



**FEEDBACK FROM MEMBER STATES
IUCLID PSN MEETING
11-12 MARCH 2025**

FEEDBACK FROM DE

- Generate Report - Document L (List of Literature References)

Missing information:

It is evident that the column 'Vert. study Y or N' remains empty throughout the document.

IUCLID section (endpoint)	Author(s)	Year	Title Report No. Document No. Source, where different from company GLP Published or not	Vert. study Y/N	Owner	Data protectio n Y/N	Justification if data protection is claimed	Previously used Y/N
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FEEDBACK FROM DE

- Missing information:
 - Neither designated picklist under 'Test animals' for 'Vert. Study - Y/N'
 - Nor automatic assignment upon picklist in the field of 'Species', 'Strain', etc.

5.3.1.1 Oral infectivity and pathogenicity1

5.3.1.1.1 Oral infectivity and pathogenicity_1989_MA 5.3.1.1/01_521-003

ACUTE ORAL TOXICITY/PATHOGENICITY STUDY IN RATS

5.3.1.2 Intratracheal / intranasal infectivity and pathogenicity1

5.3.1.3 Intravenous / intraperitoneal or subcutaneous single exposure4

5.3.2 Cell culture study1

5.4 (Cf. 5.3.1.3) Specific infectivity and pathogenicity studies on the microorganism

5.5 Information and toxicity studies on metabolites1

5.6 Additional toxicological information1

6 Residues in or on treated articles, food and feed6

7 Environmental occurrence of the microorganism, including fate and behaviour of metabolites of concern9

Test animals

Species ⓘ ⓘ ⓘ
Field identifier: ENDPOINT_STUDY_RECORD.AcuteToxicityOral.MaterialsAndMethods.TestAnimals.Species
Field type: Picklist (T02-1)
rat [common species]

Strain ⓘ ⓘ ⓘ
Field identifier: ENDPOINT_STUDY_RECORD.AcuteToxicityOral.MaterialsAndMethods.TestAnimals.Strain
Field type: Picklist (T23-123456)
Wistar [rat]

Sex
male/female

Details on test animals or test system and environmental conditions

TEST ANIMALS

- Age at study initiation: Not reported

- Weight at study initiation: Males: 100 - 120 g, Females: 80 - 100 (at administration)

- Fasting period before study: Animals were fasted overnight (approx. 18 hours) prior to treatment

- Housing: Single housing in polycarbonate cages with stainless steel mesh lid and floor in a laminar air flow rack.

- Diet: Ad libitum, Brood Stock Feed for Rats and Mice R3

- Water: Ad libitum, tap water from domestic supply acidified to approx. pH 3.

- Acclimation period: 11 days



FEEDBACK FROM DE

- Generate Report: Document L (List of Literature References) – sorted by Section

Table 1.1. Table of Literature References

IUCLID section (endpoint)	Author(s)	Year	Title Report No. Document No. Source, where different from company GLP Published or not	Vert. study Y/N	Owner	Data protecti on Y/N	Justification if data protection is claimed	Previously used Y/N
5.1.2 Medical surveillance (health surveillance data)	[REDACTED]	2024	MEMORANDUM [REDACTED] EMPLOYEES HEALTH EFFECTS Report No. not provided PP194-00015_574-001 not applicable GLP: no Unpublished (study report)		[REDACTED]	Y	Not previously submitted	N (new)
5.3.1.1 Oral infectivity and pathogenicity (acute toxicity: oral)	[REDACTED]	1989	ACUTE ORAL TOXICITY/PATHOGENICITY STUDY IN RATS [REDACTED] PP194-00015_521-003 [REDACTED] GLP: yes (incl. QA statement) Unpublished (study report)		[REDACTED]	N		Y (previously used) - evaluated for DAR 2007

N

Y



FEEDBACK FROM DE

Questions:

- How should RMS address this issue during the Admissibility Check?
- What is the anticipated approach by EFSA in this regard?



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