

FOSFOMYCIN TROMETAMOL CRS

Safety Data Sheet

Safety Data Sheet in accordance with Regulation (EC) No. 1907/2006, as amended.

Date of issue: 27/06/2013

Revision date: 27/06/2013

Supersedes: 04/02/2010

Version: 4.0

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

1.1. Product identifier

Product form : Substance
Trade name : FOSFOMYCIN TROMETAMOL CRS
EC no : 279-018-8
CAS No : 78964-85-9
Product code : F0400000
Other means of identification : RTECS No : SZ9570000

1.2. Relevant identified uses of the substance or mixture and uses advised against

1.2.1. Relevant identified uses

Main use category : The product is intended for research, analysis and scientific education.
Use of the substance/mixture : For professional use only
Function or use category : Laboratory chemicals

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

European Directorate for the Quality of Medicines & Healthcare
EDQM, Council of Europe
F-67081 Strasbourg
T +33(0)388412035 - F +33(0)388412771

1.4. Emergency telephone number

Emergency number : +44(0)1235239670

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Resp. Sens. 1 H334
Eye Irrit. 2 H319
Skin Irrit. 2 H315
Skin Sens. 1 H317

Full text of H-phrases: see section 16

Classification according to Directive 67/548/EEC or 1999/45/EC

Xn; R42
Xi; R36/38
Xi; R43

Full text of R-phrases: see section 16

Adverse physicochemical, human health and environmental effects

No additional information available

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2.2. Label elements

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

Hazard pictograms (CLP) :



Signal word (CLP) :

Danger

Hazard statements (CLP) :

H315 - Causes skin irritation
H317 - May cause an allergic skin reaction
H319 - Causes serious eye irritation
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled

Precautionary statements (CLP) :

P261 - Avoid breathing dust/fume/gas/mist/vapours/spray
P264 - Wash hands and other exposed areas thoroughly after handling
P272 - Contaminated work clothing should not be allowed out of the workplace
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P285 - In case of inadequate ventilation wear respiratory protection
P302+P352 - IF ON SKIN: Wash with plenty of soap and water
P304+P341 - IF INHALED: if breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P332+P313 - If skin irritation occurs: Get medical advice/attention
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention
P337+P313 - If eye irritation persists: Get medical advice/attention
P342+P311 - If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician
P501 - Dispose of contents/container to : Hazardous waste. Comply with applicable regulations

2.3. Other hazards

Other hazards not contributing to the classification :

Exposure may produce an allergic reaction.

SECTION 3: Composition/information on ingredients

3.1. Substances

Name	Product identifier	%	Classification according to Directive 67/548/EEC
FOSFOMYCIN TROMETAMOL (Main constituent)	(CAS No)78964-85-9 (EC no)279-018-8	≤ 100	Xn; R42 Xi; R36/38 Xi; R43

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
FOSFOMYCIN TROMETAMOL (Main constituent)	(CAS No)78964-85-9 (EC no)279-018-8	≤ 100	Resp. Sens. 1, H334 Eye Irrit. 2, H319 Skin Irrit. 2, H315 Skin Sens. 1, H317

Full text of R-, H- and EUH-phrases: see section 16

3.2. Mixture

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general : If you feel unwell, seek medical advice (show the label where possible). Delayed adverse effects possible.

First-aid measures after inhalation : Move to fresh air in case of accidental inhalation. Assure fresh air breathing. Obtain medical attention if breathing difficulty persists.

First-aid measures after skin contact : Rinse skin with water/shower. Wash with plenty of soap and water.

First-aid measures after eye contact : Rinse with water while holding the eyes wide open. Contact lenses should be removed. Obtain medical attention if pain, blinking or redness persist.

First-aid measures after ingestion : Rinse mouth out with water. The following symptoms may occur: (see section(s) : 2, 4.2). If you feel unwell, seek medical advice. Prolonged medical observation may be indicated. (see section(s) : 4.3).

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

Symptoms/injuries : See Heading 2.

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

In all cases of doubt, or when symptoms persist, seek medical attention. If possible show this sheet, if not available show packaging or label. If the occupational exposure limit is exceeded : Specific medical surveillance.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Small amounts: Use extinguishing media appropriate for surrounding fire. Water spray. Carbon dioxide. Dry powder. Foam. Large amounts: Not applicable.

5.2. Special hazards arising from the substance or mixture

No additional information available

5.3. Advice for firefighters

Precautionary measures fire : Small amounts: Use normal individual fire protective equipment. Large amounts: Not applicable.
Firefighting instructions : Dilute with water.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Avoid raising dust. Wear suitable protective clothing, gloves and eye or face protection. Avoid any direct contact with the product. Evacuate unnecessary personnel. Large amounts: Not applicable.

6.1.1. For non-emergency personnel

Protective equipment : See Headings 7 and 8.

Emergency procedures : Spill should be handled by trained cleaning personnel properly equipped with respiratory and eye protection. Wear suitable protective clothing and gloves.

