



CONSEIL DE L'EUROPE

Pyrantel impurity C

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878 Issue date: 03/04/2023 Version: 1.0

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier Product form : Substance : Pyrantel impurity C Substance name Product code 201900032 ÷ 1.2. Relevant identified uses of the substance or mixture and uses advised against 1.2.1. Relevant identified uses : The product is intended for research, analysis and scientific education. Main use category Use of the substance/mixture : For professional use only : Laboratory chemicals Function or use category 1.2.2. Uses advised against Restrictions on use : Do not use : Ingestion, Inhalation, Dermal 1.3. Details of the supplier of the safety data sheet European Directorate for the Quality of Medicines & Healthcare EDQM, Council of Europe 7, Allée Kastner, CS30026 F-67081 Strasbourg France T +33(0)388412035 - F +33(0)388412771 sds@edqm.eu - www.edqm.eu 1.4. Emergency telephone number : +33(0)390215608 Emergency number

SECTION 2: Hazards identification	n
2.1. Classification of the substance of	or mixture
Classification according to Regulation (E	C) No. 1272/2008 [CLP]
Acute toxicity (oral), Category 4 Skin corrosion/irritation, Category 2 Serious eye damage/eye irritation, Category Full text of H- and EUH-statements: see sec	
Adverse physicochemical, human health Expert judgement and weight of evidence de	
2.2. Label elements	
Labelling according to Regulation (EC) N Hazard pictograms (CLP)	
Signal word (CLP) Hazard statements (CLP)	GHS07 : Warning : H302 - Harmful if swallowed. H315 - Causes skin irritation. H319 - Causes serious eye irritation.
Precautionary statements (CLP)	 P301+P312 - IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell. P352 - Wash with plenty of soap and water.

Labelling according to: exemption for inner packaging where the contents do not exceed 10ml

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No labelling required

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substances

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Pyrantel impurity C	-	≤ 100	Acute Tox. 4 (Oral), H302 (ATE=300 mg/kg bodyweight) Skin Irrit. 2, H315 Eye Irrit. 2, H319

Full text of H- and EUH-statements: see section 16

3.2. Mixtures

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures First-aid measures after skin contact : Wipe off as much as possible (using a clean, soft, absorbent material). First-aid measures after eye contact : Rinse eyes with water as a precaution.

4.2. Most important symptoms and effects, both acute and delayed

No additional information available

4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

SECTION 5: Firefighting measures	
5.1. Extinguishing media	
Suitable extinguishing media	: Extinguishing blanket.
5.2. Special hazards arising from the substant	nce or mixture
Fire hazard	: See Heading 2.2.
5.3. Advice for firefighters	
Firefighting instructions	: Use extinguishing media appropriate for surrounding fire.
SECTION 6: Accidental release measure	'S

SECTION 6: Accidental release measures	
6.1. Personal precautions, protect	ctive equipment and emergency procedures
6.1.1. For non-emergency personnel	
Emergency procedures	: Avoid all unnecessary exposure.
6.1.2. For emergency responders	
No additional information available	

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6.2. Environmental precautions

No additional information available

6.3. Methods and material for containment and cleaning up

No additional information available

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling

No additional information available

7.2. Conditions for safe storage, including any incompatibilities

No additional information available

7.3. Specific end use(s)

See Heading 1.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

No additional information available

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate engineering controls:

Keep in a well-ventilated room. Both local exhaust and general room ventilation are usually required.

8.2.2. Personal protection equipment

8.2.2.1. Eye and face protection

No additional information available

8.2.2.2. Skin protection

Skin and body protection: Lab coat

Hand protection: Protective gloves

8.2.2.3. Respiratory protection

No additional information available

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8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

No additional information available

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Colour	: Not available
Odour	: Not available
Odour threshold	: Not available
Melting point	: Not available
Freezing point	: Not available
Boiling point	: Not available
Flammability	: Not available
Explosive limits	: Not available
Lower explosion limit	: Not available
Upper explosion limit	: Not available
Flash point	: Not available
Auto-ignition temperature	: Not available
Decomposition temperature	: Not available
рН	: Not available
Viscosity, kinematic	: Not available
Solubility	: Not available
Partition coefficient n-octanol/water (Log Kow)	: Not available
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Density	: Not available
Relative density	: Not available
Relative vapour density at 20°C	: Not available
Particle characteristics	: Not applicable

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

No additional information available

SECTION 10: Stability and reactivity 10.1. Reactivity Stable under normal conditions. 10.2. Chemical stability No additional information available 10.3. Possibility of hazardous reactions None known. 10.4. Conditions to avoid No additional information available

10.5. Incompatible materials

None under normal use. See Section 7.

