1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Gentamicin / Betamethasone Ointment Formulation

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

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

2. HAZARDS IDENTIFICATION

Emergency Overview

<table>
<thead>
<tr>
<th>Appearance</th>
<th>ointment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
</tbody>
</table>

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

GHS Classification

<table>
<thead>
<tr>
<th>Reproductive toxicity</th>
<th>Category 1B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specific target organ toxicity - repeated exposure</td>
<td>Category 1</td>
</tr>
<tr>
<td>Short-term (acute) aquatic hazard</td>
<td>Category 2</td>
</tr>
<tr>
<td>Long-term (chronic) aquatic hazard</td>
<td>Category 1</td>
</tr>
</tbody>
</table>

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.
H401: Toxic to aquatic life.
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 dust/ fume/ gas/ mist/ vapours/ spray.
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:
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>Petrolatum</td>
<td>8009-03-8</td>
<td>94.8</td>
</tr>
<tr>
<td>Paraffin oil</td>
<td>8012-95-1</td>
<td>5</td>
</tr>
<tr>
<td>Gentamicin</td>
<td>1403-66-3</td>
<td>0.1</td>
</tr>
<tr>
<td>Betamethasone</td>
<td>378-44-9</td>
<td>0.064</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 (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions: Avoid release to the environment. Prevent further leakage or spillage if safe to do so. 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: Sweep up or vacuum up spillage and collect in suitable container for disposal. 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 dust, fume, gas, mist, vapours or spray. Do not swallow. Avoid contact with eyes. Wash skin thoroughly after handling. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment. Keep container tightly closed. Do not eat, drink or smoke when using this product. Take care to prevent spills, waste and minimize release to the environment.

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>Petrolatum</td>
<td>8009-03-8</td>
<td>TWA (Inhalable particulate matter)</td>
<td>5 mg/m³ ACGIH</td>
<td></td>
</tr>
<tr>
<td>Paraffin oil</td>
<td>8012-95-1</td>
<td>TWA (Inhalable particulate matter)</td>
<td>5 mg/m³ ACGIH</td>
<td></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>Further information: Skin</td>
<td></td>
<td>Wipe limit</td>
<td>10 µg/100 cm² Internal</td>
<td></td>
</tr>
</tbody>
</table>

Engineering measures: Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., vacuum conveying from a closed system, packout head with inflatable seal from stationary container, ventilated enclosure, etc.). 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.

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: Combined particulates and organic vapour type
Eye/face 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.

Hand protection

Material: Chemical-resistant gloves
Remarks: Consider double gloving.
Gentamicin / Betamethasone Ointment Formulation

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>ointment</td>
</tr>
<tr>
<td>Colour</td>
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</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour Threshold</td>
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</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 classified as a flammability hazard</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>Water solubility: No data available</td>
</tr>
</tbody>
</table>
Partition coefficient: n-octanol/water : No data available
Auto-ignition temperature : No data available
Decomposition temperature : No data available
Viscosity
    Viscosity, kinematic : No data available
Explosive properties : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.
Molecular weight : No data available
Particle size : No data available

10. STABILITY AND REACTIVITY
Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reactions : 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 : Skin contact
Ingestion
Eye contact

Acute toxicity
Not classified based on available information.
Components:

Petrolatum:
Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
    Method: OECD Test Guideline 401
    Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg
    Method: OECD Test Guideline 402
    Assessment: The substance or mixture has no acute dermal toxicity
    Remarks: Based on data from similar materials

Paraffin oil:
Gentamicin / Betamethasone Ointment Formulation

Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
Acute dermal toxicity: LD50 (Rabbit): > 2,000 mg/kg
Assessment: The substance or mixture has no acute dermal toxicity

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

Skin corrosion/irritation
Not classified based on available information.

Components:

Petrolatum:
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation
Remarks: Based on data from similar materials

Paraffin oil:
Species: Rabbit
Result: No skin irritation

Gentamicin:
Gentamicin / Betamethasone Ointment Formulation

Species: Rabbit
Result: Mild skin irritation

**betamethasone:**
Species: Rabbit
Result: Mild skin irritation

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

**Components:**

**Petrolatum:**
Species: Rabbit
Result: No eye irritation
Method: OECD Test Guideline 405
Remarks: Based on data from similar materials

**Paraffin oil:**
Species: Rabbit
Result: No eye irritation

**Gentamicin:**
Species: Rabbit
Result: Mild eye irritation

**betamethasone:**
Species: Rabbit
Result: No eye irritation

**Respiratory or skin sensitisation**

**Skin sensitisation**
Not classified based on available information.

**Respiratory sensitisation**
Not classified based on available information.

**Components:**

**Petrolatum:**
Test Type: Buehler Test
Exposure routes: Skin contact
Species: Guinea pig
Result: negative
Remarks: Based on data from similar materials

**Gentamicin:**
Remarks: No data available
Gentamicin / Betamethasone Ointment Formula-
tion

betamethasone:
Exposure routes : Dermal
Species : Guinea pig
Result : Weak sensitizer

Germ cell mutagenicity
Not classified based on available information.

