SAFETY DATA SHEET

Gentamicin (8%) Injection Formulation

SECTION 1. IDENTIFICATION

Product name : Gentamicin (8%) Injection Formulation

Manufacturer or supplier’s details
Company name of supplier : Organon & Co.
Address : 30 Hudson Street, 33rd floor
           Jersey City, New Jersey, U.S.A 07302
Telephone : 551-430-6000
Emergency telephone : 215-631-6999
E-mail address : EHSSTEWARD@organon.com

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

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Reproductive toxicity : Category 1A

Specific target organ toxicity - repeated exposure (Oral) : Category 1 (Kidney, inner ear)

GHS label elements
Hazard pictograms :

Signal Word : Danger

Hazard Statements : H360D May damage the unborn child.
                   H372 Causes damage to organs (Kidney, inner ear) through prolonged or repeated exposure if swallowed.

Precautionary Statements :
Prevention:
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe mist or vapors.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P280 Wear protective gloves, protective clothing, eye protection and face protection.

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

Storage:
P405 Store locked up.

Disposal:
SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Gentamicin</td>
<td>1403-66-3</td>
<td>8</td>
</tr>
<tr>
<td></td>
<td>Benzyl alcohol</td>
<td>100-51-6</td>
<td>1.5</td>
</tr>
</tbody>
</table>

SECTION 4. FIRST AID MEASURES

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

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

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

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

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

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

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

Notes to physician : Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

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

Unsuitable extinguishing media : None known.

Specific hazards during firefighting : Vapors may form explosive mixtures with air. Exposure to combustion products may be a hazard to health.
### Section 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 containment and cleaning up:**
- Soak up with inert absorbent material.
- For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container.
- Clean up remaining materials from spill with suitable absorbent.
- Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
- Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

### Section 7. Handling and Storage

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

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

**Advice on safe handling:**
- Do not get on skin or clothing.
- Do not breathe mist or vapors.
- 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.

**Conditions for safe storage:**
- Keep in properly labeled 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
  - Organic peroxides
  - Explosives
  - Gases

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients 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>
<tr>
<td>Benzyl alcohol</td>
<td>100-51-6</td>
<td>TWA</td>
<td>10 ppm</td>
<td>US WEEL</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:**
- General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn.
- Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

**Hand protection Material:**
- Chemical-resistant gloves

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

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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : liquid
Color : colorless
Odor : No data available
Odor 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 : > 199.9 °F / > 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
Vapor pressure : No data available
Relative vapor 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
Autoignition 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

SECTION 10. STABILITY AND REACTIVITY

Reactivity: Not classified as a reactivity hazard.
Chemical stability: Stable under normal conditions.
Possibility of hazardous reactions
  Vapors 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.

SECTION 11. TOXICOLOGICAL INFORMATION

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: > 5,000 mg/kg
  Method: Calculation method
Acute inhalation toxicity: Acute toxicity estimate: > 200 mg/l
  Exposure time: 4 h
  Test atmosphere: dust/mist
  Method: Calculation method

