

1st PSN IUCLID subgroup meeting – 1 Oct 2021



IUCLID features: Report Generator

Adrián César Razquin

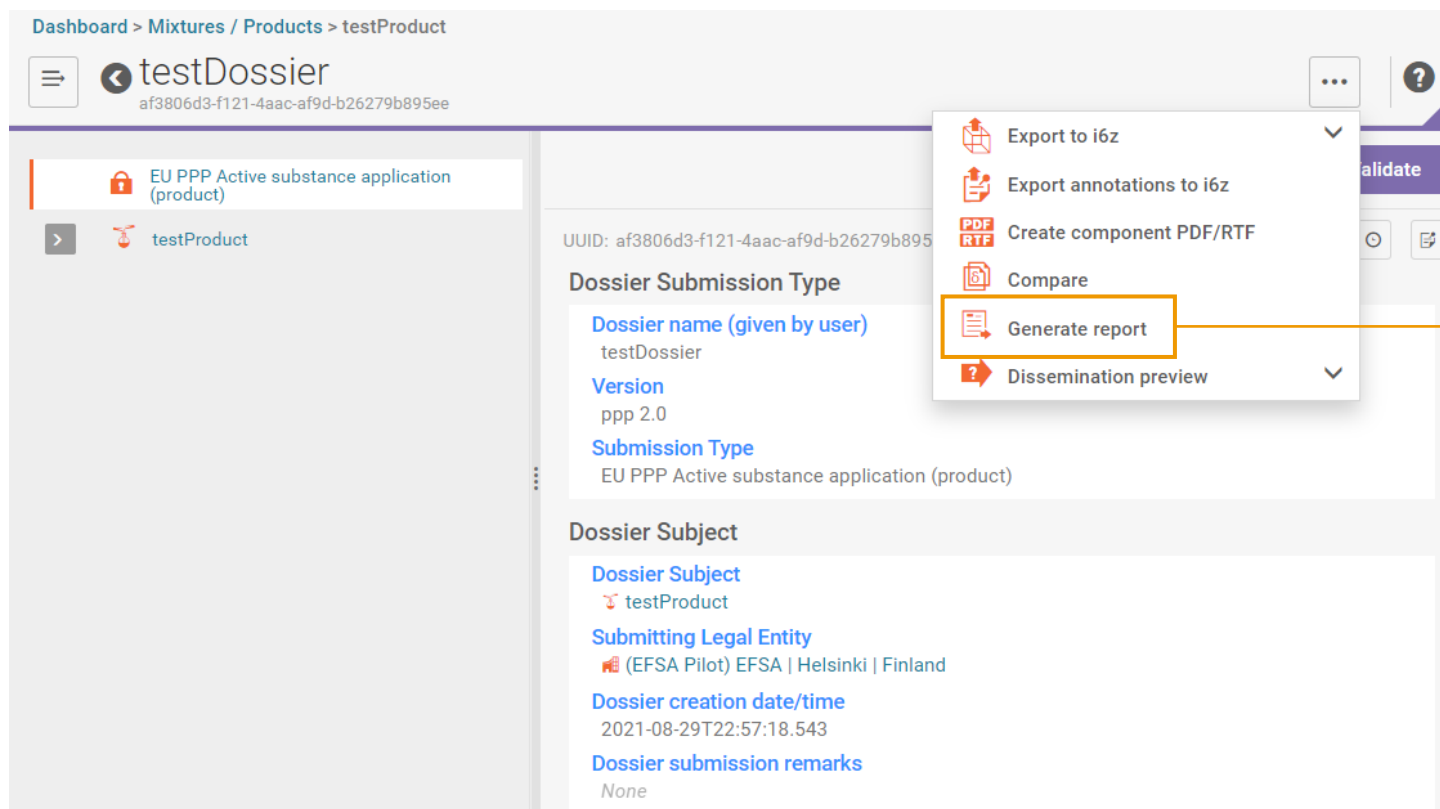
Data Officer, DATA Unit

Trusted science for safe food

- Tool to extract data from IUCLID and present it in report (PDF, RTF) or machine-readable format (XML, CSV)
 - Based on report templates (.ftl) & stylesheets (.xsl)
 - Modular approach: re-usability across reports
- Available reports added and updated in IUCLID releases
 - Templates also published in Zenodo KJ, which can be uploaded in report manager
- Detailed information at:
 - IUCLID website and manual
 - Hypercare session of May 18th 2021 on Report Generator

How to access and run Report Generator

- From a dataset or a dossier:
 - select 'Generate report' under the 3-dot menu
 - select required type of report and output format



