituents
- Issue type 8: No spectral and analytical information provided

Unclear information

- Issue type 4: Low or ambiguous degree of purity for well-defined substances
- Issue type 5: Unidentified constituent or impurity present at significant concentration
- Issue type 9: Additives without stabilising function

Please note that, in general, the examples in this presentation are invented to illustrate and explain the different issue types better. Please note that these examples have been created without any practical or scientific considerations.



Issue type 1: Missing concentration ranges



Issue type 1: Missing concentration ranges

Excerpt from the information letter:

“Missing concentration ranges

The composition with name “xxxxxx” and local UUID

“xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx” contains the constituent with reference substance name “xxxxxx” and IUPAC name “xxxxxx” for which the concentration range has not been provided.”

Section 1.2 Composition

Substance composition

test

Name: test

Brief description:

Composition ID: L-eed82217-995a-4073-8518-031d300dd2df

Degree of purity

85 100 % (w/w)

Constituents

90 % (w/w) ethanol / ethanol / ethanol / 64-17-5


Reference substance: ethanol / ethanol / ethanol / 64-17-5

EC number	EC name
200-578-6	ethanol
CAS number	CAS name
64-17-5	ethanol
IUPAC name	
ethanol	

Typical concentration: 90 % (w/w)

Concentration range:

Remarks:



Section 1.2 Composition

Substance composition

test

Name: test

Brief description:

Composition ID: L-eed82217-995a-4073-8518-031d300dd2df

Degree of purity

85 100 % (w/w)

Constituents

90 % (w/w) ethanol / ethanol / ethanol / 64-17-5


Reference substance: ethanol / ethanol / ethanol / 64-17-5

EC number	EC name
200-578-6	ethanol
CAS number	CAS name
64-17-5	ethanol
IUPAC name	
ethanol	

Typical concentration: 90 % (w/w)

Concentration range: 85 95

Remarks:



Section 1.2 Composition

Impurities

2.5 % (w/w) impurity 1

Typical concentration % (w/w)

Concentration range % (w/w)

Remarks

this impurity is considered relevant for the classification and labelling of the substance

Additives

1.5 % (w/w) additive 1

Typical concentration % (w/w)

Concentration range % (w/w)

Remarks

this additive is considered relevant for the classification and labelling of the substance



Issue type 3:

**Composition reported with no
constituents**



Issue type 3: Composition reported with no constituents

Excerpt from the information letter:

“Composition reported with no constituents

IUCLID section 1.2 does not contain any constituents identified by reference substances.”

Section 1.2 Composition

Substance composition

test

Name test

Brief description

Composition ID L-eed82217-995a-4073-8518-031d300dd2df

Degree of purity

85 100 % (w/w)

Constituents

Impurities

2.5 % (w/w) impurity 1

Additives

1.5 % (w/w) additive 1



Section 1.2 Composition

Substance composition


test

Name test

Brief description

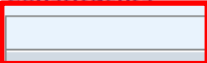
Composition ID L-eed82217-995a-4073-8518-031d300dd2df

Degree of purity



85 100 % (w/w)

Constituents



90 % (w/w) ethanol / ethanol / ethanol / 64-17-5

Impurities

2.5 % (w/w) impurity 1

Additives

1.5 % (w/w) additive 1



**Issue type 8:
No spectral and analytical
information provided**



Issue type 8: No spectral and analytical information provided


Excerpt from the information letter:

“No spectral and analytical information provided

Section 1.4 in your technical dossier does not seem to contain an attachment in a paperclip, which suggests that your registration may not include all the required spectral and analytical information.”

Section 1.4 Analytical information

Analytical information



Analytical methods and spectral data

FT-IR
NMR
UV-VIS
GC-MS

Optical activity

not applicable

Results of analysis

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Section 1.4 Analytical information

Analytical information

Analytical methods and spectral data
UV-VIS
NMR
GC-MS
IR

Optical activity

Analytical method description.doc / 21.5 KB

Results of analysis

UV-VIS

Analysis type: UV-VIS

Tested substance: sample 123

Method used

UV-VIS.doc / 21.5 KB


Remarks

NMR

GC-MS

FT-IR

You are expected to attach the document by clicking the paperclip buttons shown here.



Issue type 4:

**Low or ambiguous degree of
purity for well-defined
substances**



Issue type 4: Low or ambiguous degree of purity for well-defined substances

Excerpt from the information letter:

“Low or ambiguous degree of purity provided for well-defined substances

An unexpectedly low or wide degree of purity has been provided for the composition with name “xxxxxx” and local UUID “xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx”.

