SAFETY DATA SHEET
According to 13 December 2014, No:29204, “Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I”.

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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
Shotton Lane
NE23 3JU Cramlington NU - Great Britain
Telephone : 44 1 670 59 30 00
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 T.R. SEA No 28848
Reproductive toxicity, Category 1B
Specific target organ toxicity - repeated exposure, Category 1
Long-term (chronic) aquatic hazard, Category 1
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.

2.2 Label elements
Labelling T.R. SEA No 28848
Hazard pictograms : 
Signal word : Danger
Hazard statements :
H360D  May damage the unborn child.
H372  Causes damage to organs through prolonged or repeated exposure.
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tion

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 protec-
tion/ 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. EC-No. Index-No. Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>4-Chloro-3-methylphenol</td>
<td>59-50-7 200-431-6 604-014-00-3</td>
<td>Acute Tox.4; H302 Acute Tox.4; H312 Skin Corr.1C; H314 Eye Dam.1; H318 Skin Sens.1B; H317 STOT SE3; H335 Aquatic Acute1; H400 Aquatic Chronic3; 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>Repr.1A; H360D</td>
<td>&gt;= 0,1 - &lt; 0,25</td>
</tr>
</tbody>
</table>
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tion

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.

For explanation of abbreviations see section 16.
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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.
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<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
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<th>Date of first issue</th>
</tr>
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<tr>
<td>2.3</td>
<td>09/13/2019</td>
<td>2807397-00004</td>
<td>24.04.2019</td>
<td>18.05.2018</td>
</tr>
</tbody>
</table>

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 cannot be contained.

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:
Keep in properly labelled containers. Store locked up. Keep
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areas and containers: 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>
</tbody>
</table>

Further information

| Skin            | Wipe limit | 10 µg/100 cm² | Internal |

**Derived No Effect Level (DNEL)**

<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>
</tbody>
</table>
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<table>
<thead>
<tr>
<th>Consumers</th>
<th>Inhalation</th>
<th>Acute local effects</th>
<th>Long-term systemic effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consumers</td>
<td>Skin contact</td>
<td>0,562 mg/cm²</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Ingestion</td>
<td>0,652 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Skin contact</td>
<td>0,562 mg/cm²</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Ingestion</td>
<td>0,652 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Skin contact</td>
<td>0,652 mg/cm²</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Ingestion</td>
<td>0,652 mg/m³</td>
<td></td>
</tr>
</tbody>
</table>

**Predicted No Effect Concentration (PNEC):**

<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>
</tbody>
</table>
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| Soil             | 6,399 mg/kg dry weight (d.w.) |

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: No data available
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range
- 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
- 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.
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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:

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:**

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
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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
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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.

  - Test Type: Embryo-foetal development
    - Species: Rat
    - Application Route: Intraperitoneal
    - Developmental Toxicity: LOAEL: 50 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.

**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
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<table>
<thead>
<tr>
<th>Developmental Toxicity</th>
<th>LOAEL: 1 mg/kg body weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result: Malformations were observed.</td>
<td></td>
</tr>
</tbody>
</table>

**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:**

**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
Gentamicin / Betamethasone Cream Formulation

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
Gentamicin / Betamethasone Cream Formula-
tion

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 (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 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
Gentamicin / Betamethasone Cream Formulation

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:

- 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

- 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

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:

- EC50 (Americamysis): > 50 mg/l
  - Exposure time: 96 h

- EC50 (Pseudokirchneriella subcapitata (green algae)): > 34 mg/l
  - Exposure time: 72 h
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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:

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
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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

- **ADN**: UN 3077
- **ADR**: UN 3077
- **RID**: UN 3077
- **IMDG**: UN 3077
- **IATA**: UN 3077

14.2 UN proper shipping name

- **ADN**: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (4-Chloro-3-methylphenol, Gentamicin)
- **ADR**: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,
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N.O.S.
(4-Chloro-3-methylphenol, Gentamicin)

**RID** : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(4-Chloro-3-methylphenol, Gentamicin)

**IMDG** : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(4-Chloro-3-methylphenol, Gentamicin)

**IATA** : Environmentally hazardous substance, solid, n.o.s.
(4-Chloro-3-methylphenol, Gentamicin)

### 14.3 Transport hazard class(es)

| ADN | 9 |
| ADR | 9 |
| RID | 9 |
| IMDG| 9 |
| IATA| 9 |

### 14.4 Packing group

**ADN**
- Packing group : III
- Classification Code : M7
- 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
SAFETY DATA SHEET

According to 13 December 2014, No:29204, “Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I”.

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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

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 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

- KKDIK (30105 (Bis)) - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex 17): Not applicable

Other regulations:

According to 13 December 2014, No:29204, “Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I”.

Regulation on Classification, Labelling and Packaging of Substances and Mixtures. Dated 11 December 2013, Numbered 28848 (Bis) Ministry of Environment and Forestry.

Regulation on Health and Safety Measures Of Working with Chemicals Substances Dated 12.08.13, numbered 28733 Ministry of Labour and Social Security.
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The components of this product are reported in the following inventories:
- AICS: not determined
- DSL: not determined
- IECSC: not determined

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.

The Turkish SDS has been prepared according to the Regulation on Safety Data Sheets for Hazardous Substances and Mixtures No. 29204.

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

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 (Cana-
SAFETY DATA SHEET
According to 13 December 2014, No:29204, "Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I".

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Further information

Classification of the mixture:

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The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user’s end product, if applicable.
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