SAFETY DATA SHEET

Betamethasone / Clotrimazole Cream Formulation

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Betamethasone / Clotrimazole Cream Formulation

Manufacturer or supplier's details
Company : MSD
Address : Rua Treze de Maio, 1161
Campinas, São Paulo, Brazil 13106-054
Telephone : 908-740-4000
Emergency telephone : 55 19 3758 2000
E-mail address : EHSDATASTEWARD@msd.com
Telefax : 908-735-1496

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

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification in accordance with ABNT NBR 14725 Standard

Reproductive toxicity : Category 1B
Specific target organ toxicity - repeated exposure : Category 1 (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland)
Short-term (acute) aquatic hazard : Category 2
Long-term (chronic) aquatic hazard : Category 1

GHS label elements in accordance with ABNT NBR 14725 Standard

Hazard pictograms :

Signal Word : Danger
Hazard Statements :
H360D May damage the unborn child.
H372 Causes damage to organs (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland) through prolonged or repeated exposure.
H401 Toxic to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.
Precautionary Statements

Prevention:
- P201 Obtain special instructions before use.
- P264 Wash skin thoroughly after handling.
- P273 Avoid release to the environment.
- P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
- P308 + P313 IF exposed or concerned: Get medical advice/ attention.
- P391 Collect spillage.

Other hazards which do not result in classification
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Mixture</th>
</tr>
</thead>
</table>

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Petrolatum</td>
<td>8009-03-8</td>
<td></td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>White mineral oil (petroleum)</td>
<td>8042-47-5</td>
<td></td>
<td>&gt;= 5 - &lt; 10</td>
</tr>
<tr>
<td>Alcohols, C16-18, ethoxylated</td>
<td>68439-49-6</td>
<td>Short-term (acute) aquatic hazard, Category 2</td>
<td>&gt;= 1 - &lt; 2,5</td>
</tr>
<tr>
<td>Clotrimazole</td>
<td>23593-75-1</td>
<td>Acute toxicity (Oral), Category 4</td>
<td>&gt;= 1 - &lt; 2,5</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Acute toxicity (Dermal), Category 3</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Eye irritation, Category 2B</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Reproductive toxicity, Category 2B</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Specific target organ toxicity - repeated exposure (Oral) (Liver, Kidney, Adrenal gland), Category 2</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Short-term (acute) aquatic hazard, Category 1</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Long-term (chronic) aquatic hazard, Category 1</td>
<td></td>
</tr>
<tr>
<td>Betamethasone</td>
<td>378-44-9</td>
<td>Acute toxicity (Inhalation), Category 2</td>
<td>&gt;= 0,025 - &lt; 0,1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Reproductive toxicity, Category 1B</td>
<td></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 delayed: May damage the unborn child. Causes damage to organs through prolonged or repeated exposure.

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

Notes to physician: Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

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

Unsuitable extinguishing media: None known.

Specific hazards during firefighting: Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Carbon oxides
Specific extinguishing methods: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.

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

SECTION 6. ACCIDENTAL RELEASE MEASURES

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

Environmental precautions: Discharge into the environment must be avoided. Prevent further leakage or spillage if safe to do so. Prevent spreading over a wide area (e.g., by containment or oil barriers). Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.

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

SECTION 7. HANDLING AND STORAGE

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

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

Advice on safe handling: Do not get on skin or clothing. Do not breathe vapors or spray mist. Do not swallow. Avoid contact with eyes. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment. Keep container tightly closed. Take care to prevent spills, waste and minimize release to the environment.
Hygiene measures: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate 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>TWA (Inhalable particulate matter)</td>
<td>5 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>White mineral oil (petroleum)</td>
<td>8042-47-5</td>
<td>TWA (Inhalable particulate matter)</td>
<td>5 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>clotrimazole</td>
<td>23593-75-1</td>
<td>TWA</td>
<td>0.2 mg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Betamethasone</td>
<td>378-44-9</td>
<td>TWA</td>
<td>1 µg/m³ (OEB 4)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: Skin</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>Internal</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.

Filter type: Combined particulates and organic vapor type

Hand protection: Chemical-resistant gloves

Eye protection:
- Material: Chemical-resistant gloves
- Remarks: Consider double gloving.
- Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

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

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: cream

Color: white to off-white

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 : No data available
Autoignition temperature : No data available
Decomposition temperature : No data available
Viscosity
  Viscosity, kinematic : Not applicable
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 dermal toxicity : Acute toxicity estimate: > 5.000 mg/kg
Method: Calculation method

**Components:**

**Petrolatum:**
- **Acute oral toxicity**: LD50 (Rat): > 5.000 mg/kg
  Method: OECD Test Guideline 401
  Remarks: Based on data from similar materials
- **Acute dermal toxicity**: LD50 (Rat): > 2.000 mg/kg
  Method: OECD Test Guideline 402
  Assessment: The substance or mixture has no acute dermal toxicity
  Remarks: Based on data from similar materials

