1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name: Gentamicin / Betamethasone Formulation

Supplier’s company name, address and phone number

Company name of supplier: MSD
Address: Kumagaya, Saitama Prefecture, Xicheng 810 MSD Co., Ltd. Menuma factory
Telephone: 048-588-8411
E-mail address: EHSDATASTEWARD@msd.com
Emergency telephone number: 1-908-423-6000

Recommended use of the chemical and restrictions on use

Recommended use: Veterinary product

2. HAZARDS IDENTIFICATION

GHS classification of chemical product

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

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.
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.  

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>
<th>ENCS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Polyethylene glycol stearate</td>
<td>9004-99-3</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>Gentamicin</td>
<td>1403-66-3</td>
<td>0.49</td>
<td></td>
</tr>
<tr>
<td>betamethasone</td>
<td>378-44-9</td>
<td>0.1</td>
<td></td>
</tr>
<tr>
<td>Benzalkonium chloride</td>
<td>8001-54-5</td>
<td>0.01</td>
<td></td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES  

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

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

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

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

If swallowed: If swallowed, DO NOT induce vomiting.  
Get medical attention.  
Rinse mouth thoroughly with water.
Most important symptoms and effects, both acute and delayed:
May damage the unborn child. 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 spills 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
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

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.

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

Threshold limit value and permissible exposure limits for each component in the work environment

<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 particle)</td>
<td>3 mg/m3</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>
5. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: liquid

Colour: No data available

Odour: No data available

Odour Threshold: No data available

Melting point/freezing point: No data available

Boiling point, initial boiling point and boiling range: No data available
SAFETY DATA SHEET

Gentamicin / Betamethasone Formulation

Flammability (solid, gas) : Not applicable
Flammability (liquids) : No data available

Lower explosion limit and upper explosion limit / flammability limit
Upper explosion limit / Upper flammability limit : No data available
Lower explosion limit / Lower flammability limit : No data available

Flash point : No data available
Decomposition temperature : No data available
pH : No data available
Evaporation rate : No data available
Auto-ignition temperature : No data available
Viscosity
Viscosity, kinematic : No data available

Solubility(ies)
Water solubility : No data available
Partition coefficient: n-octanol/water : No data available

Vapour pressure : No data available
Density and / or relative density
Relative density : No data available
Density : No data available
Relative vapour density : No data available

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.
Molecular weight : No data available

Particle characteristics
Particle size : No data available

10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
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: > 5 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
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
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

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

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
SAFETY DATA SHEET

Gentamicin / Betamethasone Formulation

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:
Test Type: Human repeat insult patch test (HRIPT)
Exposure routes: Skin contact
Species: Humans
Result: negative

Germ cell mutagenicity
Not classified based on available information.

Components:
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

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

<table>
<thead>
<tr>
<th>Species</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mouse</td>
<td>Skin contact</td>
<td>80 weeks</td>
<td>negative</td>
</tr>
<tr>
<td>Rabbit</td>
<td>Skin contact</td>
<td>90 weeks</td>
<td>negative</td>
</tr>
</tbody>
</table>

### Reproductive toxicity

May damage the unborn child.

## Components:

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

- **Effects on foetal development**
  - **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
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.

  - 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.

Benzalkonium chloride:
- Effects on fertility:
  - Test Type: Two-generation reproduction toxicity study
  - Species: Rat
  - Application Route: Ingestion
  - Method: OECD Test Guideline 416
  - Result: negative
  - Remarks: Based on data from similar materials

- Effects on foetal development:
  - Test Type: Embryo-foetal development
  - Species: Rabbit
  - Application Route: Ingestion
  - Method: OECD Test Guideline 414
  - Result: negative
  - Remarks: Based on data from similar materials

STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
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

