

Welcome

Webinar: Completeness checks of chemical safety reports: practical advice

16 November 2021

Alicia LOPEZ TARRAGA
European Chemicals Agency



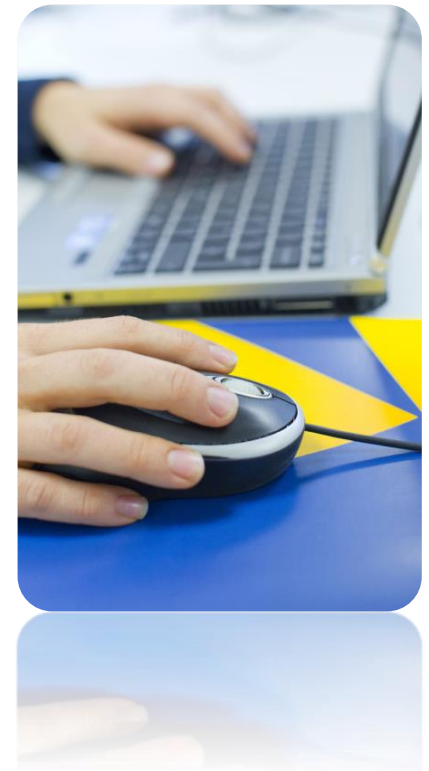
What you can expect from today

- Learn about the completeness check of chemical safety reports
- Learn how to avoid common reasons for incompleteness
- Get practical advice from experience gained so far
- Get answers to your questions



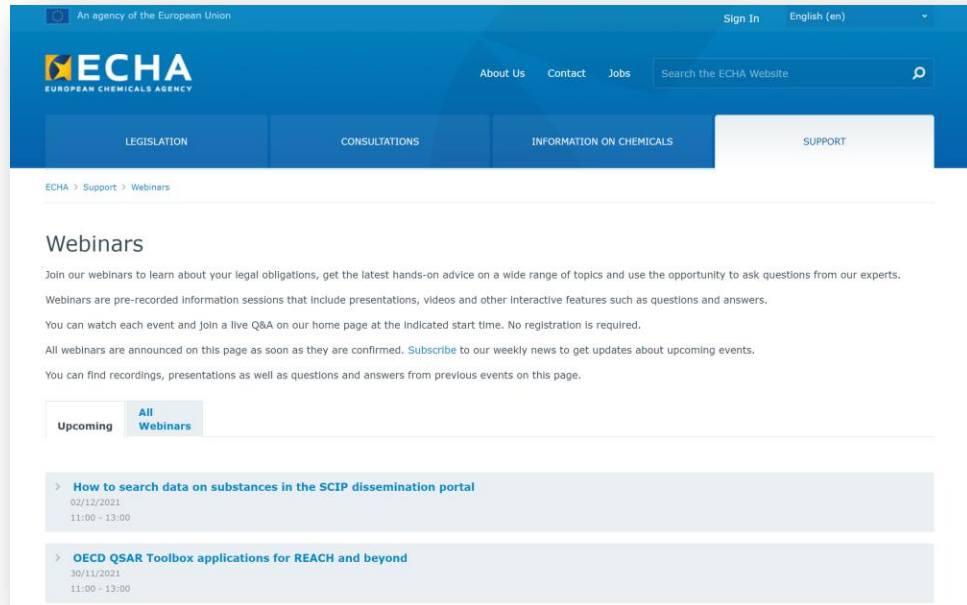
Questions

- Join Q&A at: [slido.com](https://www.slido.com)
Event code:
- Send questions from
11:00 to 13:00 (EET, GMT +2)
- Only questions within scope
- Question not answered?
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Material available

- Video recording, presentations and Q&A: echa.europa.eu/webinars
- Watch our previous webinar on completeness check: echa.europa.eu/-/revised-completeness-check-what-changes-and-how-you-can-prepare



The screenshot shows the ECHA website's 'Webinars' page. The header includes the ECHA logo, navigation links for 'About Us', 'Contact', and 'Jobs', and a search bar. The main navigation menu has categories: 'LEGISLATION', 'CONSULTATIONS', 'INFORMATION ON CHEMICALS', and 'SUPPORT'. The page content includes a breadcrumb trail 'ECHA > Support > Webinars', a title 'Webinars', and introductory text explaining that webinars are pre-recorded information sessions. Below this, there are two tabs: 'Upcoming' and 'All Webinars'. Two webinar events are listed:

Webinar Title	Date	Time
> How to search data on substances in the SCIP dissemination portal	02/12/2021	11:00 - 13:00
> OECD QSAR Toolbox applications for REACH and beyond	30/11/2021	11:00 - 13:00



