Clotrimazole / Gentamicin / Betamethasone (0.05%) Formulation

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

1.1 Product identifier
Trade name: Clotrimazole / Gentamicin / Betamethasone (0.05%) Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
Use of the Substance/Mixture: Pharmaceutical

1.3 Details of the supplier of the safety data sheet
Company: MSD
Shotton Lane
NE23 3JU Cramlington NU - Great Britain

Telephone: 44 1 670 59 30 00
Telefax: 908-735-1496
E-mail address of person responsible for the SDS: EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
1-908-423-6000

SECTION 2: Hazards identification

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

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

Precautionary statements  

Prevention: 
P201 Obtain special instructions before use.  
P264 Wash skin thoroughly after handling.  
P273 Avoid release to the environment.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response: 
P308 + P313 IF exposed or concerned: Get medical advice/ attention. 
P391 Collect spillage.

Hazardous components which must be listed on the label: 
betamethasone

2.3 Other hazards 
None known.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Registration number</th>
<th>Concentration (%) w/w</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paraffin oil</td>
<td>8012-95-1 232-384-2</td>
<td>Asp. Tox.1; H304</td>
<td>&gt;= 1 - &lt; 10</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>
<td></td>
<td></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 RE2; H373 Aquatic Acute1; H400 Aquatic Chronic1; H410</td>
<td>&gt; = 1 - &lt; 2,5</td>
<td></td>
<td></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>
<td></td>
<td></td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Clotrimazole / Gentamicin / Betamethasone
(0.05%) Formulation

Version 6.0  Revision Date: 23.03.2020  SDS Number: 613803-00012  Date of last issue: 13.09.2019
Date of first issue: 29.04.2016

<table>
<thead>
<tr>
<th>Substance</th>
<th>CAS Number</th>
<th>EC Number</th>
<th>Hazard Class</th>
<th>Hazard Statement</th>
<th>Aquatic Acute</th>
<th>Aquatic Chronic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gentamicin</td>
<td>1403-66-3</td>
<td>215-765-8</td>
<td>Repr.1A; H360</td>
<td>STOT RE1; H372</td>
<td>Aquatic Acute1;</td>
<td>Aquatic Chronic1;</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>H400</td>
<td></td>
<td>H410</td>
<td></td>
</tr>
<tr>
<td>betamethasone</td>
<td>378-44-9</td>
<td>206-825-4</td>
<td>Acute Tox.2;</td>
<td>Repr.1B; H360</td>
<td>STOT RE1; H372</td>
<td>Aquatic Chronic1;</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>H330</td>
<td></td>
<td>H410</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>M-Factor (Acute aquatic toxicity): 100</td>
<td></td>
<td>M-Factor (Chronic aquatic toxicity): 1.000</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>&gt;= 0,1 - &lt; 0,25</td>
<td></td>
<td>&gt;= 0,025 - &lt; 0,1</td>
<td></td>
</tr>
</tbody>
</table>

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

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

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

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

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

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

If swallowed: If swallowed, DO NOT induce vomiting.
Get medical attention.
Rinse mouth thoroughly with water.
4.2 Most important symptoms and effects, both acute and delayed

Risks:
- May damage the unborn child.
- Causes damage to organs through prolonged or repeated exposure.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment:
- Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

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

Unsuitable extinguishing media:
- None known.

5.2 Special hazards arising from the substance or mixture

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

Hazardous combustion products:
- Carbon oxides

5.3 Advice for firefighters

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

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

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions:
- Use personal protective equipment.
- Follow safe handling advice and personal protective equipment recommendations.
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>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 79 mg/m³</td>
<td>FOR-2011-12-06-1358</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>
</tbody>
</table>
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<table>
<thead>
<tr>
<th>Category</th>
<th>Inhalation</th>
<th>Long-term systemic effects</th>
<th>Acute systemic effects</th>
<th>Acute local effects</th>
<th>Long-term local effects</th>
<th>Acute local effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consumers</td>
<td>Alcohols, C16-18</td>
<td>50 mg/m³</td>
<td>237.76 mg/m³</td>
<td>6.52 mg/m³</td>
<td>1,124 mg/cm²</td>
<td>1,124 mg/cm²</td>
</tr>
<tr>
<td>Workers</td>
<td>Long-term systemic effects</td>
<td>237.76 mg/m³</td>
<td>6.52 mg/m³</td>
<td>1,124 mg/cm²</td>
<td>118.88 mg/m³</td>
<td>118.9 mg/m³</td>
</tr>
<tr>
<td>Consumers</td>
<td>Short-term exposure</td>
<td>5 mg/m³</td>
<td>27 mg/m³</td>
<td>22 mg/m³</td>
<td>110 mg/m³</td>
<td>22 mg/m³</td>
</tr>
<tr>
<td>Workers</td>
<td>Long-term systemic effects</td>
<td>5 mg/m³</td>
<td>27 mg/m³</td>
<td>22 mg/m³</td>
<td>110 mg/m³</td>
<td>22 mg/m³</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.
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<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>

**Hand protection**

<table>
<thead>
<tr>
<th>Material</th>
<th>Chemical-resistant gloves</th>
</tr>
</thead>
<tbody>
<tr>
<td>Remarks</td>
<td>Consider double gloving.</td>
</tr>
<tr>
<td>Skin and body protection</td>
<td>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.</td>
</tr>
</tbody>
</table>

**Respiratory protection**

<table>
<thead>
<tr>
<th>Filter type</th>
<th>Combined particulates and organic vapour type (A-P)</th>
</tr>
</thead>
</table>

**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>
</tbody>
</table>
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### 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
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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

Benzy1 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
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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

**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
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Species: Rabbit
Result: Mild skin irritation

Serious eye damage/eye irritation
Not classified based on available information.

