1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Betamethasone / Clotrimazole Ointment Formulation

Manufacturer or supplier's details
Company: MSD
Address: 199 Wenhui North Road, HEDA, Hangzhou - Zhejiang Province - CHINA 310018
Telephone: 908-740-4000
Emergency telephone number: 86-571-87268110
E-mail address: EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use
Recommended use: Pharmaceutical

2. HAZARDS IDENTIFICATION

Emergency Overview
Appearance: Viscous semi-solid
Colour: No data available
Odour: No data available

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

GHS Classification
Reproductive toxicity: Category 1B
Specific target organ toxicity - repeated exposure: Category 1
Short-term (acute) aquatic hazard: Category 2
Long-term (chronic) aquatic hazard: Category 1

GHS label elements
Hazard pictograms:
Signal word: Danger
Hazard statements:
H360D May damage the unborn child.
H372 Causes damage to organs through prolonged or repeated exposure.
H401 Toxic to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements:
Prevention:
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe dust/ fume/ gas/ mist/ vapours/ spray.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
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.

Storage:
P405 Store locked up.

Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.

Physical and chemical hazards
Not classified based on available information.

Health hazards
May damage the unborn child. Causes damage to organs through prolonged or repeated exposure.

Environmental hazards
Toxic to aquatic life. Very toxic to aquatic life with long lasting effects.

Other hazards which do not result in classification
None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Petrolatum</td>
<td>8009-03-8</td>
<td>&gt;= 90 - &lt;= 100</td>
</tr>
<tr>
<td>White mineral oil (petroleum)</td>
<td>8042-47-5</td>
<td>&gt;= 1 - &lt; 10</td>
</tr>
<tr>
<td>clotrimazole</td>
<td>23593-75-1</td>
<td>&gt;= 1 - &lt; 2.5</td>
</tr>
<tr>
<td>betamethasone</td>
<td>378-44-9</td>
<td>&gt;= 0.025 - &lt; 0.1</td>
</tr>
</tbody>
</table>
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.

5. FIREFIGHTING MEASURES

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

Unsuitable extinguishing media: None known.

Specific hazards during firefighting: 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 firefighters: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

6. ACCIDENTAL RELEASE MEASURES
## 7. HANDLING AND STORAGE

### 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 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.

**Avoidance of contact**

Oxidizing agents

### Storage

**Conditions for safe storage**

Keep in properly labelled 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

**Packaging material**

Unsuitable material: None known.

---

### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type</th>
<th>Control parameter</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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Betamethasone / Clotrimazole Ointment Formulation

<table>
<thead>
<tr>
<th></th>
<th>(Form of exposure)</th>
<th>Permissible concentration</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Petrolatum</td>
<td>8009-03-8</td>
<td>TWA (Inhalable fraction)</td>
<td>5 mg/m³ ACGIH</td>
</tr>
<tr>
<td>White mineral oil (petroleum)</td>
<td>8042-47-5</td>
<td>TWA (Inhalable fraction)</td>
<td>5 mg/m³ ACGIH</td>
</tr>
<tr>
<td>Clotrimazole</td>
<td>23593-75-1</td>
<td>TWA</td>
<td>0.2 mg/m³ (OEB 2) Internal</td>
</tr>
<tr>
<td>Betamethasone</td>
<td>378-44-9</td>
<td>TWA</td>
<td>1 µg/m³ (OEB 4) Internal</td>
</tr>
<tr>
<td>Further information: Skin</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wipe limit</td>
<td>10 µg/100 cm²</td>
<td>Internal</td>
<td></td>
</tr>
</tbody>
</table>

**Engineering measures**
- Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., vacuum conveying from a closed system, packout head with inflatable seal from stationary container, ventilated enclosure, etc.).
- 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.

**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 vapour type

**Eye/face 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.

**Hand protection**
- Material: Chemical-resistant gloves

**Remarks**
- Consider double gloving.

**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
9. PHYSICAL AND CHEMICAL PROPERTIES

- **Appearance**: Viscous semi-solid
- **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**: Not applicable
- **Evaporation rate**: Not applicable
- **Flammability (solid, gas)**: Not classified as a flammability hazard
- **Flammability (liquids)**: No data available
- **Upper explosion limit / Upper flammability limit**: No data available
- **Lower explosion limit / Lower flammability limit**: No data available
- **Vapour pressure**: Not applicable
- **Relative vapour density**: Not applicable
- **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**
Betamethasone / Clotrimazole Ointment Formulation

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<tr>
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</tbody>
</table>

Viscosity, kinematic: No data available

Explosive properties: Not explosive

Oxidizing properties: The substance or mixture is not classified as oxidizing.

