

IUCLID for microbial active substances



IUCLID version 8.0

- **Validation rules for micro's**
 - Not always appropriate IUCLID entrance checked
 - Business rules for less relevant input
 - E.g endpoint summary for study with only waivers
 - OHT's in IUCLID for non-obligatory DR for microbials

X	BR_PPP_016	9, Fate and behaviour in the environment	Section 9. Fate and behaviour in the environment: At least one endpoint study summary must be provided for this section.
X	BR_PPP_016	10.2.4, Effects on aquatic macrophytes	Section 10.2.4 Effects on aquatic macrophytes: At least one endpoint study summary must be provided for this section.

From data requirements:

Relevant studies on pathogenic/infective effects on aquatic macrophytes shall be performed if the micro-organism **is known to have an herbicidal mode of action, or to be closely related to a plant pathogen**

- Consequences of moving of the IUCLID requirements: guidelines not appropriate / up to date.
- Check units again. Some appropriate ones for m.o. missing (not only related to update)
 - Examples

Effects on aquatic organisms

Guideline ⓘ ^ ? ^

Please select





- EPA OPP 72-4 (Fish Early Life-Stage and Aquatic Invertebrate Life-Cycle Studies)
- EPA OPP 72-5 (Fish Life Cycle Toxicity)
- EPA OPPTS 885.0001 (Overview for Microbial Pest Control Agents)
- EPA OPPTS 850.1400 (Fish Early-life Stage Toxicity Test)
- EPA OPPTS 850.1500 (Fish Life Cycle Toxicity)
- EPA OPPTS 885.4000 (Background for Non-target Organism Testing of Microbial Pest Control Agents)
- EPA OPPTS 885.4700 (Microbial Pesticide, Fish Life Cycle Studies, Tier III)

Esc to

Group C – Toxicology Test Guidelines

- [885.3000 - Background--Mammalian Toxicity/Pathogenicity/Infectivity \(February 1996\)](#) 
- [885.3050 - Acute Oral Toxicity/Pathogenicity \(February 1996\)](#) 
- [885.3100 - Acute Dermal Toxicity/Pathology \(February 1996\)](#) 
- [885.3150 - Acute Pulmonary Toxicity/Pathogenicity \(February 1996\)](#) 
- [885.3200 - Acute Injection Toxicity/Pathogenicity \(February 1996\)](#) 
- [885.3400 - Hypersensitivity Incidents \(February 1996\)](#) 
- [885.3500 - Cell Culture \(February 1996\)](#) 
- [885.3550 - Acute Toxicology, Tier II \(February 1996\)](#) 
- [885.3600 - Subchronic Toxicity/Pathogenicity \(February 1996\)](#) 
- [885.3650 - Reproductive/Fertility Effects \(February 1996\)](#) 

Group D – Nontarget Organism and Environmental Expression Test Guidelines

- [885.4000 - Background for Nontarget Organism Testing of Microbial Pest Control Agents \(February 1996\)](#) 
- [885.4050 - Avian Oral, Tier I \(February 1996\)](#) 
- [885.4100 - Avian Inhalation Test, Tier I \(February 1996\)](#) 
- [885.4150 - Wild Mammal Testing, Tier I \(February 1996\)](#) 
- [885.4200 - Freshwater Fish Testing, Tier I \(February 1996\)](#) 
- [885.4240 - Freshwater Aquatic Invertebrate Testing, Tier I \(February 1996\)](#) 
- [885.4280 - Estuarine and Marine Animal Testing, Tier I \(February 1996\)](#) 
- [885.4300 - Nontarget Plant Studies, Tier I \(February 1996\)](#) 
- [885.4340 - Nontarget Insect Testing, Tier I \(February 1996\)](#) 
- [885.4380 - Honey Bee Testing, Tier I \(February 1996\)](#) 
- [885.4600 - Avian Chronic Pathogenicity and Reproduction Test, Tier III \(February 1996\)](#) 
- [885.4650 - Aquatic Invertebrate Range Testing, Tier III \(February 1996\)](#) 
- [885.4700 - Fish Life Cycle Studies, Tier III \(February 1996\)](#) 
- [885.4750 - Aquatic Ecosystem Test \(February 1996\)](#) 

