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

Clotrimazole / Gentamicin / Betamethasone (0.05%) Formulation

Version 7.0 Revision Date: 09.04.2021 SDS Number: 613803-00014 Date of last issue: 10.10.2020
Date of first issue: 29.04.2016

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: Organon & Co.
30 Hudson Street, 33nd floor
07302 Jersey City, New Jersey, U.S.A
Telephone: 551-430-6000
E-mail address of person responsible for the SDS: EHSSTEWARD@organon.com

1.4 Emergency telephone number
215-631-6999

SECTION 2: Hazards identification

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

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

- This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

- Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

- Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

### SECTION 3: Composition/information on ingredients

#### 3.2 Mixtures

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No. EC-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paraffin oil</td>
<td>8012-95-1</td>
<td>Asp. Tox. 1; H304 Aquatic Chronic 4; H413</td>
<td>&gt;= 2.5 - &lt; 10</td>
</tr>
<tr>
<td></td>
<td>232-384-2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hexadecan-1-ol. Ethoxylated</td>
<td>9004-95-9</td>
<td>Eye Irrit. 2; H319</td>
<td>&gt;= 1 - &lt; 10</td>
</tr>
<tr>
<td>clotrimazole</td>
<td>23593-75-1</td>
<td>Acute Tox. 4; H302 Acute Tox. 3; H311 Eye Irrit. 2; H319 Repr. 2; H361fd STOT RE 2; H373 (Liver, Kidney, Adrenal gland)</td>
<td>&gt;= 1 - &lt; 2.5</td>
</tr>
<tr>
<td></td>
<td>245-764-8</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## Clotrimazole / Gentamicin / Betamethasone
### (0.05%) Formulation

<table>
<thead>
<tr>
<th>Substance</th>
<th>Identifier(s)</th>
<th>Acute Tox.</th>
<th>Eye Irrit.</th>
<th>Repr.</th>
<th>STOT RE</th>
<th>Aquatic Acute</th>
<th>Aquatic Chronic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzyl alcohol</td>
<td>100-51-6 202-859-9 603-057-00-5</td>
<td>Acute Tox. 4; H302</td>
<td>Acute Tox. 4; H332</td>
<td>Eye Irrit. 2; H319</td>
<td>&gt; 1 - &lt; 10</td>
<td>M-Factor (Acute aquatic toxicity): 10</td>
<td>M-Factor (Chronic aquatic toxicity): 10</td>
</tr>
<tr>
<td>Gentamicin</td>
<td>1403-66-3 215-765-8</td>
<td>Repr. 1A; H360D</td>
<td>STOT RE 1; H372 (Kidney, inner ear)</td>
<td>Aquatic Acute 1; H400</td>
<td>Aquatic Chronic 1; H410</td>
<td>&gt;= 0,1 - &lt; 0,25</td>
<td>M-Factor (Acute aquatic toxicity): 100</td>
</tr>
<tr>
<td>Betamethasone</td>
<td>378-44-9 206-825-4</td>
<td>Acute Tox. 2; H330</td>
<td>Repr. 1B; H360D</td>
<td>STOT RE 1; H372 (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland)</td>
<td>Aquatic Chronic 1; H410</td>
<td>&gt;= 0,025 - &lt; 0,1</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.

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 (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions

Environmental precautions:
- Avoid release to the environment.
- 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.
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 mist or vapours. Do not swallow. Avoid contact with eyes. Wash skin thoroughly after handling. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment. Keep container tightly closed. Do not eat, drink or smoke when using this product. 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>Petrolatum</td>
<td>8009-03-8</td>
<td>TWA (Vapour)</td>
<td>50 mg/m³</td>
<td>FOR-2011-12-06-1358</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Mist and particles)</td>
<td>1 mg/m³</td>
<td>FOR-2011-12-06-1358</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>TWA</td>
<td>25 ppm</td>
<td>FOR-2011-12-06-1358</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>79 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Paraffin oil</td>
<td>8012-95-1</td>
<td>TWA (Vapour)</td>
<td>50 mg/m³</td>
<td>FOR-2011-12-06-1358</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Mist and particles)</td>
<td>1 mg/m³</td>
<td>FOR-2011-12-06-1358</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>
</tbody>
</table>