Components:

Petrolatum:
Genotoxicity in vitro : Test Type: Chromosome aberration test in vitro
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: Intraperitoneal injection
Method: OECD Test Guideline 474
Result: negative
Remarks: Based on data from similar materials

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

10 / 20
Application Route: Oral  
Result: equivocal

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

**Carcinogenicity**
Not classified based on available information.

**Components:**

**Petrolatum:**
Species : Rat  
Application Route : Ingestion  
Exposure time : 2 Years  
Result : negative

**Gentamicin:**
Carcinogenicity - Assessment : No data available

**Reproductive toxicity**
May damage the unborn child.

**Components:**

**Petrolatum:**
Effects on fertility : Test Type: Reproduction/Developmental toxicity screening test  
Species: Rat  
Application Route: Ingestion  
Result: negative  
Remarks: Based on data from similar materials

Effects on foetal development : Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Skin contact  
Result: negative  
Remarks: Based on data from similar materials

**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
### Gentamicin / Betamethasone Ointment Formulation

<table>
<thead>
<tr>
<th>Species</th>
<th>Application Route</th>
<th>Developmental Toxicity</th>
<th>LOAEL</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>Intraperitoneal</td>
<td>Embryo-foetal toxicity</td>
<td>LOAEL: 75 mg/kg body weight</td>
<td></td>
</tr>
<tr>
<td>Mouse</td>
<td>Intraperitoneal</td>
<td>foetal mortality</td>
<td>LOAEL: 10 mg/kg body weight</td>
<td>No malformations were observed.</td>
</tr>
<tr>
<td>Rat</td>
<td>Intraperitoneal</td>
<td>foetal mortality</td>
<td>LOAEL: 50 mg/kg body weight</td>
<td>No malformations were observed.</td>
</tr>
<tr>
<td>Rat</td>
<td>Subcutaneous</td>
<td>Malformations were observed.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mouse</td>
<td>Intramuscular</td>
<td>Malformations were observed.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rabbit</td>
<td>Intramuscular</td>
<td>Fetotoxicity</td>
<td>LOAEL: 0.05 mg/kg body weight</td>
<td>Malformations were observed.</td>
</tr>
<tr>
<td>Rat</td>
<td>Intraperitoneal</td>
<td>Malformations were observed.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Reproductive toxicity - Assessment
- Positive evidence of adverse effects on development from human epidemiological studies.
- Clear evidence of adverse effects on development, based on animal experiments.

### 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.
Gentamicin / Betamethasone Ointment Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.7</td>
<td>2021/04/09</td>
<td>1841321-00009</td>
<td>2020/10/10</td>
<td>2017/07/19</td>
</tr>
</tbody>
</table>

**betamethasone:**

- **Target Organs:** Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland
- **Assessment:** Causes damage to organs through prolonged or repeated exposure.

**Repeated dose toxicity**

**Components:**

**Petrolatum:**

- **Species:** Rat
- **NOAEL:** 5,000 mg/kg
- **Application Route:** Ingestion
- **Exposure time:** 2 yr

**Paraffin oil:**

- **Species:** Rat, female
- **LOAEL:** 161 mg/kg
- **Application Route:** Ingestion
- **Exposure time:** 90 Days

**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
SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

Gentamicin / Betamethasone Ointment Formulation

Version 2.7  Revision Date: 2021/04/09  SDS Number: 1841321-00009  Date of last issue: 2020/10/10
Date of first issue: 2017/07/19

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

**Aspiration toxicity**
Not classified based on available information.

**Components:**

**Paraffin oil:**
The substance or mixture is known to cause human aspiration toxicity hazards or has to be regarded as if it causes a human aspiration toxicity hazard.

