1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Gentamicin / Betamethasone Formulation

Manufacturer or supplier’s details

Company : MSD
Address : No. 485 Jing Tai Road
          Pu Tuo District - Shanghai - China 200331
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 : Veterinary product

2. HAZARDS IDENTIFICATION

Emergency Overview

Appearance : liquid
Colour : No data available
Odour : No data available

May damage the unborn child. Causes damage to organs through prolonged or repeated exposure. Very toxic to aquatic life with long lasting effects.

GHS Classification

Reproductive toxicity : Category 1A
Specific target organ toxicity - repeated exposure : Category 1
Short-term (acute) aquatic hazard : Category 1
Long-term (chronic) aquatic hazard : Category 1

GHS label elements

Hazard pictograms : :

Signal word : Danger
Hazard statements : H360D May damage the unborn child.
H372 Causes damage to organs through prolonged or repeated exposure.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements:
Prevention:
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe mist or vapours.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
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. Causes damage to organs through prolonged or repeated exposure.

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

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>Polyethylene glycol stearate</td>
<td>9004-99-3</td>
<td>5</td>
</tr>
<tr>
<td>Gentamicin</td>
<td>1403-66-3</td>
<td>0.49</td>
</tr>
<tr>
<td>Betamethasone</td>
<td>378-44-9</td>
<td>0.1</td>
</tr>
<tr>
<td>Benzalkonium chloride</td>
<td>8001-54-5</td>
<td>0.01</td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES
SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

Gentamicin / Betamethasone Formulation

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<tr>
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<td>2016/01/06</td>
</tr>
</tbody>
</table>

**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.

**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:**
Exposure to combustion products may be a hazard to health.

**Hazardous combustion products:**
Carbon oxides

**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 and personal protective equipment recommendations.
Environmental precautions: 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.

Methods and materials for containment and 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.

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>Polyethylene glycol stearate</td>
<td>9004-99-3</td>
<td>TWA (Inhalable particulate matter)</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable particulate matter)</td>
<td>3 mg/m³</td>
<td>ACGIH</td>
</tr>
<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>betamethasone</td>
<td>378-44-9</td>
<td>TWA</td>
<td>1 µg/m³ (OEB 4)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Further information: Skin

<table>
<thead>
<tr>
<th>Engineeri ng measures</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Essentially no open handling permitted. Use closed processing systems or containment technologies. If handled in a laboratory, use a properly designed biosafety cabinet, fume hood, or other containment device if the potential exists for aerosolization. If this potential does not exist, handle over lined trays or benchtops.</td>
</tr>
</tbody>
</table>

Personal protective equipment

<table>
<thead>
<tr>
<th>Respiratory protection</th>
<th>If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Filter type</td>
<td>Particulates type</td>
</tr>
<tr>
<td>Eye/face protection</td>
<td>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.</td>
</tr>
<tr>
<td>Skin and body protection</td>
<td>Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.</td>
</tr>
<tr>
<td>Hand protection</td>
<td></td>
</tr>
<tr>
<td>Material</td>
<td>Chemical-resistant gloves</td>
</tr>
<tr>
<td>Remarks</td>
<td>Consider double gloving.</td>
</tr>
<tr>
<td>Hygiene measures</td>
<td></td>
</tr>
</tbody>
</table>
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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>liquid</td>
</tr>
<tr>
<td>Colour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td></td>
</tr>
<tr>
<td>Water solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>No data available</td>
</tr>
</tbody>
</table>
**SAFETY DATA SHEET**
according to GB/T 16483 and GB/T 17519

**Gentamicin / Betamethasone Formulation**

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</table>

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
  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.

