1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Gentamicin Liquid Formulation

Manufacturer or supplier’s details
Company: MSD
Address: 50 Tuas West Drive
Singapore - Singapore 638408
Telephone: 908-740-4000
Emergency telephone number: 65 6697 2111 (24/7/365)
E-mail address: EHSDATASTEWARD@msd.com
Telefax: 908-735-1496

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

2. HAZARDS IDENTIFICATION

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

GHS label elements
Hazard pictograms:

- Signal word: Danger
- Hazard statements: H360D May damage the unborn child. H400 Very toxic to aquatic life.

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.

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

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

**Substance / Mixture:** Mixture

**Components**

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

### 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)
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Version 1.5 Revision Date: 09/13/2019 SDS Number: 1843175-00006 Date of last issue: 24.04.2019
Date of first issue: 21.07.2017

Dry chemical

None known.

Vapours may form explosive mixtures with air.
Exposure to combustion products may be a hazard to health.

No hazardous combustion products are known

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.

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 and personal protective equipment recommendations.

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.

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.

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.

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

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

Hand protection:
- 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.
- Wear a face shield 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.
- 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

The effective operation of a facility should include review of
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

**Flammability (solid, gas)** : Not applicable

**Flammability (liquids)** : 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.

Molecular weight : No data available

Particle size : No data available

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

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:
SAFETY DATA SHEET

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Acute oral toxicity: LD50 (Rat): 344 mg/kg
Remarks: Based on data from similar materials

Acute inhalation toxicity: LC50 (Rat): 0.25 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 (Rabbit): 3,412 mg/kg
Remarks: Based on data from similar materials

Skin corrosion/irritation
Not classified based on available information.

Components:

Gentamicin:
Species: Rabbit
Result: Mild skin irritation

Benzalkonium chloride:
Species: Rabbit
Result: Corrosive after 3 minutes to 1 hour of exposure
Remarks: Based on data from similar materials

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
Remarks: Based on data from similar materials

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
Gentamicin Liquid Formulation

Benzalkonium chloride:
Test Type: Buehler Test
Exposure routes: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative
Remarks: Based on data from similar materials

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)
Method: OECD Test Guideline 471
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
Gentamicin Liquid Formulation

Exposure time: 2 Years
Method: OECD Test Guideline 453
Result: negative
Remarks: Based on data from similar materials

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:
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 study
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 416
Result: negative
Remarks: Based on data from similar materials

Effects on foetal development:
Species: Rabbit
Application Route: Ingestion
Method: OECD Test Guideline 414
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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.

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
SAFETY DATA SHEET

Gentamicin Liquid Formulation

Version: 1.5
Revision Date: 09/13/2019
SDS Number: 1843175-00006
Date of last issue: 24.04.2019
Date of first issue: 21.07.2017

Benzalkonium chloride:
Species: Dog
NOAEL: 50 mg/kg
Application Route: Ingestion
Exposure time: 13 Weeks
Method: OECD Test Guideline 409
Remarks: Based on data from similar materials

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
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 (Oncorhynchus mykiss (rainbow trout)): 0.85 mg/l
  Exposure time: 96 h
  Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates:
- EC50 (Daphnia magna (Water flea)): 0.016 mg/l
  Exposure time: 48 h
  Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants:
- EC50 (Pseudokirchneriella subcapitata (green algae)): 0.049 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201
  Remarks: Based on data from similar materials
- EC10 (Pseudokirchneriella subcapitata (green algae)): 0.009 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201
  Remarks: Based on data from similar materials

M-Factor (Acute aquatic toxicity): 10
Toxicity to fish (Chronic toxicity):
- NOEC (Pimephales promelas (fathead minnow)): > 32.2 mg/l
  Exposure time: 34 d
  Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):
- NOEC (Daphnia magna (Water flea)): 0.0125 mg/l
  Exposure time: 21 d
  Method: OECD Test Guideline 211
  Remarks: Based on data from similar materials

M-Factor (Chronic aquatic toxicity): 1
Toxicity to microorganisms:
- EC50: 7.75 mg/l
  Exposure time: 3 h
  Method: OECD Test Guideline 209
  Remarks: Based on data from similar materials

**Persistence and degradability**

**Components:**

**Gentamicin:**
Biodegradability:
- Result: rapidly degradable
- Biodegradation: 100 %
Benzalkonium chloride:
Biodegradability : Result: Readily biodegradable.
Biodegradation: 95.5 %
Exposure time: 28 d
Method: OECD Test Guideline 301
Remarks: Based on data from similar materials

Bioaccumulative potential

Components:

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

Benzalkonium chloride:
Partition coefficient: n-octanol/water : log Pow: 0.004
Remarks: Based on data from similar materials

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)
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| 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, 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.

**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**

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

**Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations:** This product is subjected to the SDS, labelling, PEL and other requirements in the Act/Regulations.
- Environmental Protection and Management Act and Environmental Protection and Management (Hazardous Substances) Regulations: Not applicable
- Fire Safety (Petroleum and Flammable Materials) Regulations: Not applicable

**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: dd.mm.yyyy

Full text of other abbreviations

AICS - Australian Inventory of Chemical Substances; 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 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; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; 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; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; 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; WHMIS - Workplace Hazardous Materials Information System

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.