Clotrimazole / Gentamicin / Betamethasone (0.05%) Formulation

1. PRODUCT AND COMPANY IDENTIFICATION

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

Manufacturer or supplier’s details
Company : MSD
Address : 199 Wenhai 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 | liquid |
| 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 : ![ pictogram ]
Signal word : Danger
SAFETY DATA SHEET
generated according to GB/T 16483 and GB/T 17519

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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 mist or vapours.
  - 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;= 10 - &lt; 20</td>
</tr>
<tr>
<td>Paraffin oil</td>
<td>8012-95-1</td>
<td>&gt;= 1 - &lt; 10</td>
</tr>
<tr>
<td>Hexadecan-1-ol. Ethoxylated</td>
<td>9004-95-9</td>
<td>&gt;= 1 - &lt; 2.5</td>
</tr>
</tbody>
</table>
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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)

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

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 dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

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 breathe vapours or spray mist. Do not swallow. Avoid contact with eyes. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment. Keep container tightly closed. Take care to prevent spills, waste and minimize release to the environment.

Avoidance of contact: Oxidizing agents

Storage

Conditions for safe storage: Keep in properly labelled containers.
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according to GB/T 16483 and GB/T 17519

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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 (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Petrolatum</td>
<td>8009-03-8</td>
<td>TWA (Inhalable fraction)</td>
<td>5 mg/m³ ACGIH</td>
<td></td>
</tr>
<tr>
<td>Paraffin oil</td>
<td>8012-95-1</td>
<td>TWA (Inhalable fraction)</td>
<td>5 mg/m³ ACGIH</td>
<td></td>
</tr>
<tr>
<td>clotrimazole</td>
<td>23593-75-1</td>
<td>TWA</td>
<td>0.2 mg/m³ (OEB 2) Internal</td>
<td></td>
</tr>
<tr>
<td>Gentamicin</td>
<td>1403-66-3</td>
<td>TWA</td>
<td>0.1 mg/m³ (OEB 2) Internal</td>
<td></td>
</tr>
<tr>
<td>betamethasone</td>
<td>378-44-9</td>
<td>TWA</td>
<td>1 µg/m³ (OEB 4) Internal</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: Skin</td>
<td></td>
</tr>
</tbody>
</table>

Wipe limit 10 µg/100 cm² Internal

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 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.
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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.

9. 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
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: No data available
Relative vapour density: No data available
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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: Inhalation
                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 inhalation toxicity: Acute toxicity estimate: > 10 mg/l
                          Exposure time: 4 h
                          Test atmosphere: dust/mist
                          Method: Calculation method
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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

Paraffin oil:
Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
Acute dermal toxicity: LD50 (Rabbit): > 2,000 mg/kg
Assessment: The substance or mixture has no acute dermal toxicity

Hexadecan-1-ol. Ethoxylated:
Acute oral toxicity: LD50 (Rat): 2,500 mg/kg

clotrimazole:
Acute oral toxicity: LD50 (Rat): 708 mg/kg
LD50 (Mouse): 761 mg/kg
LD50 (Rabbit): > 1,000 mg/kg
Acute inhalation toxicity: LC50 (Rat): > 0.73 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Acute dermal toxicity: LD50 (Mouse): 923 mg/kg

Benzyl alcohol:
Acute oral toxicity: LD50 (Rat): 1,620 mg/kg
Acute inhalation toxicity: LC50 (Rat): > 4.178 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403

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

Paraffin oil:
Species: Rabbit
Result: No skin irritation

Clotrimazole:
Species: Rabbit
Result: No skin irritation

Benzy alcohol:
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation
Gentamicin:
Species : Rabbit
Result : Mild skin irritation

betamethasone:
Species : Rabbit
Result : Mild skin irritation

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

Components:

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

Paraffin oil:
Species : Rabbit
Result : No eye irritation

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

clotrimazole:
Species : Rabbit
Result : Mild eye irritation

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

Gentamicin:
Species : Rabbit
Result : Mild eye irritation

betamethasone:
Species : Rabbit
Result : No eye irritation
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Date of first issue: 2016/04/29

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

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

Gentamicin:
Remarks: No data available

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

Germ cell mutagenicity
Not classified based on available information.