Section 1.2 Composition

Substance composition

test

Name test

Brief description

Composition ID L-eed82217-995a-4073-8518-031d300dd2df

Degree of purity

15 25 % (w/w)

Constituents

20 % (w/w) ethanol / ethanol / ethanol / 64-17-5

Impurities

Additives



**Issue type 5:
Unidentified constituent or
impurity present at
significant
concentration**



Issue type 5: Unidentified constituent or impurity present at significant concentration

Excerpt from the information letter:

“Unidentified constituent or impurity present at significant concentration

The composition with name “xxxxxx” and local UUID “xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx” contains the constituent with reference substance name “xxxxxxxxxxxxxxxxxxxx” and IUPAC name “xxxxxxxxxxxxxxxxxxxx” which is present at a significant concentration, but for which no numerical substance identifiers (EC or CAS number) have been provided and for which the chemical name allows no conclusion to be drawn on its identity.”

Issue type 5: Unidentified constituent or impurity present at significant concentration

Example 1, Well-defined substances

Section 1.2 Composition

Substance composition


test

Name test

Brief description



Composition ID L-eed82217-995a-4073-8518-031d300dd2df

Degree of purity



90 100 % (w/w)

Constituents

70 % (w/w) ethanol / ethanol / ethanol / 64-17-5	
30 % (w/w) unidentified constituent	



Issue type 5: Unidentified constituent or impurity present at significant concentration

Example 2, UVCB substances

Section 1.2 Composition

Substance composition

Name: [REDACTED]

Brief description: [REDACTED]

Composition ID: [REDACTED]

Degree of purity

EU: REACH

100 % (w/w)

Constituents

ca. 24.1 % (w/w)	[REDACTED]
ca. 18.7 % (w/w)	[REDACTED]
ca. 6.1 % (w/w)	[REDACTED]
ca. 51.1 % (w/w)	Unknown constituents / Unknown constituents

See further information in chapter 2.1, figure 5 of the Data Submission Manual Part 18 – How to report the substance identity in IUCLID 5 for registration under REACH.



**Issue type 9:
Additives without stabilising
function**



Issue type 9: Additives without stabilising function

Excerpt from the information letter:


“Additives without stabilising function

The composition with name “xxxxxx” and local UUID “xxxxxxxxxxxxxxxxxxxxxxxxxxxx” contains the additive with reference substance name “xxxxxx” and IUPAC name “xxxxxx” that has a technical function that does not appear to be compatible with stabiliser.”

Section 1.2 Composition

Additives

additive 1 / additive 1 / additive 1 / 1111-11-1

Reference substance  additive 1 / additive 1 / additive 1 / 1111-11-1

EC number	EC name
<input type="text"/>	<input type="text"/>
CAS number	CAS name
1111-11-1	additive 1
IUPAC name	
additive 1	

Function

Typical concentration

Concentration range

Remarks

this additive is considered relevant for the classification and labelling

Pick list

Select the function

- absorbent
- adsorbent
- anticaking agent
- anticoagulant
- booster
- buffer
- coagulant

OK Cancel

Section 1.2 Composition

Additives

1% (w/w) additive 1 / additive 1 / additive 1 / 1111-11-1

Reference substance

EC number	EC name
<input type="text"/>	<input type="text"/>
CAS number	CAS name
<input type="text" value="1111-11-1"/>	<input type="text" value="additive 1"/>
IUPAC name	
<input type="text" value="additive 1"/>	

Function

Typical concentration % (w/w)

Concentration range % (w/w)

Remarks


this additive is considered relevant for the classification and labelling of the substance



Example of incorrectly reported solvent

Additives

8 % (w/w) water / water / 7732-18-5

Reference substance  water / water / 7732-18-5

EC number	EC name
231-791-2	water
CAS number	CAS name
7732-18-5	
IUPAC name	
water	

Function solvent

Typical concentration 8 % (w/w)

Concentration range 7 9 % (w/w)

Remarks


this additive is considered relevant for the classification and labelling of the substance



Example of correctly reported solvent

Impurities

8 % (w/w) water / water / 7732-18-5

Reference substance  water / water / 7732-18-5

EC number	EC name
231-791-2	water
CAS number	CAS name
7732-18-5	
IUPAC name	
water	

Typical concentration % (w/w)

Concentration range % (w/w)

Remarks **The solvent cannot be further removed without affecting the stability of the substance.**

this impurity is considered relevant for the classification and labelling of the substance



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