**Further information:**

Skin Wipe limit: 10 µg/100 cm²

### 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>Workers</td>
<td>Inhalation</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>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>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</td>
<td>118,88 mg/m³</td>
</tr>
</tbody>
</table>
Effects

**Consumers**
- **Inhalation**
  - Acute systemic effects: 118.9 mg/m³
  - Long-term local effects: 0.652 mg/m³
  - Acute local effects: 0.652 mg/m³
- **Skin contact**
  - Long-term systemic effects: 100 mg/kg bw/day
  - Acute systemic effects: 200 mg/kg bw/day
  - Long-term local effects: 0.562 mg/cm²
  - Acute local effects: 0.562 mg/cm²
- **Ingestion**
  - Long-term systemic effects: 75 mg/kg bw/day
  - Acute systemic effects: 75 mg/kg bw/day
  - Long-term systemic effects: 100 mg/kg bw/day
  - Acute systemic effects: 27 mg/kg bw/day

**Workers**
- **Inhalation**
  - Long-term systemic effects: 5 mg/m³
  - Short-term exposure: 5 mg/m³
  - Long-term local effects: 5 mg/m³
  - Acute local effects: 5 mg/m³
- **Skin contact**
  - Long-term systemic effects: 8 mg/kg bw/day
  - Acute systemic effects: 40 mg/kg bw/day
  - Acute systemic effects: 27 mg/m³
  - Long-term systemic effects: 4 mg/kg bw/day
- **Ingestion**
  - Long-term systemic effects: 20 mg/kg bw/day
  - Acute systemic effects: 20 mg/kg bw/day

**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>Propylene glycol</td>
<td>Fresh water</td>
<td>260 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>26 mg/l</td>
</tr>
<tr>
<td></td>
<td>Intermittent use/release</td>
<td>183 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>20000 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>572 mg/kg</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Clotrimazole / Gentamicin / Betamethasone
(0.05%) Formulation

<table>
<thead>
<tr>
<th>Marine sediment</th>
<th>57.2 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Soil</td>
<td>50 mg/kg</td>
</tr>
<tr>
<td>Alcohols, C16-18</td>
<td>Fresh water 0.13 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water 0.12 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant 1000 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment 13.61 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Marine sediment 1.361 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Soil 100 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Oral (Secondary Poisoning) 86.7 mg/kg food</td>
</tr>
<tr>
<td>Benzyl alcohol</td>
<td>Fresh water 1 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water 0.1 mg/l</td>
</tr>
<tr>
<td></td>
<td>Intermittent use/release 2.3 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant 39 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment 5.27 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Marine sediment 0.527 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Soil 0.456 mg/kg</td>
</tr>
</tbody>
</table>

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 NS EN 14387
SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical state</td>
<td>liquid</td>
</tr>
<tr>
<td>Colour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td>No data available</td>
</tr>
<tr>
<td>Water solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>No data available</td>
</tr>
<tr>
<td>Particle characteristics</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Particle size</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

Filter type: Combined particulates and organic vapour type (A-P)
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 hazard classes as defined in Regulation (EC) No 1272/2008
Information on likely routes of exposure: Inhalation
                                      Skin contact
                                      Ingestion
                                      Eye contact

Acute toxicity
Not classified based on available information.

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

Benzyl 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
- 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
## Clotrimazole / Gentamicin / Betamethasone (0.05%) Formulation

**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:**
### Clotrimazole / Gentamicin / Betamethasone (0.05%) Formulation

<table>
<thead>
<tr>
<th>Component</th>
<th>Test Type</th>
<th>Exposure routes</th>
<th>Species</th>
<th>Method</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clotrimazole</td>
<td>Maximisation Test</td>
<td>Skin contact</td>
<td>Rabbit</td>
<td>OECD Test Guideline 405</td>
<td>Irritation to eyes, reversing within 21 days</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td>Benzyl alcohol</td>
<td>Maximisation Test</td>
<td>Skin contact</td>
<td>Guinea pig</td>
<td>OECD Test Guideline 406</td>
<td>Negative</td>
<td></td>
</tr>
<tr>
<td>Gentamicin</td>
<td></td>
<td></td>
<td>Rabbit</td>
<td></td>
<td>Irritation to eyes, reversing within 21 days</td>
<td></td>
</tr>
<tr>
<td>Betamethasone</td>
<td></td>
<td>Dermal</td>
<td>Guinea pig</td>
<td></td>
<td>Weak sensitizer</td>
<td></td>
</tr>
</tbody>
</table>

