



IUCLID for microbial active substances



Working context

EU PPP Microorganisms - active substance inf

Type at least 3 characters

- micro-adi
 - 1 Identity of the applicant, identity of the active substance and manufacturing information
 - 2 Biological properties of the microorganism
 - Biological properties of the microorganism.001**
 - 2.1 (Cf. 2) Origin, occurrence and history of use
 - 2.1.1 (Cf. 2) Origin and isolation source
 - 2.1.2 (Cf. 2) Occurrence
 - 2.1.3 (Cf. 2) History of use
 - 2.2 (Cf. 2) Ecology and life cycle of the microorganism
 - 2.3 (Cf. 3.1) Mode of action on the target organism and host range
 - 2.4 (Cf. 2) Growth requirements
 - 2.5 (Cf. 2) Infectivity to the target organism
 - 2.6 (Cf. 2) Relationship to known human pathogens and to pathogens to non-target organisms
 - 2.7 (Cf. 2) Genetic stability and factors affecting it
 - 2.8 (Cf. 2 and product dataset 1.4.1) Information on metabolites of concern
 - 2.9 (Cf. 2) Presence of transferable

Biological properties of the microorganism.001

UUID: de55024d-e119-4923-9f24-50b637ca6232



- Administrative data
- Biological properties of th...
- Effectiveness against ta...
- Measures necessary to protect humans, ani...
- Classification & Labelling of the microorgani...
- Biological properties of the microorganis...

Administrative data

Biological properties of the microorganism

General information on the microorganism

Type of microorganisms

Strain characteristics

Reference

Data access

Data protection claimed

Historical background

Taxonomic level

Reference

Data access

Save

> **1 Identity of the applicant, identity of the active substance and manufacturing information** 1

∨ **2 Biological properties of the microorganism** 1

⋮ ● Biological properties of the microorganism.001

∨ 2.1 (Cf. 2) Origin, occurrence and history of use

2.1.1 (Cf. 2) Origin and isolation source

2.1.2 (Cf. 2) Occurrence

2.1.3 (Cf. 2) History of use

2.2 (Cf. 2) Ecology and life cycle of the microorganism

2.3 (Cf. 3.1) Mode of action on the target organism and host range

2.4 (Cf. 2) Growth requirements

2.5 (Cf. 2) Infectivity to the target organism

2.6 (Cf. 2) Relationship to known human pathogens and to pathogens to non-target organisms

2.7 (Cf. 2) Genetic stability and factors affecting it

2.8 (Cf. 2 and product dataset 1.4.1) Information on metabolites of concern

2.9 (Cf. 2) Presence of transferable antimicrobial resistance genes

Administrative data

Biological properties of th...

Effectiveness against ta...

Measures necessary to protect humans, ani...

Classification & Labelling of the microorgani...

Historical background

Taxonomic level ⓘ ^ ⓘ ^

Please select

Reference

Data access

Data protection claimed

Historical uses

Taxonomic level

QPS status

Reference

Data access

Data protection claimed

> 1 Identity of the applicant, identity of the active substance and manufacturing information 1

2 Biological properties of the microorganism 1

Biological properties of the microorganism.001

2.1 (Cf. 2) Origin, occurrence and history of use

2.1.1 (Cf. 2) Origin and isolation source

2.1.2 (Cf. 2) Occurrence

2.1.3 (Cf. 2) History of use

2.2 (Cf. 2) Ecology and life cycle of the microorganism

2.3 (Cf. 3.1) Mode of action on the target organism and host range

2.4 (Cf. 2) Growth requirements

2.5 (Cf. 2) Infectivity to the target organism

2.6 (Cf. 2) Relationship to known human pathogens and to pathogens to non-target organisms

2.7 (Cf. 2) Genetic stability and factors affecting it

2.8 (Cf. 2 and product dataset 1.4.1) Information on metabolites of concern

2.9 (Cf. 2) Presence of transferable antimicrobial resistance genes

Administrative data

Biological properties of th...

Effectiveness against ta...

Measures necessary to protect humans, ani...

Classification & Labelling of the microorgani...

