SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Gentamicin / Betamethasone Cream Formulation

Manufacturer or supplier’s details
Company : Organon & Co.
Address : Rua Treze de Maio, 1161
Campinas, São Paulo, Brazil  B-2220
Telephone : 551-430-6000
Emergency telephone : 215-631-6999
E-mail address : EHSSTEWARD@organon.com

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

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification in accordance with ABNT NBR 14725 Standard
Reproductive toxicity : Category 1B
Specific target organ toxicity - repeated exposure : Category 1 (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland)
Short-term (acute) aquatic hazard : Category 2
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.
H401 Toxic to aquatic life.
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

Substance / Mixture: Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Petrolatum</td>
<td>8009-03-8</td>
<td></td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>Paraffin oil</td>
<td>8012-95-1</td>
<td>Aspiration hazard, Category 1</td>
<td>&gt;= 5 - &lt; 10</td>
</tr>
<tr>
<td>Alcohols, C16-18, ethoxylated</td>
<td>68439-49-6</td>
<td>Short-term (acute) aquatic hazard, Category 2</td>
<td>&gt;= 1 - &lt; 2,5</td>
</tr>
<tr>
<td>4-Chloro-3-methylphenol</td>
<td>59-50-7</td>
<td>Acute toxicity (Oral), Category 4, Skin corrosion, Category 1C, Serious eye damage, Category 1 Skin sensitization, Sub-category 1B Specific target organ toxicity - single exposure, Category 3 Short-term (acute) aquatic hazard, Category 1 Long-term (chronic) aquatic hazard, Category 3</td>
<td>&gt;= 0,1 - &lt; 0,25</td>
</tr>
<tr>
<td>Gentamicin</td>
<td>1403-66-3</td>
<td>Reproductive toxicity, Category 1A Specific target organ toxicity - repeated exposure (Oral) (Kid-</td>
<td>&gt;= 0,1 - &lt; 0,25</td>
</tr>
</tbody>
</table>
**SAFETY DATA SHEET**

Gentamicin / Betamethasone Cream Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.0</td>
<td>1832924-00008</td>
<td>13.09.2019</td>
<td>13.07.2017</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Betamethasone</th>
<th>Acute toxicity (Inhalation), Category 2</th>
<th>Reproductive toxicity, Category 1B</th>
<th>Specific target organ toxicity - repeated exposure (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland), Category 1</th>
<th>Long-term (chronic) aquatic hazard, Category 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>378-44-9</td>
<td>&gt;= 0,025 - &lt; 0,1</td>
<td></td>
<td></td>
<td></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 fire fighting: Vapors may form explosive mixtures with air.
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 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.
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.

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 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>Petrolatum</td>
<td>8009-03-8</td>
<td>TWA (Inhalable particulate matter)</td>
<td>5 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Paraffin oil</td>
<td>8012-95-1</td>
<td>TWA (Inhalable particulate matter)</td>
<td>5 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Gentamicin</td>
<td>1403-66-3</td>
<td>TWA</td>
<td>0.1 mg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Betamethasone</td>
<td>378-44-9</td>
<td>TWA</td>
<td>1 µg/m³ (OEB 4)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

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

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

<table>
<thead>
<tr>
<th>Protective Equipment</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respiratory protection</td>
<td>If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.</td>
</tr>
<tr>
<td>Filter type</td>
<td>Combined particulates and organic vapor type</td>
</tr>
<tr>
<td>Hand protection</td>
<td>Chemical-resistant gloves</td>
</tr>
<tr>
<td>Material</td>
<td>Consider double gloving.</td>
</tr>
<tr>
<td>Eye protection</td>
<td>Wear safety glasses with side shields or goggles.</td>
</tr>
<tr>
<td></td>
<td>If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.</td>
</tr>
<tr>
<td></td>
<td>Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.</td>
</tr>
<tr>
<td>Skin and body protection</td>
<td>Work uniform or laboratory coat.</td>
</tr>
<tr>
<td></td>
<td>Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.</td>
</tr>
<tr>
<td></td>
<td>Use appropriate degowning techniques to remove potentially contaminated clothing.</td>
</tr>
</tbody>
</table>

### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>cream</td>
</tr>
<tr>
<td>Color</td>
<td>No data available</td>
</tr>
<tr>
<td>Odor</td>
<td>No data available</td>
</tr>
<tr>
<td>Odor Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>&gt; 93.3 °C</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>
</tbody>
</table>
SECTION 10. STABILITY AND REACTIVITY

Reactivity: Not classified as a reactivity hazard.
Chemical stability: Stable under normal conditions.
Possibility of hazardous reactions: Vapors may form explosive mixture with air. Can react with strong oxidizing agents.

