SAFETY DATA SHEET

Clotrimazole / Gentamicin / Betamethasone (0.1%) Formulation

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

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

Manufacturer or supplier’s details

Company: MSD
Address: Rua Coronel Bento Soares, 530 Cruzeiro - Sao Paulo - Brazil CEP 12730-340
Telephone: 908-740-4000
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com
Telefax: 908-735-1496

Recommended use of the chemical and restrictions on use

Recommended use: Veterinary product

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification in accordance with ABNT NBR 14725 Standard

Reproductive toxicity: Category 1A
Specific target organ toxicity - repeated exposure: Category 1 (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland)
Short-term (acute) aquatic hazard: Category 1
Long-term (chronic) aquatic hazard: Category 1

GHS label elements in accordance with ABNT NBR 14725 Standard

Hazard pictograms:

Signal Word: Danger
Hazard Statements:
H360D May damage the unborn child.
H372 Causes damage to organs (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland) 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.

**Other hazards which do not result in classification**
None known.

### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

**Substance / Mixture:** Mixture

**Components**

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>White mineral oil (petroleum)</td>
<td>8042-47-5</td>
<td></td>
<td>&gt;= 90 - &lt;= 100</td>
</tr>
<tr>
<td>clotrimazole</td>
<td>23593-75-1</td>
<td>Acute toxicity (Oral), Category 4 Acute toxicity (Dermal), Category 3 Eye irritation, Category 2B Reproductive toxicity, Category 2 Specific target organ toxicity - repeated exposure (Oral) (Liver, Kidney, Adrenal gland), Category 2 Short-term (acute) aquatic hazard, Category 1 Long-term (chronic) aquatic hazard, Category 1</td>
<td>&gt;= 1 - &lt; 2.5</td>
</tr>
<tr>
<td>Gentamicin</td>
<td>1403-66-3</td>
<td>Reproductive toxicity, Category 1A Specific target organ toxicity - repeated exposure (Oral) (Kidney, inner ear), Category 1 Short-term (acute) aquatic hazard, Category 1</td>
<td>&gt;= 0.3 - &lt; 1</td>
</tr>
</tbody>
</table>
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**Clotrimazole / Gentamicin / Betamethasone (0.1%) Formulation**

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

| Betamethasone | 378-44-9 | Acute toxicity (Inhalation), Category 2 Reproductive toxicity, Category 1B Specific target organ toxicity - repeated exposure (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland), Category 1 Long-term (chronic) aquatic hazard, Category 1 | >= 0.1 < 0.25 |

### SECTION 4. 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.

**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.

**Most important symptoms and effects, both acute and delayed**: May damage the unborn child. Causes damage to organs through prolonged or repeated exposure.

**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).

**Notes to physician**: Treat symptomatically and supportively.

### SECTION 5. FIRE-FIGHTING MEASURES

**Suitable extinguishing media**: Water spray Alcohol-resistant foam Carbon dioxide (CO2)
SAFETY DATA SHEET

Clotrimazole / Gentamicin / Betamethasone
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Unsuitable extinguishing media: None known.
Specific hazards during fire fighting: Exposure to combustion products may be a hazard to health.
Hazardous combustion products: Carbon oxides

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.

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

SECTION 6. ACCIDENTAL RELEASE MEASURES

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

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.

Methods and materials for containment and cleaning up:
Soak up with inert absorbent material.
For large spills, provide diking or other appropriate containment to keep material from spreading. If diked 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.

SECTION 7. HANDLING AND STORAGE

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 vapors 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 decontamination and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

Conditions for safe storage:
Keep in properly labeled containers.
Store locked up.
Keep tightly closed.
Store in accordance with the particular national regulations.

Materials to avoid:
Do not store with the following product types:
Strong oxidizing agents
Organic peroxides
Explosives
Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>White mineral oil (petroleum)</td>
<td>8042-47-5</td>
<td>TWA (Inhalable particulate matter)</td>
<td>5 mg/m³</td>
<td>ACGIH</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>
<tr>
<td></td>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>10 µg/100 cm²</td>
</tr>
</tbody>
</table>

Further information: Skin

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**

**Respiratory protection**
- If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
- Filter type: Combined particulates and organic vapor type

**Hand protection**
- Material: Chemical-resistant gloves
- Remarks: Consider double gloving.

**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.

**Skin and body protection**
- Work uniform or laboratory coat.
- Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.
- Use appropriate degowning techniques to remove potentially contaminated clothing.

