SAFETY DATA SHEET
Gentamicin (8%) Injection Formulation

Version 2.3  Revision Date: 10.10.2020  SDS Number: 1845027-00007  Date of last issue: 13.09.2019
Date of first issue: 25.07.2017

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

1.1 Product identifier
   Trade name : Gentamicin (8%) Injection Formulation

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
   Company : MSD
   117 16th Road
   07033 Halfway house, Midrand, South Africa
   Telephone : +27 11 655 3000
   Telefax : 908-735-1496
   E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
   1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)
   Reproductive toxicity, Category 1A
   Specific target organ toxicity - repeated exposure, Category 2
   Short-term (acute) aquatic hazard, Category 1
   Long-term (chronic) aquatic hazard, Category 2
   H360D: May damage the unborn child.
   H373: May cause damage to organs through prolonged or repeated exposure.
   H400: Very toxic to aquatic life.
   H411: Toxic to aquatic life with long lasting effects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)
   Hazard pictograms :
   Signal word : Danger
   Hazard statements :
   H360D  May damage the unborn child.
   H373  May cause damage to organs through prolonged or repeated exposure.
   H410  Very toxic to aquatic life with long lasting effects.
Precautionary statements : **Prevention:**  
P201 Obtain special instructions before use.  
P273 Avoid release to the environment.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.  

**Response:**  
P308 + P313 IF exposed or concerned: Get medical advice/ attention.  
P391 Collect spillage.  

**Storage:**  
P405 Store locked up.  

Hazardous components which must be listed on the label:  
Gentamicin  

### 2.3 Other hazards  
None known.  

## SECTION 3: Composition/information on ingredients  

### 3.2 Mixtures  

#### Components  

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
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<tr>
<td>Gentamicin</td>
<td>1403-66-3</td>
<td>215-765-8</td>
<td></td>
<td>Repr. 1A; H360D</td>
<td>8</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>STOT RE 1; H372</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>(Kidney, inner ear)</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Aquatic Acute 1; H400</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Aquatic Chronic 1; H410</td>
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<td>M-Factor (Acute aquatic toxicity): 100</td>
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<td>M-Factor (Chronic aquatic toxicity): 1</td>
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<td>Benzyl alcohol</td>
<td>100-51-6</td>
<td>202-859-9</td>
<td>603-057-00-5</td>
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<td>Acute Tox. 4; H332</td>
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<td></td>
<td></td>
<td></td>
<td>Eye Irrit. 2; H319</td>
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</table>

For explanation of abbreviations see section 16.  

## SECTION 4: First aid measures  

### 4.1 Description of first aid measures  

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

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).

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.

4.2 Most important symptoms and effects, both acute and delayed
Risks: May damage the unborn child. May cause damage to organs through prolonged or repeated exposure.

4.3 Indication of any immediate medical attention and special treatment needed
Treatment: Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media
Suitable extinguishing media: Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media: None known.

5.2 Special hazards arising from the substance or mixture
Specific hazards during firefighting: Vapours may form explosive mixtures with air. Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Carbon oxides
## 5.3 Advice for firefighters

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

### SECTION 6: Accidental release measures

#### 6.1 Personal precautions, protective equipment and emergency procedures

| Personal precautions | Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8). |

#### 6.2 Environmental precautions

| Environmental precautions | Avoid release to the environment. 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. |

#### 6.3 Methods and material for containment and cleaning up

| Methods for 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. |

#### 6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

### SECTION 7: Handling and storage

#### 7.1 Precautions for safe handling

| 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 mist or vapours.
Do not swallow.
Avoid contact with eyes.
Wash skin thoroughly after handling.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
Keep container tightly closed.
Do not eat, drink or smoke when using this product.
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.

7.2 Conditions for safe storage, including any incompatibilities
Requirements for storage areas and containers: Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.
Advice on common storage: Do not store with the following product types:
- Strong oxidizing agents
- Organic peroxides
- Explosives
- Gases

7.3 Specific end use(s)
Specific use(s): No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</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>
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</table>

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

<table>
<thead>
<tr>
<th>Substance name</th>
<th>End Use</th>
<th>Exposure routes</th>
<th>Potential health effects</th>
<th>Value</th>
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<tbody>
<tr>
<td>Benzyl alcohol</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>22 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Inhalation</td>
<td>Acute systemic effects</td>
<td>110 mg/m³</td>
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</tbody>
</table>
Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
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<tbody>
<tr>
<td>Benzyl alcohol</td>
<td>Fresh water</td>
<td>1 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>0.1 mg/l</td>
</tr>
<tr>
<td></td>
<td>Intermittent use/release</td>
<td>2.3 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>39 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>5.27 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>0.527 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>0.456 mg/kg</td>
</tr>
</tbody>
</table>

8.2 Exposure controls

**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**

**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.
- Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

**Hand protection**

- Material: Chemical-resistant gloves

**Skin and body protection**

- Work uniform or laboratory coat.

