

Gentamicin Injection, USP

Safety Data Sheet

SECTION 1: Identification

1.1. Identification

Product name : Gentamicin Injection, USP
Other means of identification : 20 mg per 2 mL (10 mg/mL) Single Dose Vial Packaged in Carton of 25; NDC 55150-401-25
80 mg per 2 mL (40 mg/mL) Multiple Dose Vials Packaged in Carton of 25; NDC 55150-402-25
800 mg per 20 mL (40 mg/mL) Multiple Dose Vials Packaged in Carton of 25; NDC 55150-403-25

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

Use of the substance/mixture : Pharmaceutical

1.3. Details of the supplier of the safety data sheet

Eugia US LLC
279 Princeton Hightstown Road
East Windsor, NJ 08520

1.4. Emergency telephone number

Emergency number : 1-888-238-7880

SECTION 2: Hazard(s) identification

2.1. Classification of the substance or mixture

GHS US classification

Skin Irrit. 2 H315
Eye Irrit. 2 H319
Resp. Sens. 1 H334
Skin Sens. 1 H317
Repr. 2 H361

Full text of hazard classes and H-statements : see section 16

2.2. Label elements

GHS US labeling

Hazard pictograms (GHS US) :



Signal word (GHS US) :

Danger

Hazard statements (GHS US) :

H315 - Causes skin irritation
H317 - May cause an allergic skin reaction
H319 - Causes serious eye irritation
H334 - May cause an allergy or asthma symptoms or breathing difficulties if inhaled
H361 - Suspected of damaging fertility or the unborn child

Precautionary statements (GHS US) :

P201 - Obtain special instructions before use.
P202 - Do not handle until all safety precautions have been read and understood.
P261 - Avoid breathing dust/fume/gas/mist/vapors/spray.
P264 - Wash hands, forearms and face thoroughly after handling.
P272 - Contaminated work clothing must not be allowed out of the workplace.
P280 - Wear protective gloves/protective clothing/eye protection/face protection.
P284 - [In case of inadequate ventilation] wear respiratory protection.
P302+P352 - If on skin: Wash with plenty of water.
P304+P341 - If inhaled: If breathing is difficult, remove person to fresh air and keep 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.
P308+P313 - If exposed or concerned: Get medical advice/attention.
P321 - Specific treatment (see supplemental first aid instruction on this label).
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.
P362+P364 - Take off contaminated clothing and wash it before reuse.
P363 - Wash contaminated clothing before reuse.

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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.

2.3. Other hazards

No additional information available

2.4. Unknown acute toxicity (GHS US)

Not applicable

SECTION 3: Composition/Information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

| Name | Product identifier | % | GHS US classification |
|---|---------------------|--------|---|
| Gentamicin sulfate | (CAS-No.) 1405-41-0 | 1 or 4 | Skin Sens. 1, H317 |
| Sodium hydroxide | (CAS-No.) 1310-73-2 | ≤ 1 | Met. Corr. 1, H290 Skin Corr. 1A, H314 Eye Dam. 1, H318 |
| Sulfuric acid | (CAS-No.) 7664-93-9 | ≤ 1 | Skin Corr. 1A, H314 |
| Sodium metabisulfite | (CAS-No.) 7681-57-4 | 0.32 | Acute Tox. 4 (Oral), H302 Eye Dam. 1, H318 |
| Benzoic acid, 4-hydroxy-, methyl ester | (CAS-No.) 99-76-3 | 0.18 | Aquatic Chronic 3, H412 |
| Propyl 4-hydroxybenzoate | (CAS-No.) 94-13-3 | 0.02 | Skin Irrit. 2, H315 Eye Irrit. 2A, H319 STOT SE 3, H335 |
| Glycine, N,N'-1,2-ethanediybis[N-(carboxymethyl)-, disodium salt, dihydrate | (CAS-No.) 6381-92-6 | 0.01 | Acute Tox. 4 (Inhalation), H332 |

Full text of hazard classes and H-statements : see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation : If not breathing, give artificial respiration.
First-aid measures after skin contact : Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.
First-aid measures after eye contact : In case of dust contact with eyes, rinse immediately with plenty of water.
First-aid measures after ingestion : Go into open air and ventilate suspected area.

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

Symptoms/effects after inhalation : May cause respiratory irritation.
Symptoms/effects after skin contact : Causes skin irritation. May cause an allergic skin reaction.
Symptoms/effects after eye contact : Causes serious eye irritation.
Symptoms/effects after ingestion : May be harmful if swallowed.

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 : Use extinguishing media appropriate for surrounding fire.
Unsuitable extinguishing media : None.

5.2. Special hazards arising from the substance or mixture

Fire hazard : None known.

5.3. Advice for firefighters

Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : No special measures required.

6.1.1. For non-emergency personnel

No additional information available

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6.1.2. For emergency responders

No additional information available

6.2. Environmental precautions

Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

For containment : Stop the flow of material, if this is without risk.
Methods for cleaning up : Recycle product or dispose safely.

