SAFETY DATA SHEET

Gentamicin (10%) Injection Formulation

Section 1: Identification

Product name : Gentamicin (10%) Injection Formulation

Manufacturer or supplier's details
Company : MSD
Address : 33 Whakatiki Street - Private Bag 908
          Upper Hutt - New Zealand
Telephone : 908-740-4000
Emergency telephone number : 1-908-423-6000
E-mail address : EHSDATASTEWARD@msd.com
Telefax : 908-735-1496

Recommended use of the chemical and restrictions on use
Recommended use : Veterinary product

Section 2: Hazard identification

GHS Classification
Reproductive toxicity : Repr.1A
Specific target organ toxicity - repeated exposure (Oral) : STOT RE1 (Kidney, inner ear)

GHS label elements
Hazard pictograms : 
Signal word : Danger
Hazard statements : H360D May damage the unborn child.
H372 Causes damage to organs (Kidney, inner ear) through prolonged or repeated exposure if swallowed.

Precautionary statements : Prevention:
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe mist or vapours.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P281 Use personal protective equipment as required.

Response:
Section 2: PPE

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

**Storage:**
P405 Store locked up.

**Disposal:**
P501 Dispose of contents/container to an approved waste disposal plant.

Other hazards which do not result in classification
None known.

Section 3: Composition/information on ingredients

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gentamicin</td>
<td>Mixture</td>
<td>Gentamicin</td>
<td>1403-66-3</td>
<td>10</td>
</tr>
</tbody>
</table>

Section 4: First-aid measures

**General advice:**
In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice.

**If inhaled:**
If inhaled, remove to fresh air.
Get medical attention.

**In case of skin contact:**
In case of contact, immediately flush skin with soap and plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.

**In case of eye contact:**
Flush eyes with water as a precaution.
Get medical attention if irritation develops and persists.

**If swallowed:**
If swallowed, DO NOT induce vomiting.
Get medical attention.
Rinse mouth thoroughly with water.

**Most important symptoms and effects, both acute and delayed:**
May damage the unborn child.
Causes damage to organs through prolonged or repeated exposure if swallowed.

**Protection of first-aiders:**
First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

**Notes to physician:**
Treat symptomatically and supportively.

Section 5: Fire-fighting measures

**Suitable extinguishing media:**
Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
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Gentamicin (10%) Injection Formulation

Ve[version]: 3.5
Revision Date: 09/13/2019
SDS Number: 804050-00010
Date of last issue: 24.04.2019
Date of first issue: 15.07.2016

Unsuitable extinguishing media : Dry chemical

Specific hazards during firefighting :
Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides

Specific extinguishing methods :
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Use water spray to cool unopened containers.
Remove undamaged containers from fire area if it is safe to do so.
Evacuate area.

Special protective equipment for firefighters :
In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

Hazchem Code : 3Z

Section 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures :
Use personal protective equipment.
Follow safe handling advice and personal protective equipment recommendations.

Environmental precautions :
Discharge into the environment must be avoided.
Prevent further leakage or spillage if safe to do so.
Prevent spreading over a wide area (e.g. by containment or oil barriers).
Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up :
Soak up with inert absorbent material.
For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.
Clean up remaining materials from spill with suitable absorbent.
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

Section 7: Handling and storage

Technical measures :
See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation :
If sufficient ventilation is unavailable, use with local exhaust ventilation.

Advice on safe handling :
Do not get on skin or clothing.
Do not breathe vapours or spray mist.
Do not swallow.
Avoid contact with eyes. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment. Keep container tightly closed. Take care to prevent spills, waste and minimize release to the environment.

**Hygiene measures**
- If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.
- When using do not eat, drink or smoke.
- Wash contaminated clothing before re-use.
- The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

**Conditions for safe storage**
- Keep in properly labelled containers.
- Store locked up.
- Keep tightly closed.
- Store in accordance with the particular national regulations.

**Materials to avoid**
- Do not store with the following product types:
  - Strong oxidizing agents

### Section 8: Exposure controls/personal protection

#### Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gentamicin</td>
<td>1403-66-3</td>
<td>TWA</td>
<td>0.1 mg/m3 (OEB 2)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

#### Engineering measures
- Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).
- All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
- Laboratory operations do not require special containment.

#### Personal protective equipment

**Respiratory protection**
- If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
  - Filter type: Particulates type
  - Hand protection Material: Chemical-resistant gloves

**Eye protection**
- Wear safety glasses with side shields or goggles.
  - If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
Skin and body protection:
- Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
- Work uniform or laboratory coat.