Agenda

- 11:00 **Introduction**
Alicia Lopez Tarraga, ECHA
- 11:05 **Completeness check of chemical safety reports**
Valerio Ceccolini, ECHA
- 11:15 **Most common issues related to reporting of hazards and uses**
Soile Niemi, ECHA
- 11:30 **Most common issues related to the chemical safety report file**
Mila Marinovic, ECHA
- 11:45 **Most common issues related to reporting and assessing article service life**
Eleni Tsitsiou, ECHA
- 11:55 **Concluding remarks**
Alicia Lopez Tarraga, ECHA
- 11:00 – 13:00 **Webinar open for questions**

Completeness check of chemical safety reports

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advice

16 November 2021

Valerio CECCOLINI
European Chemicals Agency





Background

- Chemical safety report needed when registering a hazardous substance
 - Basis for informing customers about hazards and required risk management
 - Used by authorities to source information about uses and their exposure potential to determine need for regulatory action
- As of 1 March 2021, manual completeness check also covers chemical safety report
- Completeness check:
 - Ensures registration dossier has all required elements
 - Applies to all dossiers



Chemical safety report

When is it checked?

- Substances subject to registration under the REACH Regulation (Article 10) **manufactured or imported > 10 tonnes/year**

AND

- (Self)classified as hazardous or reported as fulfilling PBT/vPvB criteria (REACH Article 14(4))



Chemical safety report

What should it contain?

- Each use reported in IUCLID section 3.5 must be addressed in a corresponding exposure scenario in the chemical safety report
- Each contributing activity reported within a use must have a corresponding contributing scenario in the related exposure scenario

If the above elements are not present, a relevant justification must be given in the relevant section of the chemical safety report file.



Chemical safety report

What should it contain?

Required elements for environmental contributing scenarios

- Conditions of use
(operational conditions and risk management)
- Local release factors for water, air and soil
- Exposure estimates and risk characterisation ratios
 - For all environmental compartments for which a PNEC has been derived
 - For indirect exposure of general population via inhalation of ambient air and via oral route (food, drinking water)
 - Combined risk via oral and inhalation route



Chemical safety report

What should it contain?

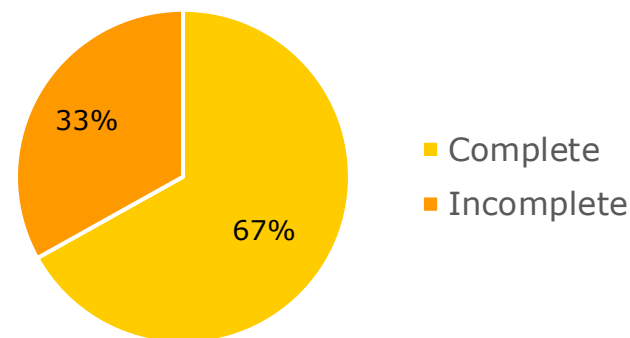
Required elements for worker/consumer contributing scenarios

- Conditions of use
(operational conditions and risk management)
- Exposure estimates and risk characterisation ratios
 - For each route of exposure where a DNEL, DMEL or other toxicological threshold reported
 - Combined risk via oral, dermal and inhalation route

Chemical safety report checks

First six months of operation

- **1 160** checked
 - 776 found complete (67%)
 - 384 found incomplete (33%)
- **47** rejected after failing second technical completeness check





Chemical safety report checks

Most common issues

- Missing contributing scenarios without a justification (most often contributing activities in section 3.5.3)
- Missing exposure scenarios without a justification (most often uses in section 3.5.6)
- No section 9 (no exposure scenarios at all) with and without a justification
- Several uses from different life cycle stages (different 3.5.x sections) covered by one exposure scenario
- Incorrect/unclear chemical safety report structure

Coming up

- Most common issues when reporting hazards and uses in IUCLID
- How to improve use descriptions
- How to include a chemical safety report file in the dossier
- How to justify absence of a chemical safety report
- How to structure a chemical safety report
- How to report and assess article service life



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Most common issues related to reporting of hazards and uses

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Soile NIEMI
European Chemicals Agency



Hazard information





Hazard information drives the need and scope of exposure assessment

- Chemical safety report must contain exposure assessment and risk characterisation if the substance is classified as hazardous or assessed to be a PBT or vPvB, in accordance with REACH Article 14(4)
- Scope of assessment defined by toxicological and ecotoxicological hazard assessment conclusions
- Release / exposure estimates need to be provided if PNECs or DNELs/DMELs derived for the substance

