SAFETY DATA SHEET

Clotrimazole / Gentamicin / Betamethasone (0.05%) Formulation

Version 5.3  Revision Date: 23.03.2020  SDS Number: 610545-00012  Date of last issue: 13.09.2019
Date of first issue: 29.04.2016

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

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

Manufacturer or supplier’s details
Company name of supplier: MSD
Address: Avenida 16 de Septiembre No. 301
Xaltocan - Xochimilco Mexico 16090
Telephone: 52 55 57284444
Telefax: 908-735-1496
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com

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

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification
Reproductive toxicity: Category 1A
Specific target organ toxicity
- repeated exposure: Category 1 (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland)
Specific target organ toxicity
- repeated exposure (Oral): Category 2 (Liver, Kidney, Adrenal gland)

GHS label elements
Hazard pictograms: 

Signal Word: Danger

Hazard Statements:
H360Df May damage the unborn child. Suspected of damaging fertility.
H372 Causes damage to organs (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland) through prolonged or repeated exposure.
H373 May cause damage to organs (Liver, Kidney, Adrenal gland) through prolonged or repeated exposure if swallowed.

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 vapors.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

<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;= 5 - &lt; 10</td>
</tr>
<tr>
<td>Hexadecan-1-ol. Ethoxylated</td>
<td>9004-95-9</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
<tr>
<td>clotrimazole</td>
<td>23593-75-1</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
<tr>
<td>Benzyl alcohol</td>
<td>100-51-6</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
<tr>
<td>Gentamicin</td>
<td>1403-66-3</td>
<td>&gt;= 0.1 - &lt; 1</td>
</tr>
<tr>
<td>Betamethasone</td>
<td>378-44-9</td>
<td>&gt;= 0.01 - &lt; 0.1</td>
</tr>
</tbody>
</table>

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 : May damage the unborn child. Suspected of damaging fertility.
### SECTION 5. FIRE-FIGHTING MEASURES

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

**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.
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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 degowning 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>Petrolatum</td>
<td>8009-03-8</td>
<td>VLE-PPT (Mist)</td>
<td>5 mg/m³</td>
<td>NOM-010-STPS-2014</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Inhalable particulate matter)</td>
<td>5 mg/m³</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>


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<table>
<thead>
<tr>
<th>Version</th>
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</table>

<table>
<thead>
<tr>
<th>Paraffin oil</th>
<th>8012-95-1</th>
<th>VLE-PPT (Mist)</th>
<th>5 mg/m³</th>
<th>NOM-010-STPS-2014</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>TWA (Inhalable particulate matter)</td>
<td>5 mg/m³</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>

| Clotrimazole | 23593-75-1 | TWA | 0.2 mg/m³ (OEB 2) | Internal |
| Gentamicin   | 1403-66-3  | TWA | 0.1 mg/m³ (OEB 2) | Internal |
| Betamethasone| 378-44-9   | TWA | 1 µg/m³ (OEB 4)   | Internal |

**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.
- Wear a face shield 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**

- Wear 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 FLAMMABILITY LIMIT:
No data available

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

VISCOITY:
Viscosity, kinematic:
No data available

EXPLOSIVE PROPERTIES:
Not explosive

OXIDIZING PROPERTIES:
The substance or mixture is not classified as oxidizing.

PARTICLE SIZE:
Not applicable
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.

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:
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:
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:
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

**Benzyl 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

Respiratory or skin sensitization

Skin sensitization
Not classified based on available information.

Respiratory sensitization
Not classified based on available information.

Components:

Petrolatum:
Test Type: Buehler Test
Routes of exposure: Skin contact
Species: Guinea pig
Result: negative
Remarks: Based on data from similar materials

Benzyl alcohol:
Test Type: Maximization Test
Routes of exposure: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
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:
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

Clotrimazole:
Genotoxicity in vitro:
- Test Type: Bacterial reverse mutation assay (AMES) (Bacterial reverse mutation assay)
  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
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. Suspected of damaging fertility.

