1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Betamethasone / Clotrimazole Cream Formulation

Manufacturer or supplier’s details

Company: MSD
Address: 50 Tuas West Drive
          Singapore - Singapore 638408
Telephone: 908-740-4000
Emergency telephone number: 65 6697 2111 (24/7/365)
E-mail address: EHSDATASTEWARD@msd.com
Telefax: 908-735-1496

Recommended use of the chemical and restrictions on use

Recommended use: Pharmaceutical

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)
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.
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 vapours.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P273 Avoid release to the environment.
P280 Wear protective gloves/protective clothing/eye protection/face protection.

Response:
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.

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>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>

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.
## SAFETY DATA SHEET

**Betamethasone / Clotrimazole Cream Formula-**

<table>
<thead>
<tr>
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<th>Date of first issue:</th>
</tr>
</thead>
</table>

Most important symptoms and effects, both acute and delayed:

Rinse mouth thoroughly with water. May damage the unborn child. Causes damage to organs through prolonged or repeated exposure.

Protection of first-aiders:

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

Notes to physician:

Treat symptomatically and supportively.

### 5. FIREFIGHTING MEASURES

**Suitable extinguishing media:**

- Water spray
- Alcohol-resistant foam
- Carbon dioxide (CO2)
- Dry chemical

**Unsuitable extinguishing media:**

None known.

**Specific hazards during firefighting:**

Exposure to combustion products may be a hazard to health.

**Hazardous combustion products:**

Carbon oxides

**Specific extinguishing methods:**

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Use water spray to cool unopened containers.

Remove undamaged containers from fire area if it is safe to do so.

Evacuate area.

**Special protective equipment for firefighters:**

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

### 6. ACCIDENTAL RELEASE MEASURES

**Personal precautions, protective equipment and emergency procedures:**

Use personal protective equipment. Follow safe handling advice and personal protective equipment recommendations.

**Environmental precautions:**

Discharge into the environment must be avoided. Prevent further leakage or spillage if safe to do so. Prevent spreading over a wide area (e.g. by containment or oil barriers). Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.

**Methods and materials for containment and cleaning up:**

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

### 7. HANDLING AND STORAGE

**Technical measures**: See Engineering measures under EXPOSURE CONTROLS/PERSOAL PROTECTION section.

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

**Advice on safe handling**: Do not get on skin or clothing. Do not breathe vapours or spray mist. Do not swallow. Avoid contact with eyes. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment. Keep container tightly closed. Take care to prevent spills, waste and minimize release to the environment.

**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

### 8. EXPOSURE CONTROLS/PERSOAL 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>PEL (long term) (Mist)</td>
<td>5 mg/m3</td>
<td>SG OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>PEL (short term) (Mist)</td>
<td>10 mg/m3</td>
<td>SG OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Inhalable particulate matter)</td>
<td>5 mg/m3</td>
<td>ACGIH</td>
</tr>
<tr>
<td>White mineral oil (petroleum)</td>
<td>8042-47-5</td>
<td>PEL (long term) (Mist)</td>
<td>5 mg/m3</td>
<td>SG OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>PEL (short term) (Mist)</td>
<td>10 mg/m3</td>
<td>SG 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>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
SAFETY DATA SHEET

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tion

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<table>
<thead>
<tr>
<th>Wipe limit</th>
<th>10 µg/100 cm²</th>
<th>Internal</th>
</tr>
</thead>
</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.

**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.

9. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance**

cream

**Colour**

white to off-white

**Odour**

No data available

**Odour Threshold**

No data available
### 10. STABILITY AND REACTIVITY

<table>
<thead>
<tr>
<th>Property</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reactivity</td>
<td>Not classified as a reactivity hazard.</td>
</tr>
<tr>
<td>Chemical stability</td>
<td>Stable under normal conditions.</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td></td>
</tr>
<tr>
<td>Water solubility</td>
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</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>No data available</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
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</tr>
<tr>
<td>Viscosity</td>
<td></td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>The substance or mixture is not classified as oxidizing.</td>
</tr>
<tr>
<td>Particle size</td>
<td>Not applicable</td>
</tr>
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**SAFETY DATA SHEET**

**Betamethasone / Clotrimazole Cream Formula-**

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<table>
<thead>
<tr>
<th>Property</th>
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</tr>
</thead>
<tbody>
<tr>
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<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
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SAFETY DATA SHEET

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Possibility of hazardous reactions:
Can react with strong oxidizing agents.

Conditions to avoid:
None known.

Incompatible materials:
Oxidizing agents

Hazardous decomposition products:
No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

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

Acute toxicity:
Not classified based on available information.

