## 1. PRODUCT AND COMPANY IDENTIFICATION

**Product name**: Betamethasone / Clotrimazole Cream Formulation

**Manufacturer or supplier's details**

<table>
<thead>
<tr>
<th>Company</th>
<th>Organon &amp; Co.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address</td>
<td>30 Hudson Street, 33nd floor</td>
</tr>
<tr>
<td></td>
<td>Jersey City, New Jersey, U.S.A 07302</td>
</tr>
<tr>
<td>Telephone</td>
<td>551-430-6000</td>
</tr>
<tr>
<td>Emergency telephone number</td>
<td>215-631-6999</td>
</tr>
<tr>
<td>E-mail address</td>
<td><a href="mailto:EHSSTEWARD@organon.com">EHSSTEWARD@organon.com</a></td>
</tr>
</tbody>
</table>

**Recommended use of the chemical and restrictions on use**

**Recommended use**: Pharmaceutical

## 2. HAZARDS IDENTIFICATION

**Manufacture, Storage and Import of Hazardous Chemicals Rules 1989**

**Classification**

Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

**GHS Classification**

- **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**

<table>
<thead>
<tr>
<th>Hazard pictograms</th>
<th>![Hazard pictogram]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Signal word</td>
<td>Danger</td>
</tr>
<tr>
<td>Hazard statements</td>
<td>H360D May damage the unborn child. H372 Causes damage to organs (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland) through pro-</td>
</tr>
</tbody>
</table>
Precautionary statements:

**Prevention:**
- P203 Obtain, read and follow all safety instructions before use.
- P260 Do not breathe mist or vapours.
- P264 Wash skin thoroughly after handling.
- P270 Do not eat, drink or smoke when using this product.
- P273 Avoid release to the environment.
- P280 Wear protective gloves/protective clothing/eye protection/face protection.

**Response:**
- P318 IF exposed or concerned, get medical advice.
- P391 Collect spillage.

**Storage:**
- P405 Store locked up.

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

Other hazards which do not result in classification

None known.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

**Substance / Mixture:** Mixture

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Petrolatum</td>
<td>8009-03-8</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>White mineral oil (petroleum)</td>
<td>8042-47-5</td>
<td>&gt;= 5 - &lt; 10</td>
</tr>
<tr>
<td>Alcohols, C16-18, ethoxylated</td>
<td>68439-49-6</td>
<td>&gt;= 1 - &lt; 2.5</td>
</tr>
<tr>
<td>clotrimazole</td>
<td>23593-75-1</td>
<td>&gt;= 1 - &lt; 2.5</td>
</tr>
<tr>
<td>betamethasone</td>
<td>378-44-9</td>
<td>&gt;= 0.025 - &lt; 0.1</td>
</tr>
</tbody>
</table>

### 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. Get medical attention if irritation develops and persists. Get medical attention. Rinse mouth thoroughly with water.

**In case of eye contact**: Flush eyes with water as a precaution. Get medical attention if irritation develops and persists. If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.

**Most important symptoms and effects, both acute and delayed**:
- May damage the unborn child.
- Causes damage to organs through prolonged or repeated exposure.

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

**Notes to physician**:
- Treat symptomatically and supportively.

### 5. FIREFIGHTING MEASURES

**Suitable extinguishing media**:
- Water spray
- Alcohol-resistant foam
- Carbon dioxide (CO2)
- 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 firefighters**:
- In the event of fire, wear self-contained breathing apparatus.
- Use personal protective equipment.

### 6. ACCIDENTAL RELEASE MEASURES

**Personal precautions, protective equipment and emergency procedures**:
- Use personal protective equipment.
- Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

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

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

7. HANDLING AND STORAGE

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 mist or vapours. Do not swallow. Avoid contact with eyes. Wash skin thoroughly after handling. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment. Keep container tightly closed. Do not eat, drink or smoke when using this product. Take care to prevent spills, waste and minimize release to the environment.


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

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>IN OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL (Mist)</td>
<td>10 mg/m³</td>
<td>IN 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>White mineral oil (petroleum)</td>
<td>8042-47-5</td>
<td>TWA (Mist)</td>
<td>5 mg/m³</td>
<td>IN OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL (Mist)</td>
<td>10 mg/m³</td>
<td>IN OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Inhalable particulate matter)</td>
<td>5 mg/m³</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>
9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : cream
## 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>
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<tr>
<td>5.4</td>
<td>10.10.2020</td>
<td>415446-00014</td>
<td>23.03.2020</td>
<td>14.12.2015</td>
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<table>
<thead>
<tr>
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<tbody>
<tr>
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<tr>
<td>Odour</td>
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</tr>
<tr>
<td>Odour Threshold</td>
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</tr>
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<td>Melting point/freezing point</td>
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<td>Initial boiling point and boiling range</td>
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<tr>
<td>Flash point</td>
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<tr>
<td>Evaporation rate</td>
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</tr>
<tr>
<td>Flammability (solid, gas)</td>
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<tr>
<td>Flammability (liquids)</td>
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<td>Upper explosion limit / Upper flammability limit</td>
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<tr>
<td>Lower explosion limit / Lower flammability limit</td>
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<td>Vapour pressure</td>
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<td>Relative vapour density</td>
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<tr>
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</tr>
<tr>
<td>Density</td>
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</tr>
<tr>
<td>Solubility(ies)</td>
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</tr>
<tr>
<td>Water solubility</td>
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<td>Partition coefficient: n-octanol/water</td>
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</tr>
<tr>
<td>Auto-ignition temperature</td>
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</tr>
<tr>
<td>Decomposition temperature</td>
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</tr>
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<td>Viscosity</td>
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</tr>
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<td>Viscosity, kinematic</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
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<tr>
<td>Oxidizing properties</td>
<td>The substance or mixture is not classified as oxidizing.</td>
</tr>
<tr>
<td>Particle size</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>
10. STABILITY AND REACTIVITY

