SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Betamethasone / Clotrimazole Cream Formulation

Manufacturer or supplier’s details
Company : MSD
Address : 26 Talavera Road, Talavera Corp Centre, Macquarie Park, New South Wales, 2113 Australia
Telephone : (61)-02-8988-8000
Emergency telephone number : (61)-02-8988-8000
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
Reproductive toxicity : Category 1B
Specific target organ toxicity - repeated exposure : Category 1 (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland)

GHS label elements
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.

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

Betamethasone / Clotrimazole Cream Formula-
tion

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>&lt; 10</td>
</tr>
<tr>
<td>White mineral oil (petroleum)</td>
<td>8042-47-5</td>
<td>&lt; 10</td>
</tr>
<tr>
<td>clotrimazole</td>
<td>23593-75-1</td>
<td>&lt; 3</td>
</tr>
<tr>
<td>betamethasone</td>
<td>378-44-9</td>
<td>&gt;= 0.01 -&lt; 0.3</td>
</tr>
</tbody>
</table>

SECTION 4. FIRST AID MEASURES

General advice :
  In the case of accident or if you feel unwell, seek medical ad-
  vice 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
SECTION 5. FIREFIGHTING MEASURES

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

Unsuitable extinguishing media : None known.

Specific hazards during fire-fighting

Hazardous combustion products : Exposure to combustion products may be a hazard to health.
Carbon oxides

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

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

Hazchem Code : •3Z

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 dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.
Clean up remaining materials from spill with suitable absorbent.
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.
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 vapours or spray mist.
- Do not swallow.
- Avoid contact with eyes.
- Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
- Keep container tightly closed.
- Take care to prevent spills, waste and minimize release to the environment.

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 labelled containers.
- Store locked up.
- Keep tightly closed.
- Store in accordance with the particular national regulations.

Materials to avoid:
- Do not store with the following product types: Strong oxidizing agents

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Petrolatum</td>
<td>8009-03-8</td>
<td>TWA (Mist)</td>
<td>5 mg/m³</td>
<td>AU OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Inhalable particulate matter)</td>
<td>5 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>TWA (particulate)</td>
<td>10 mg/m³</td>
<td>AU OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Total (vapour and particles))</td>
<td>150 ppm 474 mg/m³</td>
<td>AU OEL</td>
</tr>
<tr>
<td>White mineral oil (petroleum)</td>
<td>8042-47-5</td>
<td>TWA (Mist)</td>
<td>5 mg/m³</td>
<td>AU OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Inhalable particulate)</td>
<td>5 mg/m³</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Betamethasone / Clotrimazole Cream Formula-
tion

<table>
<thead>
<tr>
<th>Chemical</th>
<th>TWA</th>
<th>Exposure Guideline Level</th>
<th>Route of Exposure</th>
</tr>
</thead>
<tbody>
<tr>
<td>clotrimazole</td>
<td>23593-75-1</td>
<td>0.2 mg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>betamethasone</td>
<td>378-44-9</td>
<td>1 µg/m³ (OEB 4)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

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

Engineering measures : All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Essentially no open handling permitted. Use closed processing systems or containment technologies. If handled in a laboratory, use a properly designed biosafety cabinet, fume hood, or other containment device if the potential exists for aerosolization. If this potential does not exist, handle over lined trays or benchtops.

Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type : Combined particulates and organic vapour type

Hand protection Material : Chemical-resistant gloves

Remarks : Consider double gloving.

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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : cream

Colour : white to off-white

Odour : No data available

Odour Threshold : No data available

pH : No data available

Melting point/freezing point : No data available
SAFETY DATA SHEET

Betamethasone / Clotrimazole Cream Formula-
tion

Version 4.5
Revision Date: 23.03.2020
SDS Number: 412891-00013
Date of last issue: 13.09.2019
Date of first issue: 14.12.2015

Initial boiling point and boiling range: No data available
Flash point: No data available
Evaporation rate: No data available
Flammability (solid, gas): Not applicable
Flammability (liquids): No data available
Upper explosion limit / Upper flammability limit: No data available
Lower explosion limit / Lower flammability limit: No data available
Vapour pressure: No data available
Relative vapour density: No data available
Relative density: No data available
Density: No data available
Solubility(ies)
   Water solubility: No data available
Partition coefficient: n-octanol/water: No data available
Auto-ignition 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**