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

Acute dermal toxicity:
Acute toxicity estimate: > 2,000 mg/kg
Method: Calculation method

Components:

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

Acute dermal toxicity:
LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 402
Assessment: The substance or mixture has no acute dermal toxicity
Remarks: Based on data from similar materials

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

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
SAFETY DATA SHEET

Betamethasone / Clotrimazole Cream Formula-
tion

Method: OECD Test Guideline 405
Remarks: Based on data from similar materials

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

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

Germ cell mutagenicity
Not classified based on available information.

Components:

Petrolatum:
Genotoxicity in vitro: Test Type: Chromosome aberration test in vitro
Betamethasone / Clotrimazole Cream Formula-

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

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 foetal development:
  - Test Type: Embryo-foetal development
## Safety Data Sheet

### Betamethasone / Clotrimazole Cream Formulation

<table>
<thead>
<tr>
<th>Version</th>
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<th>Date of last issue</th>
<th>Date of first issue</th>
</tr>
</thead>
</table>

#### White mineral oil (petroleum):

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Species</th>
<th>Application Route</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>One-generation reproduction toxicity study</td>
<td>Rat</td>
<td>Skin contact</td>
<td>negative</td>
</tr>
</tbody>
</table>

#### Clotrimazole:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Species</th>
<th>Application Route</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fertility/early embryonic development</td>
<td>Rat</td>
<td>Oral</td>
<td>Fertility: LOAEL: 50 mg/kg body weight</td>
</tr>
<tr>
<td>Embryo-foetal development</td>
<td>Rat</td>
<td>Oral</td>
<td>Developmental Toxicity: LOAEL: 100 mg/kg body weight</td>
</tr>
<tr>
<td>Embryo-foetal development</td>
<td>Rat</td>
<td>Oral</td>
<td>Developmental Toxicity: NOAEL: 50 mg/kg body weight</td>
</tr>
<tr>
<td>Embryo-foetal development</td>
<td>Mouse</td>
<td>Oral</td>
<td>Developmental Toxicity: NOAEL: 200 mg/kg body weight</td>
</tr>
<tr>
<td>Embryo-foetal development</td>
<td>Rabbit</td>
<td>Oral</td>
<td>Developmental Toxicity: NOAEL: 180 mg/kg body weight</td>
</tr>
</tbody>
</table>

#### Reproductive toxicity - Assessment:

- Some evidence of adverse effects on sexual function and fertility, based on animal experiments.
- Some evidence of adverse effects on development, based on animal experiments.
betamethasone:
Effects on foetal development:
Species: Rabbit
Application Route: Intramuscular
Developmental Toxicity: LOAEL: 0.05 mg/kg body weight
Result: Fetotoxicity, Malformations were observed.

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

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

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

STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
Causes damage to organs (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland) through prolonged or repeated exposure.

Components:

clotrimazole:
Target Organs: Liver, Kidney, Adrenal gland
Assessment: May cause damage to organs through prolonged or repeated exposure.

betamethasone:
Target Organs: Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland
Assessment: Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

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

White mineral oil (petroleum):
Species: Rat
<table>
<thead>
<tr>
<th>LOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Species</th>
<th>LOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
<th>Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>160 mg/kg</td>
<td>Ingestion</td>
<td>90 Days</td>
<td>Rat</td>
<td>&gt;= 1 mg/l</td>
<td>Inhalation (dust/mist/fume)</td>
<td>4 Weeks</td>
<td>Skin</td>
<td>Oedema, Fissuring, Necrosis, Redness</td>
</tr>
<tr>
<td>clotrimazole:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Rabbit</td>
<td></td>
<td></td>
<td>5 - 40 mg/kg</td>
<td>Skin contact</td>
<td>3 Weeks</td>
<td>Skin</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Oral</td>
<td></td>
<td></td>
<td>10 mg/kg</td>
<td>Skin contact</td>
<td>18 Months</td>
<td>Liver, Kidney, Adrenal gland</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Dog</td>
<td></td>
<td></td>
<td>25 mg/kg</td>
<td>Oral</td>
<td>6 - 12 Months</td>
<td>Adrenal gland</td>
<td>Salivation, Lachrymation, Vomiting</td>
</tr>
<tr>
<td>betamethasone:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Rabbit</td>
<td></td>
<td></td>
<td>0.05 %</td>
<td>Skin contact</td>
<td>10 - 30 d</td>
<td>Pituitary gland, Immune system, muscle</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td></td>
<td></td>
<td>0.05 %</td>
<td>Skin contact</td>
<td>8 Weeks</td>
<td>thymus gland</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mouse</td>
<td></td>
<td></td>
<td>0.1 %</td>
<td>Skin contact</td>
<td>8 Weeks</td>
<td>thymus gland</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Dog</td>
<td></td>
<td></td>
<td>0.05 mg/kg</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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