Components:

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

Test Type: Chromosome aberration test in vitro
Result: negative

Test Type: in vitro micronucleus test
Result: negative

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

Test Type: Mammalian spermatogonial chromosome aberration test (in vivo)
Species: Hamster
Result: negative

Germ cell mutagenicity - Assessment : Weight of evidence does not support classification as a germ cell mutagen.

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

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

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

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:

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

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

Benzyl alcohol:
Species: Mouse  
Application Route: Ingestion  
Exposure time: 103 weeks  
Method: OECD Test Guideline 451  
Result: negative

Gentamicin:
Carcinogenicity - Assessment: No data available

Reproductive toxicity  
May damage the unborn child.

Components:

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

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

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

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

Species: Mouse
Application Route: Oral
Developmental Toxicity: NOAEL: 200 mg/kg body weight
Result: No effects on 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.

Benzyl alcohol:

Effects on fertility:
Species: Rat
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Effects on foetal development:

- **Remarks:** Based on data from similar materials
- **Test Type:** Embryo-foetal development
- **Species:** Mouse
- **Application Route:** Ingestion
- **Result:** negative

**Gentamicin:**

- **Effects on fertility:**
  - **Test Type:** Two-generation reproduction toxicity study
  - **Species:** Rat
  - **Fertility:** NOAEL: 20 mg/kg body weight
  - **Result:** No significant adverse effects were reported

- **Effects on foetal development:**
  - **Test Type:** Embryo-foetal development
  - **Species:** Rabbit
  - **Developmental Toxicity:** NOAEL: 3.6 mg/kg body weight
  - **Result:** No embryo-foetal toxicity

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

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

- **Test Type:** Embryo-foetal development
  - **Species:** Rat
  - **Application Route:** Intraperitoneal
  - **Developmental Toxicity:** LOAEL: 50 mg/kg body weight
  - **Result:** foetal mortality, No malformations were observed.

**Reproductive toxicity - Assessment:**

- **Positive evidence of adverse effects on development from human epidemiological studies.**

**Betamethasone:**

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

- **Species:** Rat
  - **Application Route:** Subcutaneous
  - **Developmental Toxicity:** LOAEL: 0.42 mg/kg body weight
  - **Result:** Malformations were observed.
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Species: Mouse
Application Route: Intramuscular
Developmental Toxicity: LOAEL: 1 mg/kg body weight
Result: Malformations were observed.

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

STOT - single exposure
Not classified based on available information.

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

Components:

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

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

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

Repeated dose toxicity

Components:

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

Paraffin oil:
Species: Rat, female
LOAEL: 161 mg/kg
Application Route: Ingestion
Exposure time: 90 Days
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Clotrimazole:
Species: Rabbit
LOAEL: 5 - 40 mg/kg
Application Route: Skin contact
Exposure time: 3 Weeks
Target Organs: Skin
Symptoms: Oedema, Fissuring, Necrosis, Redness

Species: Rat
LOAEL: 10 mg/kg
Application Route: Oral
Exposure time: 18 Months
Target Organs: Liver, Kidney, Adrenal gland

Species: Dog
LOAEL: 25 mg/kg
Application Route: Oral
Exposure time: 6 - 12 Months
Target Organs: Adrenal gland
Symptoms: Salivation, Lachrymation, Vomiting

Benzyl alcohol:
Species: Rat
NOAEL: 1.072 mg/l
Application Route: inhalation (dust/mist/fume)
Exposure time: 28 Days
Method: OECD Test Guideline 412

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

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

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

Species: Rat
NOAEL: 5 mg/kg
LOAEL: 10 mg/kg
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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.

