SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Gentamicin / Betamethasone Cream Formula-
tion

Version 5.0  Revision Date: 23.03.2020  SDS Number: 1833016-00008  Date of last issue: 13.09.2019
Date of first issue: 13.07.2017

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
Trade name: Gentamicin / Betamethasone Cream Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
Use of the Substance/Mixture: Pharmaceutical

1.3 Details of the supplier of the safety data sheet
Company: Organon & Co.
Shotton Lane
NE23 3JU Cramlington NU - Great Britain
Telephone: 44 1 670 59 30 00
E-mail address of person responsible for the SDS: EHSSTEWARD@organon.com

1.4 Emergency telephone number
215-631-6999

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
Classification (REGULATION (EC) No 1272/2008)
- Reproductive toxicity, Category 1B: H360D: May damage the unborn child.
- Specific target organ toxicity - repeated exposure, Category 1: H372: Causes damage to organs through prolonged or repeated exposure.
- Long-term (chronic) aquatic hazard, Category 1: H410: Very toxic to aquatic life with long lasting effects.

2.2 Label elements
Labelling (REGULATION (EC) No 1272/2008)
- Hazard pictograms:
- Signal word: Danger
- Hazard statements:
  - H360D: May damage the unborn child.
  - H372: Causes damage to organs through prolonged or repeated exposure.
  - H410: Very toxic to aquatic life with long lasting effects.
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Gentamicin / Betamethasone Cream Formula-
tion

Version 5.0  Revision Date: 23.03.2020  SDS Number: 1833016-00008  Date of last issue: 13.09.2019  Date of first issue: 13.07.2017

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.

Hazardous components which must be listed on the label:
betamethasone

Additional Labelling
EUH208  Contains 4-Chloro-3-methylphenol. May produce an allergic reaction.

2.3 Other hazards
None known.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paraffin oil</td>
<td>8012-95-1</td>
<td>232-384-2</td>
<td></td>
<td></td>
<td>Asp. Tox. 1; H304</td>
<td>&gt;= 1 - &lt; 10</td>
</tr>
<tr>
<td>4-Chloro-3-methylphenol</td>
<td>59-50-7</td>
<td>200-431-6</td>
<td>604-014-00-3</td>
<td></td>
<td>Acute Tox. 4; H302  Acute Tox. 4; H312  Skin Corr. 1C; H314  Eye Dam. 1; H318  Skin Sens. 1B; H317  STOT SE 3; H335  Aquatic Acute 1; H400  Aquatic Chronic 3; H412  M-Factor (Acute aquatic toxicity): 1</td>
<td>&gt;= 0.1 - &lt; 0.25</td>
</tr>
<tr>
<td>Gentamicin</td>
<td>1403-66-3</td>
<td>215-765-8</td>
<td></td>
<td></td>
<td>Repr. 1A; H360D  STOT RE 1; H372  Aquatic Acute 1; H400  Aquatic Chronic 1; H410</td>
<td>&gt;= 0.1 - &lt; 0.25</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET  
according to Regulation (EC) No. 1907/2006

Gentamicin / Betamethasone Cream Formula- 
tion

Version 5.0  
Revision Date: 23.03.2020  
SDS Number: 1833016-00008  
Date of last issue: 13.09.2019  
Date of first issue: 13.07.2017

M-Factor (Acute aquatic toxicity): 100  
M-Factor (Chronic aquatic toxicity): 1

betamethasone  
378-44-9  
206-825-4  
Acute Tox. 2; H330  
Repr. 1B; H360D  
STOT RE 1; H372  
Aquatic Chronic 1; H410  
M-Factor (Chronic aquatic toxicity): 1,000

>= 0.025 - < 0.1

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of 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.

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).

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.

4.2 Most important symptoms and effects, both acute and delayed

Risks: May damage the unborn child.  
Causes damage to organs through prolonged or repeated exposure.
May produce an allergic reaction.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment: Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media:
- Water spray
- Alcohol-resistant foam
- Carbon dioxide (CO2)
- Dry chemical

Unsuitable extinguishing media: None known.

5.2 Special hazards arising from the substance or mixture

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

5.3 Advice for firefighters

Special protective equipment for firefighters:
- In the event of fire, wear self-contained breathing apparatus.
- Use personal protective equipment.