Biological

Origin, natural occurrence and geographical distribution

[Occurrence in water](#)

[Occurrence in soil](#)

[Occurrence in rhizosphere](#)

[Occurrence in phyllosphere](#)

[Occurrence in host organisms](#)

[Occurrence in food or feed](#)

[Food or feed matrix](#)

[Reference](#)

[Data access](#)

[Data protection claimed](#)

Development stages / life cycle of the microorganism

2 Biological properties of the microorganism 1

Biological properties of the microorganism.001

2.1 (Cf. 2) Origin, occurrence and history of use

2.1.1 (Cf. 2) Origin and isolation source

2.1.2 (Cf. 2) Occurrence

2.1.3 (Cf. 2) History of use

2.2 (Cf. 2) Ecology and life cycle of the microorganism

2.3 (Cf. 3.1) Mode of action on the target organism and host range

2.4 (Cf. 2) Growth requirements

2.5 (Cf. 2) Infectivity to the target organism

2.6 (Cf. 2) Relationship to known human pathogens and to pathogens to non-target organisms

2.7 (Cf. 2) Genetic stability and factors affecting it

2.8 (Cf. 2 and product dataset 1.4.1) Information on metabolites of concern

2.9 (Cf. 2) Presence of transferable antimicrobial resistance genes

Development stages / life cycle of the microorganism

Life cycle

Reference

Data access

Data protection claimed

Relationships to known plant or animal or human pathogens

Related to known pathogens

Phylogenic tree

Reference

Data access

Data protection claimed

Genetic stability and factors affecting it

Robustness to environmental factors

Temperature range for growth (°C)

Generation time

Reference

Data access

Data protection claimed

Further information on the microorganism

Taxonomic level

Reference

Data access

Data protection claimed

Effectiveness against target organisms

Infectiveness, dispersal and colonisation ability

[Infectivity to the target organism](#)

[Reference](#)

[Data access](#)

[Data protection claimed](#)

Methods to prevent loss of virulence of seed stock of the microorganism

[Reference](#)

[Data access](#)

[Data protection claimed](#)

Measures necessary to protect humans, animals and the environment

Monitoring plan to be used for the active microorganism including handling, storage, transport and use

From the explanatory notes PAFF-PPL-October 2023-Doc.A.07.01

As example

- All data requirements where the requested information is not necessary 'owing to the nature of the PPP or its proposed uses, or it is not scientifically necessary, or it is technically not possible to supply' (point 1.5 of the introduction to the Annex of Regulation (EU) No 283/2013).
- According to the uniform principles the biological properties and the mode of action of a micro-organism are the first and crucial step in the evaluation process, because they define which are the aspects and elements on which the evaluation should focus, and also which aspects are not relevant for this specific micro-organism. The information provided in this Section can be used as (part of) a justification, by following a weight of evidence approach, to address certain points in other sections of the evaluation.
- From the dRR template on products example: A summary on potential infectivity and pathogenicity of the micro-organism to birds shall be provided, based on experimental data and/or the information already provided under Sections 1 (Identity), 2 (Biological properties), 3 (Further information), 5 (Effect on human health) and 7 (Environmental occurrence of the micro-organism) and that information which may be retrieved from any other reliable source.

This stresses the importance of the section and due to the unclarities mentioned by me before we would like to stress once again the importance of splitting into numbers as to the respective data requirement

Content of the active substance

Units:

- CFU
- IU
- ITU
- Spores
- Cells
- OB
- Genome copies

Issues with validation if the appropriate unit is introduced via option „Other“

Working context

EU PPP Microorganisms - active substance ap

Type at least 3 characters

EU PPP Microorganisms - active substance application (product)

test Adi

1 Identity of the applicant, identity of the plant protection product and manufacturing information

1.1 Applicant, trade name or proposed trade name

1.2 Producer of the preparation and the microorganism(s)

1.3 Producer's development code number of the preparation if appropriate

1.4 Detailed quantitative and qualitative information on the composition of the preparation

Detailed quantitative and qualitative information on the composition of the preparation.001

micro-adi

1.4.1 Information on metabolites

Information on metabolites.001

1.4.2 Other representative products

1.4.3 Impurities

1.5 (Cf. 1.4) Physical state and nature of the preparation

1.6 Method of production of the preparation and quality control

Information on metabolites.001

UUID: e57cb6a9-614b-4227-8d9d-26b45e4ab7db

Metabolites information List of metabolites

Metabolites information

Metabolites information overview
table from lit search
Parent of metabolites

List of metabolites

Metabolites + New item Import file

	Link to metabolite dataset	Remarks	Toxicological assessment	The metabolite is claimed active metabolite	Metabolite WGS-evidence	Actions
1	Metabolite B	from the tox and ecotox assessment no indication of adverse effects	metabolite of no concern (NoC)	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
2	Metabolite C Metabolite not produced by strain	no toxicological hazard no environmental exposure not present in the product	metabolite of potential concern (MoPC)	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
3	Metabolite A	not present in the product	metabolite of potential concern (MoPC)	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	

Save