**White mineral oil (petroleum):**
- **Acute oral toxicity**: LD50 (Rat): > 5.000 mg/kg
- **Acute inhalation toxicity**: LC50 (Rat): > 5 mg/l
  Exposure time: 4 h
  Test atmosphere: dust/mist
  Assessment: The substance or mixture has no acute inhalation toxicity
- **Acute dermal toxicity**: LD50 (Rabbit): > 2.000 mg/kg
  Assessment: The substance or mixture has no acute dermal toxicity

**Alcohols, C16-18, ethoxylated:**
- **Acute oral toxicity**: LD50 (Rat): > 2.000 mg/kg
  Remarks: Based on data from similar materials

**Clotrimazole:**
- **Acute oral toxicity**: LD50 (Rat): 708 mg/kg
  LD50 (Mouse): 761 mg/kg
  LD50 (Rabbit): > 1.000 mg/kg
- **Acute inhalation toxicity**: LC50 (Rat): > 0,73 mg/l
  Exposure time: 4 h
  Test atmosphere: dust/mist
- **Acute dermal toxicity**: LD50 (Mouse): 923 mg/kg

**Betamethasone:**
- **Acute oral toxicity**: LD50 (Rat): > 5.000 mg/kg
  LD50 (Mouse): > 4.500 mg/kg
SAFETY DATA SHEET

Betamethasone / Clotrimazole Cream Formulation

Version 7.0  Revision Date: 23.03.2020  SDS Number: 412893-00013  Date of last issue: 13.09.2019  Date of first issue: 14.12.2015

Acute inhalation toxicity: LC50 (Rat): 0.4 mg/l  Exposure time: 4 h

Skin corrosion/irritation:
Not classified based on available information.

Components:

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

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

Alcohols, C16-18, ethoxylated:
- Species: Rabbit
- Method: OECD Test Guideline 404
- Result: No skin irritation
- Remarks: Based on data from similar materials

Clotrimazole:
- Species: Rabbit
- Result: No skin irritation

Betamethasone:
- Species: Rabbit
- Result: Mild skin irritation

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

Components:

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

White mineral oil (petroleum):
- Species: Rabbit
- Result: No eye irritation
Alcohols, C16-18, ethoxylated:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>No eye irritation</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 405</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

clotrimazole:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>Mild eye irritation</td>
</tr>
</tbody>
</table>

Betamethasone:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>No eye irritation</td>
</tr>
</tbody>
</table>

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:

Petrolatum:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Buehler Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Routes of exposure</td>
<td>Skin contact</td>
</tr>
<tr>
<td>Species</td>
<td>Guinea pig</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

White mineral oil (petroleum):

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Buehler Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Routes of exposure</td>
<td>Skin contact</td>
</tr>
<tr>
<td>Species</td>
<td>Guinea pig</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

Alcohols, C16-18, ethoxylated:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Buehler Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Routes of exposure</td>
<td>Skin contact</td>
</tr>
<tr>
<td>Species</td>
<td>Guinea pig</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 406</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

Betamethasone:

<table>
<thead>
<tr>
<th>Routes of exposure</th>
<th>Dermal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species</td>
<td>Guinea pig</td>
</tr>
<tr>
<td>Result</td>
<td>Weak sensitizer</td>
</tr>
</tbody>
</table>
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

White mineral oil (petroleum):
- Genotoxicity in vitro: Test Type: In vitro mammalian cell gene mutation test
  Result: negative

- Genotoxicity in vivo: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
  Species: Mouse
  Application Route: Intraperitoneal injection
  Method: OECD Test Guideline 474
  Result: negative
  Remarks: Based on data from similar materials

Alcohols, C16-18, ethoxylated:
- Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
  Method: OECD Test Guideline 471
  Result: negative
  Remarks: Based on data from similar materials

  Test Type: In vitro mammalian cell gene mutation test
  Method: OECD Test Guideline 476
  Result: negative
  Remarks: Based on data from similar materials

  Test Type: Chromosome aberration test in vitro
  Method: OECD Test Guideline 473
  Result: negative
  Remarks: Based on data from similar materials

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

  Test Type: Chromosome aberration test in vitro
  Result: negative
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.

Betamethasone:

Genotoxicity in vitro:

- Test Type: Bacterial reverse mutation assay (AMES)
  - Result: negative

- Test Type: In vitro mammalian cell gene mutation test
  - Result: negative

- Test Type: Chromosome aberration test in vitro
  - Result: positive

Genotoxicity in vivo:

- Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
  - Species: Mouse
  - Application Route: Oral
  - Result: equivocal

Germ cell mutagenicity - Assessment:

- Weight of evidence does not support classification as a germ cell mutagen.