Particle size: Not applicable

10. STABILITY AND REACTIVITY

Reactivity: Not classified as a reactivity hazard.

Chemical stability: Stable under normal conditions.

Possibility of hazardous reactions: Can react with strong oxidizing agents.

Conditions to avoid: None known.

Incompatible materials: Oxidizing agents

Hazardous decomposition products: No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

Exposure routes: Skin contact, Ingestion, Eye contact

Acute toxicity
Not classified based on available information.

Product:

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

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

Components:

Petrolatum:

Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
Method: OECD Test Guideline 401
Remarks: Based on data from similar materials

Acute dermal toxicity: LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 402
Assessment: The substance or mixture has no acute dermal toxicity
Remarks: Based on data from similar materials

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

**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:**

**Petrolatum:**
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation
Remarks: Based on data from similar materials

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

**clotrimazole:**
Species: Rabbit
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Result : No skin irritation

betamethasone:
Species : Rabbit
Result : Mild skin irritation

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

Components:

Petrolatum:
Species : Rabbit
Result : No eye irritation
Method : OECD Test Guideline 405
Remarks : Based on data from similar materials

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

clotrimazole:
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:

Petrolatum:
Test Type : Buehler Test
Exposure routes : Skin contact
Species : Guinea pig
Result : negative
Remarks : Based on data from similar materials

White mineral oil (petroleum):
Test Type : Buehler Test
Exposure routes : Skin contact
Species: Guinea pig
Result: negative

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

Germ cell mutagenicity
Not classified based on available information.

Components:

Petrolatum:
Genotoxicity in vitro: Test Type: Chromosome aberration test in vitro
Result: negative
Remarks: Based on data from similar materials

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

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)
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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.

**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:**

**Petrolatum:**

Species: Rat
Application Route: Ingestion
Exposure time: 2 Years
Result: negative

**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

Reproductive toxicity
May damage the unborn child.

Components:

Petrolatum:
Effects on fertility: Test Type: Reproduction/Developmental toxicity screening test
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

Effects on foetal development: Test Type: Embryo-foetal development
Species: Rat
Application Route: Skin contact
Result: negative
Remarks: Based on data from similar materials

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

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

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

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

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

Reproductive toxicity - Assessment: Some evidence of adverse effects on sexual function and fertility, based on animal experiments., Some evidence of adverse effects on development, based on animal experiments.

betamethasone:
Effects on foetal development: Species: Rabbit
Application Route: Intramuscular
Developmental Toxicity: LOAEL: 0.05 mg/kg body weight
Result: Fetotoxicity, Malformations were observed.

Species: Rat
Application Route: Subcutaneous
Developmental Toxicity: LOAEL: 0.42 mg/kg body weight
Result: Malformations were observed.

Species: Mouse
Application Route: Intramuscular
Developmental Toxicity: LOAEL: 1 mg/kg body weight
Result: Malformations were observed.

Reproductive toxicity - Assessment: Clear evidence of adverse effects on development, based on animal experiments.

STOT - single exposure
Not classified based on available information.

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

Components:

clotrimazole:
Target Organs: Liver, Kidney, Adrenal gland
Assessment: May cause damage to organs through prolonged or repeated exposure.
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Target Organ:
- Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland

Assessment:
- Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Petrolatum:
- Species: Rat
- NOAEL: 5,000 mg/kg
- Application Route: Ingestion
- Exposure time: 2 yr

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: 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
**SAFETY DATA SHEET**  
according to GB/T 16483 and GB/T 17519

**Betamethasone / Clotrimazole Ointment Formulation**

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</tr>
</tbody>
</table>

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

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

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

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

**Aspiration toxicity**  
Not classified based on available information.

**Experience with human exposure**

**Components:**

**clotrimazole:**

**Skin contact**  
Symptoms: Rash, Itching, Blistering, Oedema, Redness

**Ingestion**  
Symptoms: Abdominal pain, Nausea, Vomiting, Diarrhoea

**betamethasone:**

**Inhalation**  
Target Organs: Adrenal gland

**Skin contact**  
Symptoms: Redness, pruritis, Irritation

---

**12. ECOLOGICAL INFORMATION**

**Ecotoxicity**

**Components:**

**Petrolatum:**

**Toxicity to fish**  
LL50 (Pimephales promelas (fathead minnow)): > 100 mg/l  
Exposure time: 96 h  
Test substance: Water Accommodated Fraction  
Method: OECD Test Guideline 203  
Remarks: Based on data from similar materials

**Toxicity to daphnia and other**  
EC50 (Daphnia magna (Water flea)): > 10,000 mg/l
### Aquatic Invertebrates

**Exposure time:** 48 h  
**Test substance:** Water Accommodated Fraction  
**Remarks:** Based on data from similar materials