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

**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.
- Test Type: Embryo-fetal development
  - Species: Rat
  - Application Route: Oral
  - Developmental Toxicity: NOAEL: 50 mg/kg body weight
  - Result: Embryo-fetal toxicity., No teratogenic effects.
Test Type: Embryo-fetal development  
Species: Mouse  
Application Route: Oral  
Developmental Toxicity: NOAEL: 200 mg/kg body weight  
Result: No effects on fetal development.

Test Type: Embryo-fetal development  
Species: Rabbit  
Application Route: Oral  
Developmental Toxicity: NOAEL: 180 mg/kg body weight  
Result: No effects on fetal 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:  
Test Type: Fertility/early embryonic development  
Species: Rat  
Application Route: Ingestion  
Result: negative  
Remarks: Based on data from similar materials

Effects on fetal development:  
Test Type: Embryo-fetal 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 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.
May cause damage to organs (Liver, Kidney, Adrenal gland) through prolonged or repeated exposure if swallowed.

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,
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 y

**Paraffin oil:**

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

**clotrimazole:**

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

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


**Benzyal 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
<table>
<thead>
<tr>
<th>LOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
<th>Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 mg/kg</td>
<td>Intramuscular</td>
<td>12 Months</td>
<td>Kidney, Salivation</td>
<td></td>
</tr>
<tr>
<td>50 mg/kg</td>
<td>Subcutaneous</td>
<td>3 Weeks</td>
<td>Kidney, inner ear</td>
<td></td>
</tr>
<tr>
<td>6 mg/kg</td>
<td>Intramuscular</td>
<td>3 Weeks</td>
<td>Blood, Kidney, inner ear, Liver</td>
<td></td>
</tr>
<tr>
<td>5 mg/kg</td>
<td>Intramuscular</td>
<td>52 Weeks</td>
<td>Kidney, Blood</td>
<td></td>
</tr>
<tr>
<td>10 mg/kg</td>
<td>Intramuscular</td>
<td>13 Weeks</td>
<td>Kidney</td>
<td></td>
</tr>
</tbody>
</table>

**Betamethasone:**

<table>
<thead>
<tr>
<th>Species</th>
<th>LOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rabbit</td>
<td>0.05 %</td>
<td>Skin contact</td>
<td>10 - 30 d</td>
<td>Pituitary gland, Immune system, muscle</td>
</tr>
<tr>
<td>Rat</td>
<td>0.05 %</td>
<td>Skin contact</td>
<td>8 Weeks</td>
<td>thymus gland</td>
</tr>
<tr>
<td>Mouse</td>
<td>0.1 %</td>
<td>Skin contact</td>
<td>8 Weeks</td>
<td>thymus gland</td>
</tr>
<tr>
<td>Dog</td>
<td>0.05 mg/kg</td>
<td>Skin contact</td>
<td>8 Weeks</td>
<td>thymus gland</td>
</tr>
</tbody>
</table>
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, Edema, Redness
Ingestion: Symptoms: Abdominal pain, Nausea, Vomiting, Diarrhea

**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

**SECTION 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)): >= 100 mg/l
Exposure time: 72 h
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

<table>
<thead>
<tr>
<th>Substance</th>
<th>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)</th>
<th>Test substance</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paraffin oil</td>
<td>NOEC (Daphnia magna (Water flea)): 10 mg/l</td>
<td>Water Accommodated Fraction</td>
<td>21 d</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Substance</th>
<th>Toxicity to fish</th>
<th>Test substance</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paraffin oil</td>
<td>LL50 (Scophthalmus maximus (turbot)): &gt; 1,028 mg/l</td>
<td>Water Accommodated Fraction</td>
<td>96 h</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

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<thead>
<tr>
<th>Substance</th>
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<th>Test substance</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paraffin oil</td>
<td>EL50 (Acartia tonsa): &gt; 3,193 mg/l</td>
<td>Water Accommodated Fraction</td>
<td>48 h</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

