SAFETY DATA SHEET

Clotrimazole / Gentamicin / Betamethasone (0.05%) Formulation

Version 5.2  Revision Date: 09/13/2019  SDS Number: 610550-00011  Date of last issue: 24.04.2019

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: MSD

117 16th Road
07033 Halfway house, Midrand, South Africa

Telephone: +27 11 655 3000

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.
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

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hexadecan-1-ol. Ethoxylated</td>
<td>9004-95-9</td>
<td></td>
<td></td>
<td>&gt;= 1 - &lt; 10</td>
</tr>
<tr>
<td>clotrimazole</td>
<td>23593-75-1</td>
<td></td>
<td></td>
<td>&gt;= 1 - &lt; 2,5</td>
</tr>
<tr>
<td></td>
<td>245-764-8</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Benzyl alcohol</td>
<td>100-51-6</td>
<td></td>
<td></td>
<td>&gt;= 1 - &lt; 10</td>
</tr>
<tr>
<td></td>
<td>202-859-9</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>603-057-00-5</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gentamicin</td>
<td>1403-66-3</td>
<td></td>
<td></td>
<td>&gt;= 0.1 - &lt; 0.25</td>
</tr>
<tr>
<td></td>
<td>215-765-8</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
4.1 Description of first aid measures

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

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

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

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

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

If swallowed: If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.

4.2 Most important symptoms and effects, both acute and delayed

Risks: May damage the unborn child. Causes damage to organs through prolonged or repeated exposure.
4.3 Indication of any immediate medical attention and special treatment needed

Treatment: Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media: Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media: None known.

5.2 Special hazards arising from the substance or mixture

Specific hazards during firefighting: Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Carbon oxides

5.3 Advice for firefighters

Special protective equipment for firefighters: In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

Specific extinguishing methods: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Use water spray to cool unopened containers.
Remove undamaged containers from fire area if it is safe to do so.
Evacuate area.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions: Use personal protective equipment.
Follow safe handling advice and personal protective equipment recommendations.

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

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>TWA OEL-RL (particulate)</td>
<td>10 mg/m³</td>
<td>ZA OEL</td>
</tr>
<tr>
<td>Further information</td>
<td>Recommended Limit</td>
<td>TWA OEL-RL (Vapour + particulates)</td>
<td>150 ppm / 470 mg/m³</td>
<td>ZA OEL</td>
</tr>
</tbody>
</table>

Further information # Recommended Limit

<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>Inhalation</td>
<td>Acute local effects</td>
<td>6.52 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>200 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Acute systemic effects</td>
<td>400 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term local effects</td>
<td>Value</td>
</tr>
<tr>
<td>--------------------------</td>
<td>---------</td>
<td>--------------</td>
<td>-------------------------</td>
<td>----------------</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Skin contact</td>
<td>Acute local effects</td>
<td>1,124 mg/cm²</td>
</tr>
<tr>
<td>Workers</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td></td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>118,88 mg/m³</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Acute systemic effects</td>
<td>118,9 mg/m³</td>
</tr>
<tr>
<td>Consumers</td>
<td></td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>0,652 mg/m³</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Skin contact</td>
<td>Acute local effects</td>
<td>0,652 mg/m³</td>
</tr>
<tr>
<td>Consumers</td>
<td></td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>100 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Skin contact</td>
<td>Acute systemic effects</td>
<td>200 mg/kg bw/day</td>
</tr>
<tr>
<td>Consumers</td>
<td></td>
<td>Skin contact</td>
<td>Long-term local effects</td>
<td>0,562 mg/cm²</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Skin contact</td>
<td>Acute local effects</td>
<td>0,562 mg/cm²</td>
</tr>
<tr>
<td>Consumers</td>
<td></td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>75 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Ingestion</td>
<td>Acute systemic effects</td>
<td>75 mg/kg bw/day</td>
</tr>
<tr>
<td>Paraffin oil</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Workers</td>
<td></td>
<td></td>
<td>Short-term exposure</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Workers</td>
<td></td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Workers</td>
<td></td>
<td>Inhalation</td>
<td>Acute local effects</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Benzyl alcohol</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>22 mg/m³</td>
</tr>
<tr>
<td>Workers</td>
<td></td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>110 mg/m³</td>
</tr>
<tr>
<td>Workers</td>
<td></td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>8 mg/kg bw/day</td>
</tr>
<tr>
<td>Workers</td>
<td></td>
<td>Skin contact</td>
<td>Acute systemic effects</td>
<td>40 mg/kg bw/day</td>
</tr>
<tr>
<td>Consumers</td>
<td></td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>5,4 mg/m³</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Ingestion</td>
<td>Acute systemic effects</td>
<td>27 mg/m³</td>
</tr>
<tr>
<td>Consumers</td>
<td></td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>4 mg/kg bw/day</td>
</tr>
<tr>
<td>Consumers</td>
<td></td>
<td>Skin contact</td>
<td>Acute systemic effects</td>
<td>20 mg/kg bw/day</td>
</tr>
<tr>
<td>Consumers</td>
<td></td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>4 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td></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>
</tbody>
</table>
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(0.05%) Formulation