Section 9: Physical and chemical properties

- Appearance: liquid
- Colour: clear
- Odour: odourless
- Odour Threshold: No data available
- pH: 3.0 - 5.5
- Melting point/freezing point: No data available
- Initial boiling point and boiling range: > 100 °C
- Flash point: No data available
- Evaporation rate: 1
- Flammability (solid, gas): Not applicable
- Flammability (liquids): No data available
- Upper explosion limit / Upper flammability limit: No data available
- Lower explosion limit / Lower flammability limit: No data available
- Vapour pressure: No data available
- Relative vapour density: No data available
- Relative density: No data available
- Density: No data available
- Solubility(ies):
  - Water solubility: soluble
- Partition coefficient: n-octanol/water: No data available
- Auto-ignition temperature: No data available
- Decomposition temperature: No data available
- Viscosity:
  - Viscosity, kinematic: No data available
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Explosive properties: Not explosive

Oxidizing properties: The substance or mixture is not classified as oxidizing.

Molecular weight: No data available

Particle size: No data available

Section 10: Stability and reactivity

Reactivity: Not classified as a reactivity hazard.

Chemical stability: Stable under normal conditions.

Possibility of hazardous reactions: Can react with strong oxidizing agents.

Conditions to avoid: None known.

Incompatible materials: Oxidizing agents

Hazardous decomposition products: No hazardous decomposition products are known.

Section 11: Toxicological information

Exposure routes: Inhalation

Skin contact

Ingestion

Eye contact

Acute toxicity
Not classified based on available information.

Components:

Gentamicin:

Acute oral toxicity: LD50 (Rat): 8,000 - 10,000 mg/kg

LD50 (Mouse): 10,000 mg/kg

Acute inhalation toxicity: LC50 (Rat): > 0.2 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Remarks: No mortality observed at this dose.

Acute toxicity (other routes of administration): LD50 (Rat): 67 - 96 mg/kg

Application Route: Intravenous

LD50 (Rat): 371 - 384 mg/kg

Application Route: Intramuscular

LDLo (Monkey): 30 mg/kg

Application Route: Intravenous

Skin corrosion/irritation
Not classified based on available information.
Components:

Gentamicin:
Species: Rabbit
Result: Mild skin irritation

Serious eye damage/eye irritation
Not classified based on available information.

Components:

Gentamicin:
Species: Rabbit
Result: Mild eye irritation

Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Components:

Gentamicin:
Remarks: No data available

Chronic toxicity

Germ cell mutagenicity
Not classified based on available information.

Components:

Gentamicin:
Genotoxicity in vitro:
Test Type: In vitro mammalian cell gene mutation test
Result: negative

Test Type: Chromosome aberration test in vitro
Result: equivocal

Genotoxicity in vivo:
Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Intravenous injection
Result: negative

Carcinogenicity
Not classified based on available information.
Components:

Gentamicin:
Carcinogenicity - Assessment : No data available

Reproductive toxicity
May damage the unborn child.

Components:

Gentamicin:
Effects on fertility : Test Type: Two-generation reproduction toxicity study
Species: Rat
Fertility: NOAEL: 20 mg/kg body weight
Result: No significant adverse effects were reported

Effects on foetal development : Test Type: Embryo-foetal development
Species: Rabbit
Developmental Toxicity: NOAEL: 3.6 mg/kg body weight
Result: No embryo-foetal toxicity

Test Type: Embryo-foetal development
Species: Rat
Application Route: Intraperitoneal
Developmental Toxicity: LOAEL: 75 mg/kg body weight
Result: Embryo-foetal toxicity

Test Type: Embryo-foetal development
Species: Mouse
Application Route: Intraperitoneal
Developmental Toxicity: LOAEL: 10 mg/kg body weight
Result: foetal mortality, No malformations were observed.

Test Type: Embryo-foetal development
Species: Rat
Application Route: Intraperitoneal
Developmental Toxicity: LOAEL: 50 mg/kg body weight
Result: foetal mortality, No malformations were observed.

Reproductive toxicity - Assessment : Positive evidence of adverse effects on development from human epidemiological studies.

STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
Causes damage to organs (Kidney, inner ear) through prolonged or repeated exposure if swallowed.