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10.6. Hazardous decomposition products

When heated to decomposition, emits dangerous fumes.

SECTION 11: Toxicological information	
11.1. Information on hazard clas	sses as defined in Regulation (EC) No 1272/2008
Acute toxicity (oral)	: Harmful if swallowed.
Acute toxicity (dermal)	: Not classified
Acute toxicity (inhalation)	· Not classified

Acute toxicity (inhalation)	: Not classified
Pyrantel impurity C	
LD50 oral rat	300 – 2000 mg/kg
Skin corrosion/irritation	: Causes skin irritation.
Serious eye damage/irritation	: Causes serious eye irritation.
Respiratory or skin sensitisation	: Not classified (Lack of data)
Germ cell mutagenicity	: Not classified (Based on available data, the classification criteria are not met)
Carcinogenicity	: Not classified (Based on available data, the classification criteria are not met)
Reproductive toxicity	: Not classified (Further details: Acute toxicity)
STOT-single exposure	: Not classified (Lack of data)
STOT-repeated exposure	: Not classified (Lack of data)
Aspiration hazard	: Not classified (Lack of data)

11.2. Information on other hazards

No additional information available

SECTION 12: Ecological information	
12.1. Toxicity	
Ecology - general Hazardous to the aquatic environment, short-term (acute) Hazardous to the aquatic environment, long-term (chronic)	 Presents no specific risk for the environment. Not classified Not classified
12.2. Persistence and degradability	
No additional information available	
12.3. Bioaccumulative potential	
No additional information available	
12.4. Mobility in soil	
No additional information available	
12.5. Results of PBT and vPvB assessment	
No additional information available	
12.6. Endocrine disrupting properties	
No additional information available	
12.7. Other adverse effects	
No additional information available	

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SECTION 13: Disposal considerations

13.1. Waste treatment methods

No additional information available

SECTION 14: Transport information

n accordance with ADR / IMDG / IATA		
ADR	IMDG	ΙΑΤΑ
14.1. UN number or ID number		
Not applicable	Not applicable	Not applicable
14.2. UN proper shipping name		
Not applicable	Not applicable	Not applicable
14.3. Transport hazard class(es)		
Not applicable	Not applicable	Not applicable
14.4. Packing group		
Not applicable	Not applicable	Not applicable
14.5. Environmental hazards		1
Not applicable	Not applicable	Not applicable
No supplementary information available		1

14.6. Special precautions for user

Overland transport Not applicable

Transport by sea Not applicable

Air transport

Not applicable

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

15.1.1. EU-Regulations

REACH Annex XVII (Restriction List)

Not listed on REACH Annex XVII

REACH Annex XIV (Authorisation List)

Not listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Not listed on the REACH Candidate List

PIC Regulation (Prior Informed Consent)

Not applicable.

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POP Regulation (Persistent Organic Pollutants)

Not applicable.

Ozone Regulation (1005/2009)

Not listed on the Ozone Depletion list (Regulation EU 1005/2009)

Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No additional information available

SECTION 16: Other information

Full text of H- and EUH-statements:

Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
H302	Harmful if swallowed.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
Skin Irrit. 2	Skin corrosion/irritation, Category 2

Safety Data Sheet (SDS), EU

DISCLAIMER OF LIABILITY The EDQM has created this SDS as a downstream user for regulatory compliance to rules applicable to chemicals only. This article is intended only for small-volume laboratory analysis and other routine testing prescribed in the pharmacopoeia or EDQM study protocol, under controlled conditions and by professionals only. Any other use of this article or the SDS information is the sole responsibility of the user. This substance is present in articles in quantities totalling under 10 kg per year. There is no human or environmental exposure under intended and foreseeable conditions of use. The user has the responsibility for handling, storage, use conditions and disposal of this article and for any use of the information in this SDS. The information has been obtained from suppliers and is without any warranty, express or implied, regarding its correctness. For this and other reasons, we do not assume responsibility and expressly disclaim liability for loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of the article.