Carcinogenicity:

Not classified based on available information.

Components:

Petrolatum:

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

White mineral oil (petroleum):

- Species: Rat
- Application Route: Ingestion
- Exposure time: 24 Months
Result : negative

**Reproductive toxicity**
May damage the unborn child.

**Components:**

**Petrolatum:**

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

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

**White mineral oil (petroleum):**

**Effects on fertility**: Test Type: One-generation reproduction toxicity study  
Species: Rat  
Application Route: Skin contact  
Result: negative

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

**Alcohols, C16-18, ethoxylated:**

**Effects on fertility**: Test Type: Two-generation reproduction toxicity study  
Species: Rat  
Application Route: Skin contact  
Result: negative  
Remarks: Based on data from similar materials

**Effects on fetal development**: Test Type: Two-generation reproduction toxicity study  
Species: Rat  
Application Route: Skin contact  
Result: negative  
Remarks: Based on data from similar materials
### clortimazole:

<table>
<thead>
<tr>
<th>Effects on fertility</th>
<th>Test Type: Fertility/early embryonic development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Rat</td>
<td></td>
</tr>
<tr>
<td>Application Route: Oral</td>
<td></td>
</tr>
<tr>
<td>Fertility: LOAEL: 50 mg/kg body weight</td>
<td></td>
</tr>
<tr>
<td>Result: Effects on fertility.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Effects on fetal development</th>
<th>Test Type: Embryo-fetal development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Rat</td>
<td></td>
</tr>
<tr>
<td>Application Route: Oral</td>
<td></td>
</tr>
<tr>
<td>Developmental Toxicity: LOAEL: 100 mg/kg body weight</td>
<td></td>
</tr>
<tr>
<td>Result: Embryo-fetal toxicity., No teratogenic effects.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Reproductive toxicity - Assessment</th>
<th>Test Type: Embryo-fetal development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Mouse</td>
<td></td>
</tr>
<tr>
<td>Application Route: Oral</td>
<td></td>
</tr>
<tr>
<td>Developmental Toxicity: NOAEL: 50 mg/kg body weight</td>
<td></td>
</tr>
<tr>
<td>Result: Embryo-fetal toxicity., No teratogenic effects.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Reproductive toxicity - Assessment</th>
<th>Test Type: Embryo-fetal development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Mouse</td>
<td></td>
</tr>
<tr>
<td>Application Route: Oral</td>
<td></td>
</tr>
<tr>
<td>Developmental Toxicity: NOAEL: 200 mg/kg body weight</td>
<td></td>
</tr>
<tr>
<td>Result: No effects on fetal development.</td>
<td></td>
</tr>
</tbody>
</table>

### Betamethasone:

<table>
<thead>
<tr>
<th>Effects on fetal development</th>
<th>Species: Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route: Intramuscular</td>
<td></td>
</tr>
<tr>
<td>Developmental Toxicity: LOAEL: 0,05 mg/kg body weight</td>
<td></td>
</tr>
<tr>
<td>Result: Fetotoxicity., Malformations were observed.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species: Rat</th>
<th>Application Route: Subcutaneous</th>
</tr>
</thead>
<tbody>
<tr>
<td>Developmental Toxicity: LOAEL: 0,42 mg/kg body weight</td>
<td></td>
</tr>
<tr>
<td>Result: Malformations were observed.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species: Mouse</th>
<th>Application Route: Intramuscular</th>
</tr>
</thead>
<tbody>
<tr>
<td>Developmental Toxicity: LOAEL: 1 mg/kg body weight</td>
<td></td>
</tr>
<tr>
<td>Result: Malformations were observed.</td>
<td></td>
</tr>
</tbody>
</table>

| Reproductive toxicity - Assessment | Clear evidence of adverse effects on development, based on animal experiments. |
**STOT-s单exposure**
Not classified based on available information.

**STOT- repeated exposure**
Causes damage to organs (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland) through prolonged or repeated exposure.