Components:

Gentamicin:
Target Organs : Kidney, inner ear
Assessment : Causes damage to organs through prolonged or repeated exposure.
Repeated dose toxicity

**Components:**

**Gentamicin:**
- **Species:** Dog
  - **LOAEL:** 3 mg/kg
  - **Application Route:** Intramuscular
  - **Exposure time:** 12 Months
  - **Target Organs:** Kidney
  - **Symptoms:** Vomiting, Salivation

- **Species:** Monkey
  - **LOAEL:** 50 mg/kg
  - **Application Route:** Subcutaneous
  - **Exposure time:** 3 Weeks
  - **Target Organs:** Kidney, inner ear

- **Species:** Monkey
  - **LOAEL:** 6 mg/kg
  - **Application Route:** Intramuscular
  - **Exposure time:** 3 Weeks
  - **Target Organs:** Blood, Kidney, inner ear, Liver

- **Species:** Rat
  - **NOAEL:** 5 mg/kg
  - **LOAEL:** 10 mg/kg
  - **Application Route:** Intramuscular
  - **Exposure time:** 52 Weeks
  - **Target Organs:** Kidney, Blood

- **Species:** Rat
  - **NOAEL:** 12.5 mg/kg
  - **LOAEL:** 50 mg/kg
  - **Application Route:** Intramuscular
  - **Exposure time:** 13 Weeks
  - **Target Organs:** Kidney

**Aspiration toxicity**
Not classified based on available information.

**Experience with human exposure**

**Components:**

**Gentamicin:**
- **Ingestion:** Target Organs: Kidney, inner ear
  - **Symptoms:** Dizziness, Vertigo, hearing loss, tinnitus, fetal deafness
Section 12: Ecological information

Ecotoxicity

Components:

Gentamicin:

Toxicity to daphnia and other aquatic invertebrates:
- EC50 (Daphnia magna (Water flea)): 86 mg/l
  Exposure time: 48 h
  Method: OECD Test Guideline 202
- LC50 (Americamysis): 30 mg/l
  Exposure time: 96 h
  Method: US-EPA OPPTS 850.1035

Toxicity to algae/aquatic plants:
- EC50 (Pseudokirchneriella subcapitata (green algae)): 10 µg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201
- NOEC (Pseudokirchneriella subcapitata (green algae)): 1.5 µg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201
- EC50 (Anabaena flos-aquae (cyanobacterium)): 4.7 µg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201
- NOEC (Anabaena flos-aquae (cyanobacterium)): 1.6 µg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201

Toxicity to microorganisms:
- EC50: 288.7 mg/l
  Exposure time: 3 h
  Test Type: Respiration inhibition
  Method: OECD Test Guideline 209

Persistence and degradability

Components:

Gentamicin:

Biodegradability:
- Result: rapidly degradable
- Biodegradation: 100 %
- Exposure time: 28 d
  Method: OECD Test Guideline 314

Bioaccumulative potential

Components:

Gentamicin:

Partition coefficient: n-octanol/water:
- log Pow: < -2
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Mobility in soil
No data available

Other adverse effects
No data available

Section 13: Disposal considerations

Disposal methods
- Waste from residues: Dispose of in accordance with local regulations.
- Contaminated packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal.
- If not otherwise specified: Dispose of as unused product.

Section 14: Transport information

International Regulations

UNRTDG
- UN number: UN 3082
- Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Gentamicin)
- Class: 9
- Packing group: III
- Labels: 9

IATA-DGR
- UN/ID No.: UN 3082
- Proper shipping name: Environmentally hazardous substance, liquid, n.o.s. (Gentamicin)
- Class: 9
- Packing group: III
- Labels: Miscellaneous
- Packing instruction (cargo aircraft): 964
- Packing instruction (passenger aircraft): 964
- Environmentally hazardous: yes

IMDG-Code
- UN number: UN 3082
- Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Gentamicin)
- Class: 9
- Packing group: III
- Labels: 9
- EmS Code: F-A, S-F
- Marine pollutant: yes

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

National Regulations
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Version: 3.5
Revision Date: 09/13/2019
SDS Number: 804050-00010
Date of last issue: 24.04.2019
Date of first issue: 15.07.2016

NZS 5433
UN number: UN 3082
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Gentamicin)
Class: 9
Packing group: III
Labels: 9
Hazchem Code: 3Z

Special precautions for user
The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

Section 15: Regulatory information

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

HSNO Approval Number
HSR100759 Veterinary Medicines Non dispersive Open System Application Group Standard 2017

HSW Controls
Certified handler certificate not required.
Tracking hazardous substance not required.
Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

The components of this product are reported in the following inventories:
AICS: not determined
DSL: not determined
IECSC: not determined

Section 16: Other information

Further information
Date format: dd.mm.yyyy

Full text of other abbreviations
The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

NZ / EN