SAFETY DATA SHEET
Clotrimazole / Gentamicin / Betamethasone (0.1%) Formulation

Version: 5.2  Revision Date: 13.09.2019  SDS Number: 808854-00012  Date of last issue: 24.04.2019

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

1.1 Product identifier
Trade name: Clotrimazole / Gentamicin / Betamethasone (0.1%) Formulation

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

1.3 Details of the supplier of the safety data sheet
Company: MSD
20 Spartan Road
1619 Spartan, South Africa
Telephone: +27119239300
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 1A: H360D: May damage the unborn child.
Specific target organ toxicity - repeated exposure, Category 1: H372: Causes damage to organs through prolonged or repeated exposure.
Short-term (acute) aquatic hazard, Category 1: H400: Very toxic to aquatic life.
Long-term (chronic) aquatic hazard, Category 1: H410: Very toxic to aquatic life with long lasting effects.

2.2 Label elements
Labelling (REGULATION (EC) No 1272/2008)
Hazard pictograms:

Signal word: Danger
Hazard statements: H360D  May damage the unborn child.  H372  Causes damage to organs through prolonged or re-
peated exposure.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements:
Prevention:
P201 Obtain special instructions before use.
P264 Wash skin thoroughly after handling.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protec-
tion/ 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:
Gentamicin
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>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>clotrimazole</td>
<td>23593-75-1</td>
<td>245-764-8</td>
<td></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 M-Factor (Acute aquatic toxicity): 10 M-Factor (Chronic aquatic toxicity): 10</td>
<td>&gt;= 1 - &lt; 2,5</td>
</tr>
<tr>
<td>Gentamicin</td>
<td>1403-66-3</td>
<td>215-765-8</td>
<td></td>
<td>Repr.1A; H360D STOT RE1; H372 Aquatic Acute1; H400 Aquatic Chronic1; H410</td>
<td>&gt;= 0,3 - &lt; 1</td>
</tr>
</tbody>
</table>
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.
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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 contain-
ment 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 absor-
rent.
Local or national regulations may apply to releases and dis-
posal of this material, as well as those materials and items
employed in the cleanup
of releases. You will need to deter-
mine 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 as-
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 contami-
nated 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
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</tr>
</thead>
</table>

Explosives
Gases

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

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

### Occupational Exposure Limits

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>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 Internal

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**

<table>
<thead>
<tr>
<th>Eye protection</th>
<th>Remarks</th>
<th>Hand protection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wear safety glasses with side shields or goggles.</td>
<td>If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.</td>
<td>Chemical-resistant gloves</td>
</tr>
<tr>
<td>Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

- **Appearance**: liquid
- **Colour**: No data available
- **Odour**: No data available
- **Odour Threshold**: No data available
- **pH**: No data available
- **Melting point/freezing point**: No data available
- **Initial boiling point and boiling range**: No data available
- **Flash point**: No data available
- **Evaporation rate**: No data available
- **Flammability (solid, gas)**: Not applicable
- **Upper explosion limit / Upper flammability limit**: No data available
- **Lower explosion limit / Lower flammability limit**: No data available
- **Vapour pressure**: No data available
- **Relative vapour density**: No data available
- **Relative density**: No data available
- **Density**: No data available
- **Solubility(ies)**
  - **Water solubility**: No data available
  - **Partition coefficient: n-octanol/water**: Not applicable
  - **Auto-ignition temperature**: No data available
  - **Decomposition temperature**: No data available
- **Viscosity**
  - **Viscosity, kinematic**: No data available
- **Explosive properties**: Not explosive
- **Oxidizing properties**: The substance or mixture is not classified as oxidizing.

9.2 Other information
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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:

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

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
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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:

clotrimazole:
Species: Rabbit
Result: Mild eye irritation

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:

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.

**Gentamicin:**

Genotoxicity in vitro

: Test Type: In vitro mammalian cell gene mutation test
Result: negative

Test Type: Chromosome aberration test in vitro
Result: equivocal

Genotoxicity in vivo

: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Intravenous injection
Result: negative

**betamethasone:**

Genotoxicity in vitro

: Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: In vitro mammalian cell gene mutation test
Result: negative

Test Type: Chromosome aberration test in vitro
Result: positive

Genotoxicity in vivo

: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Oral
Result: equivocal

**Germ cell mutagenicity- Assessment**

: Weight of evidence does not support classification as a germ cell mutagen.
Carcinogenicity
Not classified based on available information.

Components:

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

Gentamicin:
Carcinogenicity - Assessment: No data available

Reproductive toxicity
May damage the unborn child.

Components:

Clotrimazole:
Effects on fertility:
Species: Rat
Application Route: Oral
Fertility: LOAEL: 50 mg/kg body weight
Result: Effects on fertility

Effects on 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: 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.