### Toxicity to Algae/Aquatic Plants

<table>
<thead>
<tr>
<th>Test substance</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOEL (Pseudokirchneriella subcapitata (green algae))</td>
<td><a href="https://www.oecd.org/">OECD Test Guideline 201</a></td>
</tr>
</tbody>
</table>

### Toxicity to Daphnia and Other Aquatic Invertebrates (Chronic Toxicity)

<table>
<thead>
<tr>
<th>Test substance</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOEC (Daphnia magna (Water flea))</td>
<td><a href="https://www.oecd.org/">OECD Test Guideline 202</a></td>
</tr>
</tbody>
</table>

### White Mineral Oil (Petroleum)

#### Toxicity to Fish

<table>
<thead>
<tr>
<th>Test substance</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>LC50 (Oncorhynchus mykiss (rainbow trout))</td>
<td><a href="https://www.oecd.org/">OECD Test Guideline 203</a></td>
</tr>
</tbody>
</table>

#### Toxicity to Daphnia and Other Aquatic Invertebrates

<table>
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<th>Test substance</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>EC50 (Daphnia magna (Water flea))</td>
<td><a href="https://www.oecd.org/">OECD Test Guideline 202</a></td>
</tr>
</tbody>
</table>

#### Toxicity to Algae/Aquatic Plants

<table>
<thead>
<tr>
<th>Test substance</th>
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<tr>
<td>NOEC (Pseudokirchneriella subcapitata (green algae))</td>
<td><a href="https://www.oecd.org/">OECD Test Guideline 201</a></td>
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</table>

#### Toxicity to Fish (Chronic Toxicity)

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<th>Method</th>
</tr>
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<td><a href="https://www.oecd.org/">OECD Test Guideline 203</a></td>
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</table>

#### Toxicity to Daphnia and Other Aquatic Invertebrates (Chronic Toxicity)

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<tr>
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<tr>
<td>NOEC (Daphnia magna (Water flea))</td>
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### Clotrimazole

#### Toxicity to Fish

<table>
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<tr>
<th>Test substance</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>LC50 (Brachydanio rerio (zebrafish))</td>
<td><a href="https://www.oecd.org/">OECD Test Guideline 203</a></td>
</tr>
</tbody>
</table>

#### Toxicity to Daphnia and Other Aquatic Invertebrates

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<tr>
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#### Toxicity to Algae/Aquatic Plants

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<tr>
<th>Test substance</th>
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</tr>
</thead>
<tbody>
<tr>
<td>NOEC (Desmodesmus subspicatus (green algae))</td>
<td><a href="https://www.oecd.org/">OECD Test Guideline 203</a></td>
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</tbody>
</table>

### M-Factor (Acute Aquatic Toxicity)

- **Clotrimazole:** 10
SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

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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

**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:**

**Petrolatum:**

Biodegradability:
- Result: Not readily biodegradable.
Biodegradation: 31 %
Exposure time: 28 d
Method: OECD Test Guideline 301F
Remarks: Based on data from similar materials

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

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

Bioaccumulative potential

Components:
betamethasone:
Partition coefficient: n-octanol/water : log Pow: 2.11

Mobility in soil
No data available

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.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG
UN number : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(betamethasone, clotrimazole)

Class : 9
Packing group : III
Labels : 9

IATA-DGR
UN/ID No. : UN 3077
Proper shipping name : Environmentally hazardous substance, solid, n.o.s.
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- **Class**: 9
- **Packing group**: III
- **Labels**: Miscellaneous
- **Environmentally hazardous**: yes
- **IMDG-Code**
  - UN number: UN 3077
  - Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (betamethasone, clotrimazole)
- **Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**
  Not applicable for product as supplied.

**National Regulations**

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<td>Proper shipping name</td>
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</table>

- **Class**: 9
- **Packing group**: III
- **Labels**: 9

**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.

**15. REGULATORY INFORMATION**

- **National regulatory information**
  - **Law on the Prevention and Control of Occupational Diseases**

  The components of this product are reported in the following inventories:
  - **AICS**: not determined
  - **DSL**: not determined
  - **IECSC**: not determined
16. OTHER INFORMATION

Further information

Date format: yyyy/mm/dd

Full text of other abbreviations
ACGIH: USA. ACGIH Threshold Limit Values (TLV)
ACGIH / TWA: 8-hour, time-weighted average

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; 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; 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 Chemicals 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; 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; NTP - National Toxicology Program; 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; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; 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; WHMIS - Workplace Hazardous Materials Information System

Disclaimer
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...
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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.

CN / EN