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 and cleaning up

Methods for cleaning up : Sweep spilled substance into containers; if appropriate, moisten first to prevent dusting. Ensure waste is collected and contained. Clean thoroughly. Clean with water. Collect all waste in suitable and labelled containers and dispose according to local legislation. Wash the non-recoverable remainder with : Sodium hypochlorite solution.

6.4. Reference to other sections

(see section(s) : 8, 13).

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Additional hazards when processed : Small amounts: See Heading 1. When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us. 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. Avoid contact during pregnancy/while nursing.

Precautions for safe handling : Handle and open container with care. See Heading 8. Do not handle until all safety precautions have been read and understood. Avoid any direct contact with the product. Obtain special instructions before use.

Hygiene measures : Handle in accordance with good industrial hygiene and safety procedures. Small amounts: Material should be handled in a laboratory hood whenever possible.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures : Comply with applicable regulations.

Storage conditions : To guarantee the quality and properties of the product, keep : dry, Keep in a cool, well-ventilated place away from heat. Store in original container. Store according to local legislation.

Incompatible products : Strong oxidizing agents.

7.3. Specific end use(s)

See Heading 1.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

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8.2. Exposure controls

Appropriate engineering controls : Material should be handled in a laboratory hood whenever possible.
Personal protective equipment : Gloves. Safety glasses. Protective clothing. Dust production: dust mask with filter type P3.



Hand protection : Gloves. Chemical resistant PVC gloves (to European standard EN 374 or equivalent).
Eye protection : Wear eye protection. DIN EN 166.
Skin and body protection : Lab coat. Wear suitable protective clothing. DIN EN 13034.
Respiratory protection : Quarter mask (DIN EN 140). Wear appropriate breathing apparatus if air renewal not sufficient to maintain dust/vapour under TLV.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Solid
Appearance : white. Powder.
Colour : No data available
Odour : Not applicable. See Heading 2, 4.2, 8.
Odour threshold : No data available
pH : 3,5 - 5,5
Relative evaporation rate (butylacetate=1) : No data available
Melting point : 116 - 122 °C
Freezing point : No data available
Boiling point : No data available
Flash point : No data available
Self ignition temperature : No data available
Decomposition temperature : No data available
Flammability (solid, gas) : No data available
Vapour pressure : No data available
Relative vapour density at 20 °C : No data available
Relative density : No data available
Solubility : Water: > 100 mg/l
Log Pow : No data available
Log Kow : No data available
Viscosity, kinematic : No data available
Viscosity, dynamic : No data available
Explosive properties : No data available
Oxidising properties : No data available
Explosive limits : No data available

9.2. Other information

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

Small amounts: When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us. Large amounts: Not applicable.

10.4. Conditions to avoid

No additional information available

10.5. Incompatible materials

Small amounts: None under normal use. Large amounts: Not applicable.

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10.6. Hazardous decomposition products

When heated to decomposition, emits dangerous fumes. Large amounts: Not applicable.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

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LD50 oral rat	> 10000 mg/kg
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Skin corrosion/irritation : Causes skin irritation.
pH: 3,5 - 5,5

Serious eye damage/irritation : Causes serious eye irritation.
pH: 3,5 - 5,5

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

Carcinogenicity : Not classified

Reproductive toxicity : Not classified

Specific target organ toxicity (single exposure) : Not classified

Specific target organ toxicity (repeated exposure) : Not classified

Aspiration hazard : Not classified

Potential Adverse human health effects and symptoms : Avoid any direct contact with the product. Small amounts: When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us. See first aid section of this material safety data sheet. Large amounts: Not applicable.

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : Small amounts: See Heading 2. Hazardous waste. Use suitable disposal containers. Large amounts: Not applicable.

Ecology - water : Soluble in water.

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. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Regional legislation (waste) : Dispose in a safe manner in accordance with local/national regulations.

Waste disposal recommendations : Do not empty into drains, dispose of this material and its container at hazardous or special waste collection point.

SECTION 14: Transport information

In accordance with ADR / RID / ADNR / IMDG / ICAO / IATA

14.1. UN number

No dangerous good in sense of transport regulations

14.2. UN proper shipping name

Not applicable

14.3. Transport hazard class(es)

Not applicable

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14.4. Packing group

Not applicable

14.5. Environmental hazards

Other information : No supplementary information available.

14.6. Special precautions for user

14.6.1. Overland transport

No additional information available

14.6.2. Transport by sea

No additional information available

14.6.3. Air transport

No additional information available

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

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

No REACH Annex XVII restrictions

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 R-, H- and EUH-phrases::

Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Resp. Sens. 1	Sensitisation — Respiratory, category 1
Skin Irrit. 2	Skin corrosion/irritation, Category 2
Skin Sens. 1	Sensitisation — Skin, category 1
H315	Causes skin irritation
H317	May cause an allergic skin reaction
H319	Causes serious eye irritation
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled
R36/38	Irritating to eyes and skin
R42	May cause sensitization by inhalation
R43	May cause sensitisation by skin contact
Xi	Irritant
Xn	Harmful

SDS EU (REACH Annex II)

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product