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

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
Specific target organ toxicity - repeated exposure, Category 1
Long-term (chronic) aquatic hazard, Category 1

H360D: May damage the unborn child.
H372: Causes damage to organs through prolonged or repeated exposure.
H410: Very toxic to aquatic life with long lasting effects.

2.2 Label elements

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

Clotrimazole / Gentamicin / Betamethasone
(0.05%) Formulation

Version 5.2 Revision Date: 09/13/2019
SDS Number: 613798-00011 Date of last issue: 24.04.2019
Date of first issue: 29.04.2016

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. EC-No. Index-No. Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<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 / 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 / 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>
<tr>
<td>Gentamicin</td>
<td>1403-66-3 / 215-765-8</td>
<td>Repr. 1A; H360D STOT RE 1; H372 Aquatic Acute 1;</td>
<td>&gt;= 0.1 - &lt; 0.25</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Clotrimazole / Gentamicin / Betamethasone (0.05%) Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
</table>

H400
Aquatic Chronic 1; H410
M-Factor (Acute aquatic toxicity): 100
M-Factor (Chronic aquatic toxicity): 1

betamethasone
378-44-9
206-825-4
Acute Tox. 2; H330 Repr. 1B; H360D STOT RE 1; H372 Aquatic Chronic 1; H410
M-Factor (Chronic aquatic toxicity): 1,000
>= 0.025 - < 0.1

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.

Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

If inhaled : If inhaled, remove to fresh air.
Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.

In case of eye contact : Flush eyes with water as a precaution.
Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting.
Get medical attention.
Rinse mouth thoroughly with water.
Clotrimazole / Gentamicin / Betamethasone (0.05%) Formulation

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.

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

<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>Further information</td>
<td></td>
<td>TWA (Total vapour and particles)</td>
<td>150 ppm 474 mg/m³</td>
<td>GB EH40</td>
</tr>
</tbody>
</table>

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

<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></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>--------------------------</td>
<td>-------------</td>
<td>------------------------</td>
<td>------------------------</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>6.52 mg/m³</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Inhalation</td>
<td>Acute local effects</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>6.52 mg/m³</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>200 mg/kg bw/day</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Acute systemic effects</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>400 mg/kg bw/day</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term local effects</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>1.124 mg/cm²</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Acute local effects</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>1.124 mg/cm²</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>118.88 mg/m³</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Acute systemic effects</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>118.9 mg/m³</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>0.652 mg/m³</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Acute local effects</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>0.652 mg/m³</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>100 mg/kg bw/day</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Skin contact</td>
<td>Acute systemic effects</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>200 mg/kg bw/day</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term local effects</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>0.562 mg/cm²</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Skin contact</td>
<td>Acute local effects</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>0.562 mg/cm²</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>75 mg/kg bw/day</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Ingestion</td>
<td>Acute systemic effects</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>75 mg/kg bw/day</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Paraffin oil</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>5 mg/m³</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Inhalation</td>
<td>Short-term exposure</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>5 mg/m³</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>5 mg/m³</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Inhalation</td>
<td>Acute local effects</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>5 mg/m³</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Benzyl alcohol</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>22 mg/m³</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Inhalation</td>
<td>Acute systemic effects</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>110 mg/m³</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>8 mg/kg bw/day</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Acute systemic effects</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>40 mg/kg bw/day</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>5.4 mg/m³</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Acute systemic effects</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>27 mg/m³</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>4 mg/kg bw/day</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Skin contact</td>
<td>Acute systemic effects</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>20 mg/kg bw/day</td>
<td></td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Clotrimazole / Gentamicin / Betamethasone (0.05%) Formulation

Version 5.2  Revision Date: 09/13/2019  SDS Number: 613798-00011  Date of last issue: 24.04.2019

<table>
<thead>
<tr>
<th>Consumers</th>
<th>Ingestion</th>
<th>Long-term systemic effects</th>
<th>4 mg/kg bw/day</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consumers</td>
<td>Ingestion</td>
<td>Acute systemic effects</td>
<td>20 mg/kg bw/day</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Petrolatum</td>
<td>Oral (Secondary Poisoning)</td>
<td>9.33 mg/kg food</td>
</tr>
<tr>
<td>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>
<tr>
<td></td>
<td>Marine sediment</td>
<td>57.2 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>50 mg/kg</td>
</tr>
<tr>
<td>Alcohols, C16-18</td>
<td>Fresh water</td>
<td>0.13 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>0.12 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>1000 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>13.61 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>1.361 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>100 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Oral (Secondary Poisoning)</td>
<td>86.7 mg/kg food</td>
</tr>
<tr>
<td>Benzyl alcohol</td>
<td>Fresh water</td>
<td>1 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>0.1 mg/l</td>
</tr>
<tr>
<td></td>
<td>Intermittent use/release</td>
<td>2.3 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>39 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>5.27 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>0.527 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>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
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Clotrimazole / Gentamicin / Betamethasone (0.05%) Formulation