**Product:**
Acute inhalation toxicity : Acute toxicity estimate: > 10 mg/l
  Exposure time: 4 h
  Test atmosphere: dust/mist
  Method: Calculation method

**Components:**

**Polyethylene glycol stearate:**
  Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

**Gentamicin:**
  Acute oral toxicity : LD50 (Rat): 8,000 - 10,000 mg/kg
  LD50 (Mouse): 10,000 mg/kg
SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

Gentamicin / Betamethasone Formulation

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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

Betamethasone:

Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
LD50 (Mouse): > 4,500 mg/kg

Acute inhalation toxicity: LC50 (Rat): 0.4 mg/l
Exposure time: 4 h

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:

Polyethylene glycol stearate:
Species: Rabbit
Result: No skin irritation

Gentamicin:
Species: Rabbit
Result: Mild skin irritation

Betamethasone:
Species: Rabbit
Result: Mild skin irritation
Gentamicin / Betamethasone Formulation

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:

Polyethylene glycol stearate:
Species: Rabbit
Result: No eye irritation

Gentamicin:
Species: Rabbit
Result: Mild eye irritation

Betamethasone:
Species: Rabbit
Result: No 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:

Polyethylene glycol stearate:
Exposure routes: Skin contact
Species: Guinea pig
Result: negative

Gentamicin:
Remarks: No data available

Betamethasone:
Exposure routes: Dermal
Species: Guinea pig
Result: Weak sensitizer
## Benzalkonium chloride:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Exposure routes</th>
<th>Species</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Human repeat insult patch test (HRIPT)</td>
<td>Skin contact</td>
<td>Humans</td>
<td>negative</td>
</tr>
</tbody>
</table>

### Germ cell mutagenicity
Not classified based on available information.

## Components:

### Polyethylene glycol stearate:

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

### 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 |

### Betamethasone:

| Genotoxicity in vitro | Test Type: Bacterial reverse mutation assay (AMES) | Result: negative |
| Test Type: In vitro mammalian cell gene mutation test | Result: negative |
| Test Type: Chromosome aberration test in vitro | Result: positive |

| Genotoxicity in vivo | Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) | Species: Mouse | Application Route: Oral | Result: equivocal |

### Germ cell mutagenicity - Assessment
Weight of evidence does not support classification as a germ cell mutagen.

### Benzalkonium chloride:

| Genotoxicity in vitro | Test Type: Bacterial reverse mutation assay (AMES) | Result: negative |
Gentamicin / Betamethasone Formulation

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
**Gentamicin / Betamethasone Formulation**

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</tbody>
</table>

**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

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

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

- **Test Type**: Embryo-foetal development  
  **Species**: Rat  
  Application Route: Intraperitoneal  
  Developmental Toxicity: LOAEL: 50 mg/kg body weight  
  Result: foetal mortality, No malformations were observed.

**Reproductive toxicity - Assessment**

- Positive evidence of adverse effects on development from human epidemiological studies.

**Betamethasone**

- **Effects on foetal development**  
  **Species**: Rabbit  
  Application Route: Intramuscular  
  Developmental Toxicity: LOAEL: 0.05 mg/kg body weight  
  Result: Fetotoxicity, Malformations were observed.

- **Test Type**: Two-generation reproduction toxicity study  
  **Species**: Rat  
  Application Route: Ingestion  
  Developmental Toxicity: LOAEL: 0.42 mg/kg body weight  
  Result: Malformations were observed.

- **Species**: Mouse  
  Application Route: Intramuscular  
  Developmental Toxicity: LOAEL: 1 mg/kg body weight  
  Result: Malformations were observed.

**Benzalkonium chloride**

- **Effects on fertility**  
  **Test Type**: Two-generation reproduction toxicity study  
  **Species**: Rat  
  Application Route: Ingestion  
  Method: OECD Test Guideline 416  
  Result: negative

Result: No significant adverse effects were reported
Gentamicin / Betamethasone Formulation

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</table>

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
Causes damage to organs through prolonged or repeated exposure.

