SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

Gentamicin Liquid Formulation

Version 1.7  Revision Date: 2020/10/10  SDS Number: 1843164-00008  Date of last issue: 2020/03/23  Date of first issue: 2017/07/21

1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Gentamicin Liquid Formulation

Manufacturer or supplier’s details
Company: MSD
Address: 199 Wenhai North Road
          HEDA, Hangzhou - Zhejiang Province - CHINA 310018
Telephone: 908-740-4000
Emergency telephone number: 86-571-87268110
E-mail address: EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use
Recommended use: Pharmaceutical

2. HAZARDS IDENTIFICATION

Emergency Overview

<table>
<thead>
<tr>
<th>Appearance</th>
<th>liquid</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colour</td>
<td>Colorless to pale yellow</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
</tbody>
</table>

May damage the unborn child. Very toxic to aquatic life. Harmful to aquatic life with long lasting effects.

GHS Classification
Reproductive toxicity: Category 1A
Short-term (acute) aquatic hazard: Category 1
Long-term (chronic) aquatic hazard: Category 3

GHS label elements
Hazard pictograms: ⚠️ ⚠️
Signal word: Danger
Hazard statements: H360D May damage the unborn child.
                  H400 Very toxic to aquatic life.
                  H412 Harmful to aquatic life with long lasting effects.
Precautionary statements:

**Prevention:**
- P201 Obtain special instructions before use.
- P202 Do not handle until all safety precautions have been read and understood.
- 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.

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

### Physical and chemical hazards
Not classified based on available information.

### Health hazards
May damage the unborn child.

### Environmental hazards
Very toxic to aquatic life. Harmful to aquatic life with long lasting effects.

### Other hazards which do not result in classification
None known.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gentamicin</strong></td>
<td>Chemical name, CAS-No., Concentration (% w/w)</td>
</tr>
<tr>
<td></td>
<td>Gentamicin, 1403-66-3, 0.3</td>
</tr>
<tr>
<td>Benzalkonium chloride</td>
<td>8001-54-5, 0.01</td>
</tr>
</tbody>
</table>

### 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.

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.

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.

5. FIREFIGHTING MEASURES

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

Unsuitable extinguishing media:
None known.

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

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.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures:
Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

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.

Methods and materials for:
Soak up with inert absorbent material.
containment and cleaning up

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.

7. HANDLING AND STORAGE

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.

Avoidance of contact : Oxidizing agents

Storage
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

Packaging material : Unsuitable material: None known.

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., dripless 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

**Eye/face 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.

**Skin and body protection**
- Work uniform or laboratory coat.

**Hand protection**
- Chemical-resistant gloves

**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.

**9. 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
Gentamicin Liquid Formulation

10. STABILITY AND REACTIVITY

Reactivity
: Not classified as a reactivity hazard.

Chemical stability
: Stable under normal conditions.

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

Conditions to avoid
: None known.

Incompatible materials
: Oxidizing agents

Hazardous decomposition products
: No hazardous decomposition products are known.
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

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:
Gentamicin Liquid Formulation

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
Warning: negative

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

Test Type: Chromosome aberration test in vitro
Result: equivocal
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.
SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

Gentamicin Liquid Formulation

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

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

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

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.

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:
Gentamicin Liquid Formulation

Species: Rat  
NOAEL: >= 100 mg/kg  
Application Route: Ingestion  
Exposure time: 12 Weeks

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

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

M-Factor (Acute aquatic toxicity): 100  
M-Factor (Chronic aquatic toxicity): 1
Gentamicin Liquid Formulation

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

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 (Pimephales promelas (fathead minnow)): 0.032 mg/l 
Exposure time: 34 d

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

Bioaccumulative potential

Components:

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

Benzalkonium chloride:
Bioaccumulation: 
Species: Lepomis macrochirus (Bluegill sunfish) 
Bioconcentration factor (BCF): < 500 
Remarks: Based on data from similar materials

Partition coefficient: n-octanol/water: 
log Pow: 1.692 
Remarks: Calculation
SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

Gentamicin Liquid Formulation

Version: 1.7
Revision Date: 2020/10/10
SDS Number: 1843164-00008
Date of last issue: 2020/03/23
Date of first issue: 2017/07/21

Mobility in soil
No data available

Other adverse effects
No data available

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.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG
UN number: UN 3082
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
(Gentamicin, Benzalkonium chloride)
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, Benzalkonium chloride)
Class: 9
Packing group: III
Labels: Miscellaneous
Packing instruction (cargo): 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, Benzalkonium chloride)
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
SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

Gentamicin Liquid Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.7</td>
<td>2020/10/10</td>
<td>1843164-00008</td>
<td>2020/03/23</td>
<td>2017/07/21</td>
</tr>
</tbody>
</table>

**GB 6944/12268**

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

**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.

15. REGULATORY INFORMATION

**National regulatory information**

Law on the Prevention and Control of Occupational Diseases

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

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

16. OTHER INFORMATION

**Further information**


Date format : yyyy/mm/dd

**Full text of other abbreviations**

AIIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); 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; ERG - Emergency Response Guide; 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 Chemi-
SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

Gentamicin Liquid Formulation

Version 1.7  Revision Date: 2020/10/10  SDS Number: 1843164-00008  Date of last issue: 2020/03/23  Date of first issue: 2017/07/21

Disclaimer
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.

CN / EN