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

**Appearance**
- Liquid

**Color**
- No data available

**Odor**
- No data available

**Odor 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

**Flammability (liquids)**
- No data available

**Upper explosion limit / Upper**
- No data available
SAFETY DATA SHEET
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flammmability limit

Lower explosion limit / Lower flammability limit : No data available

Vapor pressure : No data available
Relative vapor 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

Autoignition 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.

Particle size : Not applicable

SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reac-
tions : Can react with strong oxidizing agents.
Conditions to avoid : None known.
Incompatible materials : Oxidizing agents
Hazardous decomposition products : No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

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

Acute toxicity
Not classified based on available information.

Product:
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Acute oral toxicity: Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Acute inhalation toxicity: Acute toxicity estimate: > 10 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method

Acute dermal toxicity: Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Components:

**White mineral oil (petroleum):**

Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg

Acute inhalation toxicity: LC50 (Rat): > 5 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Assessment: The substance or mixture has no acute inhalation toxicity

Acute dermal toxicity: LD50 (Rabbit): > 2,000 mg/kg
Assessment: The substance or mixture has no acute dermal toxicity

**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:**
- **White mineral oil (petroleum):**
  - **Species:** Rabbit
  - **Result:** No skin irritation

- **Clotrimazole:**
  - **Species:** Rabbit
  - **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:**
- **White mineral oil (petroleum):**
  - **Species:** Rabbit
  - **Result:** No eye irritation

- **Clotrimazole:**
  - **Species:** Rabbit
  - **Result:** Mild eye irritation
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Clotrimazole / Gentamicin / Betamethasone
(0.1%) Formulation

Version: 6.0  Revision Date: 23.03.2020  SDS Number: 808837-00013  Date of last issue: 13.09.2019
Date of first issue: 22.07.2016

Gentamicin:
Species: Rabbit  Result: Mild eye irritation

Betamethasone:
Species: Rabbit  Result: No eye irritation

Respiratory or skin sensitization

Skin sensitization
Not classified based on available information.

Respiratory sensitization
Not classified based on available information.

Components:

White mineral oil (petroleum):
Test Type: Buehler Test  Routes of exposure: Skin contact  Species: Guinea pig  Result: negative

Gentamicin:
Remarks: No data available

Betamethasone:
Routes of exposure: Dermal  Species: Guinea pig  Result: Weak sensitizer

Germ cell mutagenicity
Not classified based on available information.

Components:

White mineral oil (petroleum):
Genotoxicity in vitro: Test Type: In vitro mammalian cell gene mutation test  Result: negative
Genotoxicity in vivo: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  Species: Mouse  Application Route: Intraperitoneal injection  Method: OECD Test Guideline 474  Result: negative  Remarks: Based on data from similar materials

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:

White mineral oil (petroleum):
Species: Rat
Application Route: Ingestion
Exposure time: 24 Months
Result: negative

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:

White mineral oil (petroleum):
Effects on fertility: Test Type: One-generation reproduction toxicity study
Species: Rat
Application Route: Skin contact
Result: negative

Effects on fetal development: Test Type: Embryo-fetal development
Species: Rat
Application Route: Ingestion
Result: negative

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 fetal development: Test Type: Embryo-fetal development
Species: Rat
Application Route: Oral
Developmental Toxicity: LOAEL: 100 mg/kg body weight
Result: Embryo-fetal toxicity., No teratogenic effects.
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: 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 fetal development: Test Type: Embryo-fetal development
Species: Rabbit
Developmental Toxicity: NOAEL: 3.6 mg/kg body weight
Result: No embryo-fetal toxicity.

Test Type: Embryo-fetal development
Species: Rat
Application Route: Intraperitoneal
Developmental Toxicity: LOAEL: 75 mg/kg body weight
Result: Embryo-fetal toxicity.

Test Type: Embryo-fetal development
Species: Mouse
Application Route: Intraperitoneal
Developmental Toxicity: LOAEL: 10 mg/kg body weight
Result: Fetal mortality., No malformations were observed.

Test Type: Embryo-fetal development
Species: Rat
Application Route: Intraperitoneal
Developmental Toxicity: LOAEL: 50 mg/kg body weight
Result: Fetal mortality., No malformations were observed.
Reproductive toxicity - Assessment: Positive evidence of adverse effects on development from human epidemiological studies.