Components:

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

**Betamethasone:**
- Target Organs: Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland
- 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:**
- Species: Monkey
- LOAEL: 50 mg/kg
- Application Route: Subcutaneous
- Exposure time: 3 Weeks
- Target Organs: Kidney, inner ear

**Species:**
- Species: Monkey
- LOAEL: 6 mg/kg
### Gentamicin / Betamethasone Formulation

**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

**betamethasone:**  
**Species:** Rabbit  
**LOAEL:** 0.05 %  
**Application Route:** Skin contact  
**Exposure time:** 10 - 30 d  
**Target Organs:** Pituitary gland, Immune system, Muscle

**Species:** Rat  
**LOAEL:** 0.05 %  
**Application Route:** Skin contact  
**Exposure time:** 8 Weeks  
**Target Organs:** thymus gland

**Species:** Mouse  
**LOAEL:** 0.1 %  
**Application Route:** Skin contact  
**Exposure time:** 8 Weeks  
**Target Organs:** thymus gland

**Species:** Dog  
**LOAEL:** 0.05 mg/kg  
**Application Route:** Oral  
**Exposure time:** 28 d  
**Target Organs:** Blood, thymus gland, Adrenal gland

**Benzalkonium chloride:**  
**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

- **betamethasone:**

  - **Inhalation:**
    - Target Organs: Adrenal gland

  - **Skin contact:**
    - Symptoms: Redness, pruritus, Irritation

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Polyethylene glycol stearate:

- **Toxicity to fish:**
  - LC50 (Leuciscus idus (Golden orfe)): > 10,000 mg/l
  - Exposure time: 96 h
  - Method: DIN 38412

- **Toxicity to microorganisms:**
  - EC10: > 10,000 mg/l
  - Exposure time: 16 h

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

- **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
### Gentamicin / Betamethasone Formulation

<table>
<thead>
<tr>
<th>M-Factor (Acute aquatic toxicity)</th>
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</tr>
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<tbody>
<tr>
<td>M-Factor (Chronic aquatic toxicity)</td>
<td>1</td>
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</tbody>
</table>
| Toxicity to microorganisms | EC50: 288.7 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209 |

#### betamethasone:

| Toxicity to daphnia and other aquatic invertebrates | EC50 (Americamysis): > 50 mg/l  
Exposure time: 96 h |
|----------------------------------------------------|--------------------------------------------------|
| Toxicity to algae/aquatic plants | EC50 (Pseudokirchneriella subcapitata (green algae)): > 34 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
Remarks: No toxicity at the limit of solubility |
| NOEC (Pseudokirchneriella subcapitata (green algae)): 34 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
Remarks: No toxicity at the limit of solubility |
| NOEC (Pimephales promelas (fathead minnow)): 0.052 mg/l  
Exposure time: 32 d  
Method: OECD Test Guideline 210 |
| NOEC (Oryzias latipes (Japanese medaka)): 0.07 µg/l  
Exposure time: 219 d  
Method: OECD Test Guideline 229 |
| NOEC (Daphnia magna (Water flea)): 8 mg/l  
Exposure time: 21 d  
Method: OECD Test Guideline 211 |
| M-Factor (Chronic aquatic toxicity) | 1,000 |

#### 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 (algae)): 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 |
Gentamicin / Betamethasone Formulation

Persistence and degradability

Components:

Polyethylene glycol stearate:
Biodegradability: Result: Readily biodegradable.
Biodegradation: > 70 %
Exposure time: 10 d
Method: OECD Test Guideline 302B

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:

Polyethylene glycol stearate:
Partition coefficient: n-octanol/water: log Pow: 6.16

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

Betamethasone:
Partition coefficient: n-octanol/water: log Pow: 2.11

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

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 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.

National Regulations

GB 6944/12268
UN number: UN 3082
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Gentamicin, Benzalkonium chloride)
# SAFETY DATA SHEET

Gentamicin / Betamethasone Formulation

## Version

<table>
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<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
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<tbody>
<tr>
<td>9</td>
<td>III</td>
<td>9</td>
</tr>
</tbody>
</table>

### 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

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


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

<table>
<thead>
<tr>
<th>Date format</th>
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<tr>
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### Full text of other abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tr>
<td>ACGIH</td>
<td>USA. ACGIH Threshold Limit Values (TLV)</td>
</tr>
<tr>
<td>ACGIH / TWA</td>
<td>8-hour, time-weighted average</td>
</tr>
</tbody>
</table>

- **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.
Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisatin 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

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