**Exposure routes**
- Inhalation
- Skin contact
- Ingestion
- Eye contact

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

**Product**
- **Acute oral toxicity**
  - Acute toxicity estimate: > 2,000 mg/kg
  - Method: Calculation method

- **Acute dermal toxicity**
  - Acute toxicity estimate: > 2,000 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

**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

**White mineral oil (petroleum)**
- **Acute oral toxicity**
  - LD50 (Rat): > 5,000 mg/kg

- **Acute inhalation toxicity**
  - LC50 (Rat): > 5 mg/l
  - Exposure time: 4 h
  - Test atmosphere: dust/mist
  - Assessment: The substance or mixture has no acute inhalation toxicity
Acute dermal toxicity: LD50 (Rabbit): > 2,000 mg/kg
Assessment: The substance or mixture has no acute dermal toxicity

**clotrimazole:**

Acute oral toxicity: LD50 (Rat): 708 mg/kg
LD50 (Mouse): 761 mg/kg
LD50 (Rabbit): > 1,000 mg/kg

Acute inhalation toxicity: LC50 (Rat): > 0.73 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist

Acute dermal toxicity: LD50 (Mouse): 923 mg/kg

**betamethasone:**

Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
LD50 (Mouse): > 4,500 mg/kg

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

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

**Components:**

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

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

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

**clotrimazole:**
Species: Rabbit
Result: No skin irritation
**SAFETY DATA SHEET**

**Betamethasone / Clotrimazole Cream 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>
</tr>
</thead>
</table>

**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

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

**clotrimazole:**
- **Species**: Rabbit
- **Result**: Mild eye irritation

**betamethasone:**
- **Species**: Rabbit
- **Result**: No eye irritation

**Respiratory or skin sensitisation**

**Skin sensitisation**
Not classified based on available information.

**Respiratory sensitisation**
Not classified based on available information.

**Components:**

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

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

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

Chronic toxicity

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
  Remarks: Based on data from similar materials

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

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

clotrimazole:

Genotoxicity in vitro:

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

Test Type: Chromosome aberration test in vitro
Result: negative

Test Type: In vitro micronucleus test
Result: negative

Genotoxicity in vivo:

Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
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

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

**White mineral oil (petroleum):**
Species: Rat
Application Route: Ingestion
Exposure time: 24 Months
Result: negative

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

Reproductive toxicity
May damage the unborn child.

**Components:**

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

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

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

**Effects on foetal development**
- Test Type: Embryo-foetal development
- Species: Mouse
- Application Route: Ingestion
- Result: negative

### White mineral oil (petroleum):

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Species</th>
<th>Application Route</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Embryo-foetal development</td>
<td>Mouse</td>
<td>Ingestion</td>
<td>negative</td>
</tr>
</tbody>
</table>

### clotrimazole:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Species</th>
<th>Application Route</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fertility/early embryonic development</td>
<td>Rat</td>
<td>Oral</td>
<td>LOAEL: 50 mg/kg body weight. Effects on fertility</td>
</tr>
<tr>
<td>Developmental toxicity</td>
<td>Rat</td>
<td>Oral</td>
<td>LOAEL: 100 mg/kg body weight. Embryo-foetal toxicity, No teratogenic effects</td>
</tr>
<tr>
<td>Developmental Toxicity</td>
<td>Rat</td>
<td>Oral</td>
<td>NOAEL: 50 mg/kg body weight. No effects on foetal development</td>
</tr>
<tr>
<td>Developmental Toxicity</td>
<td>Mouse</td>
<td>Oral</td>
<td>NOAEL: 200 mg/kg body weight. No effects on foetal development</td>
</tr>
<tr>
<td>Developmental Toxicity</td>
<td>Rabbit</td>
<td>Oral</td>
<td>NOAEL: 180 mg/kg body weight. No effects on foetal development</td>
</tr>
</tbody>
</table>

### Reproductive toxicity - As:

- Some evidence of adverse effects on sexual function and
assessment

Betamethasone:

Effects on foetal development:

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

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

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

Reproductive toxicity - Assessment:

Clear evidence of adverse effects on development, based on animal experiments.