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.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions:
- Use personal protective equipment.
- Follow safe handling advice and personal protective equipment recommendations.

6.2 Environmental precautions

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...
6.3 Methods and material for containment and cleaning up

Methods for 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.

6.4 Reference to other sections
See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe 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.

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.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers:
Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.

Advice on common storage:
Do not store with the following product types:
Strong oxidizing agents
Organic peroxides
Explosives
Gases
### 7.3 Specific end use(s)

Specific use(s): No data available

### SECTION 8: Exposure controls/personal protection

#### 8.1 Control parameters

**Occupational Exposure Limits**

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<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></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Further information: Skin</td>
<td></td>
<td>Wipe limit</td>
<td>10 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

**Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:**

<table>
<thead>
<tr>
<th>Substance name</th>
<th>End Use</th>
<th>Exposure routes</th>
<th>Potential health effects</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alcohols, C16-18</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>237.76 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Inhalation</td>
<td>Acute systemic effects</td>
<td>237.76 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>6.52 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Inhalation</td>
<td>Acute local effects</td>
<td>6.52 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>200 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Acute systemic effects</td>
<td>400 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term local effects</td>
<td>1.124 mg/cm²</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Acute local effects</td>
<td>1.124 mg/cm²</td>
</tr>
<tr>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>118.88 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Inhalation</td>
<td>Acute systemic effects</td>
<td>118.9 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>0.652 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Inhalation</td>
<td>Acute local effects</td>
<td>0.652 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>100 mg/kg bw/day</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Skin contact</td>
<td>Acute systemic effects</td>
<td>200 mg/kg bw/day</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term local effects</td>
<td>0.562 mg/cm²</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Skin contact</td>
<td>Acute local effects</td>
<td>0.562 mg/cm²</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic</td>
<td>75 mg/kg</td>
<td></td>
</tr>
</tbody>
</table>

---

6 / 25
**SAFETY DATA SHEET**
according to Regulation (EC) No. 1907/2006

**Gentamicin / Betamethasone Cream Formula-**
**tion**

---

**Effects bw/day**

<table>
<thead>
<tr>
<th>Consumers</th>
<th>Ingestion</th>
<th>Acute systemic effects</th>
<th>75 mg/kg bw/day</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paraffin oil</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
</tr>
<tr>
<td>Workers</td>
<td>Inhalation</td>
<td>Short-term exposure</td>
<td>5 mg/m3</td>
</tr>
<tr>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>5 mg/m3</td>
</tr>
<tr>
<td>Workers</td>
<td>Inhalation</td>
<td>Acute local effects</td>
<td>5 mg/m3</td>
</tr>
<tr>
<td>4-Chloro-3-methylphenol</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
</tr>
<tr>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>3.567 mg/kg bw/day</td>
</tr>
<tr>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>1.783 mg/kg bw/day</td>
</tr>
<tr>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>0.892 mg/kg bw/day</td>
</tr>
</tbody>
</table>

---

**Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:**

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Petrolatum</td>
<td>Oral (Secondary Poisoning)</td>
<td>9.33 mg/kg food</td>
</tr>
<tr>
<td>Alcohols, C16-18</td>
<td>Fresh water</td>
<td>0.13 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>0.12 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>1000 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>13.61 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>1.361 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>100 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Oral (Secondary Poisoning)</td>
<td>86.7 mg/kg food</td>
</tr>
<tr>
<td>4-Chloro-3-methylphenol</td>
<td>Fresh water</td>
<td>0.015 mg/l</td>
</tr>
<tr>
<td></td>
<td>Intermittent use/release</td>
<td>0.015 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>0.002 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>2.286 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>13.981 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>13.981 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>6.399 mg/kg dry weight (d.w.)</td>
</tr>
</tbody>
</table>

---

**8.2 Exposure controls**

**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**

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

- **Hand protection**
  - **Material**: Chemical-resistant gloves
  - **Remarks**: Consider double gloving.

- **Skin and body protection**
  - **Material**: 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.