Dashboard > Mixtures / Products > testProduct

testDossier
af3806d3-f121-4aac-af9d-b26279b895ee

EU PPP Active substance application (product)

testProduct

UUID: af3806d3-f121-4aac-af9d-b26279b895

Dossier Submission Type

Dossier name (given by user)
testDossier

Version
ppp 2.0

Submission Type
EU PPP Active substance application (product)

Dossier Subject

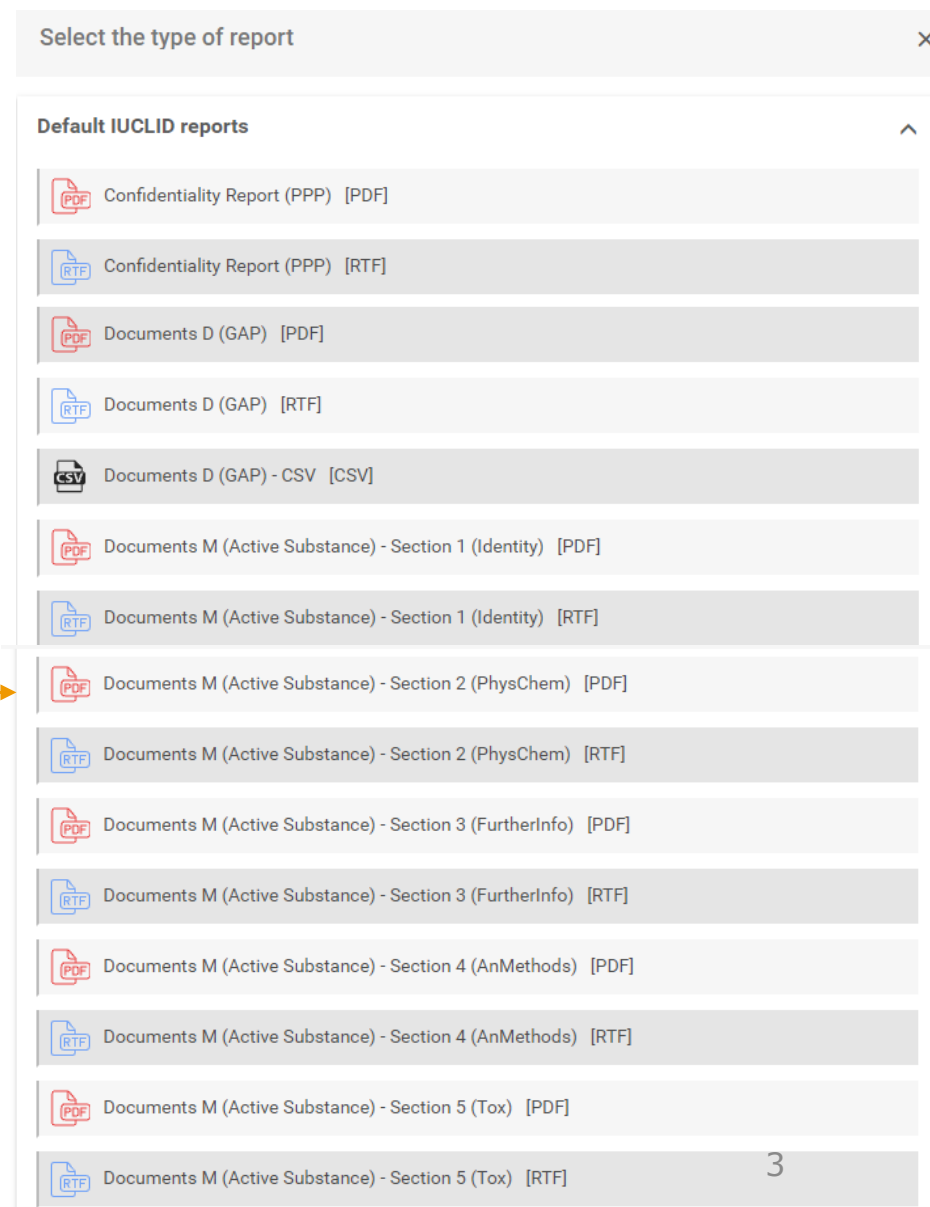
Dossier Subject
testProduct

Submitting Legal Entity
(EFSA Pilot) EFSA | Helsinki | Finland

Dossier creation date/time
2021-08-29T22:57:18.543

Dossier submission remarks
None

Export to i6z
Export annotations to i6z
Create component PDF/RTF
Compare
Generate report
Dissemination preview