**Components:**

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

**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

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

**Alcohols, C16-18, ethoxylated:**
- **Species:** Rat
- **NOAEL:** > 100 mg/kg
- **Application Route:** Ingestion
- **Exposure time:** 90 Days
- **Method:** OECD Test Guideline 408
- **Remarks:** Based on data from similar materials
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

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

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

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

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

**Aspiration toxicity**
- Not classified based on available information.
Experience with human exposure

Components:

Clotrimazole:
- Skin contact: Symptoms: Rash, Itching, Blistering, Edema, Redness
- Ingestion: Symptoms: Abdominal pain, Nausea, Vomiting, Diarrhea

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

White mineral oil (petroleum):
- Toxicity to fish: LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l
  Exposure time: 96 h
  Method: OECD Test Guideline 203

- Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 100 mg/l
  Exposure time: 48 h
  Method: OECD Test Guideline 202

- Toxicity to algae/aquatic plants: NOEC (Pseudokirchneriella subcapitata (green algae)): 100 mg/l
**Toxicity to fish (Chronic toxicity):**

- NOEC (Oncorhynchus mykiss (rainbow trout)): 1.000 mg/l
  - Exposure time: 28 d

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

- NOEC (Daphnia magna (Water flea)): 1.000 mg/l
  - Exposure time: 21 d

### Alcohols, C16-18, ethoxylated:

**Toxicity to fish:**

- LC50 (Leuciscus idus (Golden orfe)): > 1 - 10 mg/l
  - Exposure time: 96 h

**Toxicity to daphnia and other aquatic invertebrates:**

- EC50 (Daphnia magna (Water flea)): > 100 mg/l
  - Exposure time: 48 h
  - Remarks: Based on data from similar materials

### clotrimazole:

**Toxicity to fish:**

- LC50 (Brachydanio rerio (zebrafish)): > 0,29 mg/l
  - Exposure time: 96 h

**Toxicity to daphnia and other aquatic invertebrates:**

- EC50 (Daphnia magna (Water flea)): 0,02 mg/l
  - Exposure time: 48 h
- 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

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

- 10

**Toxicity to fish (Chronic toxicity):**

- NOEC (Oncorhynchus mykiss (rainbow trout)): 0,025 mg/l
  - Exposure time: 32 d

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

- NOEC (Daphnia magna (Water flea)): 0,01 mg/l
  - Exposure time: 21 d

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

- 10

**Toxicity to microorganisms:**

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

### Betamethasone:

**Toxicity to daphnia and other aquatic invertebrates:**

- EC50 (Americamysis): > 50 mg/l
  - Exposure time: 96 h
Toxicity to algae/aquatic plants:  
EC50 (Pseudokirchneriella subcapitata (green algae)): > 34 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
Remarks: No toxicity at the limit of solubility.

NOEC (Pseudokirchneriella subcapitata (green algae)): 34 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
Remarks: No toxicity at the limit of solubility.

Toxicity to fish (Chronic toxicity):  
NOEC (Pimephales promelas (fathead minnow)): 0.052 mg/l  
Exposure time: 32 d  
Method: OECD Test Guideline 210

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

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

M-Factor (Chronic aquatic toxicity): 1.000

Persistence and degradability

Components:

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

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

Alcohols, C16-18, ethoxylated:  
Biodegradability: Result: Readily biodegradable.  
Biodegradation: > 60 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301B  
Remarks: Based on data from similar materials

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

Bioaccumulative potential:

Components:

Alcohols, C16-18, ethoxylated:

Bioaccumulation: Species: Fish
Bioconcentration factor (BCF): < 500
Remarks: Based on data from similar materials

Partition coefficient: n-octanol/water: log Pow: > 4

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. (clotrimazole, betamethasone)

Class: 9
Packing group: III
Labels: 9

IATA-DGR
UN/ID No.: UN 3082
Proper shipping name: Environmentally hazardous substance, liquid, n.o.s. (clotrimazole, Betamethasone)

Class: 9
Packing group: III
Labels: Miscellaneous
Packing instruction (cargo aircraft): 964
SAFETY DATA SHEET

Betamethasone / Clotrimazole Cream Formula-
tion

Version  7.0  Revision Date:  23.03.2020  SDS Number:  412893-00013  Date of last issue:  13.09.2019

Date of first issue:  14.12.2015

Packing instruction (passen-
ger aircraft):  964
Environmentally hazardous:  yes

IMDG-Code
UN number:  UN 3082
Proper shipping name:  ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,
N.O.S.  (clotrimazole, Betamethasone)
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

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

Special precautions for user
The transport classification(s) provided herein are for informational purposes only, and solely
based upon the properties of the unpackaged material as it is described within this Safety Data
Sheet. Transportation classifications may vary by mode of transportation, package sizes, and
variations in regional or country regulations.

SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or
mixture
National List of Carcinogenic Agents for Humans - (LINACH):  Not applicable

Brazil. List of chemicals controlled by the Federal Police:  Phosphoric acid

International Regulations
The ingredients of this product are reported in the following inventories:
AICS:  not determined
DSL:  not determined
SAFETY DATA SHEET

Betamethasone / Clotrimazole Cream Formula-

Version 7.0  Revision Date: 23.03.2020  SDS Number: 412893-00013  Date of last issue: 13.09.2019  Date of first issue: 14.12.2015

IECSC : not determined

SECTION 16. OTHER INFORMATION

Further information

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

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

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.

BR / Z8