SAFETY DATA SHEET

Clotrimazole / Gentamicin / Betamethasone (0.05%) Formulation

SECTION 1. IDENTIFICATION

Product name: Clotrimazole / Gentamicin / Betamethasone (0.05%) Formulation
Other means of identification: No data available

Manufacturer or supplier’s details
Company name of supplier: Merck & Co., Inc
Address: 2000 Galloping Hill Road
Kenilworth - New Jersey - U.S.A. 07033
Telephone: 908-740-4000
Telefax: 908-735-1496
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATASTEWARD@merck.com

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

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the Hazardous Products Regulations
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.
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P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P308 + P313 IF exposed or concerned: Get medical advice/ attention.

Storage:
P405 Store locked up.

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

Other hazards
None known.

SECTION 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; 30</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>&gt;= 10 - &lt; 30</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>

Actual concentration or concentration range is withheld as a trade secret

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.

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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. Suspected of damaging fertility. Causes damage to organs through prolonged or repeated exposure.

Protection of first-aiders: First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician: Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media: Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
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
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absorbent. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

Technical measures: See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation: If sufficient ventilation is unavailable, use with local exhaust ventilation.

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

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>TWA (Mist)</td>
<td>5 mg/m³</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL (Mist)</td>
<td>10 mg/m³</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWAEV (Mist)</td>
<td>5 mg/m³</td>
<td>CA QC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEV (Mist)</td>
<td>10 mg/m³</td>
<td>CA QC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Mist)</td>
<td>1 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Inhalable fraction)</td>
<td>5 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>TWA (aerosol)</td>
<td>10 mg/m³</td>
<td>CA ON OEL</td>
</tr>
</tbody>
</table>
**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.

<table>
<thead>
<tr>
<th>Material</th>
<th>Chemical-resistant gloves</th>
</tr>
</thead>
</table>

**Eye protection:** Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

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

<table>
<thead>
<tr>
<th>Substance</th>
<th>TWA (Inhalable fraction)</th>
<th>50 ppm 155 mg/m³</th>
<th>CA ON OEL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paraffin oil</td>
<td>8012-95-1 TWA (Mist)</td>
<td>5 mg/m³</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td>STEL (Mist)</td>
<td>10 mg/m³</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td>TWAEV (Mist)</td>
<td>5 mg/m³</td>
<td>CA QC OEL</td>
</tr>
<tr>
<td></td>
<td>STEV (Mist)</td>
<td>10 mg/m³</td>
<td>CA QC OEL</td>
</tr>
<tr>
<td></td>
<td>TWA (Mist)</td>
<td>1 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td>TWA (Inhalable fraction)</td>
<td>5 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Clotrimazole</td>
<td>23593-75-1 TWA</td>
<td>0.2 mg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Gentamicin</td>
<td>1403-66-3 TWA</td>
<td>0.1 mg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Betamethasone</td>
<td>378-44-9 TWA</td>
<td>1 µg/m³ (OEB 4)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Further information: Skin Wipe limit 10 µg/100 cm² Internal
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.

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
SAFETY DATA SHEET

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Autoignition temperature : No data available
Decomposition temperature : No data available
Viscosity
  Viscosity, kinematic : No data available
Explosive properties : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.
Particle size : Not applicable

SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous 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
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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

Propylene glycol:

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

Acute inhalation toxicity
LC50 (Rabbit): > 159 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist

Acute dermal toxicity
LD50 (Rabbit): > 2,000 mg/kg
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

Propylene glycol:
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation

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

**Propylene glycol:**
Species : Rabbit
Result : No eye irritation
Method : OECD Test Guideline 405

**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

Propylene glycol:
Test Type : Maximization Test
Routes of exposure : Skin contact
Species : Guinea pig
Result : negative

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
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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

Propylene glycol:
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

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.
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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
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<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.2</td>
<td>09/13/2019</td>
<td>610534-00011</td>
<td>04/24/2019</td>
</tr>
</tbody>
</table>

---

**Propylene glycol:**
- **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

**Propylene glycol:**
- **Effects on fertility:** Test Type: Three-generation reproduction toxicity study  
  Species: Mouse  
  Application Route: Ingestion  
  Result: negative

- **Effects on fetal development:** Test Type: Embryo-fetal development  
  Species: Mouse
clotrimazole:

Effects on fertility: Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Oral
Fertility: LOAEL: 50 mg/kg body weight
Result: Effects on fertility.

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

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

Gentamicin:

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
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.
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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, 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 y

Propylene glycol:
Species: Rat, male
NOAEL: 1,700 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  
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  
Application Route : Intramuscular  
Exposure time : 52 Weeks  
Target Organs : Kidney, Blood  
Species : Rat
### SAFETY DATA SHEET

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

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
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<td>4.2</td>
<td>09/13/2019</td>
<td>610534-00011</td>
<td>04/24/2019</td>
<td>04/29/2016</td>
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</table>

**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, Edema, Redness

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

**Gentamicin**

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

- 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

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

Propylene glycol:
Toxicity to fish: LC50 (Onchorhynchus mykiss (rainbow trout)): 40,613 mg/l
  Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates: EC50 (Ceriodaphnia dubia (water flea)): 18,340 mg/l
  Exposure time: 48 h

Toxicity to algae/aquatic plants: ErC50 (Skeletonema costatum (marine diatom)): 19,300 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC (Ceriodaphnia dubia (water flea)): 13,020 mg/l
  Exposure time: 7 d

Toxicity to microorganisms: NOEC (Pseudomonas putida): > 20,000 mg/l
  Exposure time: 18 h

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:
- EL50 (Skeletonema costatum (marine diatom)): > 3,200 mg/l
  Exposure time: 72 h
  Test substance: Water Accommodated Fraction
  Remarks: Based on data from similar materials

