1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Gentamicin / Betamethasone Cream Formulation

Supplier’s company name, address and phone number

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

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

2. HAZARDS IDENTIFICATION

GHS classification of chemical product
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
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.
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.

Other hazards which do not result in classification
None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>:</th>
<th>Mixture</th>
</tr>
</thead>
</table>

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>Petrolatum</td>
<td>8009-03-8</td>
<td>&gt;= 10 - &lt; 20</td>
<td></td>
</tr>
<tr>
<td>Paraffin oil</td>
<td>8012-95-1</td>
<td>&gt;= 1 - &lt; 10</td>
<td></td>
</tr>
<tr>
<td>Alcohols, C16-18, ethoxylated</td>
<td>68439-49-6</td>
<td>&gt;= 1 - &lt; 2.5</td>
<td></td>
</tr>
<tr>
<td>4-Chloro-3-methylphenol</td>
<td>59-50-7</td>
<td>&gt;= 0.1 - &lt; 0.25</td>
<td>3-900</td>
</tr>
<tr>
<td>Gentamicin</td>
<td>1403-66-3</td>
<td>&gt;= 0.1 - &lt; 0.25</td>
<td></td>
</tr>
<tr>
<td>betamethasone</td>
<td>378-44-9</td>
<td>&gt;= 0.025 - &lt; 0.1</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.
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
- Vapours 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 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.
- 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 deter-
mine 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 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>Petrolatum</td>
<td>8009-03-8</td>
<td>OEL-M (Mist)</td>
<td>3 mg/m3</td>
<td>JP OEL JSOH</td>
</tr>
</tbody>
</table>
Further information: Substance whose OEL is set based on non-carcinogenic health effects. See III, Group 1: carcinogenic to humans.

<table>
<thead>
<tr>
<th>Substance</th>
<th>TWA (Inhalable particulate matter)</th>
<th>ACGIH</th>
<th>OEL-M (Mist)</th>
<th>JP OEL JSOH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paraffin oil</td>
<td>5 mg/m3</td>
<td></td>
<td>3 mg/m3</td>
<td></td>
</tr>
<tr>
<td>Gentamicin</td>
<td>0.1 mg/m3</td>
<td>Internal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Betamethasone</td>
<td>1 µg/m3 (OEB 4)</td>
<td>Internal</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Wipe limit</td>
<td>10 µg/100 cm²</td>
<td>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
Hand protection:
Chemical-resistant gloves
Remarks:
Consider double gloving.
Eye protection:
Wear safety glasses with side shields or 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.
9. PHYSICAL AND CHEMICAL PROPERTIES

- Physical state: cream
- 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
- Flammability (solid, gas): Not classified as a flammability hazard
- 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: > 93.3 °C
- 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
SAFETY DATA SHEET

Gentamicin / Betamethasone Cream Formulation

Version: 5.0
Revision Date: 2020/03/23
SDS Number: 1832934-00008
Date of last issue: 2019/09/13
Date of first issue: 2017/07/13

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.
Possibility of hazardous reactions:
  Vapours 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.

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
SAFETY DATA SHEET

Gentamicin / Betamethasone Cream Formulation

Version: 5.0  Revision Date: 2020/03/23  SDS Number: 1832934-00008
Date of last issue: 2019/09/13  Date of first issue: 2017/07/13

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
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

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
SAFETY DATA SHEET

Gentamicin / Betamethasone Cream Formula- tion

Version 5.0  Revision Date: 2020/03/23  SDS Number: 1832934-00008  Date of last issue: 2019/09/13

Date of first issue: 2017/07/13

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 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

Alcohols, C16-18, ethoxylated:
Test Type: Buehler Test
Exposure routes: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative
Remarks: Based on data from similar materials

4-Chloro-3-methylphenol:
Test Type: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
Assessment: Probability or evidence of low to moderate skin sensitisation rate in humans

Gentamicin:
Remarks: No data available
**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>2020/03/23</td>
<td>1832934-00008</td>
<td>2019/09/13</td>
<td>2017/07/13</td>
</tr>
</tbody>
</table>