### 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:
- **Remarks:** No data available

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

### Germ cell mutagenicity
Not classified based on available information.
Clotrimazole / Gentamicin / Betamethasone (0.05%) Formulation

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
    - 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:

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

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
### Effects on foetal development

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Species</th>
<th>Application Route</th>
<th>Developmental Toxicity</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Embryo-foetal development</td>
<td>Rat</td>
<td>Oral</td>
<td>LOAEL: 100 mg/kg body weight</td>
<td>Embryo-foetal toxicity, No teratogenic effects</td>
</tr>
<tr>
<td>Embryo-foetal development</td>
<td>Rat</td>
<td>Oral</td>
<td>NOAEL: 50 mg/kg body weight</td>
<td>Embryo-foetal toxicity, No teratogenic effects</td>
</tr>
<tr>
<td>Embryo-foetal development</td>
<td>Mouse</td>
<td>Oral</td>
<td>NOAEL: 200 mg/kg body weight</td>
<td>No effects on foetal development</td>
</tr>
<tr>
<td>Embryo-foetal development</td>
<td>Rabbit</td>
<td>Oral</td>
<td>NOAEL: 180 mg/kg body weight</td>
<td>No embryo-foetal toxicity</td>
</tr>
</tbody>
</table>

### Reproductive toxicity - Assessment

Some evidence of adverse effects on sexual function and fertility, based on animal experiments. Some evidence of adverse effects on development, based on animal experiments.

### Benzyl alcohol:

**Effects on fertility**

- Test Type: Fertility/early embryonic development
- Species: Rat
- Application Route: Ingestion
- Result: negative
- Remarks: Based on data from similar materials

**Effects on foetal development**

- Test Type: Embryo-foetal development
- Species: Mouse
- 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  
Developmental Toxicity: LOAEL: 1 mg/kg body weight  
Result: Malformations were observed.

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

STOT - single exposure  
Not classified based on available information.

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
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
LOAEL: 25 mg/kg
Application Route: Oral
Exposure time: 6 - 12 Months
Target Organs: Adrenal gland
Symptoms: Salivation, Lachrymation, Vomiting

Benzyl alcohol:
Species: Rat
NOAEL: 1,072 mg/l
Application Route: inhalation (dust/mist/fume)
Exposure time: 28 Days
Gentamicin:

<table>
<thead>
<tr>
<th>Species</th>
<th>Dog</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>3 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Intramuscular</td>
</tr>
<tr>
<td>Exposure time</td>
<td>12 Months</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Kidney</td>
</tr>
<tr>
<td>Symptoms</td>
<td>Vomiting, Salivation</td>
</tr>
</tbody>
</table>

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      |

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 % |
|          |       |
Clotrimazole / Gentamicin / Betamethasone (0.05%) Formulation

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.

11.2 Information on other hazards
Endocrine disrupting properties

Product:
Assessment: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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:**

**Paraffin oil:**
- Toxicity to fish: LL50 (Scophthalmus maximus (turbot)): > 100 mg/l
  Exposure time: 96 h
  Test substance: Water Accommodated Fraction
  Remarks: Based on data from similar materials
- Toxicity to daphnia and other aquatic invertebrates: EL50 (Acartia tonsa): > 100 mg/l
  Exposure time: 48 h
  Test substance: Water Accommodated Fraction
  Remarks: Based on data from similar materials
- Toxicity to algae/aquatic plants: EL50 (Skeletonema costatum (marine diatom)): > 100 mg/l
  Exposure time: 72 h
  Test substance: Water Accommodated Fraction
  Remarks: Based on data from similar materials
  NOELR (Skeletonema costatum (marine diatom)): > 1 mg/l
  Exposure time: 72 h
  Test substance: Water Accommodated Fraction
  Remarks: Based on data from similar materials

**Hexadecan-1-ol. Ethoxylated:**
- Toxicity to fish: LC50 : > 1 - 10 mg/l
  Exposure time: 96 h
  Remarks: Based on data from similar materials
- Toxicity to daphnia and other aquatic invertebrates: EC50 : > 1 - 10 mg/l
  Exposure time: 48 h
  Remarks: Based on data from similar materials
- Toxicity to algae/aquatic plants: EC50 : > 10 - 100 mg/l
  Exposure time: 72 h
  Remarks: Based on data from similar materials

