Clotrimazole / Gentamicin / Betamethasone (0.05%) Formulation

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

1.1 Product identifier
Trade name : Clotrimazole / Gentamicin / Betamethasone (0.05%) 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 (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 re-
peated 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

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., Index-No., 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>Asp. Tox.; H304</td>
<td>&gt;= 1 - &lt; 10</td>
</tr>
<tr>
<td>Hexadecan-1-ol. Ethoxylated</td>
<td>9004-95-9</td>
<td></td>
<td>Eye Irrit.; H319</td>
<td>&gt;= 1 - &lt; 10</td>
</tr>
<tr>
<td>clotrimazole</td>
<td>23593-75-1</td>
<td>245-764-8</td>
<td>Acute Tox.; 4; H302 Acute Tox.; 3; H311 Eye Irrit.; 2; H319 Repr. 2; H361fd STOT RE 2; H373 Aquatic Acute 1; H400 Aquatic Chronic 1; H410 M-Factor (Acute aquatic toxicity): 10 M-Factor (Chronic aquatic toxicity): 10</td>
<td>&gt;= 1 - &lt; 2.5</td>
</tr>
<tr>
<td>Benzyl alcohol</td>
<td>100-51-6</td>
<td>202-859-9 603-057-00-5</td>
<td>Acute Tox.; 4; H302 Acute Tox.; 4; H332 Eye Irrit. 2; H319</td>
<td>&gt;= 1 - &lt; 10</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Clotrimazole / Gentamicin / Betamethasone
(0.05%) Formulation

Version 6.0    Revision Date: 23.03.2020    SDS Number: 613798-00012
Date of last issue: 13.09.2019  Date of first issue: 29.04.2016

<table>
<thead>
<tr>
<th>Gentamicin</th>
<th>1403-66-3 215-765-8</th>
<th>Repr. 1A; H360D STOT RE 1; H372 Aquatic Acute 1; H400 Aquatic Chronic 1; H410</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>M-Factor (Acute aquatic toxicity): 100 M-Factor (Chronic aquatic toxicity): 1</td>
</tr>
<tr>
<td>betamethasone</td>
<td>378-44-9 206-825-4</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>
<tr>
<td></td>
<td>&gt;= 0.1 - &lt; 0.25</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>&gt;= 0.025 - &lt; 0.1</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.

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: 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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6.2 Environmental precautions
Environmental precautions: Discharge into the environment must be avoided.
Prevent further leakage or spillage if safe to do so.
Prevent spreading over a wide area (e.g. by containment or oil barriers).
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: Soak up with inert absorbent material.
For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.
Clean up remaining materials from spill with suitable absorbent.
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 breathe vapours or spray mist.
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>Propylene glycol</td>
<td>57-55-6</td>
<td>TWA (particles)</td>
<td>10 mg/m³</td>
<td>GB EH40</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Total vapour and particles)</td>
<td>150 ppm 474 mg/m³</td>
<td>GB EH40</td>
</tr>
<tr>
<td>clotrimazole</td>
<td>23593-75-1</td>
<td>TWA</td>
<td>0.2 mg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Gentamicin</td>
<td>1403-66-3</td>
<td>TWA</td>
<td>0.1 mg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>betamethasone</td>
<td>378-44-9</td>
<td>TWA</td>
<td>1 µg/m³ (OEB 4)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
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<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Further information: Where no specific short-term exposure limit is listed, a figure three times the long-term exposure limit should be used.