PNECs and environmental assessment

- If PNEC is derived for a given protection target, exposure estimation and risk characterisation must be provided for the related compartment
- Justifications referring to “no environmental hazard” or “no environmental classification” are not valid if PNECs are reported for the substance
- If no effect has been observed at limit dose, you may conclude that no hazard has been identified and not report a PNEC



DNELs and human health assessment

- If DNEL/DMEL is derived for a given exposure route, exposure estimation and risk characterisation must be provided for the related route
- Justifications referring to “no human health hazard” or “no human health classification” are **not valid** if DNEL/DMELs are reported for the substance
- If no effect has been observed at limit dose, you may conclude that no hazard has been identified and not report a DNEL/DMEL
- DNEL/DMELs for workers and general population should be consistent with each other



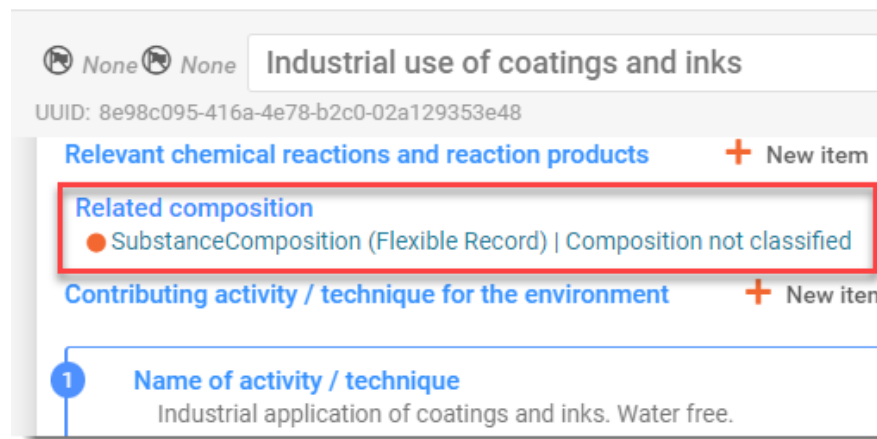
Humans via environment assessment

- Humans exposed via environment must be assessed when **general population DNELs** for long-term exposure via inhalation or oral intake have been determined and:
 - Tonnage is above 1000 tpa or,
 - Tonnage is above 100 tpa and substance classified as STOT RE 1, carcinogen, mutagen (any category), or toxic to reproduction (categories 1A or 1B)
- Assessment is provided in contributing scenarios for the environment
- Justifications referring to “no hazard” or “no classification” are **not valid** if the above-mentioned conditions are met



Substances with several hazard profiles

- If your registration covers different compositions with different hazard profiles, link them with the relevant classification and use records
- If no indication of links between compositions, classifications and uses, we assume composition with highest hazard applied in all uses



None None Industrial use of coatings and inks
UUID: 8e98c095-416a-4e78-b2c0-02a129353e48

Relevant chemical reactions and reaction products + New item

Related composition

- SubstanceComposition (Flexible Record) | Composition not classified

Contributing activity / technique for the environment + New item

1 Name of activity / technique
Industrial application of coatings and inks. Water free.



Changes in classification and labelling and hazard information

- If new hazard information becomes available and changes classification and/or PNECs and DNEs, you must update your exposure assessment accordingly
- Members who provide their own chemical safety report must also be aware of the hazard changes impacting their report

How to improve use description





Purpose of use information

- Pre-requisite for chemical safety assessment and subsequent communication on the conditions of safe use down the supply chain
- Enables authorities to understand the use pattern and exposure potential of the substance
 - Influences high/low priority for regulatory action
- Enables the public to have indications on products or articles where substance can be present



All identified uses must be reported

- Registrants must provide a brief description of their own uses and of the uses in their supply chain in the EU that they are aware of
 - Explore market knowledge existing in your company
- Once identified, use maps developed under CSR/ES roadmap can be helpful
echa.europa.eu/csr-es-roadmap/use-maps



Common misunderstandings

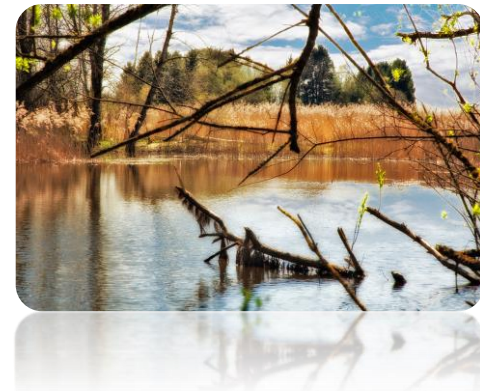
- Products in widespread professional use may be used for similar purpose at industrial sites:
 - May not be necessary to report and additionally assess as use at industrial sites – Reporting in section 3.5.4/3.5.5 would be adequate
 - Examples: General purpose room and equipment cleaners
- Transfer activities, i.e., loading-unloading; charging-discharging (“distribution”):
 - Such activities are part of many uses and may therefore take place at different lifecycle stages under variable conditions
 - Should be integrated into the various uses rather than defining a stand-alone use (“Distribution”) for them



