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 : 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)
Short-term (acute) aquatic hazard : Category 2
Long-term (chronic) aquatic hazard : Category 1

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.
H401 Toxic to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.
Precautionary Statements:

**Prevention:**
- P201 Obtain special instructions before use.
- P202 Do not handle until all safety precautions have been read and understood.
- P260 Do not breathe mist or vapors.
- 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:**
- P308 + P313 IF exposed or concerned: Get medical advice/attention.
- 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.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture: Mixture

<table>
<thead>
<tr>
<th>Components</th>
<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; 20</td>
<td></td>
</tr>
<tr>
<td>White mineral oil (petroleum)</td>
<td>8042-47-5</td>
<td>&gt;= 5 - &lt; 10</td>
<td></td>
</tr>
<tr>
<td>Alcohols, C16-18, ethoxylated</td>
<td>68439-49-6</td>
<td>&gt;= 1 - &lt; 2,5</td>
<td></td>
</tr>
<tr>
<td>Clotrimazole</td>
<td>23593-75-1</td>
<td>&gt;= 1 - &lt; 2,5</td>
<td></td>
</tr>
<tr>
<td>Betamethasone</td>
<td>378-44-9</td>
<td>&gt;= 0,025 - &lt; 0,1</td>
<td></td>
</tr>
</tbody>
</table>

SECTION 4. FIRST AID MEASURES

**General advice:**
- In the case of accident or if you feel unwell, seek medical advice immediately.
- When symptoms persist or in all cases of doubt seek medical advice.

**If inhaled:**
- If inhaled, remove to fresh air.
- Get medical attention.

**In case of skin contact:**
- In case of contact, immediately flush skin with soap and plenty of water.
- Remove contaminated clothing and shoes.
- Get medical attention.
- Wash clothing before reuse.
In case of eye contact: Thoroughly clean shoes before reuse.
Flush eyes with water as a precaution.
Get medical attention if irritation develops and persists.

If swallowed: If swallowed, DO NOT induce vomiting.
Get medical attention.
Rinse mouth thoroughly with water.

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

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

Notes to physician: Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

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

Unsuitable extinguishing media: None known.

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

Hazardous combustion products: Carbon oxides

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

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

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures:
- Use personal protective equipment.
- Follow safe handling advice (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 diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate
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 mist or vapors.
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.

Conditions for safe storage : Keep in properly labeled containers.
Store locked up.
Keep tightly closed.
Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:
Strong oxidizing agents
Organic peroxides
Explosives
Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Petrolatum</td>
<td>8009-03-8</td>
<td>CMP (Mist)</td>
<td>5 mg/m³</td>
<td>AR OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: Sampled by a method which does not include vapour, lung</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>CMP - CPT (Mist)</td>
<td>10 mg/m³</td>
<td>AR OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: lung</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>5 mg/m³</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>
**SAFETY DATA SHEET**

Betamethasone / Clotrimazole Cream Formula-tion

<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>
<tbody>
<tr>
<td>7.4</td>
<td>10.10.2020</td>
<td>415434-00014</td>
<td>23.03.2020</td>
<td>14.12.2015</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Substance</th>
<th>Source (Inhalable particulate matter)</th>
<th>Concentration</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>White mineral oil (petroleum)</td>
<td>CMP (Mist)</td>
<td>5 mg/m³</td>
<td>AR OEL</td>
</tr>
<tr>
<td></td>
<td>Further information: Sampled by a method which does not include vapour, lung</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>CMP - CPT (Mist)</td>
<td>10 mg/m³</td>
<td>AR OEL</td>
</tr>
<tr>
<td></td>
<td>Further information: lung</td>
<td></td>
<td></td>
</tr>
<tr>
<td>clotrimazole</td>
<td>TWA (Inhalable particulate matter)</td>
<td>5 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Betamethasone</td>
<td>TWA</td>
<td>0.2 mg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td>TWA</td>
<td>1 µg/m³ (OEB 4)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td>Further information: Skin</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Wipe limit</td>
<td>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 vapor 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.