Conditions to avoid: None known.
Incompatible materials: Oxidizing agents
Hazardous decomposition products: No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure:
- 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:**
- **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

**Alcohols, C16-18, ethoxylated:**
- **Acute oral toxicity**: LD50 (Rat): > 2,000 mg/kg
  - Remarks: Based on data from similar materials

**4-Chloro-3-methylphenol:**
- **Acute oral toxicity**: LD50 (Mouse): 600 mg/kg
- **Acute inhalation toxicity**: LC50 (Rat): > 2,871 mg/l
  - Exposure time: 4 h
  - Test atmosphere: dust/mist
- **Acute dermal 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
LSLo (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

Alcohols, C16-18, ethoxylated:
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation
Remarks: Based on data from similar materials

4-Chloro-3-methylphenol:
Species: Rabbit
Method: OECD Test Guideline 404
Result: Corrosive after 1 to 4 hours of exposure

Gentamicin:
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

**Alcohols, C16-18, ethoxylated:**
- Species: Rabbit
- Result: No eye irritation
- Method: OECD Test Guideline 405
- Remarks: Based on data from similar materials

**4-Chloro-3-methylphenol:**
- Species: Rabbit
- Result: Irreversible effects on the eye
- Method: OECD Test Guideline 405

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

**Betamethasone:**
- Species: Rabbit
- Result: No eye irritation

**Respiratory or skin sensitization**
- **Skin sensitization:** Not classified based on available information.
- **Respiratory sensitization:** Not classified based on available information.

**Components:**

**Petrolatum:**
- Test Type: Buehler Test
- Routes of exposure: Skin contact
- Species: Guinea pig
- Result: negative
- Remarks: Based on data from similar materials
## SAFETY DATA SHEET

### Gentamicin / Betamethasone Cream Formula-

<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>5.0</td>
<td>23.03.2020</td>
<td>1832924-00008</td>
<td>13.09.2019</td>
<td>13.07.2017</td>
</tr>
</tbody>
</table>

### Alcohols, C16-18, ethoxylated:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Routes of exposure</th>
<th>Species</th>
<th>Method</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Buehler Test</td>
<td>Skin contact</td>
<td>Guinea pig</td>
<td>OECD Test Guideline 406</td>
<td>negative</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

### 4-Chloro-3-methylphenol:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Routes of exposure</th>
<th>Species</th>
<th>Assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximization Test</td>
<td>Skin contact</td>
<td>Guinea pig</td>
<td>Probability or evidence of low to moderate skin sensitization rate in humans</td>
</tr>
</tbody>
</table>

### Gentamicin:

<table>
<thead>
<tr>
<th>Remarks</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No data available</td>
</tr>
</tbody>
</table>

### Betamethasone:

<table>
<thead>
<tr>
<th>Routes of exposure</th>
<th>Species</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dermal</td>
<td>Guinea pig</td>
<td>Weak sensitizer</td>
<td></td>
</tr>
</tbody>
</table>

### Germ cell mutagenicity

Not classified based on available information.

### Components:

#### Petrolatum:

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: Chromosome aberration test in vitro</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result: negative</td>
<td>Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Genotoxicity in vivo</th>
<th>Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Mouse</td>
<td>Application Route: Intraperitoneal injection</td>
</tr>
<tr>
<td>Method: OECD Test Guideline 474</td>
<td>Result: negative</td>
</tr>
</tbody>
</table>

#### Alcohols, C16-18, ethoxylated:

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: Bacterial reverse mutation assay (AMES)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result: negative</td>
<td>Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: In vitro mammalian cell gene mutation test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result: negative</td>
<td>Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>
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

4-Chloro-3-methylphenol:

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.