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, pruritis, 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
  Method: US-EPA OPPTS 850.1035
- Toxicity to algae/aquatic plants:
  EC50 (Pseudokirchneriella subcapitata (green algae)): 10 µg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201
  NOEC (Pseudokirchneriella subcapitata (green algae)): 1.5 µg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201
  EC50 (Anabaena flos-aquae (cyanobacterium)): 4.7 µg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201
  NOEC (Anabaena flos-aquae (cyanobacterium)): 1.6 µg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201
- M-Factor (Acute aquatic toxicity): 100
- M-Factor (Chronic aquatic toxicity): 1
- Toxicity to microorganisms:
  EC50: 288.7 mg/l
  Exposure time: 3 h
  Test Type: Respiration inhibition
  Method: OECD Test Guideline 209

betamethasone:
- Toxicity to daphnia and other aquatic invertebrates:
  EC50 (Americamysis): > 50 mg/l
  Exposure time: 96 h
### Toxicity to algae/aquatic plants

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

<table>
<thead>
<tr>
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<th>NOEC (Pseudokirchneriella subcapitata (green algae))</th>
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</thead>
<tbody>
<tr>
<td>Gentamicin</td>
<td>34 mg/l</td>
<td></td>
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<tr>
<td></td>
<td>Exposure time: 72 h</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 201</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Remarks: No toxicity at the limit of solubility</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Toxicity to fish (Chronic toxicity)

<table>
<thead>
<tr>
<th>Compound</th>
<th>NOEC (Pimephales promelas (fathead minnow))</th>
<th>0.052 mg/l</th>
<th>Exposure time: 32 d</th>
<th>Method: OECD Test Guideline 210</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gentamicin</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>NOEC (Oryzias latipes (Japanese medaka))</td>
<td>0.07 µg/l</td>
<td>Exposure time: 219 d</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)

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

### M-Factor (Chronic aquatic toxicity)

<table>
<thead>
<tr>
<th>Compound</th>
<th>1,000</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Gentamicin</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Benzalkonium chloride

<table>
<thead>
<tr>
<th>Compound</th>
<th>LC50 (Pimephales promelas (fathead minnow))</th>
<th>0.28 mg/l</th>
<th>Exposure time: 96 h</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gentamicin</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Compound</th>
<th>EC50 (Daphnia magna (Water flea))</th>
<th>0.0056 mg/l</th>
<th>Exposure time: 48 h</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gentamicin</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### M-Factor (Acute aquatic toxicity)

<table>
<thead>
<tr>
<th>Compound</th>
<th>100</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Gentamicin</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Gentamicin

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

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

<table>
<thead>
<tr>
<th>Compound</th>
<th>ER50 (Chlorella pyrenoidosa (algae))</th>
<th>0.09 mg/l</th>
<th>Exposure time: 72 h</th>
<th>Method: OECD Test Guideline 201</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gentamicin</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Compound</th>
<th>EC50 (Daphnia magna (Water flea))</th>
<th>0.032 mg/l</th>
<th>Exposure time: 34 d</th>
<th>Method: OECD Test Guideline 211</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gentamicin</td>
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</table>

<table>
<thead>
<tr>
<th>Compound</th>
<th>NOEC (Pimephales promelas (fathead minnow))</th>
<th>0.01 mg/l</th>
<th>Exposure time: 96 h</th>
<th>Method: OECD Test Guideline 210</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gentamicin</td>
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</table>

<table>
<thead>
<tr>
<th>Compound</th>
<th>EC50 (Pseudokirchneriella subcapitata (green algae))</th>
<th>&gt; 34 µg/l</th>
<th>Exposure time: 72 h</th>
<th>Method: OECD Test Guideline 201</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gentamicin</td>
<td></td>
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</tbody>
</table>
## 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

<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>
</tbody>
</table>

### Toxicty to microorganisms:

| Test Type: Respiration inhibition  | EC50: 288.7 mg/l  
  Exposure time: 3 h  
  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

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

- **Toxicity to daphnia and other aquatic invertebrates ( Chronic toxicity)**:
  - NOEC (Daphnia magna (Water flea)): 8 mg/l  
  - Exposure time: 21 d  
  - Method: OECD Test Guideline 211

| M-Factor (Chronic aquatic toxicity) | 1,000 |
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

Gentamicin:
Biodegradability: Result: rapidly degradable
Biodegradation: 100%
Exposure time: 28 d
Method: OECD Test Guideline 314

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

Gentamicin:
Partition coefficient: n-octanol/water: log Pow: < -2
19. octanol/water
20. betamethasone:
   Partition coefficient: n-octanol/water: log Pow: 2.11
21. Mobility in soil
   No data available
22. Hazardous to the ozone layer
   Not applicable
23. 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
Refer to section 15 for specific national regulation.