Components:

Paraffin oil:
Species: Rabbit
Result: No eye irritation

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

clotrimazole:
Species: Rabbit
Result: Mild eye irritation

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

Gentamicin:
Species: Rabbit
Result: Mild eye irritation

Betamethasone:
Species: Rabbit
Result: No eye irritation

Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Components:

Benzyl alcohol:
Test Type: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
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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
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| 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

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

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.
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.

**STOT - single exposure**
Not classified based on available information.

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

**Components:**

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

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

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

**Repeated dose toxicity**

**Components:**

**Paraffin oil:**
- **Species:** Rat, female
- **LOAEL:** 161 mg/kg
- **Application Route:** Ingestion
- **Exposure time:** 90 Days

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

**Species:** Rat
- **LOAEL:** 10 mg/kg
- **Application Route:** Oral
### Clotrimazole / Gentamicin / Betamethasone (0.05%) Formulation

**Version**: 6.0  
**Revision Date**: 23.03.2020  
**SDS Number**: 613803-00012  
**Date of last issue**: 13.09.2019  
**Date of first issue**: 29.04.2016

<table>
<thead>
<tr>
<th>Exposure time</th>
<th>18 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Target Organs</td>
<td>Liver, Kidney, Adrenal gland</td>
</tr>
</tbody>
</table>

| 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 |
| Application Route | Intramuscular |
| Exposure time | 13 Weeks |
| Target Organs | Kidney |
Clotrimazole / Gentamicin / Betamethasone (0.05%) Formulation

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.

Components:

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

Experience with human exposure

Components:

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

Gentamicin:
Ingestion: Target Organs: Kidney
Target Organs: inner ear
Symptoms: Dizziness, Vertigo, hearing loss, tinnitus, fetal deafness

Betamethasone:
Inhalation: Target Organs: Adrenal gland
Skin contact: Symptoms: Redness, pruritis, Irritation
12.1 Toxicity

**Components:**

**Paraffin oil:**
- **Toxicity to fish:** LL50 (Scophthalmus maximus (turbot)): > 1.028 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): > 3.193 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)): > 3.200 mg/l
  - Exposure time: 72 h
  - Test substance: Water Accommodated Fraction
  - Remarks: Based on data from similar materials
  - NOELR (Skeletonema costatum (marine diatom)): 993 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
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

**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
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according to Regulation (EC) No. 1907/2006

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(0.05%) Formulation

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:

Paraffin oil:
Biodegradability: Result: Readily biodegradable.
Biodegradation: 82 %
Exposure time: 24 d
Method: OECD Test Guideline 301F
Remarks: Based on data from similar materials

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

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

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

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

12.3 Bioaccumulative potential

Components:

Benzyl alcohol:
Partition coefficient: n- log Pow: 1,05
Clotrimazole / Gentamicin / Betamethasone (0.05%) Formulation

**12.4 Mobility in soil**
No data available

**12.5 Results of PBT and vPvB assessment**
Not relevant

**12.6 Other adverse effects**
No data available

### SECTION 13: Disposal considerations

#### 13.1 Waste treatment methods

- **Product**: Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

- **Contaminated packaging**: Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

### SECTION 14: Transport information

#### 14.1 UN number

- **ADN**: UN 3082
- **ADR**: UN 3082
- **RID**: UN 3082
- **IMDG**: UN 3082
- **IATA**: UN 3082

#### 14.2 UN proper shipping name

- **ADN**: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (betamethasone, clotrimazole)
- **ADR**: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (betamethasone, clotrimazole)
- **RID**: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,
Clotrimazole / Gentamicin / Betamethasone (0.05%) Formulation

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<tr>
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</table>

N.O.S. (betamethasone, clotrimazole)

**IMDG**

- Environmentally Hazardous Substance, Liquid, N.O.S. (betamethasone, clotrimazole)

**IATA**

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

14.3 Transport hazard class(es)

<table>
<thead>
<tr>
<th>ADN</th>
<th>ADR</th>
<th>RID</th>
<th>IMDG</th>
<th>IATA</th>
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<tr>
<td>9</td>
<td>9</td>
<td>9</td>
<td>9</td>
<td>9</td>
</tr>
</tbody>
</table>

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)**

- 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
Clotrimazole / Gentamicin / Betamethasone (0.05%) Formulation

Packing group : III
Labels : Miscellaneous

14.5 Environmental hazards

ADN
Environmentally hazardous : yes

ADR
Environmentally hazardous : yes

RID
Environmentally hazardous : yes

IMDG
Marine pollutant : yes

IATA (Passenger)
Environmentally hazardous : yes

IATA (Cargo)
Environmentally hazardous : yes

14.6 Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) : Conditions of restriction for the following entries should be considered: Number on list 3
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). : Not applicable
REACH - List of substances subject to authorisation (Annex XIV) : Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable
Regulation (EU) 2019/1021 on persistent organic pollutants (recast): Not applicable
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals

<table>
<thead>
<tr>
<th>E1</th>
<th>ENVIRONMENTAL HAZARDS</th>
<th>Quantity 1</th>
<th>Quantity 2</th>
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</thead>
<tbody>
<tr>
<td></td>
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<td>100 t</td>
<td>200 t</td>
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</tbody>
</table>

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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

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 HStatements
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.

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
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according to Regulation (EC) No. 1907/2006

Clotrimazole / Gentamicin / Betamethasone
(0.05%) Formulation

Version 6.0 Revision Date: 23.03.2020 SDS Number: 613803-00012 Date of last issue: 13.09.2019 Date of first issue: 29.04.2016

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; 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 - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organization for Standardization; KECl - 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:
Repr. 1B H360D Calculation method
STOT RE 1 H372 Calculation method
Aquatic Chronic 1 H410 Calculation method

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for
safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS 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.

NO / EN