



CONSEIL DE L'EUROPE

# Trimethoprim

## 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 name Product code Synonyms	<ul> <li>Substance</li> <li>Trimethoprim</li> <li>201600932</li> <li>Trimethoprim, salts, hydrates, isomers and impurities where applicable</li> </ul>
1.2. Relevant identified uses of the substa	ince or mixture and uses advised against
1.2.1. Relevant identified uses	
Main use category Use of the substance/mixture Function or use category	<ul> <li>The product is intended for research, analysis and scientific education.</li> <li>For professional use only</li> <li>Laboratory chemicals</li> </ul>
1.2.2. Uses advised against	
Restrictions on use	: Do not use : Ingestion, Inhalation, Dermal
1.3. Details of the supplier of the safety da	ata sheet
European Directorate for the Quality of Medicines a EDQM, Council of Europe 7, Allée Kastner, CS300 E- 67081 Strasbourg	

F- 67081 Strasbourg France T +33(0)388412035 - F +33(0)388412771

<u>sds@edqm.eu</u> - <u>www.edqm.eu</u>

1.4. Emergency telephone number

Emergency number

: +33(0)390215608

## **SECTION 2: Hazards identification**

### Classification according to Regulation (EC) No. 1272/2008 [CLP]

Respiratory sensitisation, Category 1	H334
Skin sensitisation, Category 1	H317
Reproductive toxicity, Category 2	H361d
Hazardous to the aquatic environment – Chronic Hazard, Category 3	H412
Full text of H- and EUH-statements: see section 16	

#### Adverse physicochemical, human health and environmental effects

Expert judgement and weight of evidence determination.

## 2.2. Label elements

Labelling according to Regulation (EC) N	lo. 1272/2008 [CLP]
Hazard pictograms (CLP)	
Signal word (CLP)	GHS08 : Danger
Hazard statements (CLP)	: H317 - May cause an allergic skin reaction.
Tiazaiù statements (GLF)	<ul> <li>H317 - May cause all allergic skill reaction.</li> <li>H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.</li> <li>H361d - Suspected of damaging the unborn child.</li> <li>H412 - Harmful to aquatic life with long lasting effects.</li> </ul>
Precautionary statements (CLP)	: P201 - Obtain special instructions before use.
	P202 - Do not handle until all safety precautions have been read and understood.

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P261 - Avoid breathing dust/fume/gas/mist/vapours/spray.

- P272 Contaminated work clothing should not be allowed out of the workplace.
- P273 Avoid release to the environment.

P280 - Wear protective gloves/protective clothing/eye protection/face protection.

P284 - Wear respiratory protection.

P302+P352 - IF ON SKIN: Wash with plenty of water.

P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P308+P313 - IF exposed or concerned: Get medical advice/attention.

P321 - Specific treatment (see supplemental first aid instruction on this label).

P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.

P342+P311 - If experiencing respiratory symptoms: Call a POISON CENTER or doctor.

- P362+P364 Take off contaminated clothing and wash it before reuse.
- P405 Store locked up.

P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

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

Hazard pictograms (CLP)



#### 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]
Trimethoprim	-	≤ 100	Resp. Sens. 1, H334 Skin Sens. 1, H317 Repr. 2, H361d Aquatic Chronic 3, H412

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 inhalation First-aid measures after skin contact	<ul> <li>Move to fresh air. Allow affected person to breathe fresh air.</li> <li>Wipe off as much as possible (using a clean, soft, absorbent material). Wash with plenty of water and detergent.</li> </ul>
First-aid measures after eye contact First-aid measures after ingestion	<ul> <li>Rinse with water while holding the eyes wide open.</li> <li>Rinse mouth. Specific medical surveillance. Prolonged medical observation may be indicated.</li> </ul>
4.2. Most important symptoms and ef	fects, both acute and delayed
Symptoms/effects Symptoms/effects after inhalation Symptoms/effects after skin contact	<ul> <li>Delayed adverse effects possible.</li> <li>Insufficient data available.</li> <li>Insufficient data available.</li> </ul>

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Symptoms/effects after ingestion

: Symptoms may include dizziness, headache, nausea and loss of coordination.

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

Get medical advice/attention. If possible show this sheet, if not available show packaging or label. Active substance. Pharmaceutical.

