



**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



# 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 pathogenicity	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 pathogenicity	1
5.3.1.3 Intravenous / intraperitoneal or subcutaneous single exposure	4
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
5.6 Additional toxicological information	1
6 Residues in or on treated articles, food and feed	6
7 Environmental occurrence of the microorganism, including fate and behaviour of metabolites of concern	9

**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 protection Y/N	Justification if data protection is claimed	Previously used Y/N
---------------------------	-----------	------	--	-----------------	-------	---------------------	---	---------------------

5.1.2 Medical surveillance (health surveillance data)	[REDACTED]	2024	<u>MEMORANDUM</u> <u>EMPLOYEES HEALTH EFFECTS</u> Report No. not provided PP194-00015_574-001 not applicable GLP: no Unpublished (study report)	[REDACTED]	[REDACTED]	Y	Not previously submitted	N (new)
5.3.1.1 Oral infectivity and pathogenicity (acute toxicity: oral)	[REDACTED]	1989	<u>ACUTE ORAL</u> <u>TOXICITY/PATHOGENICITY STUDY</u> IN RATS PP194-00015_521-003 [REDACTED] GLP: yes (incl. QA statement) Unpublished (study report)	[REDACTED]	[REDACTED]	N	Y (previously used) - evaluated for DAR 2007	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?



# STAY CONNECTED

SUBSCRIBE TO  
[efsa.europa.eu/en/news/newsletters](http://efsa.europa.eu/en/news/newsletters)  
[efsa.europa.eu/en/rss](http://efsa.europa.eu/en/rss)  
[Careers.efsa.europa.eu](http://Careers.efsa.europa.eu) – job alerts

FOLLOW US ON TWITTER  
[@efsa\\_eu](https://twitter.com/efsa_eu)      [@plants\\_efsa](https://twitter.com/plants_efsa)  
[@methods\\_efsa](https://twitter.com/methods_efsa)      [@animals\\_efsa](https://twitter.com/animals_efsa)

FOLLOW US ON INSTAGRAM  
[@one\\_healthenv\\_eu](https://www.instagram.com/one_healthenv_eu)

LISTEN TO OUR PODCAST  
Science on the Menu –Spotify, Apple Podcast and YouTube

FOLLOW US ON LINKEDIN  
[Linkedin.com/company/efsa](https://www.linkedin.com/company/efsa)

CONTACT US  
[efsa.europa.eu/en/contact/askefsa](http://efsa.europa.eu/en/contact/askefsa)