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>Propylene glycol</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Long-term systemic effects</td>
<td>168 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>50 mg/m³</td>
</tr>
<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></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>----------</td>
<td>----------</td>
<td>------------------------------</td>
<td>------------------</td>
<td></td>
</tr>
<tr>
<td>Workers</td>
<td>Inhalation</td>
<td>Acute systemic effects</td>
<td>237.76 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>6.52 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>200 mg/kg bw/day</td>
<td></td>
</tr>
<tr>
<td>Workers</td>
<td>Skin contact</td>
<td>Acute systemic effects</td>
<td>400 mg/kg bw/day</td>
<td></td>
</tr>
<tr>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term local effects</td>
<td>1.124 mg/cm²</td>
<td></td>
</tr>
<tr>
<td>Workers</td>
<td>Skin contact</td>
<td>Acute local effects</td>
<td>1.124 mg/cm²</td>
<td></td>
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<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>Skin contact</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 effects</td>
<td>75 mg/kg bw/day</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Ingestion</td>
<td>Acute systemic effects</td>
<td>75 mg/kg bw/day</td>
<td></td>
</tr>
<tr>
<td>Paraffin oil</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Workers</td>
<td>Inhalation</td>
<td>Short-term exposure</td>
<td>5 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>5 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Workers</td>
<td>Inhalation</td>
<td>Acute local effects</td>
<td>5 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Benzyl alcohol</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>22 mg/m³</td>
</tr>
<tr>
<td>Workers</td>
<td>Inhalation</td>
<td>Acute systemic effects</td>
<td>110 mg/m³</td>
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</tr>
<tr>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>8 mg/kg bw/day</td>
<td></td>
</tr>
<tr>
<td>Workers</td>
<td>Skin contact</td>
<td>Acute systemic effects</td>
<td>40 mg/kg bw/day</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>5.4 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Inhalation</td>
<td>Acute systemic effects</td>
<td>27 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>4 mg/kg bw/day</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Skin contact</td>
<td>Acute systemic effects</td>
<td>20 mg/kg bw/day</td>
<td></td>
</tr>
</tbody>
</table>
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(0.05%) Formulation

8.2 Exposure controls

Engineering measures
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.
If handled in a laboratory, use a properly designed biosafety cabinet, fume hood, or other containment device if the potential exists for aerosolization. If this potential does not exist, handle over lined trays or benchtops.

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. 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: liquid
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: No data available
Evaporation rate: No data available
Flammability (solid, gas): Not applicable
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
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10.2 Other information

- Flammability (liquids): No data available
- Particle size: Not applicable

### 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: 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:
- Inhalation
- Skin contact
- Ingestion
- Eye contact

Acute toxicity
Not classified based on available information.
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Date of first issue: 29.04.2016

Product:
Acute oral toxicity: Acute toxicity estimate: > 2,000 mg/kg
Method: Calculation method

Acute inhalation toxicity: Acute toxicity estimate: > 5 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method

Acute dermal toxicity: Acute toxicity estimate: > 2,000 mg/kg
Method: Calculation method

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

Hexadecan-1-ol. Ethoxylated:
Acute oral toxicity: LD50 (Rat): 2,500 mg/kg

Clotrimazole:
Acute oral toxicity: LD50 (Rat): 708 mg/kg
LD50 (Mouse): 761 mg/kg
LD50 (Rabbit): > 1,000 mg/kg

Acute inhalation toxicity: LC50 (Rat): > 0.73 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist

Acute dermal toxicity: LD50 (Mouse): 923 mg/kg

Benzy alcohol:
Acute oral toxicity: LD50 (Rat): 1,620 mg/kg

Acute inhalation toxicity: LC50 (Rat): > 4.178 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403

Gentamicin:
Acute oral toxicity: LD50 (Rat): 8,000 - 10,000 mg/kg
LD50 (Mouse): 10,000 mg/kg
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<table>
<thead>
<tr>
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<th>Date of first issue</th>
</tr>
</thead>
</table>

#### 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

#### Clotrimazole:
- **Species:** Rabbit
- **Result:** No skin irritation

#### Benzyl alcohol:
- **Species:** Rabbit
- **Method:** OECD Test Guideline 404
- **Result:** No skin irritation

#### 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

Hexadecan-1-ol. Ethoxylated:
Result: Irritation to eyes, reversing within 21 days
Remarks: Based on data from similar materials

Clotrimazole:
Species: Rabbit
Result: Mild eye irritation

Benzyl alcohol:
Species: Rabbit
Method: OECD Test Guideline 405
Result: Irritation to eyes, reversing within 21 days

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:

Benzyl alcohol:
Test Type: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative

Gentamicin:
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<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
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<th>Date of first issue</th>
</tr>
</thead>
</table>

Remarks: No data available

**Betamethasone:**
- Exposure routes: Dermal
- Species: Guinea pig
- Result: Weak sensitizer

**Germ cell mutagenicity**
Not classified based on available information.

**Components:**

**Clotrimazole:**
- Genotoxicity in vitro:
  - Test Type: Bacterial reverse mutation assay (AMES)
    Result: negative
  - Test Type: Chromosome aberration test in vitro
    Result: negative
  - Test Type: in vitro micronucleus test
    Result: negative
- Genotoxicity in vivo:
  - Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
    Species: Rat
    Application Route: Oral
    Result: negative
  - Test Type: Mammalian spermatogonial chromosome aberration test (in vivo)
    Species: Hamster
    Result: negative
- Germ cell mutagenicity assessment: Weight of evidence does not support classification as a germ cell mutagen.