Naming of uses and contributing activities

- Clear, concise and unique names for uses and contributing activities that enable quick identification
- Give a name for each of contributing activity
- Avoid copying descriptor definition as the name of the contributing activity
- Unclear naming may lead to a completeness check failure if link between each use/contributing activity and the corresponding exposure/contributing scenario is not clear

Environmental release categories (ERCs)



- Select environmental release categories (ERCs) that are relevant for the use
- Using an irrelevant category leads to an automated completeness check failure as of 1 November 2021 (visible in the validation assistant of IUCLID 6.6)
- Only ERCs relevant for a given life cycle stage are available for selection in IUCLID section 3.5 since 2016
- Example: Only ERC 1 is relevant for manufacturing



Contributing activities with multiple use descriptors

- In some cases you may want to link several use descriptors to a single contributing activity, for example, when:
 - Measured exposure dataset covers various contributing activities for workers, or
 - Release factor of one ERC may cover release factors of another ERC (e.g. indoor – outdoor)
- Use descriptors per activity must be compatible with each other
- Validation assistant in IUCLID 6.6 will trigger a quality warning if incompatible ERCs are reported within the same contributing activity/use

Uses exempted from exposure assessment

Intermediate uses under strictly controlled conditions

- Art 17/18 uses must be indicated in the 'Registration/Notification status for the use' field in the use record in IUCLID

UUID: 14fa0d2c-b998-468e-ae7b-c6541289e29b

Uses at industrial sites None None

Registration/ Notification status for the use
use registered according to REACH Article 17/18

Use number
None

Use name
Intermediate use under strictly controlled conditions

Other (partially) exempted uses

- If you report (partially) exempted uses from the exposure assessment, justify the absence of the assessment **in the chemical safety report** at the place where the exposure scenario would have been expected

Lead dossiers with own and joint uses

- If a lead registrant provides a joint chemical safety report, they must report the uses covered by the report in the IUCLID dossier and, if applicable, additional own uses (onsite or downstream)
- Use 'Related assessment' field in each use record to indicate if use is:
 - Assessed in its own chemical safety report
 - Assessed in a joint chemical safety report
 - Assessed in a joint chemical safety report but not lead's own use



None None Industrial use of coatings and inks
UUID: 8e98c095-416a-4e78-b2c0-02a129353e48

Number of staff using the substance
None

Related assessment
use assessed in a joint CSR

Insignificant exposure via the following route



Changes in use description

- When you change the use description, also update the chemical safety report
- And visa versa: When updating your chemical safety report, ensure use description in IUCLID stays aligned
- Using a tool such as Chesar, helps consistency between uses in IUCLID and the assessment in the chemical safety report
- Clear use description is a pre-requisite for passing completeness check



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Most common issues related to the chemical safety report file

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16 November 2021

Mila MARINOVIC
European Chemicals Agency



**How to provide a chemical safety
report file in the dossier?**



Chemical safety report must be provided in Section 13.1

- Field: *"Chemical safety report"*
- Other important fields:
 - *"Type of CSR"*
 - *"CSR contains"*
 - *"Chemical safety assessment/report tool used"*
 - *"Further information on the CSR attached / remarks"*

3	Manufacture, use and exposure	15
4	Physical and chemical properties	18 +
5	Environmental fate and pathways	20 +
6	Ecotoxicological information	17 +
7	Toxicological information	24 +
8	Analytical methods	+ ...
11	Guidance on safe use	+ ...
12	Literature search	+ ...
13	Assessment reports	1
13.1	Chemical Safety Report (CSR)	1 +
	CSR_report_full_20211027_161525.pdf	

Chemical Safety Report (CSR)

Type of CSR

Own CSR (own uses)

CSR contains

- ✓ Part A
- ✓ Part B section 1 to 8
- ✓ Part B section 9 and 10

Chemical safety assessment/report tool used

Chesar

Chemical safety report (CSR)

CSR_report_full_20211027_161525.pdf

Further information on the CSR attached / remarks

The latest version of CSR dated October 2021

Export file (safety assessment / exposure estimation tool)