Components:

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

Experience with human exposure

Components:

clotrimazole:
Skin contact: Symptoms: Rash, Itching, Blistering, Oedema, Redness
Ingestion:

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

**Gentamicin:**

**Ingestion:**

- **Target Organs:** Kidney
- **Target Organs:** Inner ear
  - **Symptoms:** Dizziness, Vertigo, hearing loss, tinnitus, fetal deafness

**Betamethasone:**

**Inhalation:**

- **Target Organs:** Adrenal gland

**Skin contact:**

- **Symptoms:** Redness, pruritis, Irritation

### 12. 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 aquatic invertebrates:** EC50 (Daphnia magna (Water flea)): > 10,000 mg/l
  - **Exposure time:** 48 h
  - **Test substance:** Water Accommodated Fraction
  - **Remarks:** Based on data from similar materials

- **Toxicity to algae/aquatic plants:** NOEL (Pseudokirchneriella subcapitata (green algae)): >=
  - **Exposure time:** 72 h
  - **Test substance:** Water Accommodated Fraction
  - **Method:** OECD Test Guideline 201
  - **Remarks:** Based on data from similar materials

- **Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):** NOEC (Daphnia magna (Water flea)): 10 mg/l
  - **Exposure time:** 21 d
  - **Test substance:** Water Accommodated Fraction
  - **Remarks:** Based on data from similar materials

**Paraffin oil:**

- **Toxicity to fish:** LL50 (Scophthalmus maximus (turbot)): > 1,028 mg/l
  - **Exposure time:** 96 h
  - **Test substance:** Water Accommodated Fraction
  - **Remarks:** Based on data from similar materials

- **Toxicity to daphnia and other aquatic invertebrates:** EL50 (Acartia tonsa): > 3,193 mg/l
  - **Exposure time:** 48 h
  - **Test substance:** Water Accommodated Fraction
  - **Remarks:** Based on data from similar materials
### Toxicity to algae/aquatic plants

**Clotrimazole / Gentamicin / Betamethasone (0.05%) Formulation**

<table>
<thead>
<tr>
<th>Toxicity to algae/aquatic plants</th>
<th>EL50 (Skeletonema costatum (marine diatom)): &gt; 3,200 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 72 h</td>
</tr>
<tr>
<td></td>
<td>Test substance: Water Accommodated Fraction</td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
</tr>
<tr>
<td>NOELR (Skeletonema costatum (marine diatom)): 993 mg/l</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Exposure time: 72 h</td>
</tr>
<tr>
<td></td>
<td>Test substance: Water Accommodated Fraction</td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>

### Hexadecan-1-ol. Ethoxylated:

**Toxicity to fish**

<table>
<thead>
<tr>
<th>Toxicity to fish</th>
<th>LC50: &gt; 1 - 10 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 96 h</td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>

**Toxicity to daphnia and other aquatic invertebrates**

<table>
<thead>
<tr>
<th>Toxicity to daphnia and other aquatic invertebrates</th>
<th>EC50: &gt; 1 - 10 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 48 h</td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>

**Toxicity to algae/aquatic plants**

<table>
<thead>
<tr>
<th>Toxicity to algae/aquatic plants</th>
<th>EC50: &gt; 10 - 100 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 72 h</td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>

### clotrimazole:

**Toxicity to fish**

<table>
<thead>
<tr>
<th>Toxicity to fish</th>
<th>LC50 (Brachydanio rerio (zebrafish)): &gt; 0.29 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 96 h</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 203</td>
</tr>
</tbody>
</table>

**Toxicity to daphnia and other aquatic invertebrates**

<table>
<thead>
<tr>
<th>Toxicity to daphnia and other aquatic invertebrates</th>
<th>EC50 (Daphnia magna (Water flea)): 0.02 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 48 h</td>
</tr>
</tbody>
</table>

**Toxicity to algae/aquatic plants**

<table>
<thead>
<tr>
<th>Toxicity to algae/aquatic plants</th>
<th>EC50 (Desmodesmus subspicatus (green algae)): 0.268 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 72 h</td>
</tr>
<tr>
<td></td>
<td>NOEC (Desmodesmus subspicatus (green algae)): 0.017 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 72 h</td>
</tr>
</tbody>
</table>

**M-Factor (Acute aquatic toxicity)**

| M-Factor (Acute aquatic toxicity) | 10 |

**Toxicity to fish (Chronic toxicity)**

<table>
<thead>
<tr>
<th>Toxicity to fish (Chronic toxicity)</th>
<th>NOEC (Onchorhynchus mykiss (rainbow trout)): 0.025 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 32 d</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 210</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)</th>
<th>NOEC (Daphnia magna (Water flea)): 0.01 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 21 d</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 211</td>
</tr>
</tbody>
</table>