Material : Chemical-resistant gloves
Remarks : Consider double gloving.
Skin and body protection : Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.
Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Filter type : Combined particulates and organic vapour type (A-P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance : 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) : No data available
Partition coefficient: n- : Not applicable
Clotrimazole / Gentamicin / Betamethasone
(0.05%) Formulation

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.
Clotrimazole / Gentamicin / Betamethasone (0.05%) Formulation

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:
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
Clotrimazole / Gentamicin / Betamethasone (0.05%) Formulation

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:**

**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:**

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

**clotrimazole:**
Species
: Rabbit
Clotrimazole / Gentamicin / Betamethasone (0.05%) Formulation

Result: \textbf{Mild eye irritation}

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

\textbf{Gentamicin:}
Species: Rabbit
Result: \textbf{Mild eye irritation}

\textbf{betamethasone:}
Species: Rabbit
Result: No eye irritation

\textbf{Respiratory or skin sensitisation}

\textbf{Skin sensitisation}
Not classified based on available information.

\textbf{Respiratory sensitisation}
Not classified based on available information.

\textbf{Components:}

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

\textbf{Gentamicin:}
Remarks: No data available

\textbf{betamethasone:}
Exposure routes: Dermal
Species: Guinea pig
Result: Weak sensitizer

\textbf{Germ cell mutagenicity}
Not classified based on available information.

\textbf{Components:}

\textbf{clotrimazole:}
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Clotrimazole / Gentamicin / Betamethasone
(0.05%) Formulation

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
Clotrimazole / Gentamicin / Betamethasone (0.05%) Formulation

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:
Test Type: Embryo-foetal development
Species: Rat
Application Route: Oral
Developmental Toxicity: LOAEL: 100 mg/kg body weight
Result: Embryo-foetal toxicity, No teratogenic effects
Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Oral  
Developmental Toxicity: NOAEL: 50 mg/kg body weight  
Result: Embryo-foetal toxicity, No teratogenic effects

Test Type: Embryo-foetal development  
Species: Mouse  
Application Route: Oral  
Developmental Toxicity: NOAEL: 200 mg/kg body weight  
Result: No effects on foetal development

Test Type: Embryo-foetal development  
Species: Rabbit  
Application Route: Oral  
Developmental Toxicity: NOAEL: 180 mg/kg body weight  
Result: No effects on foetal development

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

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
Clotrimazole / Gentamicin / Betamethasone (0.05%) Formulation

<table>
<thead>
<tr>
<th>Test Type: Embryo-foetal development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Mouse</td>
</tr>
<tr>
<td>Application Route: Intraperitoneal</td>
</tr>
<tr>
<td>Developmental Toxicity: LOAEL: 10 mg/kg body weight</td>
</tr>
<tr>
<td>Result: foetal mortality, No malformations were observed.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test Type: Embryo-foetal development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Rat</td>
</tr>
<tr>
<td>Application Route: Intraperitoneal</td>
</tr>
<tr>
<td>Developmental Toxicity: LOAEL: 50 mg/kg body weight</td>
</tr>
<tr>
<td>Result: foetal mortality, No malformations were observed.</td>
</tr>
</tbody>
</table>

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

**betamethasone:**

Effects on foetal development:

<table>
<thead>
<tr>
<th>Species: Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route: Intramuscular</td>
</tr>
<tr>
<td>Developmental Toxicity: LOAEL: 0.05 mg/kg body weight</td>
</tr>
<tr>
<td>Result: Fetotoxicity, Malformations were observed.</td>
</tr>
</tbody>
</table>

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 exposure.

