SAFETY DATA SHEET
Betamethasone / Clotrimazole Cream Formulation

VERSION 4.6
Revision Date: 10.10.2020
SDS Number: 412891-00014
Date of last issue: 23.03.2020
Date of first issue: 14.12.2015

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Betamethasone / Clotrimazole Cream Formulation

Manufacturer or supplier’s details
Company: Organon & Co.
Address: 30 Hudson Street, 33nd floor
       Jersey City, New Jersey, U.S.A 07302
Telephone: 551-430-6000
Emergency telephone number: 215-631-6999
E-mail address: EHSSTEWARD@organon.com

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.
P281 Use personal protective equipment as required.
Response:
P308 + P313 IF exposed or concerned: Get medical advice/attention.

Storage:
P405 Store locked up.

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

Other hazards 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>
<tbody>
<tr>
<td><strong>Components</strong></td>
<td></td>
</tr>
<tr>
<td>Chemical name</td>
<td>CAS-No.</td>
</tr>
<tr>
<td>Petrolatum</td>
<td>8009-03-8</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
</tr>
<tr>
<td>White mineral oil (petroleum)</td>
<td>8042-47-5</td>
</tr>
<tr>
<td>clotrimazole</td>
<td>23593-75-1</td>
</tr>
<tr>
<td>betamethasone</td>
<td>378-44-9</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).
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 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.

Hazchem Code: •3Z

SECTION 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 spills 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.
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.

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 matter)</td>
<td>5 mg/m³</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>
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tion

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<table>
<thead>
<tr>
<th>Substance</th>
<th>CAS Number</th>
<th>TWA</th>
<th>Limit</th>
<th>Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>clotrimazole</td>
<td>23593-75-1</td>
<td>0.2 mg/m³ (OEB 2)</td>
<td>Internal</td>
<td></td>
</tr>
<tr>
<td>betamethasone</td>
<td>378-44-9</td>
<td>1 µg/m³ (OEB 4)</td>
<td>Internal</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Wipe limit: 10 µg/100 cm²</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 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
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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: 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 oral toxicity estimate: > 2,000 mg/kg
  - Method: Calculation method

**Acute dermal toxicity**

- Acute dermal 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
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
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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

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: Embryofetal 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):**

**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

---

**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 - As:**

: Some evidence of adverse effects on sexual function and
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Assessment

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:

Species: Rat
NOAEL: 5,000 mg/kg
Application Route: Ingestion
Exposure time: 2 yr
Propylene glycol:
Species: Rat, male
NOAEL: 1,700 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

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

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

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

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)

<table>
<thead>
<tr>
<th>Substance</th>
<th>NOEC (Daphnia magna (Water flea))</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propylene glycol</td>
<td>10 mg/l</td>
<td>21 d</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td>Clotrimazole</td>
<td>13,020 mg/l</td>
<td>7 d</td>
<td></td>
</tr>
<tr>
<td>White mineral oil (petroleum)</td>
<td>&gt; 100 mg/l</td>
<td>28 d</td>
<td></td>
</tr>
</tbody>
</table>

## Toxicity to fish

<table>
<thead>
<tr>
<th>Substance</th>
<th>LC50 (Oncorhynchus mykiss (rainbow trout))</th>
<th>Exposure time</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propylene glycol</td>
<td>40,613 mg/l</td>
<td>96 h</td>
<td>OECD Test Guideline 203</td>
</tr>
<tr>
<td>Clotrimazole</td>
<td>&gt; 0.29 mg/l</td>
<td>96 h</td>
<td>OECD Test Guideline 203</td>
</tr>
</tbody>
</table>

## Toxicity to algae/aquatic plants

<table>
<thead>
<tr>
<th>Substance</th>
<th>EC50 (Daphnia magna (Water flea))</th>
<th>Exposure time</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propylene glycol</td>
<td>0.02 mg/l</td>
<td>48 h</td>
<td>OECD Test Guideline 202</td>
</tr>
<tr>
<td>Clotrimazole</td>
<td>0.268 mg/l</td>
<td>72 h</td>
<td>OECD Test Guideline 201</td>
</tr>
</tbody>
</table>

## Toxicity to microorganisms

<table>
<thead>
<tr>
<th>Substance</th>
<th>NOEC (Pseudomonas putida)</th>
<th>Exposure time</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>White mineral oil (petroleum)</td>
<td>&gt; 20,000 mg/l</td>
<td>18 h</td>
<td>OECD Test Guideline 203</td>
</tr>
</tbody>
</table>

## Toxicity to algae/aquatic plants

<table>
<thead>
<tr>
<th>Substance</th>
<th>ErC50 (Skeletonema costatum (marine diatom))</th>
<th>Exposure time</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>White mineral oil (petroleum)</td>
<td>19,300 mg/l</td>
<td>72 h</td>
<td>OECD Test Guideline 201</td>
</tr>
</tbody>
</table>

## Toxicity to microorganisms

<table>
<thead>
<tr>
<th>Substance</th>
<th>NOEC (Pseudokirchneriella subcapitata (green algae))</th>
<th>Exposure time</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>White mineral oil (petroleum)</td>
<td>100 mg/l</td>
<td>72 h</td>
<td>OECD Test Guideline 201</td>
</tr>
</tbody>
</table>

## Toxicity to fish (Chronic toxicity)

<table>
<thead>
<tr>
<th>Substance</th>
<th>NOEC (Oncorhynchus mykiss (rainbow trout))</th>
<th>Exposure time</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>White mineral oil (petroleum)</td>
<td>1,000 mg/l</td>
<td>28 d</td>
<td>OECD Test Guideline 203</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Substance</th>
<th>NOEC (Daphnia magna (Water flea))</th>
<th>Exposure time</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>White mineral oil (petroleum)</td>
<td>1,000 mg/l</td>
<td>21 d</td>
<td>OECD Test Guideline 203</td>
</tr>
</tbody>
</table>

plants

Exposure time: 72 h

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

Toxicity to fish (Chronic toxicity)

: NOEC (Oncorhynchus mykiss (rainbow trout)): 0.025 mg/l
Exposure time: 32 d
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)

: NOEC (Daphnia magna (Water flea)): 0.01 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211

Toxicity to microorganisms

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

betamethasone:

Toxicity to daphnia and other aquatic invertebrates

: EC50 (Americamysis): > 50 mg/l
Exposure time: 96 h

Toxicity to algae/aquatic plants

: EC50 (Pseudokirchneriella subcapitata (green algae)): > 34 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: No toxicity at the limit of solubility

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

Toxicity to fish (Chronic toxicity)

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

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

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)

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

Persistence and degradability

Components:

Petrolatum:

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

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 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,
SAFETY DATA SHEET

Betamethasone / Clotrimazole Cream Formula-
tion

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 (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.

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 var-
iations in regional or country regulations.

SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mix-
ture
Prohibition/Licensing Requirements: There is no applicable prohibition, authorisation and restricted use requirements, including for carcinogens referred to in Schedule 10 of the model WHS Act and Regulations.

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

Revision Date: 10.10.2020

Date format: dd.mm.yyyy

Full text of other abbreviations

- ACGIH: USA. ACGIH Threshold Limit Values (TLV)
- ACGIH / TWA: 8-hour, time-weighted average
- AU OEL / TWA: Exposure standard - time weighted average

Additional abbreviations:
- AIIC - 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 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
SAFETY DATA SHEET

Betamethasone / Clotrimazole Cream Formulation

Version 4.6
Revision Date: 10.10.2020
SDS Number: 412891-00014
Date of last issue: 23.03.2020
Date of first issue: 14.12.2015

Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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.

AU / EN