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Do not eat, drink or smoke when using this product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store at 20 to 25 °C (68 to 77 °F)

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

| Gentamicin sulfate (1405-41-0) | | |
|---|---------------------|---|
| Not applicable | | |
| Benzoic acid, 4-hydroxy-, methyl ester (99-76-3) | | |
| Not applicable | | |
| Propyl 4-hydroxybenzoate (94-13-3) | | |
| Not applicable | | |
| Glycine, N,N'-1,2-ethanediybis[N-(carboxymethyl)-, disodium salt, dihydrate (6381-92-6) | | |
| Not applicable | | |
| Sodium metabisulfite (7681-57-4) | | |
| ACGIH | ACGIH OEL TWA | 5 mg/m ³ |
| NIOSH | NIOSH REL (TWA) | 5 mg/m ³ |
| Sodium hydroxide (1310-73-2) | | |
| ACGIH | ACGIH OEL Ceiling | 2 mg/m ³ |
| OSHA | OSHA PEL (TWA) [1] | 2 mg/m ³ |
| IDLH | IDLH | 10 mg/m ³ |
| NIOSH | NIOSH REL (Ceiling) | 2 mg/m ³ |
| Sulfuric acid (7664-93-9) | | |
| ACGIH | ACGIH OEL TWA | 0.2 mg/m ³ (thoracic particulate matter) |
| OSHA | OSHA PEL (TWA) [1] | 1 mg/m ³ |
| IDLH | IDLH | 15 mg/m ³ |
| NIOSH | NIOSH REL (TWA) | 1 mg/m ³ |

8.2. Exposure controls

Appropriate engineering controls : Local exhaust and general ventilation must be adequate to meet exposure standards.
Hand protection : Use neoprene or rubber gloves.
Eye protection : Wear protective goggles.
Skin and body protection : Wear suitable working clothes.
Respiratory protection : Wear NIOSH approved respirator when handling.

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SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

| | |
|---|---------------------|
| Physical state | : Liquid |
| Appearance | : Clear. |
| Color | : Colorless |
| Odor | : Odorless |
| Odor threshold | : No data available |
| pH | : No data available |
| Melting point | : No data available |
| Freezing point | : No data available |
| Boiling point | : No data available |
| Flash point | : No data available |
| Relative evaporation rate (butyl acetate=1) | : No data available |
| Flammability | : No data available |
| Vapor pressure | : No data available |
| Relative vapor density at 20°C | : No data available |
| Relative density | : No data available |
| Solubility | : No data available |
| Partition coefficient n-octanol/water (Log Pow) | : No data available |
| Auto-ignition temperature | : No data available |
| Decomposition temperature | : No data available |
| Viscosity, kinematic | : No data available |
| Viscosity, dynamic | : No data available |
| Explosion limits | : No data available |
| Explosive properties | : No data available |
| Oxidizing properties | : No data available |

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

The product is stable at normal handling and storage conditions.

10.3. Possibility of hazardous reactions

Will not occur.

10.4. Conditions to avoid

Air contact.

10.5. Incompatible materials

None known.

10.6. Hazardous decomposition products

None known.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

Benzoic acid, 4-hydroxy-, methyl ester (99-76-3)

| | |
|---------------|------------|
| ATE US (oral) | 2100 mg/kg |
|---------------|------------|

Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, disodium salt, dihydrate (6381-92-6)

| | |
|-----------------|--------------|
| ATE US (gases) | 4500 ppmV/4h |
| ATE US (vapors) | 11 mg/l/4h |

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| Glycine, N,N'-1,2-ethanediybis[N-(carboxymethyl)-, disodium salt, dihydrate (6381-92-6) | |
|--|---|
| ATE US (dust, mist) | 1.5 mg/l/4h |
| Sodium metabisulfite (7681-57-4) | |
| LD50 oral rat | 1310 mg/kg |
| LD50 dermal rat | > 2000 mg/kg |
| ATE US (oral) | 1131 mg/kg |
| Sodium hydroxide (1310-73-2) | |
| LD50 oral rat | 140 – 340 mg/kg |
| LD50 dermal rabbit | 1350 mg/kg |
| ATE US (dermal) | 1350 mg/kg |
| Sulfuric acid (7664-93-9) | |
| LD50 oral rat | 2140 mg/kg |
| LC50 Inhalation - Rat | 85 – 103 mg/m ³ (Exposure time: 1 h) |
| ATE US (oral) | 2140 mg/kg body weight |
| ATE US (vapors) | 0.085 mg/l/4h |
| ATE US (dust, mist) | 0.085 mg/l/4h |

| | |
|-----------------------------------|--|
| Skin corrosion/irritation | : Causes skin irritation. |
| Serious eye damage/irritation | : Causes serious eye irritation. |
| Respiratory or skin sensitization | : May cause an allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction. |
| Germ cell mutagenicity | : Not classified |
| Carcinogenicity | : Not classified |

| Sodium metabisulfite (7681-57-4) | |
|--|----------------------------|
| IARC group | 3 - Not classifiable |
| Sulfuric acid (7664-93-9) | |
| IARC group | 1 - Carcinogenic to humans |
| In OSHA Hazard Communication Carcinogen list | Yes |

| | |
|-----------------------|--|
| Reproductive toxicity | : Suspected of damaging fertility or the unborn child. |
| STOT-single exposure | : Not classified |

