



12th meeting of the PSN IUCLID sub-group
11 - 12 Mar 2025

IUCLID REPORT GENERATOR USE FOR DOSSIER LIFECYCLE

OUTLINE

- IUCLID PPP Dossiers-Datasets: Terminology and Structure Overview
- Run Reports with Report Generator
 - HOW to run Reports
 - WHO should use them
 - WHEN to run Reports in Dossier lifecycle
 - WHICH Report to choose according to the stage (e.g., dossier admissibility)
 - WHY Reports should be used
- IUCLID Demo (GAP Report)



IUCLID PPP DOSSIERS - DATASETS: TERMINOLOGY AND STRUCTURE OVERVIEW

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DATASET-DOSSIER

- **Dataset*** a collection of documents that relate to a particular chemical substance, or grouping of chemical substances. It can be of type:



- **Dossier*** a read-only snapshot of a dataset. It contains a *Dossier header* that has a structure determined by the *working context*.

Datasets are editable. Dossiers are read-only.

In IUCLID EFSA Agency instance, MS have access to **Dossiers**.



GENERALIZED EU PPP DOSSIER STRUCTURE

In EU PPP working contexts **Dossiers** consist of:*

rlen **One or many Mixture Datasets**

with

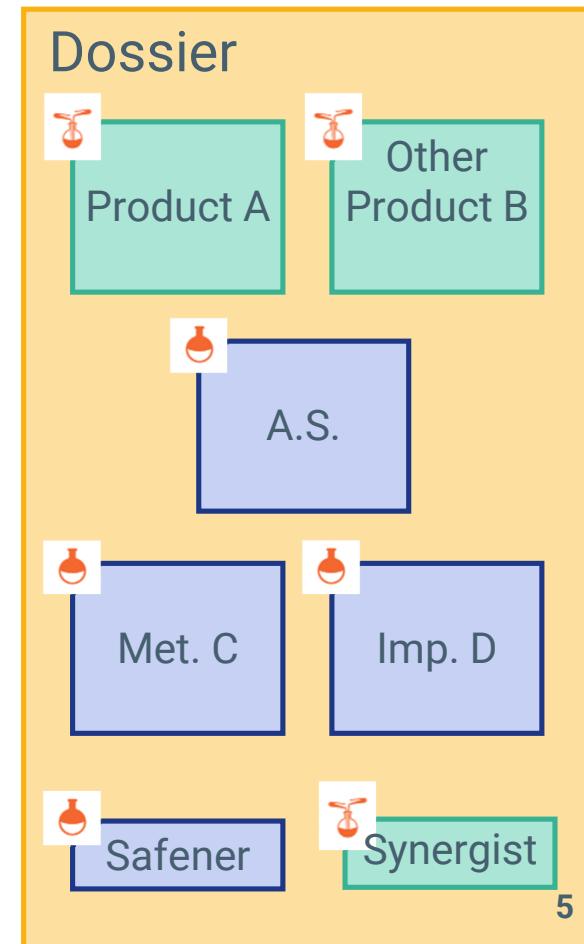
rlen **One and only one Active Substance Dataset**

plus (where applicable)

rlen **One or many Metabolites and/or Impurities Datasets**

plus (technically possible but not fully operational)

rlen **One or many Co-Formulants, Safeners and Synergists Datasets**



PRODUCT AND ACTIVE SUBSTANCE DATASETS

Product Dataset

Product Table of Contents (ToC)*

Representative product BC 1 (LoE/PhysChem)
08da4a8c-0c82-4a63-aca3-93ac951efea3

Type at least 3 characters

EU PPP Active substance application (product)

Representative product BC 1 (LoE/PhysChem)

1 Identity of the plant protection product and applicant

- 1.1 Identity of the plant protection product, trade name or proposed trade name, and applicant
- 1.2 Producer of the plant protection product
- 1.3 Producer's development code number if appropriate
- 1.4 Detailed quantitative and qualitative information on the composition of the plant protection product
 - 2023_Detailed quantitative and qualitative information on the composition of the representative plant protection product

Active substance BC (LoE/PhysChem)

