SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Gentamicin Liquid Formulation

Version 2.4  Revision Date: 10.10.2020  SDS Number: 1845339-00008  Date of last issue: 23.03.2020  Date of first issue: 21.07.2017

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

1.1 Product identifier
Trade name: Gentamicin Liquid 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
Innishannon
County Cork - Ireland

Telephone: 353 214329300
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  H360D: May damage the unborn child.
Short-term (acute) aquatic hazard, Category 1  H400: Very toxic to aquatic life.
Long-term (chronic) aquatic hazard, Category 3  H412: Harmful 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.
H410  Very toxic to aquatic life with long lasting effects.

Precautionary statements: Prevention:
Gentamicin Liquid Formulation

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

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gentamicin</td>
<td>1403-66-3</td>
<td>Repr. 1A; H360D STOT RE 1; H372 (Kidney, inner ear) Aquatic Acute 1; H400 Aquatic Chronic 1; H410</td>
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<tr>
<td></td>
<td>215-765-8</td>
<td>M-Factor (Acute aquatic toxicity): 100</td>
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<td></td>
<td>M-Factor (Chronic aquatic toxicity): 1</td>
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<tr>
<td>Benzalkonium chloride</td>
<td>8001-54-5</td>
<td>Acute Tox. 3; H301 Acute Tox. 2; H330 Acute Tox. 3; H311 Skin Corr. 1; H314 Eye Dam. 1; H318 Aquatic Acute 1; H400 Aquatic Chronic 2; H411</td>
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<tr>
<td></td>
<td></td>
<td>M-Factor (Acute aquatic toxicity): 100</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 advice 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.

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: No hazardous combustion products are known

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 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.

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

**Occupational Exposure Limits**

<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>
</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. Equipment should conform to I.S. EN 143
Filter type : Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties
Appearance : liquid
Colour : Colorless to pale yellow
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
Gentamicin Liquid Formulation

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.

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

Benzalkonium chloride:
Acute oral toxicity: LD50 (Rat): 240 mg/kg
Acute inhalation toxicity: LC50 (Rat, male): > 0.05 - 0.5 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403
Assessment: Corrosive to the respiratory tract.
Remarks: Based on data from similar materials

Acute dermal toxicity: LD50 (Rat, female): 704 mg/kg

Skin corrosion/irritation
Not classified based on available information.

Components:

Gentamicin:
Species: Rabbit
Result: Mild skin irritation
**Benzalkonium chloride:**
Species : Human
Result  : Corrosive after 4 hours or less of exposure

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

**Components:**

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

**Benzalkonium chloride:**
Species : Rabbit
Result  : Irreversible effects on the eye

**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

**Benzalkonium chloride:**
Test Type  : Human repeat insult patch test (HRIPT)
Exposure routes : Skin contact
Species : Humans
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

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

**Benzalkonium chloride:**
Genotoxicity in vitro:
Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 476
Result: negative
Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro
Method: OECD Test Guideline 473
Result: negative
Remarks: Based on data from similar materials

Genotoxicity in vivo:
Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Ingestion
Method: OECD Test Guideline 474
Result: negative
Remarks: Based on data from similar materials

**Carcinogenicity**
Not classified based on available information.

**Components:**

**Gentamicin:**
Carcinogenicity - Assessment: No data available

**Benzalkonium chloride:**
Species: Rat
Application Route: Ingestion
Exposure time: 2 Years
Method: OECD Test Guideline 453
Result: negative
Remarks: Based on data from similar materials

Species: Mouse
Application Route: Skin contact
Exposure time: 80 weeks
Result: negative

Species: Rabbit
Application Route: Skin contact
Exposure time: 90 weeks
Result: negative
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

Benzalkonium chloride:
Effects on fertility
: Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 416
Result: negative
Remarks: Based on data from similar materials

Effects on foetal development
: Test Type: Embryo-foetal development
Species: Rabbit
Application Route: Ingestion
Method: OECD Test Guideline 414
Result: negative
Remarks: Based on data from similar materials
STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
Not classified based on available information.

Components:

**Gentamicin:**
- **Target Organs:** Kidney, inner ear
- **Assessment:** Causes damage to organs through prolonged or repeated exposure.

**Benzalkonium chloride:**
- **Assessment:** No significant health effects observed in animals at concentrations of 100 mg/kg bw or less.

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

### Benzalkonium chloride:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>&gt;= 100 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>12 Weeks</td>
</tr>
</tbody>
</table>

### Aspiration toxicity

Not classified based on available information.