  NOELR (Skeletonema costatum (marine diatom)): 993 mg/l
  Exposure time: 72 h
  Test substance: Water Accommodated Fraction
  Remarks: Based on data from similar materials

Hexadecan-1-ol. Ethoxylated:
- Toxicity to fish:
  - LC50: > 1 - 10 mg/l
    Exposure time: 96 h
    Remarks: Based on data from similar materials

- Toxicity to daphnia and other aquatic invertebrates:
  - EC50: > 1 - 10 mg/l
    Exposure time: 48 h
    Remarks: Based on data from similar materials

- Toxicity to algae/aquatic plants:
  - EC50: > 10 - 100 mg/l
    Exposure time: 72 h
    Remarks: Based on data from similar materials

Clotrimazole:
- Toxicity to fish:
  - LC50 (Brachydanio rerio (zebrafish)): > 0.29 mg/l
    Exposure time: 96 h
    Method: OECD Test Guideline 203

- Toxicity to daphnia and other aquatic invertebrates:
  - EC50 (Daphnia magna (Water flea)): 0.02 mg/l
    Exposure time: 48 h

- Toxicity to algae/aquatic plants:
  - EC50 (Desmodesmus subspicatus (green algae)): 0.268 mg/l
    Exposure time: 72 h

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

- 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:
  - NOEC (Daphnia magna (Water flea)): 0.01 mg/l
### Aquatic Invertebrates

<table>
<thead>
<tr>
<th>Component</th>
<th>Toxicity to microorganisms</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>EC50: &gt; 10,000 mg/l</td>
<td>OECD Test Guideline 209</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 3 h</td>
<td></td>
</tr>
<tr>
<td></td>
<td>EC50 (Pimephales promelas)</td>
<td>OECD Test Guideline 211</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 21 d</td>
<td></td>
</tr>
<tr>
<td></td>
<td>NOEC (Daphnia magna)</td>
<td>OECD Test Guideline 211</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 21 d</td>
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</table>

### Benzyl Alcohol

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<tr>
<th>Component</th>
<th>Toxicity to fish</th>
<th>Method</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>LC50: 460 mg/l</td>
<td>OECD Test Guideline 201</td>
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<td>Exposure time: 96 h</td>
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</table>

### Gentamicin

<table>
<thead>
<tr>
<th>Component</th>
<th>Toxicity to daphnia and other aquatic invertebrates</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>EC50 (Pimephales promelas)</td>
<td>OECD Test Guideline 209</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 48 h</td>
<td></td>
</tr>
<tr>
<td></td>
<td>LC50 (Amecimys)</td>
<td>US-EPA OPPTS 850.1035</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 96 h</td>
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</tr>
</tbody>
</table>

### EC50 (Pseudokirchneriella subcapitata)

<table>
<thead>
<tr>
<th>Component</th>
<th>Toxicity to algae/aquatic plants</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>EC50: 770 mg/l</td>
<td>OECD Test Guideline 201</td>
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<td></td>
<td>Exposure time: 72 h</td>
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<tr>
<td></td>
<td>NOEC: 310 mg/l</td>
<td>OECD Test Guideline 201</td>
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<td></td>
<td>Exposure time: 72 h</td>
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</table>

### Gentamicin

<table>
<thead>
<tr>
<th>Component</th>
<th>Toxicity to algae/aquatic plants</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>EC50: 4.7 µg/l</td>
<td>OECD Test Guideline 201</td>
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<td></td>
<td>Exposure time: 72 h</td>
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### Gentamicin

<table>
<thead>
<tr>
<th>Component</th>
<th>Toxicity to algae/aquatic plants</th>
<th>Method</th>
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<tbody>
<tr>
<td></td>
<td>NOEC: 1.5 µg/l</td>
<td>OECD Test Guideline 201</td>
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<tr>
<td></td>
<td>Exposure time: 72 h</td>
<td></td>
</tr>
<tr>
<td></td>
<td>EC50 (Anabaena flos-aquae)</td>
<td>OECD Test Guideline 201</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 72 h</td>
<td></td>
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</tbody>
</table>
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:  
Exposure time: 72 h  
Method: OECD Test Guideline 201

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

Propylene glycol:  
Biodegradability:  
Result: Readily biodegradable.  
Biodegradation: 98.3 %  
Exposure time: 28 d
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:
Propylene glycol:
Partition coefficient: n-octanol/water: log Pow: -1.07

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
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**

**TDG**
UN number: UN 3082
Proper shipping name  :  ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,
                          N.O.S.  
                          (Betamethasone, clotrimazole)
Class : 9
Packing group : III
Labels : 9
ERG Code : 171
Marine pollutant : yes (Betamethasone, clotrimazole)

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

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)
CA AB OEL : Canada. Alberta, Occupational Health and Safety Code (table
            2: OEL)
CA BC OEL : Canada. British Columbia OEL
CA ON OEL : Ontario Table of Occupational Exposure Limits made under
            the Occupational Health and Safety Act.
CA QC OEL : Québec. Regulation respecting occupational health and safe-
            ty, Schedule 1, Part 1: Permissible exposure values for air-
            borne contaminants
ACGIH / TWA : 8-hour, time-weighted average
CA AB OEL / TWA : 8-hour Occupational exposure limit
CA AB OEL / STEL : 15-minute occupational exposure limit
CA BC OEL / TWA : 8-hour time weighted average
CA ON OEL / TWA : Time-Weighted Average Limit (TWA)
CA QC OEL / TWAEV : Time-weighted average exposure value
CA QC OEL / STEV : Short-term exposure 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 Sys-

Revision Date: 09/13/2019

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.

CA / Z8