**M-Factor (Chronic aquatic toxicity)**

| M-Factor (Chronic aquatic toxicity) | 10 |

**Toxicity to microorganisms**

| Toxicity to microorganisms | EC50: > 10,000 mg/l |

**Remarks**

- Based on data from similar materials
### Benzyl alcohol:

**Toxicity to fish**
- **LC50** (Pimephales promelas (fathead minnow)): 460 mg/l
  - Exposure time: 96 h
- **Method**: OECD Test Guideline 209

**Toxicity to daphnia and other aquatic invertebrates**
- **EC50** (Daphnia magna (Water flea)): 230 mg/l
  - Exposure time: 48 h
  - **Method**: OECD Test Guideline 202

**Toxicity to algae/aquatic plants**
- **EC50** (Pseudokirchneriella subcapitata (green algae)): 770 mg/l
  - Exposure time: 72 h
  - **Method**: OECD Test Guideline 201

  **NOEC** (Pseudokirchneriella subcapitata (green algae)): 310 mg/l
  - Exposure time: 72 h
  - **Method**: OECD Test Guideline 201

**Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)**
- **NOEC** (Daphnia magna (Water flea)): 51 mg/l
  - Exposure time: 21 d
  - **Method**: OECD Test Guideline 211

### Gentamicin:

**Toxicity to daphnia and other aquatic invertebrates**
- **EC50** (Daphnia magna (Water flea)): 86 mg/l
  - Exposure time: 48 h
  - **Method**: OECD Test Guideline 202

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

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

  **NOEC** (Pseudokirchneriella subcapitata (green algae)): 1.5 µg/l
  - Exposure time: 72 h
  - **Method**: OECD Test Guideline 201

- **EC50** (Anabaena flos-aquae (cyanobacterium)): 4.7 µg/l
  - Exposure time: 72 h
  - **Method**: OECD Test Guideline 201

- **NOEC** (Anabaena flos-aquae (cyanobacterium)): 1.6 µg/l
  - Exposure time: 72 h
  - **Method**: OECD Test Guideline 201
SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

Clotrimazole / Gentamicin / Betamethasone
(0.05%) Formulation

Version 5.4 Revision Date: 09/13/2019
SDS Number: 610537-00011 Date of last issue: 2019/04/24
Date of first issue: 2016/04/29

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:

Petrolatum:
Biodegradability : Result: Not readily biodegradable.
Biodegradation: 31 %
Exposure time: 28 d
Method: OECD Test Guideline 301F
Remarks: Based on data from similar materials
Clotrimazole / Gentamicin / Betamethasone
(0.05%) Formulation

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

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

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

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

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

Bioaccumulative potential

Components:

Benzyl alcohol:
Partition coefficient: n-octanol/water: log Pow: 1.05

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

Betamethasone:
Partition coefficient: n-octanol/water: log Pow: 2.11

Mobility in soil
No data available

Other adverse effects
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 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
(betamethasone, clotrimazole)
Class : 9
Packing group : III
Labels : 9

IATA-DGR
UN/ID No. : UN 3082
Proper shipping name : Environmentally hazardous substance, liquid, n.o.s.
(betamethasone, clotrimazole)
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.
(betamethasone, clotrimazole)
Class : 9
Packing group : III
Labels : 9
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.

National Regulations

GB 6944/12268
UN number : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,
Clotrimazole / Gentamicin / Betamethasone
(0.05%) Formulation

Version 5.4 Revision Date: 09/13/2019 SDS Number: 610537-00011 Date of last issue: 2019/04/24
Date of first issue: 2016/04/29

N.O.S.
(betamethasone, clotrimazole)

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:

<table>
<thead>
<tr>
<th>Inventory</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>AICS</td>
<td>not determined</td>
</tr>
<tr>
<td>DSL</td>
<td>not determined</td>
</tr>
<tr>
<td>IECSC</td>
<td>not determined</td>
</tr>
</tbody>
</table>

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 Chemi-
SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

Clotrimazole / Gentamicin / Betamethasone
(0.05%) Formulation

Version 5.4  Revision Date: 09/13/2019  SDS Number: 610537-00011  Date of last issue: 2019/04/24
Date of first issue: 2016/04/29

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.

CN / EN