Components:
Gentamicin:
<table>
<thead>
<tr>
<th>Component</th>
<th>Type</th>
<th>Species</th>
<th>Method</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gentamicin</td>
<td>Acute oral toxicity</td>
<td>Rabbit</td>
<td></td>
<td>Mild skin irritation</td>
</tr>
<tr>
<td></td>
<td>LD50 (Rat)</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>LD50 (Mouse)</td>
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<tr>
<td></td>
<td>LD50 (Rat): 67 - 96 mg/kg</td>
<td></td>
<td>Application Route: Intravenous</td>
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<tr>
<td></td>
<td>LD50 (Rat): 371 - 384 mg/kg</td>
<td></td>
<td>Application Route: Intramuscular</td>
<td></td>
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<tr>
<td></td>
<td>LDLo (Monkey): 30 mg/kg</td>
<td></td>
<td>Application Route: Intravenous</td>
<td></td>
</tr>
<tr>
<td></td>
<td>LD50 (Rat): &gt; 4.178 mg/l</td>
<td></td>
<td>Exposure time: 4 h</td>
<td></td>
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<tr>
<td></td>
<td>Test atmosphere: dust/mist</td>
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<td></td>
<td>Remarks: No mortality observed at this dose.</td>
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<tr>
<td></td>
<td>Acute inhalation toxicity</td>
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<td></td>
<td>LC50 (Rat): &gt; 0.2 mg/l</td>
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<td></td>
<td>Exposure time: 4 h</td>
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<td></td>
<td>Test atmosphere: dust/mist</td>
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<tr>
<td></td>
<td>Method: OECD Test Guideline 403</td>
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<td></td>
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</tr>
<tr>
<td></td>
<td>Skin corrosion/irritation</td>
<td></td>
<td></td>
<td>Not classified based on available information.</td>
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<tr>
<td></td>
<td>Serious eye damage/eye irritation</td>
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<td></td>
<td>Not classified based on available information.</td>
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<tr>
<td></td>
<td>Acute oral toxicity</td>
<td>Rabbit</td>
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<td></td>
<td>Method: OECD Test Guideline 404</td>
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<td>Acute inhalation toxicity</td>
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<td></td>
<td>Method: OECD Test Guideline 403</td>
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<tr>
<td></td>
<td>Benzyl alcohol</td>
<td>Rabbit</td>
<td></td>
<td>Irritation to eyes, reversing within 21 days</td>
</tr>
<tr>
<td></td>
<td>LD50 (Rat)</td>
<td></td>
<td></td>
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<tr>
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<td></td>
<td>Serious eye damage/eye irritation</td>
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<tr>
<td></td>
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<tr>
<td></td>
<td>Method: OECD Test Guideline 404</td>
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</tr>
</tbody>
</table>

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
Result: Irritation to eyes, reversing within 21 days
Method : OECD Test Guideline 405

Respiratory or skin sensitization

Skin sensitization
Not classified based on available information.

Respiratory sensitization
Not classified based on available information.

Components:

Gentamicin:
Remarks : No data available

Benzyl alcohol:
Test Type : Maximization Test
Routes of exposure : 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
                        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

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: Intraperitoneal 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

IARC
No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA
No component of this product present at levels greater than or equal to 0.1% is on OSHA’s list of regulated carcinogens.

NTP
No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

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 fetal development:
Test Type: Embryo-fetal development
Species: Rabbit
Developmental Toxicity: NOAEL: 3.6 mg/kg body weight
Result: No embryo-fetal toxicity.
Test Type: Embryo-fetal development
Species: Rat
Application Route: Intraperitoneal
Developmental Toxicity: LOAEL: 75 mg/kg body weight
Result: Embryo-fetal toxicity.
Test Type: Embryo-fetal development
Species: Mouse
Application Route: Intraperitoneal
Developmental Toxicity: LOAEL: 10 mg/kg body weight
Result: Fetal mortality; No malformations were observed.
Test Type: Embryo-fetal development
Species: Rat
Application Route: Intraperitoneal
Developmental Toxicity: LOAEL: 50 mg/kg body weight
Result: Fetal mortality; No malformations were observed.
Reproductive toxicity - Assessment:
Positive evidence of adverse effects on development from human epidemiological studies.

Benzyl alcohol:
Effects on fertility:
- Test Type: Fertility/early embryonic development
- Species: Rat
- Application Route: Ingestion
- Result: negative
- Remarks: Based on data from similar materials

Effects on fetal development:
- Test Type: Embryo-fetal development
- Species: Mouse
- Application Route: Ingestion
- Result: negative

STOT-single exposure
Not classified based on available information.

