SAFETY DATA SHEET

Gentamicin / Betamethasone Formulation

Version: 7.0    Revision Date: 23.03.2020    SDS Number: 434582-00015    Date of last issue: 13.09.2019

Date of first issue: 06.01.2016

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Gentamicin / Betamethasone Formulation

Manufacturer or supplier’s details

Company: MSD

Address: Rua Coronel Bento Soares, 530
         Cruzeiro - Sao Paulo - Brazil    CEP 12730-340

Telephone: 908-740-4000

Emergency telephone: 1-908-423-6000

E-mail address: EHSDATASTEWARD@msd.com

Telefax: 908-735-1496

Recommended use of the chemical and restrictions on use

Recommended use: Veterinary product

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification in accordance with ABNT NBR 14725 Standard

Reproductive toxicity: Category 1A

Specific target organ toxicity - repeated exposure: Category 1 (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland)

Short-term (acute) aquatic hazard: Category 1

Long-term (chronic) aquatic hazard: Category 1

GHS label elements in accordance with ABNT NBR 14725 Standard

Hazard pictograms:

Signal Word: Danger

Hazard Statements:

H360D May damage the unborn child.

H372 Causes damage to organs (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland) through prolonged or repeated exposure.

H410 Very toxic to aquatic life with long lasting effects.
Precautionary Statements:

**Prevention:**
- P201 Obtain special instructions before use.
- P264 Wash skin thoroughly after handling.
- 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.

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

### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Mixture</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Components</strong></td>
<td></td>
</tr>
<tr>
<td>Chemical name</td>
<td>CAS-No.</td>
</tr>
<tr>
<td>Polyethylene glycol stearate</td>
<td>9004-99-3</td>
</tr>
<tr>
<td>Gentamicin</td>
<td>1403-66-3</td>
</tr>
<tr>
<td>Betamethasone</td>
<td>378-44-9</td>
</tr>
<tr>
<td>Benzalkonium chloride</td>
<td>8001-54-5</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.

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

Hazardous combustion products: Carbon oxides
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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 fire-fighters: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

SECTION 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 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 vapors or spray mist. Do not swallow. Avoid contact with eyes. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment. Keep container tightly closed. Take care to prevent spills, waste and minimize release to the environment.
Hygiene measures: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

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>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>Gentamicin</td>
<td>1403-66-3</td>
<td>TWA (Respirable particulate matter)</td>
<td>3 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Betamethasone</td>
<td>378-44-9</td>
<td>TWA</td>
<td>0.1 mg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>1 µg/m³ (OEB 4)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Further information: Skin Wipe limit 10 µg/100 cm² Internal

Engineering measures: 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.

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

Hand protection: Particulates type

Material: Chemical-resistant gloves

Remarks: Consider double gloving.

Eye protection:

Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection:

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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: liquid

Color: No data available

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: No data available

Evaporation rate: No data available

Flammability (solid, gas): Not applicable

Flammability (liquids): No data available

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 : 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 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
- 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
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Gentamicin:
Species: Rabbit
Result: Mild skin irritation

Betamethasone:
Species: Rabbit
Result: Mild skin irritation

Benzalkonium chloride:
Species: Human
Result: Corrosive after 4 hours or less of exposure

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

Components:
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 sensitization
Skin sensitization
Not classified based on available information.

Respiratory sensitization
Not classified based on available information.

Components:
Polyethylene glycol stearate:
Routes of exposure: Skin contact
Species: Guinea pig
Result: negative
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<table>
<thead>
<tr>
<th>Component</th>
<th>Route of exposure</th>
<th>Species</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gentamicin</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remarks</td>
<td></td>
<td>No data available</td>
<td></td>
</tr>
<tr>
<td><strong>Betamethasone</strong></td>
<td>Dermal</td>
<td>Guinea pig</td>
<td>Weak sensitizer</td>
</tr>
</tbody>
</table>

**Benzalkonium chloride:**
- **Test Type:** Human repeat insult patch test (HRIPT)
- **Routes of exposure:** Skin contact
- **Species:** Humans
- **Result:** negative

**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
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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
- Test Type: In vitro mammalian cell gene mutation test  
  Method: OECD Test Guideline 476  
  Result: negative
  Remarks: Based on data from similar materials
- Test Type: Chromosome aberration test in vitro  
  Method: OECD Test Guideline 473  
  Result: negative
  Remarks: Based on data from similar materials

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

Carcinogenicity
Not classified based on available information.

Components:

Gentamicin:
Carcinogenicity - Assessment: No data available

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

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

- Species: Rabbit  
  Application Route: Skin contact  
  Exposure time: 90 weeks  
  Result: negative
Reproductive toxicity
May damage the unborn child.