**Benzyl alcohol:**
- Genotoxicity in vitro:
  - Test Type: Bacterial reverse mutation assay (AMES)
    Result: negative
- Genotoxicity in vivo:
  - Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
    Species: Mouse
    Application Route: Intraperitoneal injection
    Result: negative

**Gentamicin:**
- Genotoxicity in vitro:
  - Test Type: In vitro mammalian cell gene mutation test
    Result: negative
Clotrimazole / Gentamicin / Betamethasone (0.05%) Formulation

Genotoxicity in vivo: 
- Test Type: Chromosome aberration test in vitro
  Result: equivocal

Components:

Clotrimazole:
- Species: Rat
- Application Route: Oral
- Exposure time: 78 weeks
- Result: negative

Benzyl alcohol:
- Species: Mouse
- Application Route: Ingestion
- Exposure time: 103 weeks
- Method: OECD Test Guideline 451
- Result: negative

Gentamicin:
- Carcinogenicity - Assessment: No data available

Carcinogenicity:
Not classified based on available information.
Reproductive toxicity
May damage the unborn child.

Components:

**Clotrimazole:**
- **Effects on fertility**
  - Test Type: Fertility/early embryonic development
  - Species: Rat
  - Application Route: Oral
  - Fertility: LOAEL: 50 mg/kg body weight
  - Result: Effects on fertility

**Benzy alcohol:**
- **Effects on fertility**
  - Test Type: Fertility/early embryonic development
  - Species: Rat
  - Application Route: Ingestion
  - Result: negative
  - Remarks: Based on data from similar materials
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Clotrimazole / Gentamicin / Betamethasone (0.05%) Formulation

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

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

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

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
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.

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(0.05%) Formulation

STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
Causes damage to organs through prolonged or repeated exposure.

Components:

**clotrimazole:**
Target Organs : Liver, Kidney, Adrenal gland
Assessment : May cause damage to organs through prolonged or repeated exposure.

**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

**clotrimazole:**
Species : Rabbit
LOAEL : 5 - 40 mg/kg
Application Route : Skin contact
Exposure time : 3 Weeks
Target Organs : Skin
Symptoms : Oedema, Fissuring, Necrosis, Redness

Species : Rat
LOAEL : 10 mg/kg
Application Route : Oral
Exposure time : 18 Months
Target Organs : Liver, Kidney, Adrenal gland

Species : Dog
Clotrimazole / Gentamicin / Betamethasone
(0.05%) Formulation

<table>
<thead>
<tr>
<th>LOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
<th>Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>25 mg/kg</td>
<td>Oral</td>
<td>6 - 12 Months</td>
<td>Adrenal gland</td>
<td>Salivation, Lachrymation, Vomiting</td>
</tr>
</tbody>
</table>

**Benzyl alcohol:**
- Species: Rat
- NOAEL: 1.072 mg/l
- Application Route: Inhalation (dust/mist/fume)
- Exposure time: 28 Days
- Method: OECD Test Guideline 412

**Gentamicin:**
- Species: Dog
- LOAEL: 3 mg/kg
- Application Route: Intramuscular
- Exposure time: 12 Months
- Target Organs: Kidney
- Symptoms: Vomiting, Salivation

- Species: Monkey
  - LOAEL: 50 mg/kg
  - Application Route: Subcutaneous
  - Exposure time: 3 Weeks
  - Target Organs: Kidney, inner ear

- Species: Monkey
  - LOAEL: 6 mg/kg
  - Application Route: Intramuscular
  - Exposure time: 3 Weeks
  - Target Organs: Blood, Kidney, inner ear, Liver

- Species: Rat
  - NOAEL: 5 mg/kg
  - LOAEL: 10 mg/kg
  - Application Route: Intramuscular
  - Exposure time: 52 Weeks
  - Target Organs: Kidney, Blood