- **Respiratory protection**
  - **Material**: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to BS EN 14387
  - **Filter type**: Combined particulates and organic vapour type (A-P)

---

**SECTION 9: Physical and chemical properties**

9.1 **Information on basic physical and chemical properties**

- **Appearance**: cream
- **Colour**: No data available
- **Odour**: No data available
- **Odour Threshold**: No data available
- **pH**: No data available
- **Melting point/freezing point**: No data available
- **Initial boiling point and boiling range**: No data available
- **Flash point**: > 93.3 °C
- **Evaporation rate**: No data available
- **Flammability (solid, gas)**: Not classified as a flammability hazard
- **Upper explosion limit / Upper flammability limit**: No data available
Gentamicin / Betamethasone Cream Formula- 
tion

Lower explosion limit / Lower 
flammability limit : No data available

Vapour pressure : No data available

Relative vapour density : No data available

Relative density : No data available

Density : No data available

Solubility(ies)

Water solubility : No data available

Partition coefficient: n- 
octanol/water : No data available

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.

9.2 Other information

Flammability (liquids) : No data available

Molecular weight : No data available

Particle size : No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : Vapours may form explosive mixture with air.
Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : None known.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents
10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Information on likely routes of exposure:
- Skin contact
- Ingestion
- Eye contact

Acute toxicity

Not classified based on available information.

Components:

**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

**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:
  - Acute toxicity estimate: 1,100 mg/kg
  - Method: Expert judgement
  - Remarks: Based on harmonised classification in EU regulation 1272/2008, Annex VI

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

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

4-Chloro-3-methylphenol:
Species : Rabbit
Method : OECD Test Guideline 405
Result : Irreversible effects on the eye
Gentamicin / Betamethasone Cream Formulation

Species: Rabbit
Result: Mild eye irritation

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:

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

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

Germ cell mutagenicity
Not classified based on available information.

Components:

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:**

**Gentamicin**

**Carcinogenicity - Assessment**
- No data available

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

**Components:**

**4-Chloro-3-methylphenol**

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

**Effects on foetal 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 foetal development**
- Test Type: Embryo-foetal development
  - Species: Rabbit
  - Developmental Toxicity: NOAEL: 3.6 mg/kg body weight
  - Result: No embryo-foetal toxicity

  Test Type: Embryo-foetal development
  - Species: Rat
  - Application Route: Intraperitoneal
  - Developmental Toxicity: LOAEL: 75 mg/kg body weight
  - Result: Embryo-foetal toxicity

  Test Type: Embryo-foetal development
  - Species: Mouse
  - Application Route: Intraperitoneal
  - Developmental Toxicity: LOAEL: 10 mg/kg body weight
  - Result: foetal mortality, No malformations were observed.

Reproductive toxicity - Assessment: Positive evidence of adverse effects on development from human epidemiological studies.

**Beta methasone:**

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

- Species: Rat
  - Application Route: Subcutaneous
  - Developmental Toxicity: LOAEL: 0.42 mg/kg body weight
  - Result: Malformations were observed.

- Species: Mouse
  - Application Route: Intramuscular
  - Developmental Toxicity: LOAEL: 1 mg/kg body weight
  - Result: Malformations were observed.

Reproductive toxicity - Assessment: Clear evidence of adverse effects on development, based on animal experiments.
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 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:

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

- 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
<table>
<thead>
<tr>
<th>Species</th>
<th>LOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monkey</td>
<td>50 mg/kg</td>
<td>Subcutaneous</td>
<td>3 Weeks</td>
<td>Kidney, inner ear</td>
</tr>
<tr>
<td>Rat</td>
<td>6 mg/kg</td>
<td>Intramuscular</td>
<td>3 Weeks</td>
<td>Blood, Kidney, inner ear, Liver</td>
</tr>
<tr>
<td>Rat</td>
<td>10 mg/kg</td>
<td>Intramuscular</td>
<td>52 Weeks</td>
<td>Kidney, Blood</td>
</tr>
<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>
<tr>
<td>Mouse</td>
<td>0.1 %</td>
<td>Skin contact</td>
<td>8 Weeks</td>
<td>thymus gland</td>
</tr>
<tr>
<td>Dog</td>
<td>0.05 mg/kg</td>
<td>Oral</td>
<td>28 d</td>
<td>Blood, thymus gland, Adrenal gland</td>
</tr>
</tbody>
</table>
**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