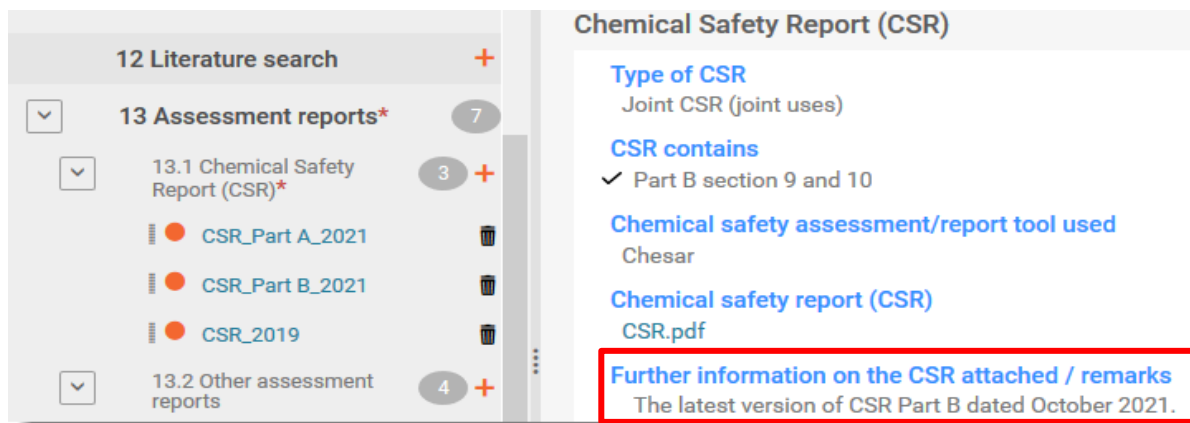
Substance_20211027_161527.chr3

Further information on the attached export file / remarks

None

Several chemical safety report files in Section 13.1

- Each chemical safety report requires a separate record under Section 13.1
- “*Further information on the CSR attached / remarks*” to indicate which file covers what



The screenshot displays the ECHA database interface. On the left, a sidebar shows a hierarchical list of assessment reports under '13 Assessment reports*'. Under '13.1 Chemical Safety Report (CSR)*', three files are listed: 'CSR_Part A_2021', 'CSR_Part B_2021', and 'CSR_2019'. On the right, a detailed view of a 'Chemical Safety Report (CSR)' is shown. The 'Further information on the CSR attached / remarks' field is highlighted with a red box and contains the text: 'The latest version of CSR Part B dated October 2021.'

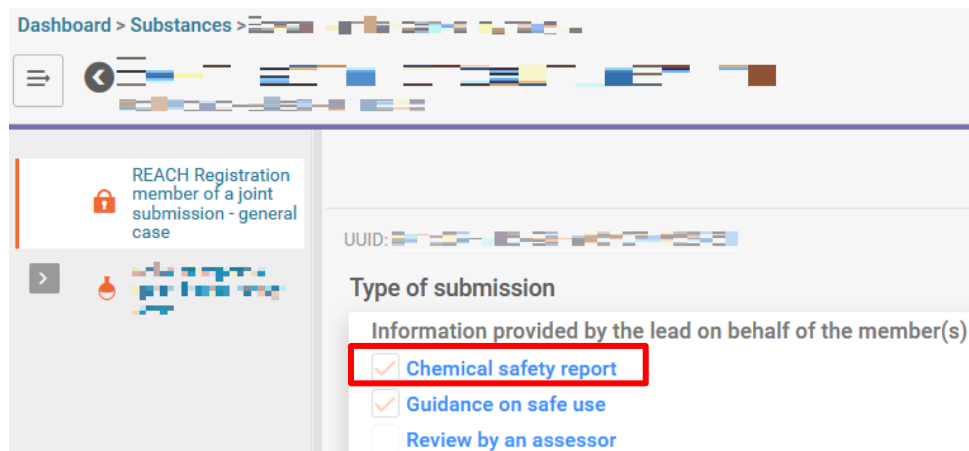
- Only the latest version will be checked unless a clear reference to other files is made
- **Advice:** delete obsolete versions

**How to justify the absence of a
chemical safety report?**



Who provides a chemical safety report in a joint submission?

- Always needed if registration tonnage band is above **10** tonnes per year
- If lead registrant provides on behalf of members, members need to select the relevant checkbox in dossier header
- If lead does **not** provide on behalf of members, every registrant must provide a chemical safety report in their own dossier



Dashboard > Substances > [breadcrumb]

REACH Registration member of a joint submission - general case

UUID: [UUID]

Type of submission

Information provided by the lead on behalf of the member(s)

- Chemical safety report
- Guidance on safe use
- Review by an assessor

No chemical safety report based on Article 14(2)

- **Substance in imported mixture**
 - Statement that the substance is imported in a mixture
 - Concentration of the substance in the mixture
 - Applicable concentration threshold for the substance as indicated in Art 14(2) (depending on hazard profile)
- Justification needs to be provided in the “*Discussion*” field in Section 13.1

Further information on the CSR attached / remarks

None

Export file (safety assessment / exposure estimation tool)

None

Further information on the attached export file / remarks

None

Discussion

CSR is not provided in accordance with Article 14(2) as the substance is imported in

How to structure a chemical safety report?