Reactivity: Not classified as a reactivity hazard.
Chemical stability: Stable under normal conditions.
Possibility of hazardous reactions: Can react with strong oxidizing agents.
Conditions to avoid: None known.
Incompatible materials: Oxidizing agents
Hazardous decomposition products: No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

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

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

**Alcohols, C16-18, ethoxylated:**
Species: Rabbit
Method: OECD Test Guideline 405
Result: No eye irritation
Remarks: Based on data from similar materials

**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

White mineral oil (petroleum):

Test Type: Buehler Test
Exposure routes: Skin contact
Species: Guinea pig
Result: negative

Alcohols, C16-18, ethoxylated:

Test Type: Buehler Test
Exposure routes: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative
Remarks: Based on data from similar materials

betamethasone:

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

Germ cell mutagenicity
Not classified based on available information.

Components:

Petrolatum:
Genotoxicity in vitro: Test Type: Chromosome aberration test in vitro
Result: negative
Remarks: Based on data from similar materials

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

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

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

Genotoxicity in vitro:
- **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

Genotoxicity in vitro:
- **Test Type:** Chromosome aberration test in vitro
- **Result:** negative

Genotoxicity in vitro:
- **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

Genotoxicity in vivo:
- **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

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

Genotoxicity in vitro:
- **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

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
White mineral oil (petroleum):
Effects on fertility
: Test Type: One-generation reproduction toxicity study
  Species: Rat
  Application Route: Skin contact
  Result: negative

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

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

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

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

  Test Type: Embryo-foetal development
  Species: Mouse
  Application Route: Oral
  Developmental Toxicity: NOAEL: 200 mg/kg body weight
  Result: No effects on foetal development

  Test Type: Embryo-foetal development
  Species: Rabbit
  Application Route: Oral
Developmental Toxicity: NOAEL: 180 mg/kg body weight
Result: No effects on foetal development

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

**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:
SAFETY DATA SHEET
Betamethasone / Clotrimazole Cream Formula-
tion

Version 5.4  Revision Date: 10.10.2020  SDS Number: 415446-00014  Date of last issue: 23.03.2020  Date of first issue: 14.12.2015

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

White mineral oil (petroleum):
Species: Rat  LOAEL: 160 mg/kg  Application Route: Ingestion  Exposure time: 90 Days
Species: Rat  LOAEL: >= 1 mg/l  Application Route: inhalation (dust/mist/fume)  Exposure time: 4 Weeks  Method: OECD Test Guideline 412

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

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:

clopimazole:
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, pruritus, Irritation

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Petrolatum:
Toxicity to fish: LL50 (Pimephales promelas (fathead minnow)): > 100 mg/l
Exposure time: 96 h
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 203
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 10,000 mg/l
Exposure time: 48 h
Test substance: Water Accommodated Fraction
Remarks: Based on data from similar materials

Toxicity to algae/aquatic: NOEL (Pseudokirchneriella subcapitata (green algae)): >=
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):

- NOEC: 10 mg/l
- Exposure time: 21 d
- Species: Daphnia magna (Water flea)
- 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
- Exposure time: 72 h
- Method: OECD Test Guideline 201

Toxicity to fish (Chronic toxicity):

- NOEC: 1,000 mg/l
- Exposure time: 28 d
- Species: Oncorhynchus mykiss (rainbow trout)

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

- NOEC: 1,000 mg/l
- Exposure time: 21 d
- Species: Daphnia magna (Water flea)

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
- 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

M-Factor (Acute aquatic toxicity): 10

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

Toxicity to fish (Chronic toxicity): NOEC: 0.025 mg/l
Exposure time: 32 d
Species: Oncorhynchus mykiss (rainbow trout)
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC: 0.01 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
Method: OECD Test Guideline 211

M-Factor (Chronic aquatic toxicity): 10

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: 0.052 mg/l
Exposure time: 32 d
Species: Pimephales promelas (fathead minnow)
Method: OECD Test Guideline 210

NOEC: 0.07 µg/l
Exposure time: 219 d
Species: Oryzias latipes (Japanese medaka)
Method: OECD Test Guideline 229
### Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):

- **NOEC**: 8 mg/l
- **Exposure time**: 21 d
- **Species**: Daphnia magna (Water flea)
- **Method**: OECD Test Guideline 211

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

- **Value**: 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
13. DISPOSAL CONSIDERATIONS

Disposal methods
- Waste from residues: Dispose of in accordance with local regulations.
- Contaminated packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal.
  If not otherwise specified: Dispose of as unused product.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG
- UN number: UN 3082
- Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (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 IMO instruments
Not applicable for product as supplied.
SAFETY DATA SHEET

Betamethasone / Clotrimazole Cream Formula-
tion

Version 5.4  Revision Date: 10.10.2020  SDS Number: 415446-00014  Date of last issue: 23.03.2020
Date of first issue: 14.12.2015

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

15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

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

16. OTHER INFORMATION

Further information
Date format: dd.mm.yyyy

Full text of other abbreviations
- ACGIH: USA. ACGIH Threshold Limit Values (TLV)
- IN OEL: India. Permissible levels of certain chemical substances in work environment.
- ACGIH / TWA: 8-hour, time-weighted average
- IN OEL / TWA: Time-Weighted Average Concentration (TWA) (8 hrs.)
- IN OEL / STEL: Short-term exposure Limit STEL (15 min)

AIIIC - Australian Inventory of Industrial Chemicals; 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
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.