SECTION 5: Firefighting measu	ıres	
5.1. Extinguishing media		
Suitable extinguishing media	: Extinguishing blanket.	
5.2. Special hazards arising from the substance 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 measures		
6.1. Personal precautions, protective equipr	nent and emergency procedures	
General measures	: Avoid any direct contact with the product. Do not breathe dust/fume/gas/mist/vapours/spray.	
6.1.1. For non-emergency personnel		
Emergency procedures	: Wear suitable protective clothing, gloves and eye or face protection.	
6.1.2. For emergency responders		
No additional information available		
6.2. Environmental precautions		
No additional information available		
6.3. Methods and material for containment a	and cleaning up	
Methods for cleaning up	: Ensure waste is collected and contained. Clean thoroughly. Wash the non-recoverable remainder with : Sodium hypochlorite solution.	
6.4. Reference to other sections		
No additional information available		
SECTION 7: Handling and storage		

7.1. Precautions for safe handling	
Additional hazards when processed	: The attention of the user is drawn to the risks possibly incurred by using the product for any other purpose than that for which it was intended.
Precautions for safe handling	: Material should be handled with caution. Avoid any direct contact with the product. Material should be handled in a laboratory hood whenever possible.
Hygiene measures	: Handle in accordance with good industrial hygiene and safety procedures.
7.2. Conditions for safe storage, including a	any incompatibilities
Technical measures Storage conditions	<ul><li>Comply with applicable regulations.</li><li>Store locked up.</li></ul>
7.3. Specific end use(s)	

See Heading 1.

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#### **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. Use only in a exhaust booth with integrated air filter. High efficiency particulate air filter (HEPA filter).

8.2.2. Personal protection equipment

#### 8.2.2.1. Eye and face protection

#### Eye protection: Safety glasses. DIN EN 166

8.2.2.2. Skin protection

## Skin and body protection:

Use chemically protective clothing. DIN EN 13034

#### Hand protection:

Chemically resistant protective gloves. ISO 374-1

#### 8.2.2.3. Respiratory protection

#### **Respiratory protection:**

Dust production: dust mask with filter type P3. DIN EN 140 & 149. Liquid product : Aerosol mask. Wear breathing apparatus if exposed to vapours/dusts/aerosols

#### 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	: Solid	
Colour	: Not available	
Appearance	: Powder.	
Odour	: Not applicable.	
Odour threshold	: Not available	
Melting point	: Not available	
Freezing point	: Not available	

: Not available : Not available

: Not applicable

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Lower explosion limit	: Not applicable
Upper explosion limit	: Not applicable
Flash point	: Not applicable
Auto-ignition temperature	: Not applicable
Decomposition temperature	: Not available
рН	: Not available
pH solution	: Not available
Viscosity, kinematic	: Not applicable
Solubility	: Water: 0.1 – 1 g/l
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 applicable
Particle size	: Not available

#### 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

No additional information available

10.4. Conditions to avoid

No additional information available

**10.5. Incompatible materials** 

None under normal use. See Section 7.

**10.6. Hazardous decomposition products** 

When heated to decomposition, emits dangerous fumes.

## **SECTION 11: Toxicological information**

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008		
Acute toxicity (oral)	: Not classified	
Acute toxicity (dermal)	: Not classified	
Acute toxicity (inhalation)	: Not classified	
Skin corrosion/irritation	: Not classified (Lack of data)	
Serious eye damage/irritation	: Not classified (Lack of data)	
Respiratory or skin sensitisation	: May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction.	
Germ cell mutagenicity	: Not classified (Lack of data)	
Carcinogenicity	: Not classified (Lack of data)	

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Reproductive toxicity	: Suspected of damaging the unborn child.
STOT-single exposure	: Not classified (Lack of data)
STOT-repeated exposure	: Not classified (Lack of data)
Aspiration hazard	: Not classified (Based on available data, the classification criteria are not met)
11.2 Information on other herorde	

**11.2.** Information on other hazards

No additional information available

## **SECTION 12: Ecological information**

# 12.1. Toxicity Ecology - general : Hazardous waste. Use suitable disposal containers. Hazardous to the aquatic environment, short-term (acute) : Not classified Hazardous to the aquatic environment, long-term (chronic) : Harmful to aquatic life with long lasting effects. 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

SECTION 13: Disposal conside	erations
13.1. Waste treatment methods	
Regional legislation (waste)	: Dispose in a safe manner in accordance with local/national regulations.

## **SECTION 14: Transport information**

#### In 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		

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ADR	IMDG	ΙΑΤΑ		
14.4. Packing group				
Not applicable	Not applicable	Not applicable		
14.5. Environmental hazards				
Not applicable	Not applicable	Not applicable		
No supplementary information available				
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.

#### **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

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SECTION 16: Other information		
Full text of H- and EUH-statements:		
Aquatic Chronic 3	Hazardous to the aquatic environment – Chronic Hazard, Category 3	
H317	May cause an allergic skin reaction.	
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.	
H361d	Suspected of damaging the unborn child.	
H412	Harmful to aquatic life with long lasting effects.	
Repr. 2	Reproductive toxicity, Category 2	
Resp. Sens. 1	Respiratory sensitisation, Category 1	
Skin Sens. 1	Skin sensitisation, Category 1	

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.