6th meeting of the PSN IUCLID sub-group
28 March 2023

IUCLID FEATURES: REPORT GENERATOR

Tomas ROVESTI

EUROPEAN FOOD SAFETY AUTHORITY

APRIL RELEASE & OUTLOOK

- Updates in upcoming IUCLID release (Apr-23) include:
  - changes to existing reports
  - work on reports for microorganisms following April release (reopening PSN subgroup, volunteers welcomed)

- MRL application report (collaboration with ANSES)
  - report modifications - existing MRL tables, graphical improvements, elimination of duplicated information
  - proposed format changes for IUCLID 2024
  - annotations based on feedback

- Report generator workshop with ECHA, BFR and industry (Nov-22)
  - List of Study Summaries

LIST OF STUDY SUMMARIES

- Overview of all Endpoint studies contained in a product or active substance dataset
- Format type: CSV – can be sorted and filtered

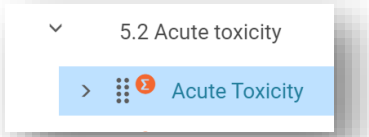
A	B	C	D	E	F	H	K	L	O	P	R	T
Entity Type	Entity Name	Section Name	Section Nu	Document Name	Document UUID	Reference Substance	Reference Substance IU	Robust St	Type of information	Reliability	Guideline (materials a	Test Material Informati
SUBSTANCE	The Active Su	Earthworms	8.4.1	Rufli H. (1988)-Acute toxicity to	00a7845e-cf14-4bb1-bf1e-	clodinafop-propargyl	(R)-2-[4-(5-chloro-3-fluc	Yes	experimental study	1 (reliable witho	OECD Guideline 207 (	clodinafop_3 (105512-(
SUBSTANCE	The Active Su	Earthworms	8.4.1	Long-term tox to earthworms	9fcc78ff-cda7-463c-bf31-c	clodinafop-propargyl	(R)-2-[4-(5-chloro-3-fluc	No				
SUBSTANCE	The Active Su	Effects on soil nitrogen trar	8.5	Morgenroth U. (1992) (summary	0009206b-9289-4284-8658-	clodinafop-propargyl	(R)-2-[4-(5-chloro-3-fluc	Yes	experimental study	1 (reliable witho	BBA Part VI, 1-1	Clodinafop_2 (105512-(
SUBSTANCE	The Active Su	Effects on other terrestrial	8.7	Grade, R. (2001) (summary)	424f9c9b-1741-47ba-b178-	clodinafop-propargyl	(R)-2-[4-(5-chloro-3-fluc	Yes	experimental study	1 (reliable witho	OECD Guideline 209: A	Clodinafop_2 (105512-(
SUBSTANCE	The Active Su	Effects on biological metho	8.8	Effects on biological methods fo	0f561cb9-69f2-4a5e-99ee-	clodinafop-propargyl	(R)-2-[4-(5-chloro-3-fluc	No	experimental study			

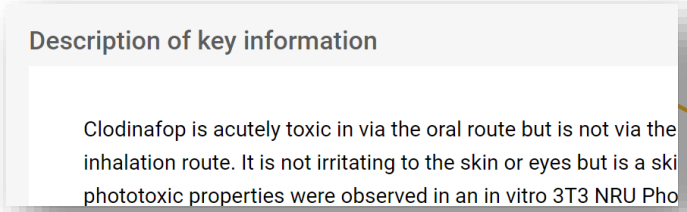
Columns: Entity, Section, **Document Name**, UUID, **Reference Substance** (Name, CAS Nr, EC Nr, IUPAC and Ichi), Adequacy of Study, Study period, **Reliability**, **Data waiving**, Guideline (materials and methods), Test Material Information, **Test organisms**, Strain / cell type, **Route of application / dose method**, Exposure duration, Metabolic activation, **Key Results, Literature Reference** (Type, Title, Author, Year, Source, Testing Facility, Report Date), etc.

https://iuclid6.echa.europa.eu/cross-regulatory-reports

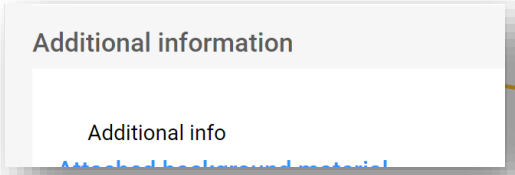
DAR: LEVEL 2 OF VOLUME 1 (DOCUMENT N1) (PART 1)

- Status: development
- Dataset: active substance / metabolites / products
- Sections:

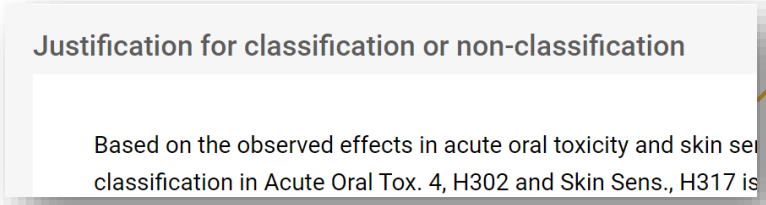




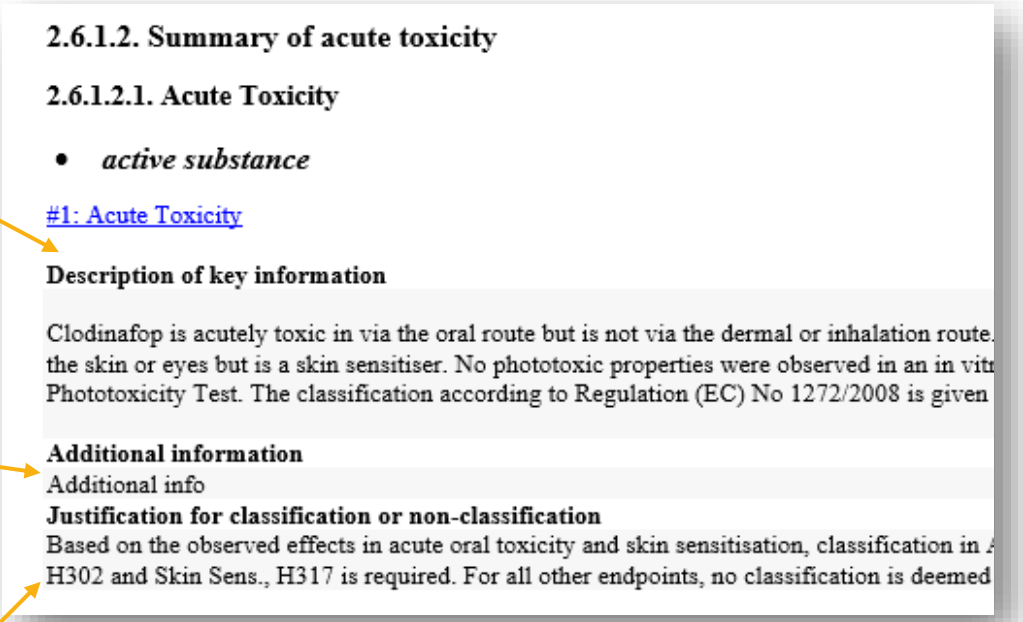
ENDPOINT_SUMMARY.xxx.KeyInformation



ENDPOINT_SUMMARY.xxx.Discussion

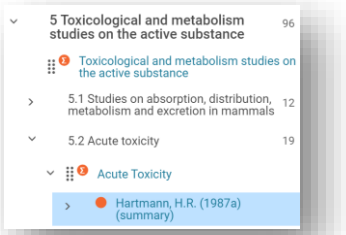


ENDPOINT_SUMMARY.xxx.JustificationForClassificationOrNonClassification

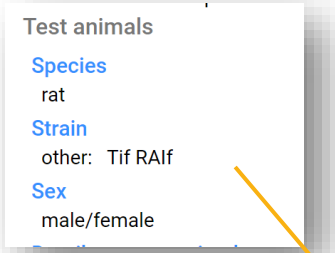


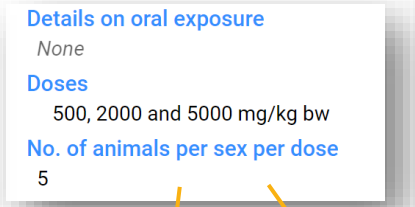
DAR: LEVEL 2 OF VOLUME 1 (DOCUMENT N1) (PART 2)

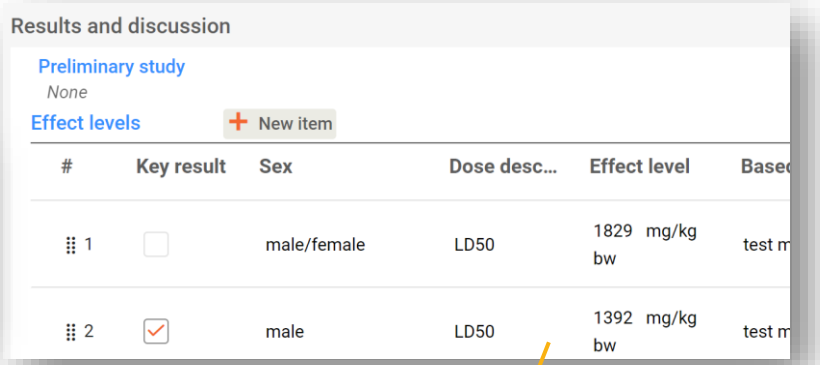
- Summary tables with all studies link to the section



ENDPOINT_STUDY_RECORD.







