

Netilmicin sulfate

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
Issue date: 08/09/2023 Revision date: 08/09/2023 Supersedes version of: 03/04/2023 Version: 2.0

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

1.1. Product identifier

Product form : Substance
Substance name : Netilmicin sulfate
Chemical name : Netilmicin sulfate
Product code : 201600624
Synonyms : Netilmicin, salts, hydrates, isomers and impurities where applicable

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

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

Emergency number : +33(0)390215608

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Reproductive toxicity, Category 1B H360D
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) No. 1272/2008 [CLP]

Hazard pictograms (CLP) :



GHS08

Signal word (CLP) : Danger
Hazard statements (CLP) : H360D - May damage the unborn child.
Precautionary statements (CLP) : P201 - Obtain special instructions before use.
P202 - Do not handle until all safety precautions have been read and understood.
P280 - Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
P308+P313 - IF exposed or concerned: Get medical advice/attention.
P405 - Store locked up.

Netilmicin sulfate

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

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) :



GHS08

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] |
|--------------------|--------------------|-------|---|
| Netilmicin sulfate | - | ≤ 100 | Repr. 1B, H360D |

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 | : Move to fresh air. Allow affected person to breathe fresh air. |
| First-aid measures after skin contact | : Wipe off as much as possible (using a clean, soft, absorbent material). Wash with plenty of water and detergent. |
| First-aid measures after eye contact | : Rinse with water while holding the eyes wide open. |
| First-aid measures after ingestion | : Rinse mouth. Specific medical surveillance. Prolonged medical observation may be indicated. |

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

| | |
|-------------------------------------|--|
| Symptoms/effects | : Delayed adverse effects possible. |
| Symptoms/effects after inhalation | : Insufficient data available. |
| Symptoms/effects after skin contact | : Insufficient data available. |
| Symptoms/effects after eye contact | : Insufficient data available. |
| 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 measures

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.

Netilmicin sulfate

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

5.3. Advice for firefighters

Firefighting instructions : Use extinguishing media appropriate for surrounding fire.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment 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 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 any incompatibilities

Technical measures : Comply with applicable regulations.

Storage conditions : Store locked up.

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

Netilmicin sulfate

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

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 |
| Boiling point | : Not available |
| Flammability | : Not available |
| Explosive limits | : Not applicable |
| Lower explosion limit | : Not applicable |
| Upper explosion limit | : Not applicable |
| Flash point | : Not applicable |
| Auto-ignition temperature | : Not applicable |
| Decomposition temperature | : Not available |
| pH | : 3,5 – 5,5 |
| pH solution | : Not available |
| Viscosity, kinematic | : Not applicable |
| Solubility | : Water: > 1000 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 |

Netilmicin sulfate

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

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 (Based on available data, the classification criteria are not met) |
| Acute toxicity (dermal) | : Not classified (Lack of data) |
| Acute toxicity (inhalation) | : Not classified (Lack of data) |
| Skin corrosion/irritation | : Not classified (Lack of data) pH: 3,5 – 5,5 |
| Serious eye damage/irritation | : Not classified (Lack of data) pH: 3,5 – 5,5 |
| Respiratory or skin sensitisation | : Not classified (Lack of data) |
| Germ cell mutagenicity | : Not classified (Lack of data) |
| Carcinogenicity | : Not classified (Lack of data) |
| Reproductive toxicity | : May damage the unborn child. |
| STOT-single exposure | : Not classified (Lack of data) |
| STOT-repeated exposure | : Not classified (Lack of data) |
| Aspiration hazard | : Not classified (Technical impossibility to obtain the data) |

11.2. Information on other hazards

No additional information available

Netilmicin sulfate

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

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 (Lack of data)
Hazardous to the aquatic environment, long-term (chronic) : Not classified (Lack of data)

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 considerations

13.1. Waste treatment methods

Regional waste regulation : Dispose in a safe manner in accordance with local/national regulations.

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA

| ADR | IMDG | IATA |
|---|----------------|----------------|
| 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 | | |
| Not applicable | Not applicable | Not applicable |
| No supplementary information available | | |

Netilmicin sulfate

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

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

SECTION 16: Other information

Indication of changes

| Section | Changed item | Change | Comments |
|---------|-----------------------|----------|----------|
| | Supersedes version of | Added | |
| | Revision date | Added | |
| 1.1 | Name | Modified | |

Netilmicin sulfate

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

| Indication of changes | | | |
|-----------------------|---|--------|----------|
| Section | Changed item | Change | Comments |
| 1.2 | Restrictions on use | Added | |
| 1.2 | Use of the substance/mixture | Added | |
| 1.2 | Main use category | Added | |
| 1.2 | Function or use category | Added | |
| 2.1 | Adverse physicochemical, human health and environmental effects | Added | |
| 2.1 | Classification according to Regulation (EC) No. 1272/2008 [CLP] | Added | |
| 2.2 | Precautionary statements (CLP) | Added | |
| 2.2 | Hazard statements (CLP) | Added | |
| 2.2 | Signal word (CLP) | Added | |
| 2.2 | Hazard pictograms (CLP) | Added | |
| 4.1 | First-aid measures after ingestion | Added | |
| 4.1 | First-aid measures after eye contact | Added | |
| 4.1 | First-aid measures after skin contact | Added | |
| 4.1 | First-aid measures after inhalation | Added | |
| 4.2 | Symptoms/effects | Added | |
| 4.2 | Symptoms/effects after ingestion | Added | |
| 4.2 | Symptoms/effects after skin contact | Added | |
| 4.2 | Symptoms/effects after inhalation | Added | |
| 4.2 | Symptoms/effects after eye contact | Added | |
| 4.3 | Other medical advice or treatment | Added | |
| 5.1 | Suitable extinguishing media | Added | |
| 5.2 | Fire hazard | Added | |
| 5.3 | Firefighting instructions | Added | |
| 6.1 | Emergency procedures | Added | |
| 6.1 | General measures | Added | |
| 6.3 | Methods for cleaning up | Added | |
| 7.1 | Additional hazards when processed | Added | |
| 7.1 | Precautions for safe handling | Added | |
| 7.1 | Hygiene measures | Added | |
| 7.2 | Technical measures | Added | |
| 7.2 | Storage conditions | Added | |
| 7.3 | Specific end uses | Added | |
| 8.2 | Respiratory protection | Added | |
| 8.2 | Eye protection | Added | |
| 8.2 | Appropriate engineering controls | Added | |
| 8.2 | Skin and body protection | Added | |
| 8.2 | Hand protection | Added | |

Netilmicin sulfate

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

| Indication of changes | | | |
|-----------------------|----------------------------------|----------|----------|
| Section | Changed item | Change | Comments |
| 9.1 | Odour | Added | |
| 9.1 | pH | Added | |
| 10.1 | Reactivity | Added | |
| 10.5 | Incompatible materials | Added | |
| 10.6 | Hazardous decomposition products | Added | |
| 11.1 | Reason for no classification | Modified | |
| 12.1 | Ecology - general | Added | |
| 13.1 | Regional waste regulation | Added | |

| Full text of H- and EUH-statements: | |
|-------------------------------------|------------------------------------|
| H360D | May damage the unborn child. |
| Repr. 1B | Reproductive toxicity, Category 1B |

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.