### Experience with human exposure

#### Components:

**Gentamicin:**

<table>
<thead>
<tr>
<th>Ingestion</th>
<th>Target Organs: Kidney</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Target Organs: inner ear</td>
</tr>
<tr>
<td></td>
<td>Symptoms: Dizziness, Vertigo, hearing loss, tinnitus, fetal deafness</td>
</tr>
</tbody>
</table>

### SECTION 12: Ecological information

#### 12.1 Toxicity

##### Components:

**Gentamicin:**

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

<table>
<thead>
<tr>
<th>Toxicity to algae/aquatic plants</th>
<th>EC50 (Pseudokirchneriella subcapitata (green algae)): 10 µg/l</th>
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</thead>
<tbody>
<tr>
<td>Exposure time: 72 h</td>
<td>Method: OECD Test Guideline 201</td>
</tr>
<tr>
<td>NOEC (Pseudokirchneriella subcapitata (green algae)): 1.5 µg/l</td>
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<tr>
<td>Exposure time: 72 h</td>
<td>Method: OECD Test Guideline 201</td>
</tr>
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<table>
<thead>
<tr>
<th>EC50 (Anabaena flos-aquae (cyanobacterium)): 4.7 µg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time: 72 h</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>NOEC (Anabaena flos-aquae (cyanobacterium)): 1.6 µg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time: 72 h</td>
</tr>
</tbody>
</table>
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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

Benzalkonium chloride:
Toxicity to fish: LC50 (Pimephales promelas (fathead minnow)): 0.28 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): 0.0056 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants: ErC50 (Chlorella pyrenoidosa (aglae)): 0.09 mg/l
Exposure time: 72 h

M-Factor (Acute aquatic toxicity): 100

Toxicity to fish (Chronic toxicity): NOEC: 0.032 mg/l
Exposure time: 34 d
Species: Pimephales promelas (fathead minnow)

12.2 Persistence and degradability

Components:

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

Benzalkonium chloride:
Biodegradability: Result: Readily biodegradable.
Method: OECD Test Guideline 301D
Remarks: Based on data from similar materials

12.3 Bioaccumulative potential

Components:

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

Benzalkonium chloride:
Bioaccumulation: Species: Lepomis macrochirus (Bluegill sunfish)
Gentamicin Liquid Formulation

Bioconcentration factor (BCF): < 500
Remarks: Based on data from similar materials

Partition coefficient: n-octanol/water
: log Pow: 1.692
Remarks: Calculation

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, Benzalkonium chloride)

ADR : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
(Gentamicin, Benzalkonium chloride)

RID : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
(Gentamicin, Benzalkonium chloride)

IMDG : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
SAFETY DATA SHEET according to Regulation (EC) No. 1907/2006

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(Gentamicin, Benzalkonium chloride)

IATA: Environmentally hazardous substance, liquid, n.o.s.
(Gentamicin, Benzalkonium chloride)

14.3 Transport hazard class(es)

<table>
<thead>
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<th>Code</th>
<th>Value</th>
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<td>IATA</td>
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14.4 Packing group

<table>
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<td>Tunnel restriction code</td>
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<td>EmS Code</td>
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<table>
<thead>
<tr>
<th>IATA (Cargo)</th>
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<tbody>
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<td>Packing instruction (cargo aircraft)</td>
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<tr>
<td>Packing instruction (LQ)</td>
<td>Y964</td>
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<tr>
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<tr>
<td>Labels</td>
<td>Miscellaneous</td>
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<th>IATA (Passenger)</th>
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<td>Packing instruction (passenger aircraft)</td>
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<tr>
<td>Packing instruction (LQ)</td>
<td>Y964</td>
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14.5 Environmental hazards

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<th>ADN</th>
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Date of last issue: 23.03.2020
Date of first issue: 21.07.2017

Version 2.4
Revision Date: 10.10.2020
SDS Number: 1845339-00008
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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII): Conditions of restriction for the following entries should be considered: Number on list 3

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59): Not applicable

REACH - List of substances subject to authorisation (Annex XIV): Not applicable

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer: Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast): Not applicable

Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals: Not applicable


Other regulations:

Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.

Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

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

AICS: not determined

<table>
<thead>
<tr>
<th>E1</th>
<th>ENVIRONMENTAL HAZARDS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quantity 1</td>
<td>Quantity 2</td>
</tr>
<tr>
<td>100 t</td>
<td>200 t</td>
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</tbody>
</table>
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Gentamicin Liquid Formulation

Version: 2.4
Revision Date: 10.10.2020
SDS Number: 1845339-00008
Date of last issue: 23.03.2020
Date of first issue: 21.07.2017

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

H301: Toxic if swallowed.
H311: Toxic in contact with skin.
H314: Causes severe skin burns and eye damage.
H318: Causes serious eye damage.
H330: Fatal 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.
H411: 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 Dam.: Serious eye damage
Repr.: Reproductive toxicity
Skin Corr.: Skin corrosion
STOT RE: Specific target organ toxicity - repeated exposure

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 Stand-
FURTHER INFORMATION

Sources of key data used to compile the Safety Data Sheet:

CLASSIFICATION OF THE MIXTURE:

<table>
<thead>
<tr>
<th>Classification</th>
<th>Category</th>
<th>Hazard Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Repr. 1A</td>
<td></td>
<td>H360D</td>
</tr>
<tr>
<td>Aquatic Acute 1</td>
<td></td>
<td>H400</td>
</tr>
<tr>
<td>Aquatic Chronic 3</td>
<td></td>
<td>H412</td>
</tr>
</tbody>
</table>

CLASSIFICATION PROCEDURE:
- Calculation method

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.