STOT-repeated exposure : Not classified

Aspiration hazard : Not classified

SECTION 12: Ecological information

12.1. Toxicity

| Sodium metabisulfite (7681-57-4) | |
|---|---|
| LC50 - Fish [1] | 32 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static]) |
| Sodium hydroxide (1310-73-2) | |
| LC50 - Fish [1] | 45.4 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static]) |
| Sulfuric acid (7664-93-9) | |
| LC50 - Fish [1] | > 500 mg/l (Exposure time: 96 h - Species: Brachydanio rerio [static]) |

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

| Sodium metabisulfite (7681-57-4) | |
|---|-----------------|
| Partition coefficient n-octanol/water (Log Pow) | -3.7 (at 25 °C) |

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Sulfuric acid (7664-93-9)

BCF - Fish [1]

(no bioaccumulation)

12.4. Mobility in soil

No additional information available

12.5. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Product/Packaging disposal recommendations : Dispose of contents/container in accordance with local/regional/national/international regulations.

SECTION 14: Transport information

Department of Transportation (DOT)

In accordance with DOT

Not applicable

International Air Transport Association (IATA)

In accordance with IATA

Not applicable

SECTION 15: Regulatory information

15.1. US Federal regulations

Benzoic acid, 4-hydroxy-, methyl ester (99-76-3)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

Propyl 4-hydroxybenzoate (94-13-3)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

Sodium metabisulfite (7681-57-4)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

Sodium hydroxide (1310-73-2)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

CERCLA RQ

1000 lb

Sulfuric acid (7664-93-9)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

Listed on the United States SARA Section 302

Subject to reporting requirements of United States SARA Section 313

CERCLA RQ

1000 lb

SARA Section 302 Threshold Planning Quantity (TPQ)

1000 lb

SARA Section 313 - Emission Reporting

1 % (acid aerosols including mists, vapors, gas, fog, and other airborne forms of any particle size)

15.2. US State regulations

Sodium metabisulfite (7681-57-4)

U.S. - Massachusetts - Right To Know List

U.S. - Minnesota - Hazardous Substance List

U.S. - New Jersey - Right to Know Hazardous Substance List

U.S. - Pennsylvania - RTK (Right to Know) List

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Sodium hydroxide (1310-73-2)

U.S. - Massachusetts - Right To Know List
U.S. - Minnesota - Hazardous Substance List
U.S. - New Jersey - Right to Know Hazardous Substance List
U.S. - Pennsylvania - RTK (Right to Know) List

Sulfuric acid (7664-93-9)

U.S. - Massachusetts - Right To Know List
U.S. - Minnesota - Hazardous Substance List
U.S. - New Jersey - Right to Know Hazardous Substance List
U.S. - Pennsylvania - RTK (Right to Know) List

SECTION 16: Other information

Full text of H-phrases:

| | |
|---------------------------|--|
| Acute Tox. 4 (Inhalation) | Acute toxicity (inhalation) Category 4 |
| Acute Tox. 4 (Oral) | Acute toxicity (oral) Category 4 |
| Aquatic Chronic 3 | Hazardous to the aquatic environment – Chronic Hazard Category 3 |
| Eye Dam. 1 | Serious eye damage/eye irritation Category 1 |
| Eye Irrit. 2 | Serious eye damage/eye irritation Category 2 |
| Eye Irrit. 2A | Serious eye damage/eye irritation Category 2A |
| Met. Corr. 1 | Corrosive to metals Category 1 |
| Repr. 2 | Reproductive toxicity Category 2 |
| Resp. Sens. 1 | Respiratory sensitization, Category 1 |
| Skin Corr. 1A | Skin corrosion/irritation Category 1A |
| Skin Irrit. 2 | Skin corrosion/irritation Category 2 |
| Skin Sens. 1 | Skin sensitization, Category 1 |
| STOT SE 3 | Specific target organ toxicity – Single exposure, Category 3, Respiratory tract irritation |
| H290 | May be corrosive to metals |
| H302 | Harmful if swallowed |
| H314 | Causes severe skin burns and eye damage |
| H315 | Causes skin irritation |
| H317 | May cause an allergic skin reaction |
| H318 | Causes serious eye damage |
| H319 | Causes serious eye irritation |
| H332 | Harmful if inhaled |
| H334 | May cause an allergy or asthma symptoms or breathing difficulties if inhaled |
| H335 | May cause respiratory irritation |
| H361 | Suspected of damaging fertility or the unborn child |
| H412 | Harmful to aquatic life with long lasting effects |

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.