- **Hygiene measures**: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the
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 decontamination and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

- **Appearance**: cream
- **Color**: white to off-white
- **Odor**: No data available
- **Odor Threshold**: No data available
- **pH**: No data available
- **Melting point/freezing point**: No data available
- **Initial boiling point and boiling range**: No data available
- **Flash point**: No data available
- **Evaporation rate**: No data available
- **Flammability (solid, gas)**: Not applicable
- **Flammability (liquids)**: No data available
- **Upper explosion limit / Upper flammability limit**: No data available
- **Lower explosion limit / Lower flammability limit**: No data available
- **Vapor pressure**: No data available
- **Relative vapor density**: No data available
- **Relative density**: No data available
- **Density**: No data available
- **Solubility(ies)**
  - **Water solubility**: No data available
- **Partition coefficient: n-octanol/water**: No data available
- **Autoignition temperature**: No data available
Decomposition temperature : No data available

Viscosity
Viscosity, kinematic : Not applicable

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Particle size : Not applicable

SECTION 10. STABILITY AND REACTIVITY

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

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure : Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity
Not classified based on available information.

Product:
Acute oral toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Components:

Petrolatum:
Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
Method: OECD Test Guideline 401
Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 402
Assessment: The substance or mixture has no acute dermal toxicity
Remarks: Based on data from similar materials
White mineral oil (petroleum):
Acute oral toxicity : LD50 (Rat): > 5.000 mg/kg
Acute inhalation toxicity : LC50 (Rat): > 5 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Assessment: The substance or mixture has no acute inhalation toxicity
Acute dermal toxicity : LD50 (Rabbit): > 2.000 mg/kg
Assessment: The substance or mixture has no acute dermal toxicity

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

Clotrimazole:
Acute oral toxicity : LD50 (Rat): 708 mg/kg
LD50 (Mouse): 761 mg/kg
LD50 (Rabbit): > 1.000 mg/kg
Acute inhalation toxicity : LC50 (Rat): > 0.73 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Acute dermal toxicity : LD50 (Mouse): 923 mg/kg

Betamethasone:
Acute oral toxicity : LD50 (Rat): > 5.000 mg/kg
LD50 (Mouse): > 4.500 mg/kg
Acute inhalation toxicity : LC50 (Rat): 0.4 mg/l
Exposure time: 4 h

Skin corrosion/irritation
Not classified based on available information.

Components:

Petrolatum:
Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation
Remarks : Based on data from similar materials
White mineral oil (petroleum):
Species : Rabbit
Result : No skin irritation

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

clotrimazole:
Species : Rabbit
Result : No skin irritation

Betamethasone:
Species : Rabbit
Result : Mild skin irritation

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

Components:

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

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

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

clotrimazole:
Species : Rabbit
Result : Mild eye irritation

Betamethasone:
Species : Rabbit
Result : No eye irritation
Respiratory or skin sensitization

Skin sensitization
Not classified based on available information.

Respiratory sensitization
Not classified based on available information.

Components:

Petrolatum:
Test Type: Buehler Test
Routes of exposure: Skin contact
Species: Guinea pig
Result: negative
Remarks: Based on data from similar materials

White mineral oil (petroleum):
Test Type: Buehler Test
Routes of exposure: Skin contact
Species: Guinea pig
Result: negative

Alcohols, C16-18, ethoxylated:
Test Type: Buehler Test
Routes of exposure: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative
Remarks: Based on data from similar materials

Betamethasone:
Routes of exposure: 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

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

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

**Clotrimazole:**

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

Test Type: Chromosome aberration test in vitro
Result: negative

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

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

**White mineral oil (petroleum):**

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

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

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

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

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

**clotrimazole:**

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

Effects on fetal development: Test Type: Embryo-fetal development  
Species: Rat  
Application Route: Oral  
Developmental Toxicity: LOAEL: 100 mg/kg body weight  
Result: Embryo-fetal toxicity., No teratogenic effects.  
Test Type: Embryo-fetal development
Species: Rat  
Application Route: Oral  
Developmental Toxicity: NOAEL: 50 mg/kg body weight  
Result: Embryo-fetal toxicity., No teratogenic effects.