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

#### Alcohols, C16-18, ethoxylated:
- **Effects on fertility**: Test Type: Two-generation reproduction toxicity study
  - Species: Rat
  - Application Route: Skin contact
  - Result: negative
  - Remarks: Based on data from similar materials

- **Effects on fetal development**: Test Type: Two-generation reproduction toxicity study
  - Species: Rat
  - Application Route: Skin contact
  - Result: negative
  - Remarks: Based on data from similar materials

#### 4-Chloro-3-methylphenol:
- **Effects on fertility**: Test Type: One-generation reproduction toxicity study
  - Species: Rat
  - Application Route: Ingestion
  - Result: negative

- **Effects on fetal development**: Test Type: Reproduction/Developmental toxicity screening test
  - Species: Rat
  - Application Route: Ingestion
  - Result: negative
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.
SAFETY DATA SHEET

Gentamicin / Betamethasone Cream Formula-tion

Version 5.0 Revision Date: 23.03.2020 SDS Number: 1832924-00008 Date of last issue: 13.09.2019 Date of first issue: 13.07.2017

STOT-single exposure
Not classified based on available information.

Components:

4-Chloro-3-methylphenol:
Assessment: May cause respiratory irritation.

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.

Repeated dose toxicity

Components:

Petrolatum:
Species: Rat
NOAEL: 5.000 mg/kg
Application Route: Ingestion
Exposure time: 2 y

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

Alcohols, C16-18, ethoxylated:
Species: Rat
NOAEL: > 100 mg/kg
Application Route: Ingestion
Exposure time: 90 Days
Method: OECD Test Guideline 408
Remarks: Based on data from similar materials

4-Chloro-3-methylphenol:
## Gentamicin / Betamethasone Cream Formulation

**Species**: Rat  
**NOAEL**: 200 mg/kg  
**LOAEL**: 400 mg/kg  
**Application Route**: Ingestion  
**Exposure time**: 28 Days

### Gentamicin:

<table>
<thead>
<tr>
<th><strong>Species</strong></th>
<th><strong>LOAEL</strong></th>
<th><strong>Application Route</strong></th>
<th><strong>Exposure time</strong></th>
<th><strong>Target Organs</strong></th>
<th><strong>Symptoms</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Dog</td>
<td>3 mg/kg</td>
<td>Intramuscular</td>
<td>12 Months</td>
<td>Kidney</td>
<td></td>
</tr>
<tr>
<td>Monkey</td>
<td>50 mg/kg</td>
<td>Subcutaneous</td>
<td>3 Weeks</td>
<td>Kidney, inner ear</td>
<td>Vomiting, Salivation</td>
</tr>
<tr>
<td>Monkey</td>
<td>6 mg/kg</td>
<td>Intramuscular</td>
<td>3 Weeks</td>
<td>Kidney, inner ear</td>
<td></td>
</tr>
<tr>
<td>Rat</td>
<td>5 mg/kg</td>
<td>Intramuscular</td>
<td>52 Weeks</td>
<td>Kidney, Blood</td>
<td></td>
</tr>
<tr>
<td>Rat</td>
<td>12.5 mg/kg</td>
<td>Intramuscular</td>
<td>13 Weeks</td>
<td>Kidney</td>
<td></td>
</tr>
</tbody>
</table>

### Betamethasone:

<table>
<thead>
<tr>
<th><strong>Species</strong></th>
<th><strong>LOAEL</strong></th>
<th><strong>Application Route</strong></th>
<th><strong>Exposure time</strong></th>
<th><strong>Target Organs</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Rabbit</td>
<td>0.05 %</td>
<td>Skin contact</td>
<td>10 - 30 d</td>
<td>Pituitary gland, Immune system, muscle</td>
</tr>
<tr>
<td>Rat</td>
<td>0.05 %</td>
<td>Skin contact</td>
<td>8 Weeks</td>
<td>thymus gland</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Gentamicin / Betamethasone Cream Formula-

Version: 5.0  Revision Date: 23.03.2020  SDS Number: 1832924-00008  Date of last issue: 13.09.2019

Date of first issue: 13.07.2017

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 reg-
arded 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

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Petrolatum:
Toxicity to fish: LL50 (Pimephales promelas (fathead minnow)): > 100 mg/l
Exposure time: 96 h
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 203
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 10.000 mg/l
Exposure time: 48 h
Test substance: Water Accommodated Fraction
Remarks: Based on data from similar materials
Toxicity to algae/aquatic plants: NOEL (Pseudokirchneriella subcapitata (green algae)): >= 100 mg/l
Exposure time: 72 h
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

