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

Gentamicin / Betamethasone Cream Formulation

Version 4.2 Revision Date: 09/13/2019 SDS Number: 1833017-00007 Date of last issue: 24.04.2019
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 : MSD
Innishannon
County Cork - Ireland

Telephone : 353 214329300
Telefax : 908-735-1496
E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
1-908-423-6000

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.
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>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 4.2  Revision Date: 09/13/2019  SDS Number: 1833017-00007  Date of last issue: 24.04.2019

Date of first issue: 13.07.2017

<table>
<thead>
<tr>
<th>Betamethasone</th>
<th>M-Factor (Acute aquatic toxicity): 100</th>
<th>M-Factor (Chronic aquatic toxicity): 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>378-44-9</td>
<td>206-825-4</td>
<td>Acute Tox. 2; H330 Repr. 1B; H360D STOT RE 1; H372 Aquatic Chronic 1; H410</td>
</tr>
<tr>
<td></td>
<td></td>
<td>M-Factor (Chronic aquatic toxicity): 1,000</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Suitable extinguishing media</th>
<th>Water spray</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Alcohol-resistant foam</td>
</tr>
<tr>
<td></td>
<td>Carbon dioxide (CO2)</td>
</tr>
<tr>
<td></td>
<td>Dry chemical</td>
</tr>
</tbody>
</table>

| Unsuitable extinguishing media | None known. |

5.2 Special hazards arising from the substance or mixture

<table>
<thead>
<tr>
<th>Specific hazards during firefighting</th>
<th>Vapours may form explosive mixtures with air.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure to combustion products may be a hazard to health.</td>
</tr>
</tbody>
</table>

| Hazardous combustion products | Carbon oxides |

5.3 Advice for firefighters

<table>
<thead>
<tr>
<th>Special protective equipment for firefighters</th>
<th>In the event of fire, wear self-contained breathing apparatus.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Use personal protective equipment.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Specific extinguishing methods</th>
<th>Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Use water spray to cool unopened containers.</td>
</tr>
<tr>
<td></td>
<td>Remove undamaged containers from fire area if it is safe to do so.</td>
</tr>
<tr>
<td></td>
<td>Evacuate area.</td>
</tr>
</tbody>
</table>

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

<table>
<thead>
<tr>
<th>Personal precautions</th>
<th>Use personal protective equipment.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Follow safe handling advice and personal protective equipment recommendations.</td>
</tr>
</tbody>
</table>

6.2 Environmental precautions

<table>
<thead>
<tr>
<th>Environmental precautions</th>
<th>Discharge into the environment must be avoided.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Prevent further leakage or spillage if safe to do so.</td>
</tr>
<tr>
<td></td>
<td>Retain and dispose of contaminated wash water.</td>
</tr>
<tr>
<td></td>
<td>Local authorities should be advised if significant spillages cannot be contained.</td>
</tr>
</tbody>
</table>
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/PERSOANAL 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
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Gentamicin / Betamethasone Cream Formulation

Version 4.2
Revision Date: 09/13/2019
SDS Number: 1833017-00007
Date of last issue: 24.04.2019
Date of first issue: 13.07.2017

7.3 Specific end use(s)
Specific use(s): No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

<table>
<thead>
<tr>
<th>Occupational Exposure Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Components</td>
</tr>
<tr>
<td>Petrolatum</td>
</tr>
<tr>
<td>Further information</td>
</tr>
<tr>
<td>Paraffin oil</td>
</tr>
<tr>
<td>Further information</td>
</tr>
<tr>
<td>Gentamicin</td>
</tr>
<tr>
<td>betamethasone</td>
</tr>
<tr>
<td>Further information</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></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>118.88 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Acute systemic effects</td>
<td>118.9 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>0.652 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Acute local effects</td>
<td>0.652 mg/m³</td>
</tr>
</tbody>
</table>
# Gentamicin / Betamethasone Cream Formula- tion

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

Gentamicin / Betamethasone Cream Formula-
tion

Version 4.2  Revision Date: 09/13/2019  SDS Number: 1833017-00007  Date of last issue: 24.04.2019
Date of first issue: 13.07.2017

9.2 Other information

9.2.1 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.
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>
<th>Date of first issue:</th>
</tr>
</thead>
</table>

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

<table>
<thead>
<tr>
<th>Information on likely routes of exposure</th>
<th>4-Chloro-3-methylphenol:</th>
<th>Gentamicin:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin contact</td>
<td>Acute oral toxicity: LD50 (Mouse): 600 mg/kg</td>
<td>Acute oral toxicity: LD50 (Rat): 8,000 - 10,000 mg/kg</td>
</tr>
<tr>
<td>Ingestion</td>
<td>Acute inhalation toxicity: LC50 (Rat): &gt; 2.871 mg/l</td>
<td>LD50 (Mouse): 10,000 mg/kg</td>
</tr>
<tr>
<td>Eye contact</td>
<td>Exposure time: 4 h</td>
<td>Acute inhalation toxicity: LC50 (Rat): &gt; 0.2 mg/l</td>
</tr>
<tr>
<td></td>
<td>Test atmosphere: dust/mist</td>
<td>Exposure time: 4 h</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Test atmosphere: dust/mist</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Remarks: No mortality observed at this dose.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Application Route: Intravenous</td>
</tr>
</tbody>
</table>

