

IUCLID for microbial active substances



➤ Validation rules for micro's

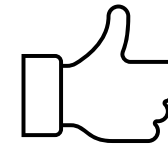
- Not always appropriate IUCLID entrance level checked
 - **BR_PPP_015** Section <x.x>: At least one endpoint study record indicated as either a key study, weight of evidence, or data waiving must be provided for this section. Supporting studies should be provided as appropriate, as additional endpoint study records, but they cannot be used to fulfil the information requirement. - To indicate an endpoint study record as a key study or as part of a weight of evidence approach, select 'key study' or 'weight of evidence' in the 'adequacy of study' picklist and fill in all relevant fields under 'Administrative data', 'Data source', 'Materials and methods', and 'Results and discussion' for this endpoint. Other types of study summaries (e.g., Supporting studies) should be filled in as much as possible. - To indicate an endpoint study record as data waiving, make a selection in the field 'Data waiving' and provide a justification in the field 'Justification for data waiving'.

Business rules for less relevant input

- E.g endpoint summary required for data requirement (DR) with only waivers **BR_PPP_016**

Need for update of report generator for microbial dossiers

- Section toxicology has different numbering and content than data requirements
- Section residues: the IUCLID entrance is not reflected in report
- Related to slide above; OHT format for publications
- With rtf output report can be edited in Word



Report generator

measures		
>	5.1.2 Medical surveillance	1
>	5.1.3 Information on sensitisation / allergenicity	1
>	5.1.4 Direct observation	1
✓	5.2 Assessment on potential infectivity and pathogenicity of the microorganism to humans	1
>	Assessment on potential infectivity and pathogenicity of the microorganism to humans	
✓	5.3 Infectivity and pathogenicity studies on the microorganism	6
✓	5.3.1 Infectivity and pathogenicity	5
>	Infected and pathogenicity.001	
>	5.3.1.1 Oral infectivity and pathogenicity	2
>	5.3.1.2 Intratracheal / intranasal infectivity and pathogenicity	1
>	5.3.1.3 Intravenous / intraperitoneal or subcutaneous single exposure	1
>	5.3.2 Cell culture study	1
	5.4 (Cf. 5.3.1.3) Specific infectivity and pathogenicity studies on the microorganism	
✓	5.5 Information and toxicity studies on metabolites	1
>	5.5.1 Information and toxicity of metabolites	1
	5.5.2 (Cf. metabolite dataset, 5) Additional toxicity studies on metabolites of concern	
B.6. Toxicology and metabolism data.....→		
B.6.1. Basic information.....→		
B.6.1.1. Medical data.....→		
B.6.1.2. Medical surveillance on manufacturing plant personnel.....→		
B.6.1.3. Sensitisation/allergenicity observations, if appropriate.....→		
B.6.1.4. Direct observation, e.g. clinical cases.....→		
B.6.2. Basic studies.....→		
B.6.2.1. Sensitisation.....→		
B.6.2.2. Acute toxicity, pathogenicity and infectiveness.....→		
B.6.2.2.1. Acute oral toxicity, pathogenicity and infectiveness.....→		
B.6.2.2.2. Acute inhalation toxicity, pathogenicity and infectiveness.....→		
B.6.2.2.3. Intraperitoneal/subcutaneous single dose.....→		
B.6.2.3. Genotoxicity testing.....→		
B.6.2.3.1. In vitro studies.....→		
B.6.2.4. Cell culture study.....→		
B.6.2.5. Information on short-term toxicity and pathogenicity.....→		
B.6.2.5.1. Health effects after repeated inhalatory exposure.....→		
B.6.2.5.2. Health effects after repeated exposure by other routes.....→		
B.6.2.6. Proposed treatment: first aid measures, medical treatment.....→		
B.6.3. Specific toxicity, pathogenicity and infectiveness studies.....→		
B.6.4. In vivo studies in somatic cells.....→		
B.6.5. Genotoxicity - In vivo studies in germ cells.....→		
B.6.6. Summary of mammalian toxicity, pathogenicity and infectiveness and overall evaluation.....→		
B.6.7. REFERENCES RELIED ON.....→		

- In line with the current data requirements some points are no longer in IUCLID but still in report generator (genotoxicity)
- Point 5.2 on infectivity and pathogenicity to humans is missing in the report!

Report generator

✓	6 Residues in or on treated articles, food and feed	18
✓	6.1 Estimation of consumer exposure to residues	2
	<div> <div>⋮</div> <div>Σ</div> </div> Estimation of consumer exposure to residues_SecMetB	
	<div> <div>⋮</div> <div>Σ</div> </div> Estimation of consumer exposure to residues.002	
>	6.2 Further information required	16
>	7 Environmental occurrence of the microorganism, including fate and behaviour of metabolites of concern	10

B.7. RESIDUE DATA

B.7.1. PERSISTENCE AND LIKELIHOOD OF MULTIPLICATION IN OR ON CROPS, FEEDINGSTUFFS OR FOODSTUFFS




Summary

Studies

No individual studies available for migration of residues.

❖ The entrance is not reflected

Report generator

✓	6.2 Further information required	16
✓	6.2.1 Storage stability of residues	2
>	 Storage stability of residues.001	
	 Justification-Non-submission_ storage stability of residues	
>	6.2.2 Magnitude of residues in plants and in rotational crops	2
>	6.2.3 Magnitude of the residues in processed commodities	3
>	6.2.4 Feeding studies	2
>	6.2.5 Proposed residue definitions	2
>	6.2.6 Proposed maximum residue levels	1
>	6.2.7 Effect on the residue level in pollen and bee products	2
>	6.2.8 Other studies	

DR 2023: 6.2 Data generation on residues

B.7.2. FURTHER INFORMATION REQUIRED

B.7.2.1. Viable and non-viable residues

B.7.2.1.1. Magnitude of residues in plants



Old DR

Summary

B.7.2.1.2. Magnitude of residues in processed commodities

B.7.2.2. Additional information on residues in food and feedingstuffs

Summary

In the surface tension summary record, only a single value for the surface tension can be added (under key value for chemical safety assessment), while often, there are more. The same for viscosity.


For the surface tension, the concentration has to be indicated, but you can only pick $\mu\text{g/L}$, mg/L or g/L , which is far too limited. Percentages, either % w/w, % w/v or % v/v should be allowed.

Key value for assessment

Surface tension

at the temperature of

Critical micelle concentration (CMC)

at the concentration of  ^

Non-GLP studies:

- In study records, under 'data source' you can indicate data access and data protection claimed. For data protection claimed there is no option 'no' or 'not applicable'.
- It is needed for non-GLP studies.

Thank you!

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