

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



IUCLID FEATURES: REPORT GENERATOR

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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 No	Document Name	Document UUID	Reference Substance	Reference Substance IU	Robust St	Type of information	Reliability	Guideline (materials	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 (t	clodinafop_3 (105512-C
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-C
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: 8	Clodinafop_2 (105512-C
SUBSTANCE	The Active Su	Effects on biological methc	8.8	Effects on biological methods f	0f561cb9-69f2-4a5e-99ee	clodinafop-propargyl	(R)-2-[4-(5-chloro-3-fluc	No	experimental study			

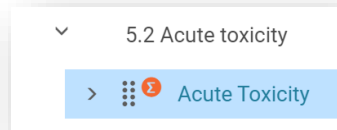
Columns: Entity, Section, **Document Name**, UUID, **Reference Substance** (Name, CAS Nr, EC Nr, IUPAC and Ichi), Adequacy of Study, Study period, **Reliability**, **Data waiving**, Guideline (materials and methods), Test Material Information, **Test organisms**, Strain / cell type, **Route of application / 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:



Description of key information

Clodinafop is acutely toxic in via the oral route but is not via the inhalation route. It is not irritating to the skin or eyes but is a skin sensitiser. No phototoxic properties were observed in an in vitro 3T3 NRU Photo

ENDPOINT_SUMMARY.xxx.KeyInformation

Additional information

Additional info

Attached background material

ENDPOINT_SUMMARY.xxx.Discussion

Justification for classification or non-classification

Based on the observed effects in acute oral toxicity and skin sensitisation, classification in Acute Oral Tox. 4, H302 and Skin Sens., H317 is required.

ENDPOINT_SUMMARY.xxx.JustificationForClassificationOrNonClassification

2.6.1.2. Summary of acute toxicity

2.6.1.2.1. Acute Toxicity

- *active substance*

[#1: Acute Toxicity](#)

Description of key information

Clodinafop is acutely toxic in via the oral route but is not via the dermal or inhalation route. It is not irritating to the skin or eyes but is a skin sensitiser. No phototoxic properties were observed in an in vitro Phototoxicity Test. The classification according to Regulation (EC) No 1272/2008 is given in Table 1.

Additional information

Additional info

Justification for classification or non-classification

Based on the observed effects in acute oral toxicity and skin sensitisation, classification in Acute Oral Tox. 4, H302 and Skin Sens., H317 is required. For all other endpoints, no classification is deemed necessary.



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

- Summary tables with all studies link to the section

- 5 Toxicological and metabolism studies on the active substance 96
 - Toxicological and metabolism studies on the active substance
 - 5.1 Studies on absorption, distribution, metabolism and excretion in mammals 12
 - 5.2 Acute toxicity 19
 - Acute Toxicity
 - Hartmann, H.R. (1987a) (summary)

ENDPOINT_STUDY_RECORD.

Test animals

Species
rat

Strain
other: Tif RAIf

Sex
male/female

Details on oral exposure

None

Doses
500, 2000 and 5000 mg/kg bw

No. of animals per sex per dose
5

Results and discussion

Preliminary study
None

Effect levels + New item

#	Key result	Sex	Dose desc...	Effect level	Base
1	<input type="checkbox"/>	male/female	LD50	1829 mg/kg bw	test m
2	<input checked="" type="checkbox"/>	male	LD50	1392 mg/kg bw	test m

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
<p>Method: standard acute method</p> <p>Guideline: OECD Guideline 401 (Acute Oral Toxicity) [before 2002]</p> <p>Deviation: yes - 5000 mg/kg bw was used as highest dose,</p> <p>Guideline: EU Method B.1 (Acute Toxicity (Oral))</p> <p>Deviation: yes - 5000 mg/kg bw was used as highest dose</p>	<p>Species: rat [common species]</p> <p>Strain: Tif RAIf</p> <p>Sex: male/female</p> <p>No/group: 5</p>	clodinafop_3	<p>Dose levels: 500, 2000 and 5000 mg/kg bw</p> <p>No duration of exposure available</p>	1392 mg/kg bw	CGA 184927 - Acute oral toxicity study in the rat

Materials and methods

Test guideline + New item Import file

#	Qualifier	Guideline	Version / rem...	Deviations
1	according to guideline	OECD Guideline 401 (Acute Oral Toxicity)	None	yes 5000 mg/kg bw was dose
2	according to guideline	EU Method B.1 (Acute Toxicity (Oral))	None	yes 5000 mg/kg bw was

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/compo und	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](#)*