**Clotrimazole:**
- Toxicity to fish: LC50 (Brachydanio rerio (zebrafish)): > 0,29 mg/l
  Exposure time: 96 h
  Method: OECD Test Guideline 203
- Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): 0,02 mg/l
  Exposure time: 48 h
- Toxicity to algae/aquatic plants: EC50 (Desmodesmus subspicatus (green algae)): 0,268 mg/l
  Exposure time: 72 h
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according to Regulation (EC) No. 1907/2006

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<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue: 10.10.2020</th>
<th>Date of first issue: 29.04.2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.0</td>
<td>09.04.2021</td>
<td>613803-00014</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**NOEC** (Desmodesmus subspicatus (green algae)): 0,017 mg/l
Exposure time: 72 h

M-Factor (Acute aquatic toxicity): 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 (Chronic toxicity): 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 (Chronic toxicity): NOEC: 0,01 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
Method: OECD Test Guideline 211

M-Factor (Chronic aquatic toxicity): 10

**Benzy alcohol:**

Toxicity to fish: LC50 (Pimephales promelas (fathead minnow)): 460 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): 230 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

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

NOEC (Pseudokirchneriella subcapitata (green algae)): 310 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC: 51 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
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Toxicity to algae/aquatic plants
LC50 (Americamysis): 30 mg/l
Exposure time: 96 h
Method: US-EPA OPPTS 850.1035

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:

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
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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:

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

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

Benzy1 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:

Paraffin oil:
Partition coefficient: n-Octanol/water: log Pow: > 4
Remarks: Calculation

Benzy1 alcohol:
Partition coefficient: n-Octanol/water: log Pow: 1.05

Gentamicin:

Clotrimazole / Gentamicin / Betamethasone (0.05%) Formulation

12.4 Mobility in soil
No data available

12.5 Results of PBT and vPvB assessment

**Product:**
**Assessment:**
This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Other adverse effects

**Product:**
**Endocrine disrupting potential:**
The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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 or ID number

<table>
<thead>
<tr>
<th>ADN</th>
<th>UN 3082</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADR</td>
<td>UN 3082</td>
</tr>
<tr>
<td>RID</td>
<td>UN 3082</td>
</tr>
<tr>
<td>IMDG</td>
<td>UN 3082</td>
</tr>
<tr>
<td>IATA</td>
<td>UN 3082</td>
</tr>
</tbody>
</table>
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, 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)

- **ADN**: 9
- **ADR**: 9
- **RID**: 9
- **IMDG**: 9
- **IATA**: 9

14.4 Packing group

**ADN**
- Packing group: III
- Classification Code: M6
- Hazard Identification Number: 90
- Labels: 9

**ADR**
- Packing group: III
- Classification Code: M6
- Hazard Identification Number: 90
- Labels: 9
- Tunnel restriction code: (-)

**RID**
- Packing group: III
- Classification Code: M6
- Hazard Identification Number: 90
- Labels: 9

**IMDG**
- Packing group: III
- Labels: 9
- EmS Code: F-A, S-F

**IATA (Cargo)**
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Packing instruction (cargo aircraft) : 964
Packing instruction (LQ) : Y964
Packing group : III
Labels : Miscellaneous

IATA (Passenger)
Packing instruction (passenger aircraft) : 964
Packing instruction (LQ) : Y964
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 Maritime transport in bulk according to IMO instruments
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 pollu-
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Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals:

Other regulations:
Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.
Young people under the age of 18 are not allowed to use or be exposed to the product professionally. Young people above the age of 15 are, however, except from this rule if the product is a necessary part of their education.

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

E1 ENVIRONMENTAL HAZARDS
Quantity 1  Quantity 2
100 t  200 t

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: Harmful 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.
H413: May cause long lasting harmful effects to aquatic life.
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Clotrimazole / Gentamicin / Betamethasone (0.05%) Formulation

Version 7.0 Revision Date 09.04.2021 SDS Number 613803-00014 Date of last issue: 10.10.2020

Date of first issue: 29.04.2016

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
FOR-2011-12-06-1358 : Norway. Occupational Exposure limits
FOR-2011-12-06-1358 / : Long term exposure limit
TWA

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; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELX - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; ILO - International Labour Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Further information

Classification of the mixture: Classification procedure:
SAFETY DATA SHEET
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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.
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