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

Components:

4-Chloro-3-methylphenol:
- Acute oral toxicity: LD50 (Mouse): 600 mg/kg
- Acute inhalation toxicity: LC50 (Rat): > 2.871 mg/l
- Acute dermal toxicity: Acute toxicity estimate: 1,100 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
- Application Route: Intravenous

Acute toxicity (other routes of administration): LD50 (Rat): 67 - 96 mg/kg

Application Route: Intramuscular

LD50 (Rat): 371 - 384 mg/kg

Application Route: Intramuscular

LDLo (Monkey): 30 mg/kg
**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>
<th>Date of first issue:</th>
</tr>
</thead>
</table>

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:**

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:**

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

**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:

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
| Reproductive toxicity - Assessment | \begin{itemize}
  \item Positive evidence of adverse effects on development from human epidemiological studies.
\end{itemize} |

**betamethasone:**

| Effects on foetal development | \begin{itemize}
  \item Species: Rabbit
  \item Application Route: Intramuscular
  \item Developmental Toxicity: LOAEL: 0.05 mg/kg body weight
  \item Result: Fetotoxicity, Malformations were observed.
\end{itemize} |

| 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 | \begin{itemize}
  \item Clear evidence of adverse effects on development, based on animal experiments.
\end{itemize} |

**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:**

**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
Gentamicin / Betamethasone Cream Formulation

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.

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:

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

Gentamicin / Betamethasone Cream Formula-
tion

Version 4.2 Revision Date: 09/13/2019 SDS Number: 1833017-00007 Date of last issue: 24.04.2019 Date of first issue: 13.07.2017

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

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

12.2 Persistence and degradability

Components:

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

14.2 UN proper shipping name

<table>
<thead>
<tr>
<th>ADN</th>
<th>ADR</th>
<th>RID</th>
<th>IMDG</th>
<th>IATA</th>
</tr>
</thead>
<tbody>
<tr>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (4-Chloro-3-methylphenol, Gentamicin)</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (4-Chloro-3-methylphenol, Gentamicin)</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (4-Chloro-3-methylphenol, Gentamicin)</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (4-Chloro-3-methylphenol, Gentamicin)</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>ADR</th>
<th>RID</th>
<th>IMDG</th>
<th>IATA</th>
</tr>
</thead>
<tbody>
<tr>
<td>9</td>
<td>9</td>
<td>9</td>
<td>9</td>
<td>9</td>
</tr>
</tbody>
</table>

14.4 Packing group

<table>
<thead>
<tr>
<th>ADN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Packing group: III</td>
</tr>
<tr>
<td>Classification Code: M7</td>
</tr>
</tbody>
</table>
Hazard Identification Number : 90
Labels : 9

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

RID
Packing group : III
Classification Code : M7
Hazard Identification Number : 90
Labels : 9

IMDG
Packing group : III
Labels : 9
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 Formula-
tion

Version 4.2 Revision Date: 09/13/2019 SDS Number: 1833017-00007 Date of last issue: 24.04.2019
Date of first issue: 13.07.2017

Sheet. Transportation classifications may vary by mode of transportation, package sizes, and vari-
ations 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 mix-
ture

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 de-
plete the ozone layer : Not applicable
Regulation (EC) No 850/2004 on persistent organic pol-
lutants : Not applicable
Regulation (EC) No 649/2012 of the European Parlia-
ment and the Council concerning the export and import of
dangerous chemicals : Not applicable
REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) : 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.
Full text of H-Statements

H302 : Harmful if swallowed.
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
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
IE OEL : Ireland. List of Chemical Agents and Occupational Exposure Limit Values - Schedule 1
IE OEL / OELV - 8 hrs (TWA) : Occupational exposure limit value (8-hour reference period)
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Gentamicin / Betamethasone Cream Formulation

Version 4.2    Revision Date: 09/13/2019    SDS Number: 1833017-00007    Date of last issue: 24.04.2019

Date of first issue: 13.07.2017

Further information

Classification of the mixture:

<table>
<thead>
<tr>
<th>Component</th>
<th>Classification</th>
<th>Classification procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Repr. 1B</td>
<td>H360D</td>
<td>Calculation method</td>
</tr>
<tr>
<td>STOT RE 1</td>
<td>H372</td>
<td>Calculation method</td>
</tr>
<tr>
<td>Aquatic Chronic 1</td>
<td>H410</td>
<td>Calculation method</td>
</tr>
</tbody>
</table>

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.

IE / EN