Chemical safety record structure

- CSR (Sections 9 and 10) must be structured according to exposure scenarios
- Each exposure scenario must contain both, assessment related to the environment and to human health (worker or consumer)
- Exposure scenario titles must be consistent with the use names reported in IUCLID Section 3.5

IUCLID

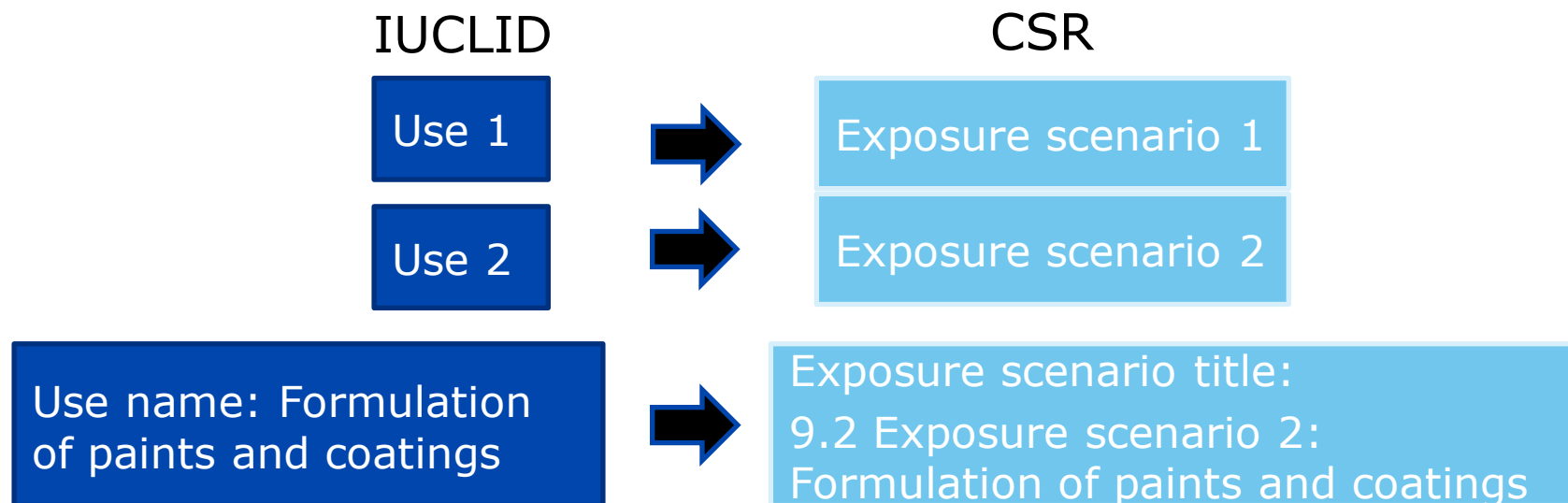


CSR

9.1. Exposure scenario 1: Manufacture - Manufacture of Substance	
Environment contributing scenario(s):	
Manufacture of Substance	ERC 1
Worker contributing scenario(s):	
Use in closed process, no likelihood of exposure	PROC 1
Use in closed, continuous process with occasional controlled exposure	PROC 2

Use – Exposure scenario

- Each use should have its own exposure scenario in the chemical safety report
- Exposure scenario title must clearly correspond to the use name (if ECHA cannot establish the correspondence, chemical safety report fails)



Contributing activity – Contributing scenario

- Each contributing activity reported in IUCLID must have a corresponding contributing scenario in the chemical safety report
 - Environment: Environmental release category (ERC)
 - Workers: Process category (PROC)
 - Consumers: Article category (AC) or Product category (PC)
- Contributing scenario title must clearly refer to the contributing activity (ERC/PROC/AC/PC) reported in IUCLID (if ECHA cannot establish the correspondence, CSR fails)

Chemical safety report structure

IUCLID

Formulation of liquid mixtures
 5.1 Manufacture
 5.2 Formulation or re-packing
 Formulation of liquid mixtures
 5.3 Uses at industrial sites
 5.4 Widespread uses by professional workers
 5.5 Consumer uses
 5.6 Service life