**Gentamicin:**

Target Organs: Kidney, inner ear
Assessment: Causes damage to organs through prolonged or repeated exposure.
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Clotrimazole / Gentamicin / Betamethasone
(0.05%) Formulation

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:

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

Benzyal 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
Clotrimazole / Gentamicin / Betamethasone (0.05%) Formulation

<table>
<thead>
<tr>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subcutaneous</td>
<td>3 Weeks</td>
<td>Kidney, inner ear</td>
</tr>
</tbody>
</table>

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

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

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

betamethasone:

Species: Rabbit
LOAEL: 0.05 %
Application Route: Skin contact
Exposure time: 10 - 30 d
Target Organs: Pituitary gland, Immune system, muscle

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

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

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

Aspiration toxicity
Not classified based on available information.
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:

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
  NOEC (Desmodesmus subspicatus (green algae)): 0.017 mg/l
  Exposure time: 72 h
- M-Factor (Acute aquatic tox-): 10
Clotrimazole / Gentamicin / Betamethasone
(0.05%) Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue</th>
<th>Date of first issue</th>
</tr>
</thead>
</table>

**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: Onchorhyncus 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

**Benzyl 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

**Gentamicin:**
- **Toxicity to daphnia and other aquatic invertebrates:**
  - NOEC: 51 mg/l
  - Exposure time: 21 d
  - Species: Daphnia magna (Water flea)
  - Method: OECD Test Guideline 211

- **EC50 (Daphnia magna (Water flea)): 86 mg/l**
- **Exposure time: 48 h**
- **Method: OECD Test Guideline 202**

**LC50 (Americamysis):**
- 30 mg/l
- Exposure time: 96 h
Toxicity to algae/aquatic plants:
- EC50 (Pseudokirchneriella subcapitata (green algae)): 10 µg/l
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201

  NOEC (Pseudokirchneriella subcapitata (green algae)): 1.5 µg/l
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201

EC50 (Anabaena flos-aquae (cyanobacterium)): 4.7 µg/l
- Exposure time: 72 h
  - Method: OECD Test Guideline 201

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

M-Factor (Acute aquatic toxicity): 100

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

M-Factor (Chronic aquatic toxicity): 1

betamethasone:

Toxicity to daphnia and other aquatic invertebrates:
- EC50 (Americamysis): > 50 mg/l
  - Exposure time: 96 h

Toxicity to algae/aquatic plants:
- EC50 (Pseudokirchneriella subcapitata (green algae)): > 34 mg/l
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201
  - Remarks: No toxicity at the limit of solubility

NOEC (Pseudokirchneriella subcapitata (green algae)): 34 mg/l
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201
  - Remarks: No toxicity at the limit of solubility

Toxicity to fish (Chronic toxicity):
- NOEC: 0.052 mg/l
  - Exposure time: 32 d
  - Species: Pimephales promelas (fathead minnow)
  - Method: OECD Test Guideline 210

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

Clotrimazole / Gentamicin / Betamethasone (0.05%) Formulation

Version 5.2  Revision Date: 09/13/2019  SDS Number: 613798-00011  Date of last issue: 24.04.2019
Date of first issue: 29.04.2016

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)

**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-octanol/water: 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
Clotrimazole / Gentamicin / Betamethasone (0.05%) Formulation

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

Clotrimazole / Gentamicin / Betamethasone
(0.05%) Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
</table>

ADR : 9
RID : 9
IMDG : 9
IATA : 9

14.4 Packing group

ADR
Packing group : III
Classification Code : M6
Hazard Identification Number : 90
Labels : 9

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

IMDG
Packing group : III
Labels : 9

IATA (Cargo)
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

ADR
Environmentally hazardous : yes

RID
Environmentally hazardous : yes
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Clotrimazole / Gentamicin / Betamethasone
(0.05%) Formulation

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 - 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 (EC) No 850/2004 on persistent organic pollutants : Not applicable
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable
REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) : Conditions of restriction for the following entries should be considered: Number on list 3


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

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

The components of this product are reported in the following inventories:

AICS : not determined

DSL : not determined
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Clotrimazole / Gentamicin / Betamethasone
(0.05%) Formulation

Version 5.2  Revision Date: 09/13/2019  SDS Number: 613798-00011  Date of last issue: 24.04.2019
Date of first issue: 29.04.2016

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.
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.

Full text of other abbreviations
Acute Tox. : Acute toxicity
Aquatic Acute : Short-term (acute) aquatic hazard
Aquatic Chronic : Long-term (chronic) aquatic 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)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - In-
Clotrimazole / Gentamicin / Betamethasone (0.05%) Formulation

Further information


Classification of the mixture:

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

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

GB / EN