Appropriate Units

Environmental exposure

Use description
● Good agricultural practices (GAP). USE 1

Parent / metabolite
parent

Substance

Route of exposure
incorporation

Method of calculation
CFU per soil unit

PEC ⓘ ^

10000000	other: ▼	Add other
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press Esc to close

Move of data points

Appropriate Units

Tox and ecotox

Nominal and measured concentrations

- Nominal test concentrations: 1×10^4 , 1×10^5 , 1×10^6 , 1×10^7 , and 1×10^8 spores/g in diet. 1.1×10^2 , 1.1×10^3 , 1.1×10^4 , 1.1×10^5 , and 1.1×10^6 (Expected CFU in diet).

Results and discussion

Effect concentrations

+ New item

Import file

#	Key result	Duration	Dose descrip...	Effect conc.	95% CI	Nominal / m...	Conc. based ...	Life stage	Basis for eff...	Remarks on ...	Actions
1	<input type="checkbox"/>	10 d	NOEC	ca. 1000000000 other: spores/kg diet (migrated information)		nominal	act. ingr.		behaviour		
2	<input checked="" type="checkbox"/>	10 d	LC50	> 100000000000 other: spores/kg diet (migrated information)		nominal	act. ingr.		mortality		

- Endpoint study summary template: information required for chemical safety assessment (header).
- a new box requiring data on studies. For most datapoints 3 requirements on short term, long term and higher tier studies. This is totally non-relevant for m.o.
- The dose descriptor is for lethal/toxic effects which is not appropriate for m.o. where infectivity/pathogenicity is the relevant endpoint. Entrance/units not appropriate.

The IUCLID set up as it was, was much more appropriate.

Data descriptor

Key value for chemical safety assessment

Birds – short-term

[Link to relevant study record\(s\)](#)

Dose descriptor

Effect concentration

Birds – long-term

[Link to relevant study record\(s\)](#)

Dose descriptor

Effect concentration

Higher tier testing

[Link to relevant study record\(s\)](#)

[Key information from higher tier testing](#)

Data descriptor

Key value for chemical safety assessment

Toxicity to bees – acute oral

[Link to relevant study record\(s\)](#)

Dose descriptor

Effect concentration

Toxicity to bees – acute contact

[Link to relevant study record\(s\)](#)

Dose descriptor

Effect concentration

Toxicity to bees – chronic

[Link to relevant study record\(s\)](#)

Dose descriptor

Effect concentration

Toxicity to bee larvae – chronic

[Link to relevant study record\(s\)](#)

➤ Submitting issues

For applicants dependent on using the cloud

- ✓ The IUCLID cloud is not updated to the latest version
- ✓ Submission portal is the latest version
 - Not possible to submit dossier (version updated)
 - Business rules that need to be solved

Work around

- use the test portal
- see the BR and QLT
- go to the dataset and adapt
- generate dossier, create i6z file, upload in trial submission portal, submit again

This action cost like 20 minutes per cycle. As it appears hard to solve all issues at once (more colleagues on one dossier) it takes a lot of time

Message from ECHA:

Update of cloud version foreseen for the end of June only

Horror for dossiers ongoing with current short deadlines

Desktop version not solution with multiple experts

- Issues with existing dossiers after update
 - ✓ The algorithm applied seems not appropriate.
Especially with the update to the new DR for m.o. in 2023
 - ✓ Studies did not only end in obsolete but additionally in other sections. Some studies can be found multiple times at unlogic sections and headers.

- For applicants each service update of IUCLID causes issues
 - the burden is huge
 - version control requirement stressed again
- Turnaround time of dossiers must be shortened to avoid multiple updates
- Changes to regulations should be better prepared before release



Thank you!

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