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

Test Type: Embryo-fetal development  
Species: Rabbit  
Application Route: Oral  
Developmental Toxicity: NOAEL: 180 mg/kg body weight  
Result: No effects on fetal 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 fetal development : Species: Rabbit  
Application Route: Intramuscular  
Developmental Toxicity: LOAEL: 0,05 mg/kg body weight  
Result: Fetotoxicity., Malformations were observed.

Species: Rat  
Application Route: Subcutaneous  
Developmental Toxicity: LOAEL: 0,42 mg/kg body weight  
Result: Malformations were observed.

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

Reproductive toxicity - Assessment : Clear evidence of adverse effects on development, based on animal experiments.

STOT-single exposure  
Not classified based on available information.

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
### 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**:

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>5,000 mg/kg</td>
<td>Ingestion</td>
<td>2 y</td>
</tr>
</tbody>
</table>

**White mineral oil (petroleum)**:

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

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>&gt; 1 mg/l</td>
<td>inhalation (dust/mist/fume)</td>
<td>4 Weeks</td>
</tr>
</tbody>
</table>

**Method**: OECD Test Guideline 412

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

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>&gt; 100 mg/kg</td>
<td>Ingestion</td>
<td>90 Days</td>
</tr>
</tbody>
</table>

**Method**: OECD Test Guideline 408

**Remarks**: Based on data from similar materials

**clotrimazole**:

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

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

### Species
Dog

### LOAEL
25 mg/kg

### Application Route
Oral

### Exposure time
6 - 12 Months

### Betamethasone:

#### Species
Rabbit

#### LOAEL
0.05 %

#### Application Route
Skin contact

#### Exposure time
10 - 30 d

#### Target Organs
Pituitary gland, Immune system, muscle

#### Species
Rat

#### LOAEL
0.05 %

#### Application Route
Skin contact

#### Exposure time
8 Weeks

#### Target Organs
thymus gland

#### Species
Mouse

#### LOAEL
0.1 %

#### Application Route
Skin contact

#### Exposure time
8 Weeks

#### Target Organs
thymus gland

#### Species
Dog

#### LOAEL
0.05 mg/kg

#### Application Route
Oral

#### Exposure time
28 d

#### Target Organs
Blood, thymus gland, Adrenal gland

### Aspiration toxicity
Not classified based on available information.

### Experience with human exposure

#### Components:

##### clotrimazole:

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

##### Betamethasone:

- **Inhalation**: Target Organs: Adrenal gland
- **Skin contact**: Symptoms: Redness, pruritis, Irritation
SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

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

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 10.000 mg/l
Exposure time: 48 h
Test substance: Water Accommodated Fraction
Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants: NOEL (Pseudokirchneriella subcapitata (green algae)): >= 100 mg/l
Exposure time: 72 h
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC (Daphnia magna (Water flea)): 10 mg/l
Exposure time: 21 d
Test substance: Water Accommodated Fraction
Remarks: Based on data from similar materials

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

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

Toxicity to algae/aquatic plants: NOEC (Pseudokirchneriella subcapitata (green algae)): 100 mg/l
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

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**

<table>
<thead>
<tr>
<th>Substance</th>
<th>EC50 (Daphnia magna (Water flea)): &gt; 100 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 48 h</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

**Clotrimazole:**

**Toxicity to fish**

<table>
<thead>
<tr>
<th>Substance</th>
<th>LC50 (Brachydanio rerio (zebrafish)): &gt; 0,29 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 96 h</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 203</td>
</tr>
</tbody>
</table>

**Toxicity to daphnia and other aquatic invertebrates**

<table>
<thead>
<tr>
<th>Substance</th>
<th>EC50 (Daphnia magna (Water flea)): 0,02 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 48 h</td>
</tr>
</tbody>
</table>

**Toxicity to algae/aquatic plants**

<table>
<thead>
<tr>
<th>Substance</th>
<th>EC50 (Desmodesmus subspicatus (green algae)): 0,268 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>NOEC (Desmodesmus subspicatus (green algae)): 0,017 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 72 h</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Substance</th>
<th>10</th>
</tr>
</thead>
</table>