- Species: Rat
  - NOAEL: 12.5 mg/kg
  - LOAEL: 50 mg/kg
  - Application Route: Intramuscular
  - Exposure time: 13 Weeks
  - Target Organs: Kidney

**betamethasone:**
- Species: Rabbit
- LOAEL: 0.05 %
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(0.05%) Formulation

Application Route: Skin contact
Exposure time: 10 - 30 d
Target Organs: Pituitary gland, Immune system, muscle

Species: Rat
LOAEL: 0.05 %
Application Route: Skin contact
Exposure time: 8 Weeks
Target Organs: thymus gland

Species: Mouse
LOAEL: 0.1 %
Application Route: Skin contact
Exposure time: 8 Weeks
Target Organs: thymus gland

Species: Dog
LOAEL: 0.05 mg/kg
Application Route: Oral
Exposure time: 28 d
Target Organs: Blood, thymus gland, Adrenal gland

Aspiration toxicity
Not classified based on available information.

Components:

Paraffin oil:
The substance or mixture is known to cause human aspiration toxicity hazards or has to be regarded as if it causes a human aspiration toxicity hazard.

Experience with human exposure

Components:

Clotrimazole:
Skin contact: Symptoms: Rash, Itching, Blistering, Oedema, Redness
Ingestion: Symptoms: Abdominal pain, Nausea, Vomiting, Diarrhoea

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:**

<table>
<thead>
<tr>
<th>Compound</th>
<th>Toxicity to fish</th>
<th>Toxicity to daphnia and other aquatic invertebrates</th>
<th>Toxicity to algae/aquatic plants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paraffin oil</td>
<td>LL50 (Scophthalmus maximus (turbot)): &gt; 1,028 mg/l</td>
<td>EL50 (Acartia tonsa): &gt; 3,193 mg/l</td>
<td>EL50 (Skeletonema costatum (marine diatom)): &gt; 3,200 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 96 h</td>
<td>Exposure time: 48 h</td>
<td>Exposure time: 72 h</td>
</tr>
<tr>
<td></td>
<td>Test substance: Water Accommodated Fraction</td>
<td>Test substance: Water Accommodated Fraction</td>
<td>Test substance: Water Accommodated Fraction</td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
<td>Remarks: Based on data from similar materials</td>
<td>Remarks: Based on data from similar materials</td>
</tr>
<tr>
<td>Hexadecan-1-ol. Ethoxylated:</td>
<td>LC50 : &gt; 1 - 10 mg/l</td>
<td>EC50 : &gt; 1 - 10 mg/l</td>
<td>EC50 : &gt; 10 - 100 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 96 h</td>
<td>Exposure time: 48 h</td>
<td>Exposure time: 72 h</td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
<td>Remarks: Based on data from similar materials</td>
<td>Remarks: Based on data from similar materials</td>
</tr>
<tr>
<td>clotrimazole:</td>
<td>LC50 (Brachydanio rerio (zebrafish)): &gt; 0.29 mg/l</td>
<td>EC50 (Daphnia magna (Water flea)): 0.02 mg/l</td>
<td>EC50 (Desmodesmus subspicatus (green algae)): 0.268 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 96 h</td>
<td>Exposure time: 48 h</td>
<td>Exposure time: 72 h</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 203</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Clotrimazole / Gentamicin / Betamethasone (0.05%) Formulation

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<tr>
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</tr>
</thead>
</table>

### NOEC (Desmodesmus subspicatus (green algae)):
- **Benzyl alcohol:**
  - **Toxicity to fish**:
    - EC50: > 10,000 mg/l
    - Exposure time: 3 h
    - Test Type: Respiration inhibition
    - Method: OECD Test Guideline 209

### M-Factor (Acute aquatic toxicity):
- **Clotrimazole / Gentamicin / Betamethasone**: 10

### Toxicity to microorganisms:
- EC50: > 10,000 mg/l
- Exposure time: 3 h
- Test Type: Respiration inhibition
- Method: OECD Test Guideline 209

### Toxicity to fish:
- NOEC: 0.025 mg/l
- Exposure time: 32 d
- Species: Oncorhynchus mykiss (rainbow trout)
- Method: OECD Test Guideline 210

### Toxicity to daphnia and other aquatic invertebrates:
- NOEC: 0.01 mg/l
- Exposure time: 21 d
- Species: Daphnia magna (Water flea)
- Method: OECD Test Guideline 211