### Gentamicin:

#### Effects on fertility

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Species</th>
<th>Fertility NOAEL</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Two-generation reproduction toxicity study</td>
<td>Rat</td>
<td>20 mg/kg body weight</td>
<td>No significant adverse effects were reported</td>
</tr>
</tbody>
</table>

#### Effects on foetal development

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Species</th>
<th>Application Route</th>
<th>Developmental Toxicity NOAEL</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Embryo-foetal development</td>
<td>Rabbit</td>
<td>Intraperitoneal</td>
<td>3.6 mg/kg body weight</td>
<td>No embryo-foetal toxicity</td>
</tr>
</tbody>
</table>

### betamethasone:

#### Effects on foetal development

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Species</th>
<th>Application Route</th>
<th>Developmental Toxicity LOAEL</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fetotoxicity</td>
<td>Rabbit</td>
<td>Intramuscular</td>
<td>0.05 mg/kg body weight</td>
<td>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.
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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
Gentamicin:
Species: Dog
LOAEL: 3 mg/kg
Application Route: Intramuscular
Exposure time: 12 Months
Target Organs: Kidney
Symptoms: Vomiting, Salivation
Species: Monkey
LOAEL: 50 mg/kg
Application Route: Subcutaneous
Exposure time: 3 Weeks
Target Organs: Kidney, inner ear
Species: Monkey
LOAEL: 6 mg/kg
Application Route: Intramuscular
Exposure time: 3 Weeks
Target Organs: Blood, Kidney, inner ear, Liver
Species: Rat
NOAEL: 5 mg/kg
LOAEL: 10 mg/kg
Application Route: Intramuscular
Exposure time: 52 Weeks
Target Organs: Kidney, Blood
Species: Rat
NOAEL: 12.5 mg/kg
LOAEL: 50 mg/kg
Application Route: Intramuscular
Exposure time: 13 Weeks
Target Organs: Kidney
betamethasone:
Species: Rabbit
LOAEL: 0.05 %
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
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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:
Ingestion:

Symptoms: Rash, Itching, Blistering, Oedema, Redness

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

betamethasone:
Inhalation:
Skin contact:

Target Organs: Adrenal gland
Symptoms: Redness, pruritis, Irritation

SECTION 12: Ecological information

12.1 Toxicity

Components:

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

#### 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)

- **M-Factor**: 10

#### 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)

- **M-Factor**: 100

**Toxicity to microorganisms**

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

**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:

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

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

12.3 Bioaccumulative potential

Components:

Gentamicin:
Partition coefficient: n-octanol/water: log Pow: < -2
### betamethasone:
- Partition coefficient: n-octanol/water
  - log Pow: 2.11

### 12.4 Mobility in soil
- No data available

### 12.5 Results of PBT and vPvB assessment
- Not relevant

### 12.6 Other adverse effects
- No data available

### SECTION 13: Disposal considerations

#### 13.1 Waste treatment methods
- **Product**: Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.
- **Contaminated packaging**: Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

### SECTION 14: Transport information

#### 14.1 UN number
- **ADN**: UN 3082
- **ADR**: UN 3082
- **RID**: UN 3082
- **IMDG**: UN 3082
- **IATA**: UN 3082

#### 14.2 UN proper shipping name
- **ADN**: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (clotrimazole, Gentamicin)
- **ADR**: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (clotrimazole, Gentamicin)
- **RID**: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (clotrimazole, Gentamicin)
- **IMDG**: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (clotrimazole, Gentamicin)
- **IATA**: Environmentally hazardous substance, liquid, n.o.s.
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Clotrimazole / Gentamicin / Betamethasone (0.1%) Formulation

14.3 Transport hazard class(es)

| ADN | : 9 |
| ADR | : 9 |
| RID | : 9 |
| IMDG| : 9 |
| IATA| : 9 |

14.4 Packing group

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<td>Labels</td>
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<td>Labels</td>
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14.5 Environmental hazards

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<td>ADR</td>
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<tr>
<td>Environmentally hazardous</td>
</tr>
</tbody>
</table>
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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
The components of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
IECSC : not determined

15.2 Chemical safety assessment
A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

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

Full text of H-Statements
H302 : Harmful if swallowed.
H311 : Toxic in contact with skin.
H319 : Causes serious eye irritation.
H330 : Fatal 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.
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Clotrimazole / Gentamicin / Betamethasone (0.1%) Formulation

Version 5.2  Revision Date: 13.09.2019  SDS Number: 808854-00012

Date of last issue: 24.04.2019  Date of first issue: 22.07.2016

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

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 Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Further information

Classification of the mixture: Classification procedure:
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Date of first issue: 22.07.2016

Repr. 1A  H360D  Calculation method
STOT RE 1  H372  Calculation method
Aquatic Acute 1  H400  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.

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