**SECTION 12: Ecological information**

12.1 Toxicity

**Components:**

**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

**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 (algae)): 15 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

EC10 (Chlorella pyrenoidosa (algae)): 2.3 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

M-Factor (Acute aquatic toxicity): 1

Toxicity to microorganisms:

EC50: 22.86 mg/l
Exposure time: 60 h

Toxicity to fish (Chronic toxicity):

NOEC: 0.15 mg/l
Exposure time: 28 d
Species: Oncorhynchus mykiss (rainbow trout)
Method: OECD Test Guideline 204

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

NOEC: 0.32 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
Method: OECD Test Guideline 211

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
**Gentamicin / Betamethasone Cream 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>5.0</td>
<td>23.03.2020</td>
<td>1833016-00008</td>
<td>13.09.2019</td>
<td>13.07.2017</td>
</tr>
</tbody>
</table>

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

**M-Factor (Acute aquatic toxicity)**: 100

**Toxicity to microorganisms**:
- **EC50**: 288.7 mg/l
- Exposure time: 3 h
- Test Type: Respiration inhibition
- Method: OECD Test Guideline 209

**M-Factor (Chronic aquatic toxicity)**: 1

**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**: 0.052 mg/l
- Exposure time: 32 d
- Species: Pimephales promelas (fathead minnow)
- Method: OECD Test Guideline 210

**NOEC**: 0.07 µg/l
- Exposure time: 219 d
- Species: Oryzias latipes (Japanese medaka)
- Method: OECD Test Guideline 229

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

**M-Factor (Chronic aquatic toxicity)**: 1,000

### 12.2 Persistence and degradability

**Components:**

- **Paraffin oil:**
Biodegradability: Result: Readily biodegradable.
Biodegradation: 82 %
Exposure time: 24 d
Method: OECD Test Guideline 301F
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

12.3 Bioaccumulative potential

Components:

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

12.4 Mobility in soil
No data available

12.5 Results of PBT and vPvB assessment
Not relevant

12.6 Other adverse effects
No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods
Product: Dispose of in accordance with local regulations.
According to the European Waste Catalogue, Waste Codes
are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

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

14.1 UN number

<table>
<thead>
<tr>
<th>ADN</th>
<th>UN 3077</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADR</td>
<td>UN 3077</td>
</tr>
<tr>
<td>RID</td>
<td>UN 3077</td>
</tr>
<tr>
<td>IMDG</td>
<td>UN 3077</td>
</tr>
<tr>
<td>IATA</td>
<td>UN 3077</td>
</tr>
</tbody>
</table>

14.2 UN proper shipping name

<table>
<thead>
<tr>
<th>ADN</th>
<th>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (4-Chloro-3-methylphenol, Gentamicin)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADR</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (4-Chloro-3-methylphenol, Gentamicin)</td>
</tr>
<tr>
<td>RID</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (4-Chloro-3-methylphenol, Gentamicin)</td>
</tr>
<tr>
<td>IMDG</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (4-Chloro-3-methylphenol, Gentamicin)</td>
</tr>
<tr>
<td>IATA</td>
<td>Environmentally hazardous substance, solid, n.o.s. (4-Chloro-3-methylphenol, Gentamicin)</td>
</tr>
</tbody>
</table>

14.3 Transport hazard class(es)

<table>
<thead>
<tr>
<th>ADN</th>
<th>9</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADR</td>
<td>9</td>
</tr>
<tr>
<td>RID</td>
<td>9</td>
</tr>
<tr>
<td>IMDG</td>
<td>9</td>
</tr>
<tr>
<td>IATA</td>
<td>9</td>
</tr>
</tbody>
</table>

14.4 Packing group

<table>
<thead>
<tr>
<th>ADN</th>
<th>Packing group : III</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Classification Code : M7</td>
</tr>
<tr>
<td></td>
<td>Hazard Identification Number : 90</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Gentamicin / Betamethasone Cream Formula-
tion

Version 5.0  Revision Date: 23.03.2020  SDS Number: 1833016-00008  Date of last issue: 13.09.2019
Date of first issue: 13.07.2017

Labels: 9 (ENVIRONM.)