Formulation of liquid mixtures
 UID: f1fa2726-1447-4cb1-aa3b-a5dd7b291642

Contributing activity / technique for the environment

- Name of activity / technique: Formulation of mixture in closed and open systems
- Environmental release category (ERC): ✓ ERC2: Formulation into mixture

Contributing activity / technique for workers

- Name of activity / technique: Receiving and charging of the substance
- Process category (PROC): ✓ PROC 8b: Transfer of substance or mixture (charging and discharging) at dedicated facilities




CSR

9.2. Exposure scenario 2: Formulation or re-packing - Formulation of liquid mixtures

Environment contributing scenario(s):		
CS 1	Formulation of mixture in closed and open systems	ERC 2
Worker contributing scenario(s):		
CS 2	Receiving and charging of the substance	PROC 8b

How to export uses from Chesar

- If you use Chesar, you can synchronise the use descriptions in the chemical safety report (generated by Chesar) and in Section 3.5 of IUCLID with each other
- **Suggested workflow:** describe your uses in Chesar, and once your assessment is finished, export them to IUCLID (select “Remove all existing uses” in Box 4 of Chesar) before generating your CSR
After, if necessary: add uses not to be assessed (e.g. intermediates under strictly control conditions) in IUCLID Section 3.5
- For chemical safety report update: Chesar has different options to support the update of the use descriptions in IUCLID. More information is available in the help-text  embedded in Chesar (Box 4)

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Most common issues related to reporting and assessing article service life

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16 November 2021

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When to report article service life?

- **REACH:** all life-cycle stages of a substance to be addressed in registration dossier incl. stages subsequent to use of the substance as such or in a mixture
- When a substance is expected to be present in articles, one or more **service life** uses are to be created in **IUCLID section 3.5.6**
- Examples:
 - Dyes in textile articles
 - Plasticiser in articles made from soft-plastic material
 - Flame-retardants in plastic articles
 - Pigment in dried coating after application in/on the article



Reporting a service life use

- **Environmental contributing activities (CAs)** should contain Environmental Release Categories (ERCs) leading to a **clear use type definition**
 - Reported use should cover either industrial sites (ERC 12a/b/c) or use of articles by professional workers or consumers (ERC 10a/b, 11a/b)
 - If both use types are to be described, create a use record in IUCLID section 3.5.6 for each use-type
- Inconsistencies trigger quality warnings in IUCLID 6.6 validation assistant



Reporting example

3.5.6 Service life 2 +

Processing of used tyres (industrial site)

None None **Processing of used tyres (industrial site)**

UUID: 61511ac6-f478-4341-a0fc-2f540ca50d84

None

Article used by
✓ workers

Article category (AC)
None

Substance intended to be released from article
None

Contributing activity / technique for the environment + New item

1 **Name of activity / technique**
Low dust processes with no water contact

Environmental release category (ERC)
✓ **ERC12a: Processing of articles at industrial sites with low release**

2 **Name of activity / technique**
Handling with no promotion of releases

Environmental release category (ERC)
✓ **ERC11a: Widespread use of articles with low release (indoor)**

Reporting example



3.5.6 Service life 2 +

- Processing of used tyres (industrial site)
- Handling of tyres and other rubber articles**

Handling of tyres and other rubber articles

None None **Handling of tyres and other rubber articles**

UUID: 5d903672-a169-497c-a91e-8aa389004ef6

Related composition
None

Article used by
✓ workers

Article category (AC)
None

Contributing activity / technique for the environment + New item

1 **Name of activity / technique**
Handling with no promotion of releases

Environmental release category (ERC)
✓ **ERC11a: Widespread use of articles with low release (indoor)**

3.5.6 Service life 2 +

- Processing of used tyres (industrial site)**
- Handling of tyres and other rubber articles

Processing of used tyres (industrial site)

None None **Processing of used tyres (industrial site)**

UUID: 61511ac6-f478-4341-a0fc-2f540ca50d84

Article used by
✓ workers

Article category (AC)
None

Contributing activity / technique for the environment + New item

1 **Name of activity / technique**
Low dust processes with no water contact

Environmental release category (ERC)
✓ **ERC12a: Processing of articles at industrial sites with low release**



Reporting a service life use (2)

- **Human health contributing activities (CAs)** should be consistent with “Article used by” option
 - If article used by workers, only worker CAs can be reported
 - If article used by consumers, only consumer CAs can be reported
- If uses described before 2016, review your CAs and remove any inconsistencies that trigger quality warnings in IUCLID 6.6 validation assistant