**Toxicity to fish (Chronic toxicity)**

<table>
<thead>
<tr>
<th>Substance</th>
<th>NOEC (Oncorhynchus mykiss (rainbow trout)): 0,025 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 32 d</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 210</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)): 0,01 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 21 d</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 211</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Substance</th>
<th>10</th>
</tr>
</thead>
</table>

**Toxicity to microorganisms**

<table>
<thead>
<tr>
<th>Substance</th>
<th>EC50: &gt; 10.000 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 3 h</td>
</tr>
<tr>
<td>Test Type</td>
<td>Respiration inhibition</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 209</td>
</tr>
</tbody>
</table>

**Betamethasone:**

**Toxicity to daphnia and other aquatic invertebrates**

<table>
<thead>
<tr>
<th>Substance</th>
<th>EC50 (Americamysis): &gt; 50 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 96 h</td>
</tr>
</tbody>
</table>

**Toxicity to algae/aquatic plants**

<table>
<thead>
<tr>
<th>Substance</th>
<th>EC50 (Pseudokirchneriella subcapitata (green algae)): &gt; 34 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 72 h</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 201</td>
</tr>
<tr>
<td>Remarks</td>
<td>No toxicity at the limit of solubility.</td>
</tr>
<tr>
<td></td>
<td>NOEC (Pseudokirchneriella subcapitata (green algae)): 34 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 72 h</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 201</td>
</tr>
<tr>
<td>Remarks</td>
<td>No toxicity at the limit of solubility.</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET
Betamethasone / Clotrimazole Cream Formula-
tion

Version 7.4  Revision Date: 10.10.2020  SDS Number: 415434-00014  Date of last issue: 23.03.2020  Date of first issue: 14.12.2015

Toxicity to fish (Chronic toxicity):
- NOEC (Pimephales promelas (fathead minnow)): 0.052 mg/l
  Exposure time: 32 d
  Method: OECD Test Guideline 210
- NOEC (Oryzias latipes (Japanese medaka)): 0.07 µg/l
  Exposure time: 219 d
  Method: OECD Test Guideline 229

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

M-Factor (Chronic aquatic toxicity):
- 1.000

Persistence and degradability

Components:

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

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

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

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

Bioaccumulative potential

Components:

Alcohols, C16-18, ethoxylated:
Bioaccumulation: Species: Fish
  Bioconcentration factor (BCF): < 500
  Remarks: Based on data from similar materials

Partition coefficient: n-Log Pow: > 4
Betamethasone / Clotrimazole Cream Formula- 

octanol/water

**Betamethasone:**
Partition coefficient: n-octanol/water: log Pow: 2.11

**Mobility in soil**
No data available

**Other adverse effects**
No data available

### SECTION 13. DISPOSAL CONSIDERATIONS

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

### SECTION 14. TRANSPORT INFORMATION

**International Regulations**

**UNRTDG**
- UN number: UN 3082
- Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (clotrimazole, betamethasone)

**Class:** 9
**Packing group:** III
**Labels:** 9

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

**Class:** 9
**Packing group:** III
**Labels:** Miscellaneous
**Packing instruction (cargo aircraft):** 964
**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.

**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**

- **Argentina. Carcinogenic Substances and Agents Registry.**
  - Not applicable

- **Control of precursors and essential chemicals for the preparation of drugs.**
  - Not applicable

**International Regulations**

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

### SECTION 16. OTHER INFORMATION

**Further information**

Sources of key data used to compile the Material Safety Data Sheet:

**Full text of other abbreviations**

- **ACGIH**: USA. ACGIH Threshold Limit Values (TLV)
- **AR OEL**: Argentina. Occupational Exposure Limits
- **ACGIH / TWA**: 8-hour, time-weighted average
- **AR OEL / CMP**: TLV (Threshold Limit Value)
- **AR OEL / CMP - CPT**: STEL (Short Term Limit Value)

**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;
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.