ADR
Packing group: III
Classification Code: M7
Hazard Identification Number: 90
Labels: 9 (ENVIRONM.)
Tunnel restriction code: (-)

RID
Packing group: III
Classification Code: M7
Hazard Identification Number: 90
Labels: 9 (ENVIRONM.)

IMDG
Packing group: III
Labels: 9 (ENVIRONM.)
EmS Code: F-A, S-F

IATA (Cargo)
Packing instruction (cargo aircraft): 956
Packing instruction (LQ): Y956
Packing group: III
Labels: Miscellaneous,

IATA (Passenger)
Packing instruction (passenger aircraft): 956
Packing instruction (LQ): Y956
Packing group: III
Labels: Miscellaneous,

14.5 Environmental hazards

ADN
Environmentally hazardous: yes

ADR
Environmentally hazardous: yes

RID
Environmentally hazardous: yes

IMDG
Marine pollutant: yes

IATA (Passenger)
Environmentally hazardous: yes

IATA (Cargo)
Environmentally hazardous: yes

14.6 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
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Gentamicin / Betamethasone Cream Formulation

Version 5.0  Revision Date: 23.03.2020  SDS Number: 1833016-00008  Date of last issue: 13.09.2019
Date of first issue: 13.07.2017

Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code
Remarks: Not applicable for product as supplied.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII): Not applicable
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59): Not applicable
REACH - List of substances subject to authorisation (Annex XIV): Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer: Not applicable
Regulation (EU) 2019/1021 on persistent organic pollutants (recast): Not applicable
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals: Not applicable

<table>
<thead>
<tr>
<th>E1</th>
<th>ENVIRONMENTAL HAZARDS</th>
<th>Quantity 1</th>
<th>Quantity 2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>100 t</td>
<td>200 t</td>
</tr>
</tbody>
</table>

Other regulations:
Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.
Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

The components of this product are reported in the following inventories:
AICS: not determined
DSL: not determined
IECSC: not determined

15.2 Chemical safety assessment
A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information: Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Gentamicin / Betamethasone Cream Formulation

Version 5.0
Revision Date: 23.03.2020
SDS Number: 1833016-00008
Date of last issue: 13.09.2019
Date of first issue: 13.07.2017

Full text of H-Statements
H302 : Harmful if swallowed.
H304 : May be fatal if swallowed and enters airways.
H312 : Harmful in contact with skin.
H314 : Causes severe skin burns and eye damage.
H317 : May cause an allergic skin reaction.
H318 : Causes serious eye damage.
H330 : Fatal if inhaled.
H335 : May cause respiratory irritation.
H360D : May damage the unborn child.
H372 : Causes damage to organs through prolonged or repeated exposure.
H372 : Causes damage to organs through prolonged or repeated exposure if swallowed.
H400 : Very toxic to aquatic life.
H410 : Very toxic to aquatic life with long lasting effects.
H412 : Harmful to aquatic life with long lasting effects.

Full text of other abbreviations
Acute Tox. : Acute toxicity
Aquatic Acute : Short-term (acute) aquatic hazard
Aquatic Chronic : Long-term (chronic) aquatic hazard
Asp. Tox. : Aspiration hazard
Eye Dam. : Serious eye damage
Repr. : Reproductive toxicity
Skin Corr. : Skin corrosion
Skin Sens. : Skin sensitisation
STOT RE : Specific target organ toxicity - repeated exposure
STOT SE : Specific target organ toxicity - single exposure

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Develop-
# SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Gentamicin / Betamethasone Cream Formula-
tion

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.0</td>
<td>23.03.2020</td>
<td>1833016-00008</td>
<td>13.09.2019</td>
</tr>
</tbody>
</table>

Further information:

<table>
<thead>
<tr>
<th>Classification of the mixture:</th>
<th>Classification procedure:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Repr. 1B</td>
<td>H360D</td>
</tr>
<tr>
<td>STOT RE 1</td>
<td>H372</td>
</tr>
<tr>
<td>Aquatic Chronic 1</td>
<td>H410</td>
</tr>
</tbody>
</table>

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

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.