Article used by
 workers

Article category (AC)
 AC 7: Metal articles

Substance intended to be released from article
yes



Reporting example

3.5.6 Service life 1 +

● Handling of tyres and other rubber articles 🗑️

🔇 None 🔇 None **Handling of tyres and other rubber articles**


UUID: e928a57b-e795-40e2-88b1-482902cd3596

Article used by
 workers

Article category (AC)
None

Substance intended to be released from article
None

Contributing activity / technique for consumers + New item 📄 Import file ▾

1 Name of activity / technique
Handling tyres 

Article category
 AC10g: Other rubber articles

Percentage (w/w) of substance in mixture /article (%)
None

Details on the percentage of substance in mixture/article
None

Contributing activity / technique for workers + New item 📄 Import file ▾

1 Name of activity / technique
Handling of rubber articles no energy applied

Process category (PROC)
 PROC 21: Low energy manipulation of substances bound in materials and/or articles

Reporting example



3.5.6 Service life 1 +

● Handling of tyres and other rubber articles 🗑️

🚫 None 🚫 None **Handling of tyres and other rubber articles**

UUID: e928a57b-e795-40e2-88b1-482902cd3596

Article used by
✓ workers

Article category (AC)
None

Substance intended to be released from article
None

Contributing activity / technique for consumers + New item 📄 Import file ▼

Contributing activity / technique for workers + New item 📄 Import file ▼

1 **Name of activity / technique**
Handling of rubber articles no energy applied

Process category (PROC)
✓ PROC 21: Low energy manipulation of substances bound in materials and/or articles

Percentage (w/w) of substance in mixture /article (%)
None

Details on the percentage of substance in mixture/article
None



Assessing service life use

- Claiming no/negligible release is **not** a valid argument to justify absence of assessment
- If no “reasonably quantifiable” release is expected for some routes in a contributing scenario:
 - Describe relevant conditions of use; examples:
 - No water contact: material not to be used outdoors or in pipes and no cleaning with water is foreseen
 - No dermal contact: substance embedded in internal parts of the article
 - No oral contact: mouthing of the material or food contact by consumers not foreseen
 - Set relevant release estimates to 0



When assessment may not be needed

- A. Substance is contained in concentration in the article material **below the cut-off values** as laid down in Regulation 1272/2008 (CLP) in relation to the mixture classification (using by analogy Article 14(2) of REACH, as a benchmark)
- B. Substance **reacts on use**, and hence is not available for exposure anymore during service life, and the reaction product is not hazardous

In case situation A or B applies, the **corresponding contributing scenario** in the Chemical Safety Report (CSR) should contain the relevant **justification**



A. Justification

Low concentration in article

Justification must include concentration of the substance in the article material

- If concentration is $<0.1\%$, no further reasoning is expected (**exceptions:** specific concentration limits and Aquatic Acute 1/Aquatic Chronic 1)
- If concentration is $>0.1\%$, give hazard categories and classes of your substance and corresponding cut-offs from CLP



B. Justification

Reaction on use

Include the following elements in the **corresponding contributing scenario (CS)**

- To justify absence of assessment of your **substance**:
 - how the substance transforms (incl. reaction mechanism and transformation products)
 - Quantification of the remaining residual concentration of the substance in article
 - Concentration of the substance in article (as specified in the previous slide)
- to justify the absence of assessment for **transformation products**:
 - Explanation that the transformation products are not hazardous

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Concluding remarks

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advice

16 November 2021

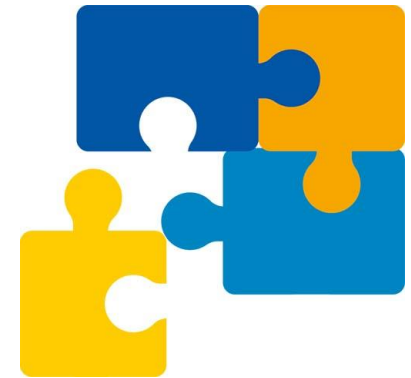
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Take-home messages

- Clear hazard profile and use description are a prerequisite for a complete chemical safety report
- Make sure uses in IUCLID and chemical safety report are synchronised and the chemical safety report covers each use and activity reported in the dossier
- Report and assess article service life if it is relevant for your substance
- Any changes in the dossier/chemical safety report will be subject to a new completeness check when you submit your updated dossier



Support

- More on technical completeness check:
echa.europa.eu/technical-completeness-check
- Contact us if you have questions on a completeness check failure:
echa.europa.eu/contact

Q&A panel

- Webinar open until 13:00 Helsinki time (EET, GMT+2) to answer questions
- If your question is not answered by the end of the webinar, send it via our contact form:
echa.europa.eu/contact



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