SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Betamethasone / Clotrimazole Cream Formulation

Manufacturer or supplier's details
Company: Organon & Co.
Address: Rua Treze de Maio, 1161
Campinas, São Paulo, Brazil  B-2220
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 in accordance with ABNT NBR 14725 Standard
Reproductive toxicity: Category 1B
Specific target organ toxicity - repeated exposure: Category 1 (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland)
Short-term (acute) aquatic hazard: Category 2
Long-term (chronic) aquatic hazard: Category 1

GHS label elements in accordance with ABNT NBR 14725 Standard
Hazard pictograms:
- Danger

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

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

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

Other hazards which do not result in classification
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Substance / Mixture</strong></td>
<td>Mixture</td>
</tr>
<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>White mineral oil (petroleum)</td>
<td>8042-47-5</td>
</tr>
<tr>
<td>Alcohols, C16-18, ethoxylated</td>
<td>68439-49-6</td>
</tr>
<tr>
<td>clotrimazole</td>
<td>23593-75-1</td>
</tr>
<tr>
<td>Betamethasone</td>
<td>378-44-9</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Betamethasone / Clotrimazole Cream Formulation

Version 7.1 Revision Date: 10.10.2020 SDS Number: 412893-00014 Date of last issue: 23.03.2020 Date of first issue: 14.12.2015

Toxicity - repeated exposure (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland), Category 1 Long-term (chronic) aquatic hazard, Category 1

SECTION 4. FIRST AID MEASURES

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

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

In case of skin contact: In case of contact, immediately flush skin with soap and plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.

In case of eye contact: Flush eyes with water as a precaution. Get medical attention if irritation develops and persists.

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

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

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

Notes to physician: Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

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

Unsuitable extinguishing media: None known.

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

Hazardous combustion products: Carbon oxides

Specific extinguishing method: Use extinguishing measures that are appropriate to local cir-
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 container.
- Clean up remaining materials from spill with suitable absorbent.
- Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
- Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

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

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

Advice on safe handling:
- Do not get on skin or clothing.
- Do not breathe 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
Hygiene measures: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

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

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

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Petrolatum</td>
<td>8009-03-8</td>
<td>TWA (Inhalable particulate matter)</td>
<td>5 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>White mineral oil (petroleum)</td>
<td>8042-47-5</td>
<td>TWA (Inhalable particulate matter)</td>
<td>5 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>clotrimazole</td>
<td>23593-75-1</td>
<td>TWA</td>
<td>0.2 mg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Betamethasone</td>
<td>378-44-9</td>
<td>TWA</td>
<td>1 µg/m³ (OEB 4)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Further information: Skin

| Wipe limit | 10 µg/100 cm² | Internal |

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

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

Filter type: Combined particulates and organic vapor type

Hand protection: 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

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
<table>
<thead>
<tr>
<th>Test Type</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>in vitro micronucleus test</td>
<td>negative</td>
</tr>
<tr>
<td>Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)</td>
<td>negative</td>
</tr>
<tr>
<td>Mammalian spermatogonial chromosome aberration test (in vivo)</td>
<td>negative</td>
</tr>
<tr>
<td>Bacterial reverse mutation assay (AMES)</td>
<td>negative</td>
</tr>
<tr>
<td>In vitro mammalian cell gene mutation test</td>
<td>negative</td>
</tr>
<tr>
<td>Chromosome aberration test in vitro</td>
<td>positive</td>
</tr>
<tr>
<td>Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)</td>
<td>equivocal</td>
</tr>
</tbody>
</table>

**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:** 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:**
- 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...
SAFETY DATA SHEET

Betamethasone / Clotrimazole Cream Formulation

Version 7.1 Revision Date: 10.10.2020 SDS Number: 412893-00014 Date of last issue: 23.03.2020 Date of first issue: 14.12.2015

assessment 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 y

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: Edema, Fissuring, Necrosis, Redness

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

Species: Dog
LOAEL: 25 mg/kg
Application Route: Oral
Exposure time: 6 - 12 Months
Target Organs: Adrenal gland
Symptoms: Salivation, Lachrymation, Vomiting