**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

**Alcohols, C16-18, ethoxylated:**
- **Genotoxicity in vitro**
  - Test Type: Bacterial reverse mutation assay (AMES)
    - Method: OECD Test Guideline 471
    - Result: negative
    - Remarks: Based on data from similar materials
  - 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

**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
SAFETY DATA SHEET
Gentamicin / Betamethasone Cream Formulation

Version 5.0  Revision Date: 2020/03/23  SDS Number: 1832934-00008  Date of last issue: 2019/09/13  Date of first issue: 2017/07/13

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 foetal development:
Test Type: Embryo-foetal development
<table>
<thead>
<tr>
<th>Component</th>
<th>Effects on fertility</th>
<th>Effects on foetal development</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Alcohols, C16-18, ethoxylated</strong></td>
<td>Test Type: Two-generation reproduction toxicity study</td>
<td>Test Type: Two-generation reproduction toxicity study</td>
</tr>
<tr>
<td></td>
<td>Species: Rat</td>
<td>Species: Rat</td>
</tr>
<tr>
<td></td>
<td>Application Route: Skin contact</td>
<td>Application Route: Skin contact</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
<td>Result: negative</td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
<td>Remarks: Based on data from similar materials</td>
</tr>
<tr>
<td><strong>4-Chloro-3-methylphenol</strong></td>
<td>Test Type: One-generation reproduction toxicity study</td>
<td>Test Type: Reproduction/Developmental toxicity screening test</td>
</tr>
<tr>
<td></td>
<td>Species: Rat</td>
<td>Species: Rat</td>
</tr>
<tr>
<td></td>
<td>Application Route: Ingestion</td>
<td>Application Route: Ingestion</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
<td>Result: negative</td>
</tr>
<tr>
<td><strong>Gentamicin</strong></td>
<td>Test Type: Two-generation reproduction toxicity study</td>
<td>Test Type: Embryo-foetal development</td>
</tr>
<tr>
<td></td>
<td>Species: Rat</td>
<td>Species: Rabbit</td>
</tr>
<tr>
<td></td>
<td>Fertility: NOAEL: 20 mg/kg body weight</td>
<td>Developmental Toxicity: NOAEL: 3.6 mg/kg body weight</td>
</tr>
<tr>
<td></td>
<td>Result: No significant adverse effects were reported</td>
<td>Result: No embryo-foetal toxicity</td>
</tr>
<tr>
<td></td>
<td>Test Type: Embryo-foetal development</td>
<td>Test Type: Embryo-foetal development</td>
</tr>
<tr>
<td></td>
<td>Species: Rat</td>
<td>Species: Rat</td>
</tr>
<tr>
<td></td>
<td>Application Route: Intraperitoneal</td>
<td>Application Route: Intraperitoneal</td>
</tr>
<tr>
<td></td>
<td>Developmental Toxicity: LOAEL: 75 mg/kg body weight</td>
<td>Developmental Toxicity: LOAEL: 75 mg/kg body weight</td>
</tr>
<tr>
<td></td>
<td>Result: Embryo-foetal toxicity</td>
<td>Result: Embryo-foetal toxicity</td>
</tr>
<tr>
<td></td>
<td>Test Type: Embryo-foetal development</td>
<td>Test Type: Embryo-foetal development</td>
</tr>
<tr>
<td></td>
<td>Species: Mouse</td>
<td>Species: Mouse</td>
</tr>
<tr>
<td></td>
<td>Application Route: Intraperitoneal</td>
<td>Application Route: Intraperitoneal</td>
</tr>
<tr>
<td></td>
<td>Developmental Toxicity: LOAEL: 10 mg/kg body weight</td>
<td>Developmental Toxicity: LOAEL: 10 mg/kg body weight</td>
</tr>
</tbody>
</table>
### Reproductive toxicity - Assessment

**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**

- 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.