**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:**

**Petrolatum:**

<table>
<thead>
<tr>
<th>Toxicity to fish</th>
<th>Test substance: Water Accommodated Fraction</th>
<th>Method: OECD Test Guideline 203</th>
<th>Remarks: Based on data from similar materials</th>
</tr>
</thead>
<tbody>
<tr>
<td>LL50 (Pimephales promelas (fathead minnow)): &gt; 100 mg/l</td>
<td>Exposure time: 96 h</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exposure time: 96 h</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity to daphnia and other aquatic invertebrates</th>
<th>Test substance: Water Accommodated Fraction</th>
<th>Method: OECD Test Guideline 203</th>
<th>Remarks: Based on data from similar materials</th>
</tr>
</thead>
<tbody>
<tr>
<td>EC50 (Daphnia magna (Water flea)): &gt; 10,000 mg/l</td>
<td>Exposure time: 48 h</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exposure time: 48 h</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity to algae/aquatic plants</th>
<th>Test substance: Water Accommodated Fraction</th>
<th>Method: OECD Test Guideline 201</th>
<th>Remarks: Based on data from similar materials</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOEL (Pseudokirchneriella subcapitata (green algae)): &gt;= 100 mg/l</td>
<td>Exposure time: 72 h</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exposure time: 72 h</td>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)</th>
<th>Test substance: Water Accommodated Fraction</th>
<th>Method: OECD Test Guideline 201</th>
<th>Remarks: Based on data from similar materials</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOEC (Daphnia magna (Water flea)): 10 mg/l</td>
<td>Exposure time: 21 d</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exposure time: 21 d</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Paraffin oil:**

<table>
<thead>
<tr>
<th>Toxicity to fish</th>
<th>Test substance: Water Accommodated Fraction</th>
<th>Method: OECD Test Guideline 203</th>
<th>Remarks: Based on data from similar materials</th>
</tr>
</thead>
<tbody>
<tr>
<td>LL50 (Scophthalmus maximus (turbot)): &gt; 100 mg/l</td>
<td>Exposure time: 96 h</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exposure time: 96 h</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity to daphnia and other aquatic invertebrates</th>
<th>Test substance: Water Accommodated Fraction</th>
<th>Method: OECD Test Guideline 203</th>
<th>Remarks: Based on data from similar materials</th>
</tr>
</thead>
<tbody>
<tr>
<td>EL50 (Acartia tonsa): &gt; 100 mg/l</td>
<td>Exposure time: 48 h</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exposure time: 48 h</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity to algae/aquatic plants</th>
<th>Test substance: Water Accommodated Fraction</th>
<th>Method: OECD Test Guideline 201</th>
<th>Remarks: Based on data from similar materials</th>
</tr>
</thead>
<tbody>
<tr>
<td>EL50 (Skeletonema costatum (marine diatom)): &gt; 100 mg/l</td>
<td>Exposure time: 72 h</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exposure time: 72 h</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| NOELR (Skeletonema costatum (marine diatom)): > 1 mg/l | Exposure time: 72 h | | |
| Exposure time: 72 h | | | |

Test substance: Water Accommodated Fraction
Remarks: Based on data from similar materials
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: 
- 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
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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

Exposure time: 32 d  Method: OECD Test Guideline 210

NOEC (Daphnia magna (Water flea)): 8 mg/l  Exposure time: 21 d  Method: OECD Test Guideline 211

Exposure time: 28 d  Method: OECD Test Guideline 301F

Result: Not readily biodegradable  Biodegradation: 31 %  Remarks: Based on data from similar materials

Result: rapidly degradable  Biodegradation: 100 %  Remarks: Based on data from similar materials

log Pow: > 4  Remarks: Calculation

log Pow: < -2

log Pow: 2.11

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 3077
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(betamethasone, Gentamicin)
Class: 9
Packing group: III
Labels: 9

IATA-DGR
UN/ID No.: UN 3077
Proper shipping name: Environmentally hazardous substance, solid, n.o.s.
(betamethasone, Gentamicin)
Class: 9
Packing group: III
Labels: Miscellaneous
Packing instruction (cargo aircraft): 956
Packing instruction (passenger aircraft): 956
Environmentally hazardous: yes

IMDG-Code
UN number: UN 3077
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(betamethasone, Gentamicin)
Class: 9
Packing group: III
Labels: 9
EmS Code: F-A, S-F
Marine pollutant: yes

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

National Regulations

GB 6944/12268
UN number: UN 3077
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,
SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

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N.O.S. (betamethasone, Gentamicin)

Class: 9
Packing group: III
Labels: 9

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

Date format: yyyy/mm/dd

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

AIIIC - Australian Inventory of Industrial Chemicals; 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 Chemic-
SAFETY DATA SHEET
generated according to GB/T 16483 and GB/T 17519

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SDS Number: 1841321-00009
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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.

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