Betamethasone:
Effects on fetal 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 (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland) 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:

White mineral oil (petroleum):
- **Species**: Rat
- **LOAEL**: 160 mg/kg
- **Application Route**: Ingestion
- **Exposure time**: 90 Days

- **Species**: Rat
- **LOAEL**: >= 1 mg/l
- **Application Route**: Inhalation (dust/mist/fume)
- **Exposure time**: 4 Weeks
- **Method**: OECD Test Guideline 412

Clotrimazole:
- **Species**: Rabbit
- **LOAEL**: 5 - 40 mg/kg
- **Application Route**: Skin contact
- **Exposure time**: 3 Weeks
- **Target Organs**: Skin
- **Symptoms**: Edema, 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
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LOAEL: 6 mg/kg
Application Route: Intramuscular
Exposure time: 3 Weeks
Target Organs: Blood, Kidney, inner ear, Liver

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

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

Betamethasone:

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

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

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

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

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:

Clotrimazole:
Skin contact: Symptoms: Rash, Itching, Blistering, Edema, Redness
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<thead>
<tr>
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<th>Date of last issue</th>
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</thead>
</table>

### Ingestion

#### Gentamicin:
- **Ingestion**
  - **Symptoms**: Abdominal pain, Nausea, Vomiting, Diarrhea
  - **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

#### Ecotoxicity

**Components:**

<table>
<thead>
<tr>
<th>White mineral oil (petroleum):</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Toxicity to fish</strong></td>
</tr>
<tr>
<td>LC50 (Oncorhynchus mykiss (rainbow trout)): &gt; 100 mg/l</td>
</tr>
<tr>
<td>Exposure time: 96 h</td>
</tr>
<tr>
<td>Method: OECD Test Guideline 203</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Toxicity to daphnia and other aquatic invertebrates</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>EC50 (Daphnia magna (Water flea)): &gt; 100 mg/l</td>
</tr>
<tr>
<td>Exposure time: 48 h</td>
</tr>
<tr>
<td>Method: OECD Test Guideline 202</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Toxicity to algae/aquatic plants</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>NOEC (Pseudokirchneriella subcapitata (green algae)): 100 mg/l</td>
</tr>
<tr>
<td>Exposure time: 72 h</td>
</tr>
<tr>
<td>Method: OECD Test Guideline 201</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Toxicity to fish (Chronic toxicity)</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>NOEC (Oncorhynchus mykiss (rainbow trout)): 1.000 mg/l</td>
</tr>
<tr>
<td>Exposure time: 28 d</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>NOEC (Daphnia magna (Water flea)): 1.000 mg/l</td>
</tr>
<tr>
<td>Exposure time: 21 d</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>clotrimazole:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Toxicity to fish</strong></td>
</tr>
<tr>
<td>LC50 (Brachydanio rerio (zebrafish)): &gt; 0,29 mg/l</td>
</tr>
<tr>
<td>Exposure time: 96 h</td>
</tr>
<tr>
<td>Method: OECD Test Guideline 203</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Toxicity to daphnia and other aquatic invertebrates</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>EC50 (Daphnia magna (Water flea)): 0,02 mg/l</td>
</tr>
<tr>
<td>Exposure time: 48 h</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Toxicity to algae/aquatic plants</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>EC50 (Desmodesmus subspicatus (green algae)): 0,268 mg/l</td>
</tr>
<tr>
<td>Exposure time: 72 h</td>
</tr>
<tr>
<td>NOEC (Desmodesmus subspicatus (green algae)): 0,017 mg/l</td>
</tr>
<tr>
<td>Exposure time: 72 h</td>
</tr>
</tbody>
</table>

| M-Factor (Acute aquatic toxicity): 10 |
Toxicity to fish (Chronic toxicity):

- NOEC (Oncorhynchus mykiss (rainbow trout)): 0.025 mg/l
  - Exposure time: 32 d
  - Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):

- NOEC (Daphnia magna (Water flea)): 0.01 mg/l
  - Exposure time: 21 d
  - Method: OECD Test Guideline 211

M-Factor (Chronic aquatic toxicity):

- 10

Toxicity to microorganisms:

- EC50: > 10.000 mg/l
  - Exposure time: 3 h
  - Test Type: Respiration inhibition
  - Method: OECD Test Guideline 209

**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

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

M-Factor (Chronic aquatic toxicity):

- 1

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 (Pimephales promelas (fathead minnow)): 0.052 mg/l
Exposure time: 32 d
Method: OECD Test Guideline 210

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

### Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)
NOEC (Daphnia magna (Water flea)): 8 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211

### M-Factor (Chronic aquatic toxicity)
1.000

### Persistence and degradability

#### Components:

**White mineral oil (petroleum):**
Biodegradability: Result: Not readily biodegradable.
Biodegradation: 31 %
Exposure time: 28 d

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

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

### Bioaccumulative potential

#### Components:

**Gentamicin:**
SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods
- Waste from residues: Dispose of in accordance with local regulations.
- 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

International Regulations

UNRTDG
- UN number: UN 3082
- Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (clotrimazole, Gentamicin)
- Class: 9
- Packing group: III
- Labels: 9

IATA-DGR
- UN/ID No.: UN 3082
- Proper shipping name: Environmentally hazardous substance, liquid, n.o.s. (clotrimazole, Gentamicin)
- Class: 9
- Packing group: III
- Labels: Miscellaneous
- Packing instruction (cargo aircraft): 964
- Packing instruction (passenger aircraft): 964
- Environmentally hazardous: yes

IMDG-Code
- UN number: UN 3082
- Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (clotrimazole, Gentamicin)
- Class: 9
- Packing group: III
- Labels: 9
SAFETY DATA SHEET

Clotrimazole / Gentamicin / Betamethasone
(0.1%) Formulation

EmS Code : F-A, S-F
Marine pollutant : yes

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

Domestic regulation

ANTT
UN number : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
(clotrimazole, Gentamicin)
Class : 9
Packing group : III
Labels : 9
Hazard Identification Number : 90

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.

SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture
National List of Carcinogenic Agents for Humans - (LINACH) : Not applicable
Brazil. List of chemicals controlled by the Federal Police : Not applicable

International Regulations

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

SECTION 16. OTHER INFORMATION

Further information
Clotrimazole / Gentamicin / Betamethasone (0.1%) 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>

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 other abbreviations**

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH</td>
<td>USA. ACGIH Threshold Limit Values (TLV)</td>
</tr>
<tr>
<td>ACGIH / TWA</td>
<td>8-hour, time-weighted average</td>
</tr>
</tbody>
</table>

Additional abbreviations include:

- AICS: Australian Inventory of Chemical Substances
- ANTT: National Agency for Transport by Land of Brazil
- ASTM: American Society for the Testing of Materials
- bw: Body weight
- CMR: Carcinogen, Mutagen or Reproductive Toxicant
- DIN: Standard of the German Institute for Standardisation
- DSL: Domestic Substances List (Canada)
- ECx: Concentration associated with x% response
- EmS: Emergency Schedule
- ENCS: Existing and New Chemical Substances (Japan)
- ERG: Emergency Response Guide
- 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 Substan ces in China
- IMDG: International Maritime Dangerous Goods
- IMO: International Maritime Organization
- ISHL: Industrial Safety and Health Law (Japan)
- ITPS: Office of Chemical Safety and Pollution Prevention
- NTRODUCTION OF CHEMICALS IN Bulk; n.o.s.: Not Otherwise Specified
- Nch: Chilean Norm
- NO(A)EC: No Observed (Adverse) Effect Concentration
- NO(A)EL: No Observed (Adverse) Effect Level
- NOELR: No Observable Effect Loading Rate
- NOM: Official Mexican Norm
- OPPTS: Office of Chemical Safety and Pollution Prevention
- PBT: Persistent, Bioaccumulative and Toxic substance
- PIICCS: Philippines Inventory of Chemicals and Chemical Substances
- (Q)SAR: (Quantitative) Structure Activity Relationship
- SDAT: Self-Accelerating Decomposition Temperature
- SDS: Safety Data Sheet
- TCSI: Taiwan Chemical Substance Inventory
- TDG: Transport of Dangerous Goods
- TSCA: Toxic Substances Control Act (United States)
- UN: United Nations
- vPvB: Very Persistent and Very Bioaccumulative
- WHMIS: Workplace Hazardous Materials Information System

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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