**Components:**

**Gentamicin:**

*Effects on fertility*
- Test Type: Two-generation reproduction toxicity study
  - Species: Rat
  - Fertility: NOAEL: 20 mg/kg body weight
  - Result: No significant adverse effects were reported

*Effects on 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.

**Betamethasone:**

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

  - Species: Rat
    - Application Route: Subcutaneous
    - 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.

**Reproductive toxicity - Assessment:**
Clear evidence of adverse effects on development, based on animal experiments.
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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 fetal development: Test Type: Embryo-fetal 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 (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland) 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: 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

### 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**: \( >= 100 \text{ mg/kg} \)
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, pruritis, Irritation

SECTION 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
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
<table>
<thead>
<tr>
<th>Method</th>
<th>NOEC (Anabaena flos-aquae (cyanobacterium)): 1,6 µg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 72 h</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 201</td>
</tr>
</tbody>
</table>

**Betamethasone:**

<table>
<thead>
<tr>
<th>M-Factor (Acute aquatic toxicity)</th>
<th>100</th>
</tr>
</thead>
<tbody>
<tr>
<td>M-Factor (Chronic aquatic toxicity)</td>
<td>1</td>
</tr>
<tr>
<td>Toxicity to microorganisms</td>
<td>EC50: 288.7 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 3 h</td>
</tr>
<tr>
<td></td>
<td>Test Type: Respiration inhibition</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 209</td>
</tr>
</tbody>
</table>

**Betamethasone:**

<table>
<thead>
<tr>
<th>Toxicity to daphnia and other aquatic invertebrates</th>
<th>EC50 (Americamysis): &gt; 50 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time: 96 h</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity to algae/aquatic plants</th>
<th>EC50 (Pseudokirchneriella subcapitata (green algae)): &gt; 34 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time: 72 h</td>
<td></td>
</tr>
<tr>
<td>Method: OECD Test Guideline 201</td>
<td></td>
</tr>
<tr>
<td>Remarks: No toxicity at the limit of solubility.</td>
<td></td>
</tr>
</tbody>
</table>

**Toxicity to fish (Chronic toxicity):**

<table>
<thead>
<tr>
<th>NOEC (Pimephales promelas (fathead minnow)): 0,052 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time: 32 d</td>
</tr>
<tr>
<td>Method: OECD Test Guideline 210</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>NOEC (Oryzias latipes (Japanese medaka)): 0,07 µg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time: 219 d</td>
</tr>
<tr>
<td>Method: OECD Test Guideline 229</td>
</tr>
</tbody>
</table>

**Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):**

<table>
<thead>
<tr>
<th>NOEC (Daphnia magna (Water flea)): 8 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time: 21 d</td>
</tr>
<tr>
<td>Method: OECD Test Guideline 211</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>M-Factor (Chronic aquatic toxicity)</th>
<th>1,000</th>
</tr>
</thead>
</table>

**Benzalkonium chloride:**

<table>
<thead>
<tr>
<th>Toxicity to fish</th>
<th>LC50 (Pimephales promelas (fathead minnow)): 0,28 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time: 96 h</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity to daphnia and other aquatic invertebrates</th>
<th>EC50 (Daphnia magna (Water flea)): 0,0056 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time: 48 h</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity to algae/aquatic plants</th>
<th>ErC50 (Chlorella pyrenoidosa): 0,09 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time: 72 h</td>
<td></td>
</tr>
</tbody>
</table>
### M-Factor (Acute aquatic toxicity)
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### Toxicity to fish (Chronic toxicity)
- NOEC (Pimephales promelas (fathead minnow)): 0.032 mg/l
- Exposure time: 34 d

### 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**: log Pow: 6.16

#### Gentamicin:
- **Partition coefficient**: log Pow: < -2

#### Betamethasone:
- **Partition coefficient**: 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**: log Pow: 1.692
  - Remarks: Calculation

### Mobility in soil
- No data available
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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, 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.

Domestic regulation

ANTT
- UN number: UN 3082
- Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,
N.O.S. (Gentamicin, Benzalkonium chloride)

Class: 9
Packing group: III
Labels: 9
Hazard Identification Number: 90

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

Safety, health and environmental regulations/legislation specific for the substance or mixture
National List of Carcinogenic Agents for Humans - (LINACH): Not applicable

Brazil. List of chemicals controlled by the Federal Police: Not applicable

International Regulations

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

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

Full text of other abbreviations
ACGIH: USA. ACGIH Threshold Limit Values (TLV)
ACGIH / TWA: 8-hour, time-weighted average

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
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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.

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