Other identifiers

Contact persons

Mixture/Product name*
Representative product BC 1
Public name

Legal entity owner
EFSA IUCLID demo | Parm
Third party

Other identifiers

Contact persons

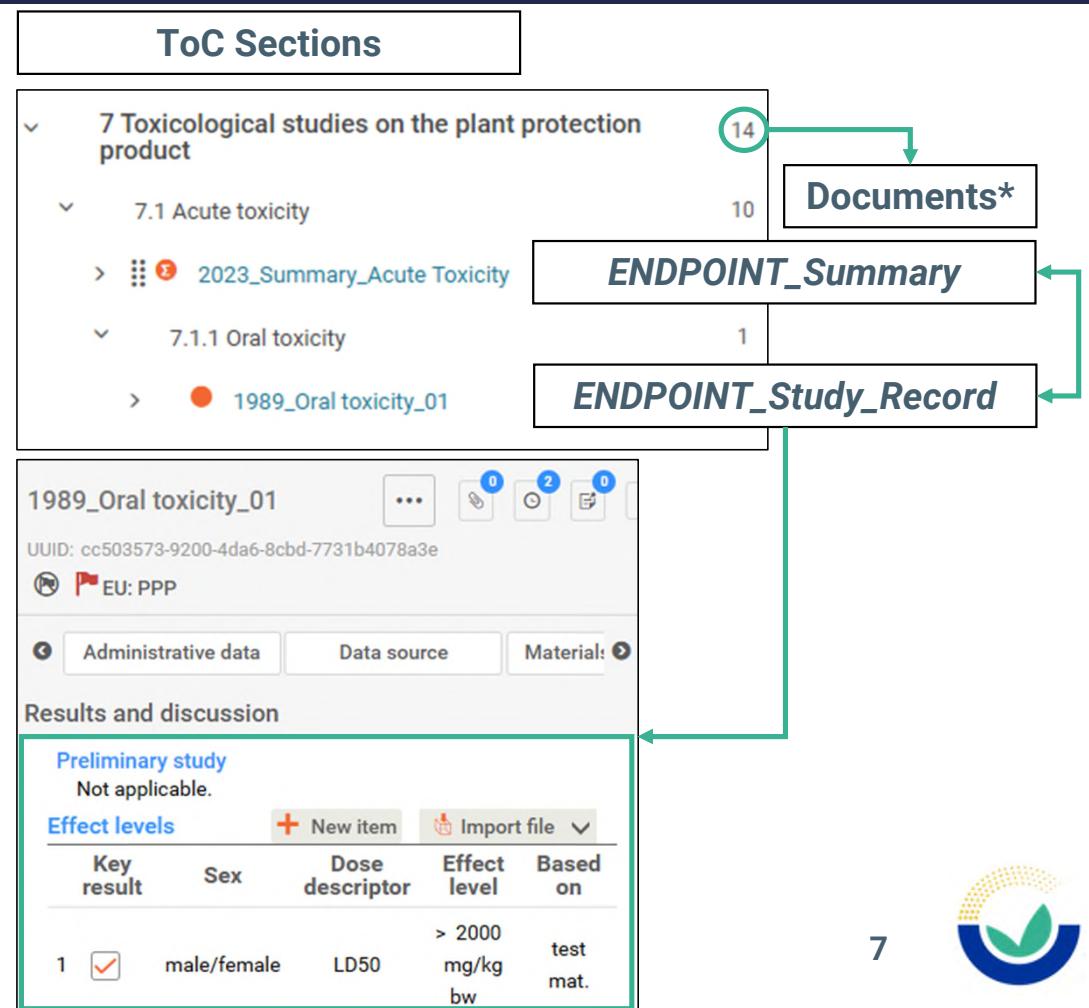
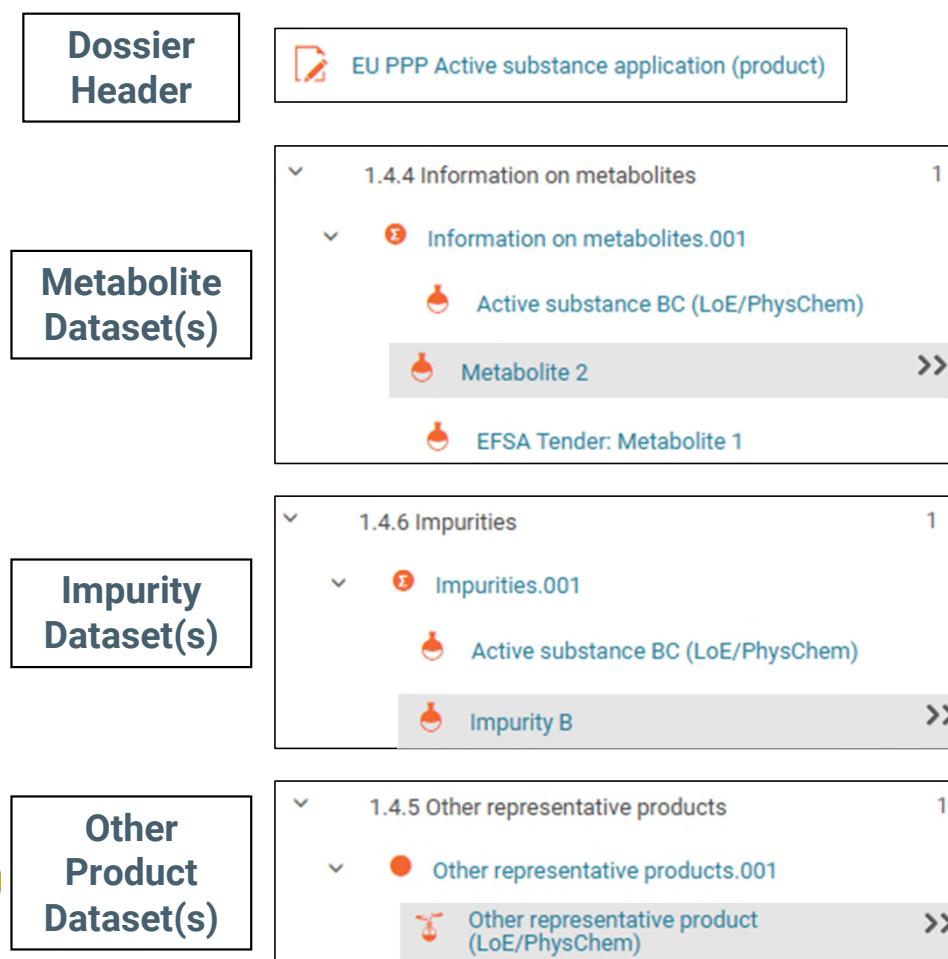
Active substance BC (LoE/PhysChem)	
>	1 Identity of the active substance and applicant 21
>	2 Physical and chemical properties of the active substance 38
>	3 Further information on the active substance 8
>	4 Analytical methods 22
>	5 Toxicological and metabolism studies on the active substance 81
>	6 Residues in or on treated products, food and feed 44
>	7 Fate and behaviour in the environment 30
>	8 Ecotoxicological studies on the active substance 49
>	9 Literature data and change log 13
>	10 Classification and labelling of the active substance 3
>	11 Summary and evaluation 7
Inherited templates	