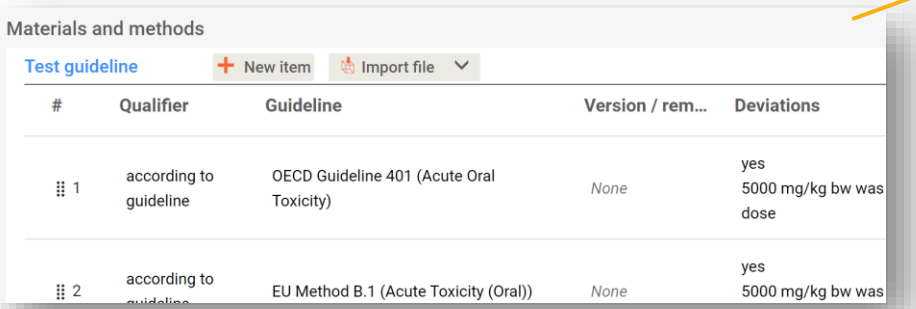
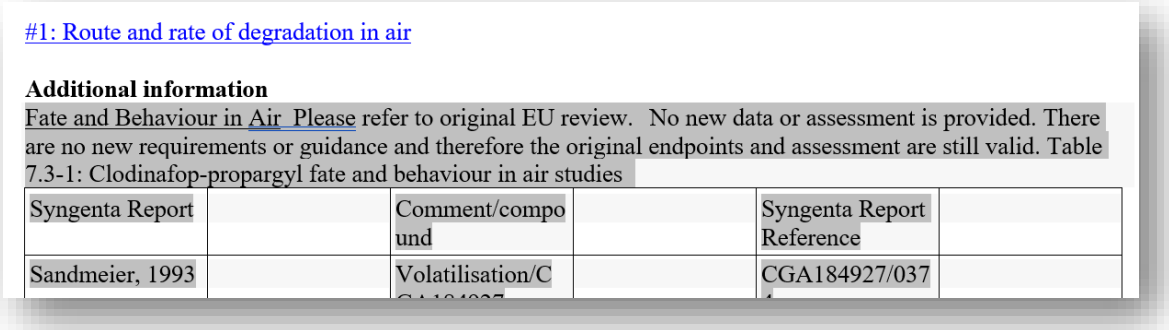


Table 2.8. Summary table of animal studies on acute oral toxicity

Method, guideline, deviations if any	Species, strain, sex, no/group	Test substance	Dose levels, duration of exposure	Value LD_{50}	Reference
Method: standard acute method **Guideline:** OECD Guideline 401 (Acute Oral Toxicity) [before 2002] **Deviation:** yes - 5000 mg/kg bw was used as highest dose, **Guideline:** EU Method B.1 (Acute Toxicity (Oral)) **Deviation:** yes - 5000 mg/kg bw was used as highest dose	**Species:** rat [common species] **Strain:** Tif RAIf **Sex:** male/female **No/group:** 5	clodinafop_3	**Dose levels:** 500, 2000 and 5000 mg/kg bw No duration of exposure available	1392 mg/kg bw	CGA 184927 - Acute oral toxicity study in the rat

DAR: LEVEL 2 OF VOLUME 1 (DOCUMENT N1) (PART 3)

- Rich text fields with highlighted text



#1: Route and rate of degradation in air

Additional information

Fate and Behaviour in Air_Please refer to original EU review. No new data or assessment is provided. There are no new requirements or guidance and therefore the original endpoints and assessment are still valid. Table 7.3-1: Clodinafop-propargyl fate and behaviour in air studies

Syngenta Report		Comment/compound		Syngenta Report Reference	
Sandmeier, 1993		Volatilisation/C		CGA184927/037	

- Including annotations provided by the RMS
- Publishes only as DAR
- Prototype with evaluations of MS available in 2nd half 2023
- Define process for DAR production including export/import of annotations for newer dossier versions

DISCUSSION

- *Your feedback on report needs is always welcome: Report Generator backlog*