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Date of first issue: 29.04.2016

<table>
<thead>
<tr>
<th>Intermittent use/release</th>
<th>183 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sewage treatment plant</td>
<td>20000 mg/l</td>
</tr>
<tr>
<td>Fresh water sediment</td>
<td>572 mg/kg</td>
</tr>
<tr>
<td>Marine sediment</td>
<td>57.2 mg/kg</td>
</tr>
<tr>
<td>Soil</td>
<td>50 mg/kg</td>
</tr>
<tr>
<td>Alcohols, C16-18</td>
<td></td>
</tr>
<tr>
<td>Fresh water</td>
<td>0.13 mg/l</td>
</tr>
<tr>
<td>Marine water</td>
<td>0.12 mg/l</td>
</tr>
<tr>
<td>Sewage treatment plant</td>
<td>1000 mg/l</td>
</tr>
<tr>
<td>Fresh water sediment</td>
<td>13.61 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td>Marine sediment</td>
<td>1,361 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td>Soil</td>
<td>100 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td>Oral (Secondary Poisoning)</td>
<td>86.7 mg/kg food</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>benzyl alcohol</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Fresh water</td>
<td>1 mg/l</td>
</tr>
<tr>
<td>Marine water</td>
<td>0.1 mg/l</td>
</tr>
<tr>
<td>Intermittent use/release</td>
<td>2.3 mg/l</td>
</tr>
<tr>
<td>Sewage treatment plant</td>
<td>39 mg/l</td>
</tr>
<tr>
<td>Fresh water sediment</td>
<td>5.27 mg/kg</td>
</tr>
<tr>
<td>Marine sediment</td>
<td>0.527 mg/kg</td>
</tr>
<tr>
<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

Material
Chemical-resistant gloves

Remarks
Consider double gloving.

Skin and body protection
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 rec-
## 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>Appearance</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>pH</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>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</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>Vapour pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapour density</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>Solubility(ies)</td>
<td></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>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td></td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>No data available</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>The substance or mixture is not classified as oxidizing.</td>
</tr>
</tbody>
</table>
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SDS Number: 610550-00011 Date of last issue: 24.04.2019
Date of first issue: 29.04.2016

9.2 Other information

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

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions: Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid: None known.

10.5 Incompatible materials

Materials to avoid: Oxidizing agents

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Information on likely routes of exposure:
- Inhalation
- Skin contact
- Ingestion
- Eye contact

Acute toxicity

Not classified based on available information.

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
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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
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
Result: Mild eye irritation

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

**Gentamicin:**
Species: Rabbit
Result: Mild eye irritation

**Betamethasone:**
Species: Rabbit
Result: No eye irritation

Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Components:

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

Gentamicin:
Remarks: No data available

betamethasone:
Exposure routes: Dermal
Species: Guinea pig
Result: Weak sensitizer

Germ cell mutagenicity
Not classified based on available information.

Components:

clotrimazole:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: Chromosome aberration test in vitro
Result: negative

Test Type: in vitro micronucleus test
Result: negative

Genotoxicity in vivo: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Rat
Application Route: Oral
Result: negative

Test Type: Mammalian spermatogonial chromosome aberration test (in vivo)
Species: Hamster
Result: negative
Germ cell mutagenicity- Assessment: Weight of evidence does not support classification as a germ cell mutagen.