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

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

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

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

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

Components:

**clotrimazole:**

<table>
<thead>
<tr>
<th>Skin contact</th>
<th>Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ingestion</td>
<td>Symptoms: Abdominal pain, Nausea, Vomiting, Diarrhea</td>
</tr>
</tbody>
</table>

**Betamethasone:**

<table>
<thead>
<tr>
<th>Inhalation</th>
<th>Target Organs: Adrenal gland</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin contact</td>
<td>Symptoms: Redness, pruritis, Irritation</td>
</tr>
</tbody>
</table>

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

**Petrolatum:**

<table>
<thead>
<tr>
<th>Toxicity to fish</th>
<th>LL50 (Pimephales promelas (fathead minnow)): &gt; 100 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 96 h</td>
</tr>
<tr>
<td></td>
<td>Test substance: Water Accommodated Fraction</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 203</td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity to daphnia and other aquatic invertebrates</th>
<th>EC50 (Daphnia magna (Water flea)): &gt; 10.000 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 48 h</td>
</tr>
<tr>
<td></td>
<td>Test substance: Water Accommodated Fraction</td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity to algae/aquatic plants</th>
<th>NOEL (Pseudokirchneriella subcapitata (green algae)): &gt;= 100 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 72 h</td>
</tr>
<tr>
<td></td>
<td>Test substance: Water Accommodated Fraction</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 201</td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>

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

**White mineral oil (petroleum):**

<table>
<thead>
<tr>
<th>Toxicity to fish</th>
<th>LC50 (Oncorhynchus mykiss (rainbow trout)): &gt; 100 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 96 h</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 203</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity to daphnia and other aquatic invertebrates</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></td>
<td>Test substance: Water Accommodated Fraction</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 202</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity to algae/aquatic plants</th>
<th>NOEC (Pseudokirchneriella subcapitata (green algae)): 100 mg/l</th>
</tr>
</thead>
</table>
### SAFETY DATA SHEET

**Betamethasone / Clotrimazole Cream Formulation**

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.1</td>
<td>10.10.2020</td>
<td>412893-00014</td>
<td>23.03.2020</td>
<td>14.12.2015</td>
</tr>
</tbody>
</table>

**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:**  
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  
Exposure time: 72 h  
NOEC (Desmodesmus subspicatus (green algae)): 0,017 mg/l  
Exposure time: 72 h

**M-Factor (Acute aquatic toxicity):**  
10

**Toxicity to fish (Chronic toxicity):**  
NOEC (Oncorhynchus mykiss (rainbow trout)): 0,025 mg/l  
Exposure time: 32 d  
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

**M-Factor (Chronic aquatic toxicity):**  
10

**Toxicity to microorganisms:**  
EC50: > 10.000 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209

**Betamethasone:**

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

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

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

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

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

M-Factor (Chronic aquatic toxicity): 1.000

Persistence and degradability

Components:

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

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

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

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

Bioaccumulative potential

Components:

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

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

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

Mobility in soil
No data available

Other adverse effects
No data available

SECTION 13. DISPOSAL CONSIDERATIONS

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

SECTION 14. TRANSPORT INFORMATION

International Regulations

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

Class : 9
Packing group : III
Labels : 9

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

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

Betamethasone / Clotrimazole Cream Formula-
tion

Version 7.1  Revision Date: 10.10.2020  SDS Number: 412893-00014  Date of last issue: 23.03.2020  Date of first issue: 14.12.2015

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

IMDG-Code
UN number : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (clotrimazole, Betamethasone)
Class : 9
Packing group : III
Labels : 9
EmS Code : F-A, S-F
Marine pollutant : yes

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

Domestic regulation

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

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

SECTION 15. REGULATORY INFORMATION

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

National List of Carcinogenic Agents for Humans - (LINACH) : Not applicable

Brazil. List of chemicals controlled by the Federal Police : Not applicable

International Regulations

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

AICS : not determined
DSL : 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)
- ACGIH / TWA: 8-hour, time-weighted average

All abbreviations listed are as follows:
- AIC - 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 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; SDAT - 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.

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