**Respiratory protection**

- If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
- Filter type: Combined particulates and organic vapour type (A-P)

**SECTION 9: Physical and chemical properties**

9.1 Information on basic physical and chemical properties
## Appearance
- liquid

## Colour
- colourless

## Odour
- No data available

## Odour Threshold
- No data available

## pH
- No data available

## Melting point/freezing point
- No data available

## Initial boiling point and boiling range
- No data available

## Flash point
- > 93.3 °C

## Evaporation rate
- No data available

## Flammability (solid, gas)
- Not applicable

## 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
  - No data available

## 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

## Explosive properties
- Not explosive

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

### 9.2 Other information
- Flammability (liquids)
  - Not applicable

- Molecular weight
  - No data available

- Particle size
  - No data available
SECTION 10: Stability and reactivity

10.1 Reactivity
Not classified as a reactivity hazard.

10.2 Chemical stability
Stable under normal conditions.

10.3 Possibility of hazardous reactions
Hazardous reactions: Vapours may form explosive mixture with air. Can react with strong oxidizing agents.

10.4 Conditions to avoid
Conditions to avoid: None known.

10.5 Incompatible materials
Materials to avoid: Oxidizing agents

10.6 Hazardous decomposition products
No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects
Information on likely routes of exposure: Inhalation, Skin contact, Ingestion, Eye contact

Acute toxicity
Not classified based on available information.

Product:
Acute oral toxicity: Acute toxicity estimate: > 2.000 mg/kg Method: Calculation method

Acute inhalation toxicity: Acute toxicity estimate: > 5 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: Calculation method

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

### Benzyl alcohol:
- **Acute oral toxicity:** LD50 (Rat): 1.620 mg/kg
- **Acute inhalation toxicity:** LC50 (Rat): > 4,178 mg/l
  - Exposure time: 4 h
  - Test atmosphere: dust/mist
  - Method: OECD Test Guideline 403

### Skin corrosion/irritation
Not classified based on available information.

#### Components:

**Gentamicin:**
- **Species:** Rabbit
- **Result:** Mild skin irritation

**Benzyl alcohol:**
- **Species:** Rabbit
- **Method:** OECD Test Guideline 404
- **Result:** No skin irritation

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

#### Components:

**Gentamicin:**
- **Species:** Rabbit
- **Result:** Mild eye irritation

**Benzyl alcohol:**
- **Species:** Rabbit
- **Method:** OECD Test Guideline 405
- **Result:** Irritation to eyes, reversing within 21 days

### Respiratory or skin sensitisation

#### Skin sensitisation
Not classified based on available information.
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Respiratory sensitisation
Not classified based on available information.

Components:

Gentamicin:
Remarks : No data available

Benzyl alcohol:
Test Type : Maximisation Test
Exposure routes : Skin contact
Species : Guinea pig
Method : OECD Test Guideline 406
Result : negative

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

Genotoxicity in vivo : Test Type: Chromosome aberration test in vitro
Result: equivocal

Benzyl alcohol:
Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

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
Benzyl alcohol:
Species: Mouse
Application Route: Ingestion
Exposure time: 103 weeks
Method: OECD Test Guideline 451
Result: negative

Reproductive toxicity
May damage the unborn child.

Components:

Gentamicin:
Effects on fertility:
Species: Rat
Fertility: NOAEL: 20 mg/kg body weight
Result: No significant adverse effects were reported

Effects on 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.