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

Related Regulations

Fire Service Law
Not applicable to dangerous materials / designated flammables.

Chemical Substance Control Law
Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture
Not applicable

Harmful Substances Required Permission for Manufacture
Not applicable

Substances Prevented From Impairment of Health
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity
Not applicable

Substances Subject to be Notified Names
Not applicable

Substances Subject to be Indicated Names
Not applicable

Ordinance on Prevention of Hazards Due to Specified Chemical Substances
Not applicable

Ordinance on Prevention of Lead Poisoning
Not applicable
Ordinance on Prevention of Tetraalkyl Lead Poisoning
Not applicable

Ordinance on Prevention of Organic Solvent Poisoning
Not applicable

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)
Not applicable

Poisonous and Deleterious Substances Control Law
Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof
Not applicable

High Pressure Gas Safety Act
Not applicable

Explosive Control Law
Not applicable

Vessel Safety Law
Miscellaneous dangerous substances and articles (Article 2 and 3 of rules on shipping and storage of dangerous goods and its Attached Table 1)

Aviation Law
Miscellaneous dangerous substances and articles (Article 194 of The Enforcement Rules of Aviation Law and its Attached Table 1)

Marine Pollution and Sea Disaster Prevention etc Law
Bulk transportation : Not classified as noxious liquid substance
Pack transportation : Classified as marine pollutant

Narcotics and Psychotropics Control Act
Narcotic or Psychotropic Raw Material (Export / Import Permission)
Not applicable
Specific Narcotic or Psychotropic Raw Material (Export / Import permission)
Not applicable

Waste Disposal and Public Cleansing Law
Industrial waste

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
SAFETY DATA SHEET

Gentamicin / Betamethasone Formulation

Version 6.0  Revision Date: 2020/03/23  SDS Number: 434592-00015  Date of last issue: 2019/09/13
Date of first issue: 2016/01/06

Sources of key data used to compile the Safety Data Sheet:
- Internal technical data, data from raw material SDSs,

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

Date format: yyyy/mm/dd

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

Abbreviations:
- AIICS - Australian Inventory of Chemical Substances
- ANTT - National Agency for Transport by Land of Brazil
- ASTM - American Society for the Testing of Materials
- bw - Body weight
- CMR - Carcinogen, Mutagen or Reproductive Toxicant
- DIN - Standard of the German Institute for Standardisation
- DSL - Domestic Substances List (Canada)
- ECx - Concentration associated with x% response
- ELx - Loading rate associated with x% response
- EmS - Emergency Schedule
- ENCS - Existing and New Chemical Substances (Japan)
- ErCx - Concentration associated with x% growth rate response
- ERG - Emergency Response Guide
- GHS - Globally Harmonized System
- GLP - Good Laboratory Practice
- IARC - International Agency for Research on Cancer
- IATA - International Air Transport Association
- IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk
- IC50 - Half maximal inhibitory concentration
- ICAO - International Civil Aviation Organization
- IECSC - Inventory of Existing Chemical Substances in China
- IMDG - International Maritime Dangerous Goods
- IMO - International Maritime Organization
- ISHL - Industrial Safety and Health Law (Japan)
- ISO - International Organisation for Standardization
- KECI - Korea Existing Chemicals Inventory
- LC50 - Lethal Concentration to 50% of a test population
- LD50 - Lethal Dose to 50% of a test population
- 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
- SADT - Self-Accelerating Decomposition Temperature
- SDS - Safety Data Sheet
- TCSI - Taiwan Chemical Substance Inventory
- TDG - Transportation of Dangerous Goods
- TSCA - Toxic Substances Control Act (United States)
- UN - United Nations
- UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods
- vPvB - Very Persistent and Very Bioaccumulative
- WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.
<table>
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JP / EN