Active Substance (A.S.) Dataset

Active Substance ToC*



MAIN ELEMENTS WITHIN A PPP DOSSIER-DATASET



RUN REPORTS WITH REPORT GENERATOR (RG) - HOW

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RG TOOL – HOW TO ACCESS IT

The image shows two screenshots of the RG Tool interface. The left screenshot displays the dossier structure for 'Representative product BC 1 (LoE/PhysChem)' with a search bar and a tree view of data points. The right screenshot shows the 'View Dossiers' page with a context menu open, highlighting the 'Generate report' option. A dropdown menu for file formats (RTF, DOCX, PDF, CSV, HTML, XML, TXT) is also visible.

Representative product BC 1 (LoE/PhysChem)
08da4a8c-0c82-4a63-aca3-93ac951efea3

Type at least 3 characters

EU PPP Active substance application (product)

Representative product BC 1 (LoE/PhysChem)

1 Identity of the plant protection product and applicant

1.1 Identity of the plant protection product, trade name or proposed trade name, and applicant

1.2 Producer of the plant protection product

1.3 Producer's development code number if appropriate

1.4 Detailed quantitative and qualitative information on the composition of the plant protection product

2023_Detailed quantitative and qualitative information on the composition of the representative plant protection product

Active substance BC (LoE/PhysChem)

UUID: 08da4a8c-0c82-4a63-aca3-93ac951efea3

Other identifiers

Mixture/Product name*
Representative product BC 1

Public name

Legal entity owner
EFSA IUCLID demo | Partner
Third party

Other identifiers

Contact persons

View Dossiers

Validate

Create dossier

...

Export to i6z

Create PDF/RTF

Generate report

Compare

Clone

Copy data from ...

Bulk operations

RTF

DOCX

PDF

CSV

HTML

XML

TXT

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HOW TO RUN REPORTS FOR OTHER REPR. PRODUCTS

IUCOLID USER INTERFACE

MIXTURE Document
UUID: 540600f8-15ff-444d-95ce-7dafb89326dc

Other identifiers Contact persons Role in the supply chain

Mixture/Product name*
Other representative product (LoE/PhysChem)
Public name

Legal entity owner

Third party

Other identifiers + New item Import file

Contact persons + New item Import file

Role in the supply chain

Manufacturer
Importer
Only representative
Downstream user

View Dossiers Validate Create dossier X

Compare Document
Generate sub entity report

Important Note: sub-entity report generation is required with **Dossiers** and it is needed to generate reports for other representative Products datasets.

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RUN REPORTS WITH REPORT GENERATOR (RG) – WHO, WHEN, WHICH, WHY

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RUN REPORTS WITH RG – WHO AND WHEN

Report Generator should be used as much as possible during the entire Dossier lifecycle and in support to the DAR/RAR preparation:

- a) To check if IUCLID Datasets are complete during compilation (**Applicant**).
- b) To check if IUCLID Dossiers information is complete and consistent during admissibility (**RMS**) – a dossier update might be needed before proceeding to the next steps.
- c) Use all available reports in RG to prepare DAR/RAR (**RMS**): this will ensure consistency of information among the Assessment Report and the IUCLID Dossier.