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

**Gentamicin:**
- Genotoxicity in vitro: Test Type: In vitro mammalian cell gene mutation test Result: negative
- Genotoxicity in vitro: 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
- Genotoxicity in vitro: Test Type: In vitro mammalian cell gene mutation test Result: negative
- Genotoxicity in vitro: 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
<table>
<thead>
<tr>
<th>Reproductive toxicity - Assessment</th>
<th>Result: No effects on foetal development</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
<td></td>
</tr>
<tr>
<td><strong>Benzyl alcohol:</strong></td>
<td></td>
</tr>
<tr>
<td>Effects on fertility</td>
<td>Test Type: Fertility/early embryonic development</td>
</tr>
<tr>
<td>Species: Rat</td>
<td></td>
</tr>
<tr>
<td>Application Route: Ingestion</td>
<td></td>
</tr>
<tr>
<td>Result: negative</td>
<td></td>
</tr>
<tr>
<td>Remarks: Based on data from similar materials</td>
<td></td>
</tr>
<tr>
<td>Effects on foetal development</td>
<td>Test Type: Embryo-foetal development</td>
</tr>
<tr>
<td>Species: Mouse</td>
<td></td>
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<tr>
<td>Application Route: Ingestion</td>
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</tr>
<tr>
<td>Result: negative</td>
<td></td>
</tr>
<tr>
<td><strong>Gentamicin:</strong></td>
<td></td>
</tr>
<tr>
<td>Effects on fertility</td>
<td>Test Type: Two-generation reproduction toxicity study</td>
</tr>
<tr>
<td>Species: Rat</td>
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<tr>
<td>Fertility: NOAEL: 20 mg/kg body weight</td>
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</tr>
<tr>
<td>Result: No significant adverse effects were reported</td>
<td></td>
</tr>
<tr>
<td>Effects on foetal development</td>
<td>Test Type: Embryo-foetal development</td>
</tr>
<tr>
<td>Species: Rabbit</td>
<td></td>
</tr>
<tr>
<td>Developmental Toxicity: NOAEL: 3,6 mg/kg body weight</td>
<td></td>
</tr>
<tr>
<td>Result: No embryo-foetal toxicity</td>
<td></td>
</tr>
<tr>
<td>Test Type: Embryo-foetal development</td>
<td></td>
</tr>
<tr>
<td>Species: Rat</td>
<td></td>
</tr>
<tr>
<td>Application Route: Intraperitoneal</td>
<td></td>
</tr>
<tr>
<td>Developmental Toxicity: LOAEL: 75 mg/kg body weight</td>
<td></td>
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<tr>
<td>Result: Embryo-foetal toxicity</td>
<td></td>
</tr>
<tr>
<td>Test Type: Embryo-foetal development</td>
<td></td>
</tr>
<tr>
<td>Species: Mouse</td>
<td></td>
</tr>
<tr>
<td>Application Route: Intraperitoneal</td>
<td></td>
</tr>
<tr>
<td>Developmental Toxicity: LOAEL: 10 mg/kg body weight</td>
<td></td>
</tr>
<tr>
<td>Result: foetal mortality, No malformations were observed.</td>
<td></td>
</tr>
<tr>
<td>Test Type: Embryo-foetal development</td>
<td></td>
</tr>
<tr>
<td>Species: Rat</td>
<td></td>
</tr>
<tr>
<td>Application Route: Intraperitoneal</td>
<td></td>
</tr>
<tr>
<td>Developmental Toxicity: LOAEL: 50 mg/kg body weight</td>
<td></td>
</tr>
<tr>
<td>Result: foetal mortality, No malformations were observed.</td>
<td></td>
</tr>
<tr>
<td>Reproductive toxicity - Assessment</td>
<td>Positive evidence of adverse effects on development from human epidemiological studies.</td>
</tr>
</tbody>
</table>

**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 exposure.

Gentamicin:
Target Organs: Kidney, inner ear
Assessment: Causes damage to organs through prolonged or repeated exposure.

Betamethasone:
Target Organs: Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland
Assessment: Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity
Components:
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
Method: OECD Test Guideline 412

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

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

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

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

Species: Rat
NOAEL: 12.5 mg/kg
LOAEL: 50 mg/kg
**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>Intramuscular</td>
<td>13 Weeks</td>
<td>Kidney</td>
</tr>
</tbody>
</table>

**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 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):**

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**SAFETY DATA SHEET**

**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:**

**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  
  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

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

- **Toxicity to algae/aquatic plants**: EC50 (Pseudokirchneriella subcapitata (green algae)): 10 µg/l  
  Exposure time: 72 h  
  Method: OECD Test Guideline 201  
  NOEC (Pseudokirchneriella subcapitata (green algae)): 1,5 µg/l  
  Exposure time: 72 h  
  Method: OECD Test Guideline 201

  EC50 (Anabaena flos-aquae (cyanobacterium)): 4,7 µg/l  
  Exposure time: 72 h  
  Method: OECD Test Guideline 201

  NOEC (Anabaena flos-aquae (cyanobacterium)): 1,6 µg/l  
  Exposure time: 72 h  
  Method: OECD Test Guideline 201

- **M-Factor (Acute aquatic toxicity)**: 100
Toxicity to microorganisms: EC50: 288.7 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

M-Factor (Chronic aquatic toxicity): 1

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

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

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

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

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

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):
NOEC: 8 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
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)
SAFETY DATA SHEET

Clotrimazole / Gentamicin / Betamethasone (0.05%) Formulation

Version 5.2  Revision Date: 09/13/2019  SDS Number: 610550-00011  Date of last issue: 24.04.2019

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

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
SAFETY DATA SHEET

Clotrimazole / Gentamicin / Betamethasone (0.05%) Formulation

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

| 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 |
| 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  |
SAFETY DATA SHEET

Clotrimazole / Gentamicin / Betamethasone (0.05%) Formulation

<table>
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<td>610550-00011</td>
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</tbody>
</table>

14.5 Environmental hazards

- **ADN**
  - Environmentally hazardous: yes

- **ADR**
  - Environmentally hazardous: yes

- **RID**
  - Environmentally hazardous: yes

- **IMDQ**
  - 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

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

- **AICS**: not determined
SAFETY DATA SHEET

Clotrimazole / Gentamicin / Betamethasone (0.05%) Formulation

Version 5.2  Revision Date: 09/13/2019  SDS Number: 610550-00011  Date of last issue: 24.04.2019  Date of first issue: 29.04.2016

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
ZA OEL : South Africa. Hazardous Chemical Substances Regulations, Occupational Exposure Limits
ZA OEL / TWA OEL-RL : Long term occupational exposure limits - recommended limit

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-
Further information


Classification of the mixture:

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<th>Classification procedure:</th>
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<tr>
<td>Repr. 1B</td>
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<tr>
<td>STOT RE 1</td>
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<td>Aquatic Chronic 1</td>
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