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</tr>
</thead>
<tbody>
<tr>
<td>Paraffin oil</td>
<td>LC50: &gt; 1 - 10 mg/l</td>
<td>Water Accommodated Fraction</td>
<td>96 h</td>
<td>Based on data from similar materials</td>
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<tr>
<td>Paraffin oil</td>
<td>EC50: &gt; 10 - 100 mg/l</td>
<td>Water Accommodated Fraction</td>
<td>72 h</td>
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<tr>
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<th>Exposure time</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Paraffin oil</td>
<td>EC50 (Daphnia magna (Water flea)): 0.02 mg/l</td>
<td>Water Accommodated Fraction</td>
<td>48 h</td>
<td></td>
</tr>
</tbody>
</table>

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</tr>
</thead>
<tbody>
<tr>
<td>Paraffin oil</td>
<td>EC50 (Desmodesmus subspicatus (green algae)): 0.268 mg/l</td>
<td>Water Accommodated Fraction</td>
<td>72 h</td>
<td></td>
</tr>
</tbody>
</table>

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<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hexadecan-1-ol. Ethoxylated</td>
<td>LC50: &gt; 1 - 10 mg/l</td>
<td>Water Accommodated Fraction</td>
<td>96 h</td>
<td>Based on data from similar materials</td>
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</tbody>
</table>

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</thead>
<tbody>
<tr>
<td>Hexadecan-1-ol. Ethoxylated</td>
<td>EC50: &gt; 10 - 100 mg/l</td>
<td>Water Accommodated Fraction</td>
<td>72 h</td>
<td>Based on data from similar materials</td>
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<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clotrimazole</td>
<td>LC50 (Brachydanio rerio (zebrafish)): &gt; 0.29 mg/l</td>
<td>Water Accommodated Fraction</td>
<td>96 h</td>
<td>OECD Test Guideline 203</td>
</tr>
</tbody>
</table>

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<tr>
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<tr>
<td>Clotrimazole</td>
<td>EC50 (Daphnia magna (Water flea)): 0.02 mg/l</td>
<td>Water Accommodated Fraction</td>
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<tr>
<td>Clotrimazole</td>
<td>EC50 (Desmodesmus subspicatus (green algae)): 0.268 mg/l</td>
<td>Water Accommodated Fraction</td>
<td>72 h</td>
<td></td>
</tr>
</tbody>
</table>
plants
Exposure time: 72 h

NOEC (Desmodesmus subspicatus (green algae)): 0.017 mg/l
Exposure time: 72 h

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

Toxicity to microorganisms
EC50: > 10,000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

**Benzyl alcohol:**

Toxicity to fish
LC50 (Pimephales promelas (fathead minnow)): 460 mg/l
Exposure time: 96 h

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

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

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

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

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

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

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

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. (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.

Domestic regulation

NOM-002-SCT
UN number: UN 3082
SAFETY DATA SHEET

Clotrimazole / Gentamicin / Betamethasone (0.05%) Formulation

Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, 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.

SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture
Federal Law for the control of chemical precursors, essential chemical products and machinery for producing capsules, tablets and pills: Not applicable

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

SECTION 16. OTHER INFORMATION

Full text of other abbreviations
ACGIH: USA. ACGIH Threshold Limit Values (TLV)
NOM-010-STPS-2014: Mexico. Norm NOM-010-STPS-2014 on Chemicals Polluting the Work Environment - Identification, Assessment and Control - Appendix 1 Occupational Exposure Limits
ACGIH / TWA: 8-hour, time-weighted average
NOM-010-STPS-2014 / VLE-PPT: Time weighted average limit value

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; ICS0 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemi-
SAFETY DATA SHEET

Clotrimazole / Gentamicin / Betamethasone (0.05%) Formulation

Version 5.3  Revision Date: 23.03.2020  SDS Number: 610545-00012  Date of last issue: 13.09.2019
Date of first issue: 29.04.2016


Revision Date: 23.03.2020

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

MX / Z8