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Causes damage to organs (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 yr
### Propylene glycol:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat, male</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>1,700 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>2 yr</td>
</tr>
</tbody>
</table>

### White mineral oil (petroleum):

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>160 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>90 Days</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>&gt;= 1 mg/l</td>
</tr>
<tr>
<td>Application Route</td>
<td>inhalation (dust/mist/fume)</td>
</tr>
<tr>
<td>Exposure time</td>
<td>4 Weeks</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 412</td>
</tr>
</tbody>
</table>

### Clotrimazole:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>5 - 40 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Skin contact</td>
</tr>
<tr>
<td>Exposure time</td>
<td>3 Weeks</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Skin</td>
</tr>
<tr>
<td>Symptoms</td>
<td>Oedema, Fissuring, Necrosis, Redness</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>10 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>18 Months</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Liver, Kidney, Adrenal gland</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Dog</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>25 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>6 - 12 Months</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Adrenal gland</td>
</tr>
<tr>
<td>Symptoms</td>
<td>Salivation, Lachrymation, Vomiting</td>
</tr>
</tbody>
</table>

### Betamethasone:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>0.05 %</td>
</tr>
<tr>
<td>Application Route</td>
<td>Skin contact</td>
</tr>
<tr>
<td>Exposure time</td>
<td>10 - 30 d</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Pituitary gland, Immune system, muscle</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>0.05 %</td>
</tr>
<tr>
<td>Application Route</td>
<td>Skin contact</td>
</tr>
<tr>
<td>Exposure time</td>
<td>8 Weeks</td>
</tr>
</tbody>
</table>
Target Organs : thymus gland
Species : Mouse
LOAEL : 0.1 %
Application Route : Skin contact
Exposure time : 8 Weeks
Target Organs : thymus gland
Species : Dog
LOAEL : 0.05 mg/kg
Application Route : Oral
Exposure time : 28 d
Target Organs : Blood, thymus gland, Adrenal gland

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:

clotrimazole:
Skin contact : Symptoms: Rash, Itching, Blistering, Oedema, Redness
Ingestion : Symptoms: Abdominal pain, Nausea, Vomiting, Diarrhoea

betamethasone:
Inhalation : Target Organs: Adrenal gland
Skin contact : Symptoms: Redness, pruritis, Irritation

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

  Toxinity 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

  Toxinity 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
### Propylene glycol:

- **Toxicity to fish**: LC50 (Oncorhynchus 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

### 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
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201

- **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

### 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
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

**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 %
SAFETY DATA SHEET

Betamethasone / Clotrimazole Cream Formula-
tion

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
Method: OECD Test Guideline 301F

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

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

Bioaccumulative potential

Components:

Propylene glycol:
Partition coefficient: n-
octanol/water : log Pow: -1.07

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 han-
dling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRRTDG
UN number : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,
**SAFETY DATA SHEET**

**Betamethasone / Clotrimazole Cream Formulation**

**Version 4.5**  
Revision Date: 23.03.2020  
SDS Number: 412891-00013  
Date of last issue: 13.09.2019  
Date of first issue: 14.12.2015

---

**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
- **Packing instruction (passenger 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.

**National Regulations**

**ADG**

- **UN number**: UN 3082
- **Proper shipping name**: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (clotrimazole, betamethasone)
- **Class**: 9
- **Packing group**: III
- **Labels**: 9
- **Hazchem Code**: •3Z

**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
Prohibition/Licensing Requirements

There is no applicable prohibition or notification/licensing requirements, including for carcinogens under Commonwealth, State or Territory legislation.

The components of this product are reported in the following inventories:

- AICS: not determined
- DSL: not determined
- IECSC: not determined

SECTION 16. OTHER INFORMATION

Further information

<table>
<thead>
<tr>
<th>Revision Date</th>
<th>Sources of key data used to compile the Safety Data Sheet</th>
<th>Date format</th>
<th>Full text of other abbreviations</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>AU OEL - Australia. Workplace Exposure Standards for Airborne Contaminants.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>ACGIH / TWA - 8-hour, time-weighted average</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>AU OEL / TWA - Exposure standard - time weighted average</td>
</tr>
</tbody>
</table>
|               |                                                           |             | AICS - Australian Inventory of Chemical Substances; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50% of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organisation for Economic Co-operation and Development; OEL - Occupational Exposure Limit; OELx - Loading rate associated with x% response; OELxR - Loading rate associated with x% response at risk; OELxS - Loading rate associated with x% response at risk and safety factor; OELxSxR - Loading rate associated with x% response at risk and safety factor; OELxSxR - Loading rate associated with x% response at risk and safety factor;"
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.