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

Components:

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

Repeated dose toxicity

Components:

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

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

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

Gentamicin (8%) Injection Formulation

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>5 mg/kg</td>
</tr>
<tr>
<td>LOAEL</td>
<td>10 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Intramuscular</td>
</tr>
<tr>
<td>Exposure time</td>
<td>52 Weeks</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Kidney, Blood</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>12.5 mg/kg</td>
</tr>
<tr>
<td>LOAEL</td>
<td>50 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Intramuscular</td>
</tr>
<tr>
<td>Exposure time</td>
<td>13 Weeks</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Kidney</td>
</tr>
</tbody>
</table>

**Benzyl alcohol:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>1.072 mg/l</td>
</tr>
<tr>
<td>Application Route</td>
<td>inhalation (dust/mist/fume)</td>
</tr>
<tr>
<td>Exposure time</td>
<td>28 Days</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 412</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>

**Ecotoxicity**

**Components:**

**Gentamicin:**

Toxicity to daphnia and other aquatic invertebrates:

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

Toxicity to algae/aquatic plants:

<table>
<thead>
<tr>
<th>EC50 (Pseudokirchneriella subcapitata (green algae)): 10 µg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time: 72 h</td>
</tr>
<tr>
<td>Method: OECD Test Guideline 201</td>
</tr>
<tr>
<td>NOEC (Pseudokirchneriella subcapitata (green algae)): 1.5</td>
</tr>
</tbody>
</table>

SECTION 12. ECOLOGICAL INFORMATION
Toxicity to microorganisms:

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

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 (Daphnia magna (Water flea)): 51 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211

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
Bioaccumulative potential

Components:

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

Benzyl alcohol:
Partition coefficient: n-octanol/water: log Pow: 1.05

Mobility in soil
No data available

Other adverse effects
No data available

SECTION 13. DISPOSAL CONSIDERATIONS

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

SECTION 14. TRANSPORT INFORMATION

International Regulations

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

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

IMDG-Code
UN number: UN 3082
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,
SAFETY DATA SHEET

Gentamicin (8%) Injection Formulation

Version 3.4  Revision Date: 10/10/2020  SDS Number: 1845025-00008  Date of last issue: 03/23/2020
Date of first issue: 07/25/2017

N.O.S. (Gentamicin)

Class: 9
Packing group: III
Labels: 9
EmS Code: F-A, S-F
Marine pollutant: yes

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

Domestic regulation

49 CFR
UN/ID/NA number: UN 3082
Proper shipping name: Environmentally hazardous substance, liquid, n.o.s. (Gentamicin)
Class: 9
Packing group: III
Labels: CLASS 9
ERG Code: 171
Marine pollutant: yes (Gentamicin)
Remarks: Above applies only to containers over 119 gallons or 450 liters., Shipment by ground under DOT is non-regulated; however it may be shipped per the applicable hazard classification to facilitate multi-modal transport involving ICAO (IATA) or IMO.

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

SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantity

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Component RQ (lbs)</th>
<th>Calculated product RQ (lbs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium hydrogensulfite</td>
<td>7631-90-5</td>
<td>5000</td>
<td>*</td>
</tr>
</tbody>
</table>

*: Calculated RQ exceeds reasonably attainable upper limit.

SARA 304 Extremely Hazardous Substances Reportable Quantity
This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity
This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards: Reproductive toxicity
Specific target organ toxicity (single or repeated exposure)

SARA 313: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.
US State Regulations

Pennsylvania Right To Know

Water 7732-18-5
Gentamicin 1403-66-3
Benzyl alcohol 100-51-6
Sodium hydrogensulfite 7631-90-5

California Prop. 65
WARNING: This product can expose you to chemicals including Gentamicin, which is/are known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

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

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

SECTION 16. OTHER INFORMATION

Further information

NFPA 704: 

<table>
<thead>
<tr>
<th>Health</th>
<th>Flammability</th>
<th>Instability</th>
<th>Special hazard</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

HMIS® IV:

<table>
<thead>
<tr>
<th>HEALTH</th>
<th>FLAMMABILITY</th>
<th>PHYSICAL HAZARD</th>
</tr>
</thead>
<tbody>
<tr>
<td>*</td>
<td>3</td>
<td>1</td>
</tr>
</tbody>
</table>

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "0" represents the absence of a chronic hazard.

Full text of other abbreviations

US WEEL: USA. Workplace Environmental Exposure Levels (WEEL)
US WEEL / TWA: 8-hr TWA

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Haz-
ardous Substance; 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; HMIS - Hazardous Materials Identification System; 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; 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


Revison Date : 10/10/2020

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.

US / Z8