RUN REPORTS WITH RG – WHICH

The below reports (at least) are recommended to be used during the admissibility check and in the preparation of the DAR/RAR:

- **GAP Table (mandatory)** – new GAP mapping file will be published in Zenodo in May 2025 following next IUCLID release. A video demonstration on how to use this report will be presented in the final slide.
- **List of Substances and Metabolites** – fill in the “Remarks” field to populate the column “Compound found in” in the report (see next slides).
- **Table of Analytical Methods** – use the cross-reference function to ensure a method is included in the report (see next slides).

Refer to Agenda item 6_ “IUCLID report generator updates” to check the status of other reports.



RUN REPORTS WITH RG – LIST OF SUBSTANCES AND METABOLITES

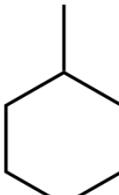
IUCLID METABOLITES DOCUMENT

1.4.4 Information on metabolites	1
> Information on metabolites	
1.4.5 Other representative products	1
1.4.6 Impurities	
1.5 (Cf. 1.4) Type and code of the plant protection product	

Report

1. Substances and metabolites: structures, codes, synonyms

Table 1.1.

Name and CAS number	IUPAC name, SMILES, InChi	Structural formula	Compound found in
EFSA Tender: Metabolite 1 (ref.: Metabolite_example 1) 147-965	IUPAC name SMILES InChi		Where found: soil

Metabolites + New item Import file

Link to metabolite dataset

1

EFSA Tender: Metabolite 1 | Metabolite_example 1 | IUPAC name | 147-965

Remarks

Where found: soil

IUCLID

REF.SUBSTANCE

Reference substance name*
Metabolite_example 1

IUPAC name
IUPAC name

Description
Dummy metabolite

CAS number
147-965

SMILES notation

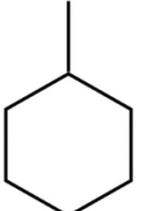
SMILES

InChi

InChi

InChIKey

Structural formula





RUN REPORTS WITH RG – TABLE OF ANALYTICAL METHODS

2023_Physical and chemical properties of the active substance

- 2.1 Melting point and boiling point 5
- > 2.1.1 Melting point 2
- ✓ 2.1.2 Boiling point 3
- > 2023_Boiling point
- > 2023_Boiling point
- Boiling point_Waiver
- 2.2 Vapour pressure, volatility 4
- 2.3 Appearance (physical state) 5

2023_Boiling point

UUID: e2f772eb-9e3c-40a0-8bd5-e3c734b38ad6

EU: PPP

IUCLID
ENDPOINT_STUDY_RECORD

Cross-reference		Reason / purpose for cross-reference		Related information	
		1 method used in study *		RA_physchem2 1 (reliable without restriction)	
		2 method used in study *		RA_physchem	

Analytical (primary) method

Instrument / detector

✓ HPLC-DAD

Residue method

multi analyte

Analytical (primary) method

Instrument / detector

✓ GC-MS/MS

1. Table of Analytical Methods (Appendix D)

Report

Table 1.1. Analytical Methods

#	IUCLID section	Author, date	Study title	Analytical method Author, date, No.	Technique, residue method, LOQ of the method, validated working range	Method meets analytical validation criteria	Remarks	Acceptability of the method
1	2.1.2 Boiling point	Author, 2023	Technical BC: physical and chemical characteristics	1. Me M., 2021, Analytical method physchem 2 2. Serafimova R., 2021, Analytical method physchem1	<p>1. Primary:</p> <ul style="list-style-type: none"> Instrument: HPLC-DAD Residue method: multi analyte LOQ: ISO name active substance BC = 0.07 mg/kg <p>2. Primary:</p> <ul style="list-style-type: none"> Instrument: GC-MS/MS LOQ: ISO name active substance BC = 0.01 mg/kg 	<p>1. not specified</p> <p>2. yes</p>	1. unclear	1. 1 (reliable without restriction)



RUN REPORTS WITH RG – WHY

- **RMS** is reminded to ensure alignment among the information which will be included in the DAR/RAR and the information contained in the IUCLID dossier. The DAR/RAR preparation should start from all available reports. Therefore, we recommend to make full use of the IUCLID Report Generator functionality.
- **EFSA** will ensure alignment among the DAR/RAR and the IUCLID dossier before entering the peer-view phase.



Missing info in this GAP example

- MS/Country codes (therefore assumed to be all EU)
- Crop location according to EPPO codes (F/G/I)
- Formulation Type
- Re-treatment interval in days (min-max)
- Concentration a.s. in dilution (min-max)
- Pre-Harvest Interval in days