### 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 yr

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

<table>
<thead>
<tr>
<th>Component</th>
<th>Ingestion</th>
<th>Inhalation</th>
<th>Skin contact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gentamicin</td>
<td>Target Organs: Kidney</td>
<td>Target Organs: Adrenal gland</td>
<td>Symptoms: Redness, pruritis, Irritation</td>
</tr>
<tr>
<td></td>
<td>Target Organs: inner ear</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Symptoms: Dizziness, Vertigo, hearing loss, tinnitus, fetal deafness</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Betamethasone</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

12. ECOLOGICAL INFORMATION

Ecotoxicity

**Components:**

<table>
<thead>
<tr>
<th>Component</th>
<th>Toxicity to fish</th>
<th>Toxicity to daphnia and other aquatic invertebrates</th>
<th>Toxicity to algae/aquatic plants</th>
<th>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Petrolatum</td>
<td>LL50 (Pimephales promelas (fathead minnow)): &gt; 100 mg/l</td>
<td>EC50 (Daphnia magna (Water flea)): &gt; 10,000 mg/l</td>
<td>NOEL (Pseudokirchneriella subcapitata (green algae)): &gt;= 100 mg/l</td>
<td>NOEC (Daphnia magna (Water flea)): 10 mg/l</td>
</tr>
</tbody>
</table>
### 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:
- **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:
- **LC50** (Oncorhynchus mykiss (rainbow trout)): 917 µg/l
- Exposure time: 96 h
- **EC50** (Daphnia magna (Water flea)): 1.5 mg/l
- Exposure time: 48 h
- Method: OECD Test Guideline 202
- **ErC50** (Chlorella pyrenoidosa (aglae)): 15 mg/l
- Exposure time: 72 h
- Method: OECD Test Guideline 201
- **EC10** (Chlorella pyrenoidosa (aglae)): 2.3 mg/l
- Exposure time: 72 h
- Method: OECD Test Guideline 201

### M-Factor
- **Acute aquatic toxicity**: 1
- **Chronic toxicity**: NOEC (Oncorhynchus mykiss (rainbow trout)): 0.15 mg/l
  - Exposure time: 28 d
  - Method: OECD Test Guideline 204
- NOEC (Daphnia magna (Water flea)): 0.32 mg/l
  - Exposure time: 21 d
  - Method: OECD Test Guideline 211
- **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

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
### Gentamicin / Betamethasone Cream Formulation

**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

### 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 plants:**
- ErC50 (Chlorella pyrenoidosa (aglae)): 15 mg/l
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201
- EC10 (Chlorella pyrenoidosa (aglae)): 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

**Exposure Time:**
- 32 d
- 219 d
- 21 d
- 72 h
- 72 h
- 48 h
- 28 d
- 21 d
- 60 h
- 96 h
Toxicity to algae/aquatic plants:

EC₅₀ (Pseudokirchneriella subcapitata (green algae)): 10 µg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 1.5 µg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

EC₅₀ (Anabaena flos-aquae (cyanobacterium)): 4.7 µg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Anabaena flos-aquae (cyanobacterium)): 1.6 µg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

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

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

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

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

Mobility in soil  
No data available

Hazardous to the ozone layer  
Not applicable

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.  
- **Class**: 9  
- **Packing group**: III  
- **Labels**: 9

**IATA-DGR**

- **UN/ID No.**: UN 3077  
- **Proper shipping name**: Environmentally hazardous substance, solid, n.o.s.  
- **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
SAFETY DATA SHEET

Gentamicin / Betamethasone Cream Formulation

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.

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
Designated Flammable Substances, Flammable solid, (3000 kilogram)

Chemical Substance Control Law
Priority Assessment Chemical Substance

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>2,2,4,6,6-Pentamethylheptane</td>
<td>212</td>
</tr>
</tbody>
</table>

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
Article 57-2 (Enforcement Order Table 9)

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
<th>Concentration (%)</th>
</tr>
</thead>
</table>
SAFETY DATA SHEET

Gentamicin / Betamethasone Cream Formulation

Version 5.0  Revision Date: 2020/03/23  SDS Number: 1832934-00008  Date of last issue: 2019/09/13  Date of first issue: 2017/07/13

| Mineral oil | 168 | >=20 - <30 |

Substances Subject to be Indicated Names
Article 57 (Enforcement Order Article 18)

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 : Noxious liquid substance(Category Z)
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


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)
- AICS / TWA: 8-hour, time-weighted average
- JP OEL JSOH / OEL-M: Occupational Exposure Limit-Mean

AICS - Australian Inventory of Chemical Substances; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organization 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 Substanc-
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.

JP / EN