Select the type of report

Default IUCLID reports

- Confidentiality Report (PPP) [PDF]
- Confidentiality Report (PPP) [RTF]
- Documents D (GAP) [PDF]
- Documents D (GAP) [RTF]
- Documents D (GAP) - CSV [CSV]
- Documents M (Active Substance) - Section 1 (Identity) [PDF]
- Documents M (Active Substance) - Section 1 (Identity) [RTF]
- Documents M (Active Substance) - Section 2 (PhysChem) [PDF]
- Documents M (Active Substance) - Section 2 (PhysChem) [RTF]
- Documents M (Active Substance) - Section 3 (FurtherInfo) [PDF]
- Documents M (Active Substance) - Section 3 (FurtherInfo) [RTF]
- Documents M (Active Substance) - Section 4 (AnMethods) [PDF]
- Documents M (Active Substance) - Section 4 (AnMethods) [RTF]
- Documents M (Active Substance) - Section 5 (Tox) [PDF]
- Documents M (Active Substance) - Section 5 (Tox) [RTF]

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- For applicants:

- **Documents M** (summary dossier) sections [PDF, RTF], for:

- active substance (MCA/MMA), incl. studies on metabolites (sec. 1.4.4 of the mixture)

- 10 sections: 01 – Identity, 02 – PhysChem, 03 – FurtherInfo, 04 – AnMethods, 05 – Tox, 06 – Residues, 07 – Fate, 08 – Ecotox, 09 – LitData, 10 – C&L

- product (MCP/MMP)

- 11 sections: 01 – Identity, 02 – PhysChem, 03 – Application, 04 – FurtherInfo, 05 – AnMethods, 06 – Efficacy, 07 – Tox, 09 – Fate, 10 – Ecotox, 11 – LitData, 12 – C&L

→ Summaries of the different sections of the PPP dossier used to prepare DAR/RAR

→ ToC as close as possible to requirements in legislation (EU Reg 283/2013 & 284/2013)

- not necessarily the same as in IUCLID!
- based on selected endpoint and/or other fields - see the [crosswalks](#)

→ Studies structured as in Appendix E of the [administrative guidance](#)

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- **Documents D** (GAP) [PDF, RTF, CSV]

- Detailed summary of the uses of the PPP in table format

- Incl. intended (D1, D3) and authorised (D2) uses

- For evaluators:

- **NoS Extraction Request** [PDF, RTF, CSV]

- Summary of all the studies included in the application together with:

- Notification of Studies (NoS) IDs or justification for not providing them
 - relevant information e.g. endpoint, GLP, test facility, test period...

- To be used by RMS to cross-check with EFSA's Notification of Studies database

- **Confidentiality Report for PPP** [PDF, RTF]

- List of confidentiality claims made by the applicant for assessment by RMS

- (on-going) To be harmonised with a cross-domain Confidentiality Report

- Reports developed by ECHA also applicable to PPP applications:
 - **Literature references report** [RTF, CSV]
 - Substitute of the Documents L, only one document for all sections
 - CSV version allows filtering for specific IUCLID sections e.g. physchem, tox...
 - confidential fields in vertebrate studies hidden if run from the filtered dossier as per the filter rules
 - **List of annotations** [PDF, RTF]
 - **List of attachments** [RTF, CSV]

Report		Description & remarks
MRL Evaluation Report		<ul style="list-style-type: none"> possibility to reuse existing templates for Documents M, GAP
Documents N	N1 – Overall Conclusions	<ul style="list-style-type: none"> summary documents in IUCLID
	N2 – List of Endpoints	<ul style="list-style-type: none"> key values for chemical safety assessment from summary documents (not always available)
	N3 – Substance & Metabolites	<ul style="list-style-type: none"> reference substance info in metabolites documents + inbound references (difficulty in extracting levels in matrices/compartments)
	N4 – Metabolites in Groundwater	<ul style="list-style-type: none"> existing document in IUCLID
	N5 – Isomeric Composition	<ul style="list-style-type: none"> missing document?

Future reports – open for discussion (cont')

Report	Description & remarks
Assessment from other authorities	<ul style="list-style-type: none">• related to backlog item 2064• compilation of all information on MRLs in one table
Study comparison	<ul style="list-style-type: none">• table comparing main results from all studies of same/similar endpoints
Data waivers	<ul style="list-style-type: none">• list of all the data waivers in a dossier
...	<ul style="list-style-type: none">• ...

- all data in a IUCLID dataset can be used, processed & presented in different formats with Report Generator
 - exception: rich-text fields (only possible to present as such) & attached docs
 - limitations:
 - not possible to combine data from different datasets/dossiers
 - not possible to (pre-)select documents to be used by the tool
 - complex error-handling / bug-fixing in web interface
- for discussions on reports and sharing use cases and code please join the [OECD IUCLID Customisation Forum](#)
- to discuss: which reports are needed and should be prioritised?





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