Benzyl alcohol:
Effects on fertility:
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

Effects on foetal development:
Species: Mouse
Application Route: Ingestion
Result: negative

**STOT - single exposure**
Not classified based on available information.

**STOT - repeated exposure**
May cause damage to organs through prolonged or repeated exposure.

**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

**Benzyl alcohol:**
Species : Rat
NOAEL : 1,072 mg/l
Application Route : inhalation (dust/mist/fume)
Exposure time : 28 Days
Method : OECD Test Guideline 412

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

**Experience with human exposure**

**Components:**

**Gentamicin:**
Ingestion : Target Organs: Kidney
            Target Organs: inner ear
            Symptoms: Dizziness, Vertigo, hearing loss, tinnitus, fetal deafness

**SECTION 12: Ecological information**

12.1 **Toxicity**

**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

M-Factor (Acute aquatic toxicity) : 100

Toxicity to microorganisms : EC50 : 288,7 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

M-Factor (Chronic aquatic toxicity) : 1

**Benzyl alcohol:**
Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 460 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 230 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): 770 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 310 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 51 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
Method: OECD Test Guideline 211

### 12.2 Persistence and degradability

**Components:**

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

**Benzyl alcohol:**
Biodegradability : Result: Readily biodegradable.
Biodegradation: 92 - 96 %
Exposure time: 14 d

### 12.3 Bioaccumulative potential

**Components:**

**Gentamicin:**
Partition coefficient: n-octanol/water : log Pow: < -2

**Benzyl alcohol:**
12.4 Mobility in soil
No data available

12.5 Results of PBT and vPvB assessment
Not relevant

12.6 Other adverse effects
No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods
Product: Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

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

14.1 UN number
ADN: UN 3082
ADR: UN 3082
RID: UN 3082
IMDG: UN 3082
IATA: UN 3082

14.2 UN proper shipping name
ADN: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Gentamicin)
ADR: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Gentamicin)
RID: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Gentamicin)
IMDG: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Gentamicin)
IATA: Environmentally hazardous substance, liquid, n.o.s. (Gentamicin)

14.3 Transport hazard class(es)
14.4 Packing group

**ADN**
Packing group: III
Classification Code: M6
Hazard Identification Number: 90
Labels: 9

**ADR**
Packing group: III
Classification Code: M6
Hazard Identification Number: 90
Labels: 9
Tunnel restriction code: (−)

**RID**
Packing group: III
Classification Code: M6
Hazard Identification Number: 90
Labels: 9

**IMDG**
Packing group: III
Labels: 9

**IATA (Cargo)**
Packing instruction (cargo aircraft): 964
Packing instruction (LQ): Y964
Labels: Miscellaneous

**IATA (Passenger)**
Packing instruction (passenger aircraft): 964
Packing instruction (LQ): Y964
Labels: Miscellaneous

14.5 Environmental hazards

**ADN**
Environmentally hazardous: yes

**ADR**
Environmentally hazardous: yes

**RID**
Environmentally hazardous: yes

**IMDG**
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<table>
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<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
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<tbody>
<tr>
<td>2.3</td>
<td>10.10.2020</td>
<td>1845027-00007</td>
<td>13.09.2019</td>
<td>25.07.2017</td>
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</table>

Marine pollutant : yes

IATA (Passenger)
Environmentally hazardous : yes

IATA (Cargo)
Environmentally hazardous : yes

14.6 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.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

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

The components of this product are reported in the following inventories:

- AICS : not determined
- DSL : not determined
- IECSC : not determined

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information : Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Full text of H-statements

- **H302** : Harmful if swallowed.
- **H319** : Causes serious eye irritation.
- **H332** : Harmful if inhaled.
- **H360D** : May damage the unborn child.
- **H372** : Causes damage to organs through prolonged or repeated exposure if swallowed.
- **H400** : Very toxic to aquatic life.
- **H410** : Very toxic to aquatic life with long lasting effects.

Full text of other abbreviations

- **Acute Tox.** : Acute toxicity
- **Aquatic Acute** : Short-term (acute) aquatic hazard
- **Aquatic Chronic** : Long-term (chronic) aquatic hazard
- **Eye Irrit.** : Eye irritation
- **Repr.** : Reproductive toxicity
- **STOT RE** : Specific target organ toxicity - repeated exposure
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Gentamicin (8%) Injection Formulation

Version: 2.3  Revision Date: 10.10.2020  SDS Number: 1845027-00007  Date of last issue: 13.09.2019

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50% of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Further information

Classification of the mixture:

Classification procedure:

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<thead>
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<th>Classification procedure:</th>
<th>Classification of the mixture:</th>
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<tbody>
<tr>
<td>H360D</td>
<td>Repr. 1A</td>
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<tr>
<td>H373</td>
<td>STOT RE 2</td>
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<tr>
<td>H400</td>
<td>Aquatic Acute 1</td>
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<tr>
<td>H411</td>
<td>Aquatic Chronic 2</td>
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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.

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