### Benzyl alcohol:
- LC50 (Pimephales promelas (fathead minnow)): 460 mg/l
- Exposure time: 96 h

### Toxicity to algae/aquatic plants:
- EC50 (Pseudokirchneriella subcapitata (green algae)): 770 mg/l
- Exposure time: 72 h
- Method: OECD Test Guideline 201

### Gentamicin:
- EC50 (Daphnia magna (Water flea)): 86 mg/l
- Exposure time: 48 h
- Method: OECD Test Guideline 202
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<table>
<thead>
<tr>
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</tr>
</thead>
</table>

LC50 (Americamysis): 30 mg/l
Exposure time: 96 h
Method: US-EPA OPPTS 850.1035

**Toxicity to algae/aquatic plants**

<table>
<thead>
<tr>
<th>Test Type</th>
<th>EC50 (Pseudokirchneriella subcapitata (green algae)): 10 µg/l</th>
<th>NOEC (Pseudokirchneriella subcapitata (green algae)): 1.5 µg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 72 h</td>
<td>Exposure time: 72 h</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 201</td>
<td>Method: OECD Test Guideline 201</td>
</tr>
</tbody>
</table>

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 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
Clotrimazole / Gentamicin / Betamethasone (0.05%) Formulation

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

Hexadecan-1-ol. Ethoxylated:
- Biodegradability: Result: Readily biodegradable.
  - Biodegradation: >99%
  - Exposure time: 19 d

Clotrimazole:
- Stability in water: Hydrolysis: 50%(242 d)

Benzyl alcohol:
- Biodegradability: Result: Readily biodegradable.
  - Biodegradation: 92 - 96%
  - Exposure time: 14 d

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

12.3 Bioaccumulative potential

Components:

Benzyl alcohol:
- Partition coefficient: n- log Pow: 1.05
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  
ADN : UN 3082  
ADR : UN 3082  
RID : UN 3082  
IMDG : UN 3082  
IATA : UN 3082

14.2 UN proper shipping name  
ADN : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (betamethasone, clotrimazole)
ADR : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (betamethasone, clotrimazole)
RID : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,
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</tr>
</thead>
</table>

N.O.S.  
(betamethasone, clotrimazole)

IMDG  
: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.  
(betamethasone, clotrimazole)

IATA  
: Environmentally hazardous substance, liquid, n.o.s.  
(betamethasone, clotrimazole)

14.3 Transport hazard class(es)

<table>
<thead>
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<th>ADN</th>
<th>ADR</th>
<th>RID</th>
<th>IMDG</th>
<th>IATA</th>
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14.4 Packing group

<table>
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</table>

<table>
<thead>
<tr>
<th>IATA (Cargo)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Packing instruction (cargo aircraft)</td>
</tr>
<tr>
<td>Packing instruction (LQ)</td>
</tr>
<tr>
<td>Packing group</td>
</tr>
<tr>
<td>Labels</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>IATA (Passenger)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Packing instruction (passenger aircraft)</td>
</tr>
<tr>
<td>Packing instruction (LQ)</td>
</tr>
</tbody>
</table>
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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 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)
Conditions of restriction for the following entries should be considered: Number on list 3

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>
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<td>100 t</td>
<td>200 t</td>
</tr>
</tbody>
</table>
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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.
H304: May be fatal if swallowed and enters airways.
H311: Toxic in contact with skin.
H319: Causes serious eye irritation.
H330: Fatal if inhaled.
H332: Hazardous if inhaled.
H360D: May damage the unborn child.
H361fd: Suspected of damaging fertility. Suspected of damaging 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.
H373: May cause 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.

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 Irrit.: Eye irritation
- Repr.: Reproductive toxicity
- STOT RE: Specific target organ toxicity - repeated exposure
- GB EH40: UK. EH40 WEL - Workplace Exposure Limits
- GB EH40 / TWA: Long-term exposure limit (8-hour TWA reference period)
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Date of first issue: 29.04.2016

Further information

Classification of the mixture:

| Repr. 1B | H360D | Calculation method |
| STOT RE 1 | H372 | Calculation method |
| Aquatic Chronic 1 | H410 | Calculation method |

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 mate-
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<thead>
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</thead>
</table>

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.

GB / EN