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

<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>Betamethasone</td>
<td>&gt; 100 mg/l</td>
<td>48 h</td>
<td>OECD Test Guideline 202</td>
</tr>
<tr>
<td>Clotrimazole</td>
<td>0.02 mg/l</td>
<td>48 h</td>
<td>OECD Test Guideline 211</td>
</tr>
</tbody>
</table>

Toxicity to algae/aquatic plants

<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>Betamethasone</td>
<td>100 mg/l</td>
<td>72 h</td>
<td>OECD Test Guideline 201</td>
</tr>
<tr>
<td>Clotrimazole</td>
<td></td>
<td></td>
<td></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>Betamethasone</td>
<td>1,000 mg/l</td>
<td>28 d</td>
<td>OECD Test Guideline 210</td>
</tr>
<tr>
<td>Clotrimazole</td>
<td></td>
<td></td>
<td></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>Betamethasone</td>
<td>1,000 mg/l</td>
<td>21 d</td>
<td>OECD Test Guideline 211</td>
</tr>
<tr>
<td>Clotrimazole</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

M-Factor (Acute aquatic toxicity)

<table>
<thead>
<tr>
<th>Substance</th>
<th>10</th>
<th></th>
<th></th>
</tr>
</thead>
</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>Betamethasone</td>
<td>0.025 mg/l</td>
<td>32 d</td>
<td>OECD Test Guideline 210</td>
</tr>
<tr>
<td>Clotrimazole</td>
<td></td>
<td></td>
<td></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>Betamethasone</td>
<td>0.01 mg/l</td>
<td>21 d</td>
<td>OECD Test Guideline 211</td>
</tr>
<tr>
<td>Clotrimazole</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

M-Factor (Chronic aquatic toxicity)

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

Toxicity to microorganisms

<table>
<thead>
<tr>
<th>Substance</th>
<th>EC50: &gt; 10,000 mg/l</th>
<th>Exposure time:</th>
<th>Test Type:</th>
<th>Method:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Betamethasone</td>
<td></td>
<td>3 h</td>
<td>Respiration inhibition</td>
<td>OECD Test Guideline 209</td>
</tr>
</tbody>
</table>

Clotrimazole:

<table>
<thead>
<tr>
<th>Substance</th>
<th>LC50 (Brachydanio rerio (zebrafish)):</th>
<th>Exposure time:</th>
<th>Method:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Betamethasone</td>
<td>&gt; 0.29 mg/l</td>
<td>96 h</td>
<td>OECD Test Guideline 203</td>
</tr>
</tbody>
</table>

Betamethasone:

<table>
<thead>
<tr>
<th>Substance</th>
<th>EC50 (Americamysis):</th>
<th>Exposure time:</th>
<th>Method:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Betamethasone</td>
<td>&gt; 50 mg/l</td>
<td>96 h</td>
<td>OECD Test Guideline 202</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Substance</th>
<th>EC50 (Pseudokirchneriella subcapitata (green algae)):</th>
<th>Exposure time:</th>
<th>Method:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Betamethasone</td>
<td>&gt; 34</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
plants  
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  

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

Bioaccumulative potential  

Components:  

betamethasone:  
Partition coefficient: n-octanol/water: log Pow: 2.11
13. DISPOSAL CONSIDERATIONS

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

14. TRANSPORT INFORMATION

International Regulations

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

IATA-DGR
UN/ID No.: UN 3082
Proper shipping name: Environmentally hazardous substance, liquid, n.o.s. (clotrimazole, betamethasone)
Class: 9
Packing group: III
Labels: Miscellaneous
Packing instruction (cargo aircraft): 964
Packing instruction (passenger aircraft): 964
Environmentally hazardous: yes

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

Transport in bulk according to 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.

15. REGULATORY INFORMATION

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

Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations: This product is subjected to the SDS, labelling, PEL and other requirements in the Act/Regulations.

Environmental Protection and Management Act and Environmental Protection and Management (Hazardous Substances) Regulations: Not applicable

Fire Safety (Petroleum and Flammable Materials) Regulations: Not applicable

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

AICS: not determined

DSL: not determined

IECSC: not determined

16. OTHER INFORMATION

Further information


Date format: dd.mm.yyyy

Full text of other abbreviations

ACGIH: USA. ACGIH Threshold Limit Values (TLV)

SG OEL: Singapore. Workplace Safety and Health Act - First Schedule

Permissible Exposure Limits of Toxic Substances

ACGIH / TWA: 8-hour, time-weighted average

SG OEL / PEL (long term): Permissible Exposure Level (PEL) Long Term

SG OEL / PEL (short term): Permissible Exposure Level (PEL) Short Term

AICS - Australian Inventory of Chemical Substances; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for
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.

SG / EN