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

Paraffin oil:

Toxicity to fish: LL50 (Scophthalmus maximus (turbot)): > 1.028 mg/l
Exposure time: 96 h
Test substance: Water Accommodated Fraction
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates: EL50 (Acartia tonsa): > 3.193 mg/l
Exposure time: 48 h
Test substance: Water Accommodated Fraction
Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants: EL50 (Skeletonema costatum (marine diatom)): > 3.200 mg/l
Exposure time: 72 h
Test substance: Water Accommodated Fraction
Remarks: Based on data from similar materials

NOELR (Skeletonema costatum (marine diatom)): 993 mg/l
Exposure time: 72 h
Test substance: Water Accommodated Fraction
Remarks: Based on data from similar materials

Alcohols, C16-18, ethoxylated:

Toxicity to fish: LC50 (Leuciscus idus (Golden orfe)): > 1 - 10 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h
Remarks: Based on data from similar materials

4-Chloro-3-methylphenol:

Toxicity to fish: LC50 (Oncorhynchus mykiss (rainbow trout)): 917 µg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): 1,5 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic: ErC50 (Chlorella pyrenoidosa): 15 mg/l
| Plants | Exposure time: 72 h  
|        | Method: OECD Test Guideline 201  
|        | EC10 (Chlorella pyrenoidosa): 2,3 mg/l  
|        | Exposure time: 72 h  
|        | Method: OECD Test Guideline 201  

**M-Factor (Acute aquatic toxicity):** 1  
**Toxicity to fish (Chronic toxicity):**  
  NOEC (Oncorhynchus mykiss (rainbow trout)): 0,15 mg/l  
  Exposure time: 28 d  
  Method: OECD Test Guideline 204  

**Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):**  
  NOEC (Daphnia magna (Water flea)): 0,32 mg/l  
  Exposure time: 21 d  
  Method: OECD Test Guideline 211  

**Toxicity to microorganisms:**  
  EC50: 22,86 mg/l  
  Exposure time: 60 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: 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:

Petrolatum:

Biodegradability: Result: Not readily biodegradable.
Biodegradation: 31 %
Exposure time: 28 d
Method: OECD Test Guideline 301F
Remarks: Based on data from similar materials

Paraffin oil:

Biodegradability: Result: Readily biodegradable.
Biodegradation: 82 %
Exposure time: 24 d
Method: OECD Test Guideline 301F
Remarks: Based on data from similar materials

Alcohols, C16-18, ethoxylated:
Biodegradability: Result: Readily biodegradable.
Biodegradation: > 60%
Exposure time: 28 d
Method: OECD Test Guideline 301B
Remarks: Based on data from similar materials

4-Chloro-3-methylphenol:
Biodegradability: Result: Readily biodegradable.
Biodegradation: 78%
Exposure time: 15 d
Method: OECD Test Guideline 301

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

Bioaccumulative potential

Components:
Alcohols, C16-18, ethoxylated:
Bioaccumulation:
Species: Fish
Bioconcentration factor (BCF): < 500
Remarks: Based on data from similar materials
Partition coefficient: n-octanol/water:
log Pow: > 4

4-Chloro-3-methylphenol:
Bioaccumulation:
Species: Cyprinus carpio (Carp)
Bioconcentration factor (BCF): 5,5 - 13
Partition coefficient: n-octanol/water:
log Pow: 0,477

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

Betamethasone:
Partition coefficient: n-octanol/water:
log Pow: 2,11

Mobility in soil
No data available

Other adverse effects
No data available
SECTION 13. DISPOSAL CONSIDERATIONS

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

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG
UN number: UN 3077
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(4-Chloro-3-methylphenol, 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.
(4-Chloro-3-methylphenol, 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.
(4-Chloro-3-methylphenol, Gentamicin)
Class: 9
Subsidiary risk: ENVIRONM.
Packing group: III
Labels: 9 (ENVIRONM.)
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 3077
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,
SAFETY DATA SHEET

Gentamicin / Betamethasone Cream Formula-
tion

Version 5.0
Revision Date: 23.03.2020
SDS Number: 1832924-00008
Date of last issue: 13.09.2019
Date of first issue: 13.07.2017

N.O.S.
(4-Chloro-3-methylphenol, Gentamicin)

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: Phosphoric acid

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 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 Chemicals in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50% of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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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