SAFETY DATA SHEET

Tolnaftate Ointment Formulation

Section 1: Identification

Product name : Tolnaftate Ointment Formulation

Manufacturer or supplier’s details

Company : MSD
Address : 33 Whakatiki Street - Private Bag 908
          Upper Hutt - New Zealand
Telephone : 908-740-4000
Emergency telephone number : 1-908-423-6000
E-mail address : EHSDATASTEWARD@msd.com
Telefax : 908-735-1496

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

Section 2: Hazard identification

GHS Classification
Not a hazardous substance or mixture.

GHS label elements
Not a hazardous substance or mixture.

Other hazards which do not result in classification
None known.

Section 3: Composition/information on ingredients

Substance / Mixture : Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>&gt;= 30 -&lt; 60</td>
</tr>
<tr>
<td>Tolnaftate</td>
<td>2398-96-1</td>
<td>&lt; 10</td>
</tr>
</tbody>
</table>

Section 4: First-aid measures

If inhaled : If inhaled, remove to fresh air.
            Get medical attention if symptoms occur.
In case of skin contact : Wash with water and soap as a precaution.
                         Get medical attention if symptoms occur.
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 if symptoms occur. Rinse mouth thoroughly with water.

**Most important symptoms and effects, both acute and delayed**

None known.

**Protection of first-aiders**

No special precautions are necessary for first aid responders.

**Notes to physician**

Treat symptomatically and supportively.

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### 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 firefighters**

Wear self-contained breathing apparatus for firefighting if necessary.

Use personal protective equipment.

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### Section 6: Accidental release measures

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

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.

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**

Sweep up or vacuum up spillage and collect in suitable container for disposal.

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.

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### Section 7: Handling and storage

**Technical measures**

See Engineering measures under EXPOSURE
Local/Total ventilation: Use only with adequate ventilation.

Advice on safe handling: Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
Take care to prevent spills, waste and minimize release to the environment.

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

Conditions for safe storage: Keep in properly labelled containers.
Store in accordance with the particular national regulations.

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

Section 8: Exposure controls/personal protection

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters/Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>WES-TWA (particulate)</td>
<td>10 mg/m³</td>
<td>NZ OEL</td>
</tr>
<tr>
<td>Tolnaftate</td>
<td>2398-96-1</td>
<td>TWA</td>
<td>1 mg/m³ (OEB 1)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Engineering measures: Use feasible engineering controls to minimize exposure to compound.
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

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: Particulates type

Hand protection: Chemical-resistant gloves

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.

**Section 9: Physical and chemical properties**

**Appearance** : ointment

**Colour** : No data available

**Odour** : No data available

**Odour 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** : Not applicable

**Evaporation rate** : Not applicable

**Flammability (solid, gas)** : Not classified as a flammability hazard

**Flammability (liquids)** : No data available

**Upper explosion limit / Upper flammability limit** : No data available

**Lower explosion limit / Lower flammability limit** : No data available

**Vapour pressure** : Not applicable

**Relative vapour density** : Not applicable

**Relative density** : No data available

**Density** : No data available

**Solubility(ies)**

- **Water solubility** : No data available

**Partition coefficient: n-octanol/water** : Not applicable

**Auto-ignition temperature** : No data available

**Decomposition temperature** : No data available

**Viscosity**

- **Viscosity, kinematic** : Not applicable
Explosive properties: Not explosive

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

Particle size: No data available

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

Exposure routes:
- Skin contact
- Ingestion
- Eye contact

Acute toxicity:
Not classified based on available information.

Components:

Propylene glycol:
- Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
- Acute inhalation toxicity: LC50 (Rabbit): > 159 mg/l
  Exposure time: 4 h
  Test atmosphere: dust/mist
- Acute dermal toxicity: LD50 (Rabbit): > 2,000 mg/kg
  Assessment: The substance or mixture has no acute dermal toxicity

Tolnaftate:
- Acute oral toxicity: LD50 (Rat): > 6,000 mg/kg
  LD50 (Mouse): > 10,000 mg/kg
  LD50 (Dog): > 14,000 mg/kg

Skin corrosion/irritation:
Not classified based on available information.

Components:

Propylene glycol:
- Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation

Tolnaftate:
Species: Rabbit
Result: No skin irritation

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

Components:

Propylene glycol:
Species: Rabbit
Result: No eye irritation
Method: OECD Test Guideline 405

Tolnaftate:
Species: Rabbit
Result: Irritation to eyes, reversing within 7 days

Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Components:

Propylene glycol:
Test Type: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
Result: negative

Chronic toxicity

Germ cell mutagenicity
Not classified based on available information.

Components:

Propylene glycol:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Genotoxicity in vivo: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Intraperitoneal injection
Result: negative
**Tolnaftate Ointment Formulation**

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

Carcinogenicity:
Not classified based on available information.

**Components:**

<table>
<thead>
<tr>
<th>Propylene glycol:</th>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
<td></td>
</tr>
<tr>
<td>Exposure time</td>
<td>2 Years</td>
<td></td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
<td></td>
</tr>
</tbody>
</table>

**Reproductive toxicity**:
Not classified based on available information.

**Components:**

<table>
<thead>
<tr>
<th>Propylene glycol:</th>
<th>Effects on fertility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species</td>
<td>Mouse</td>
</tr>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Propylene glycol:</th>
<th>Effects on foetal development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species</td>
<td>Mouse</td>
</tr>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
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</table>

<table>
<thead>
<tr>
<th>Tolnaftate:</th>
<th>Effects on foetal development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species</td>
<td>Mouse</td>
</tr>
<tr>
<td>Application Route</td>
<td>Subcutaneous</td>
</tr>
<tr>
<td>Developmental Toxicity: LOAEL: 1,000 mg/kg body weight</td>
<td></td>
</tr>
<tr>
<td>Result: Reduced foetal weight</td>
<td></td>
</tr>
<tr>
<td>Remarks: Maternal toxicity observed.</td>
<td></td>
</tr>
<tr>
<td>Test Type: Embryo-foetal development</td>
<td></td>
</tr>
<tr>
<td>Species: Rat</td>
<td></td>
</tr>
<tr>
<td>Application Route: Oral</td>
<td></td>
</tr>
<tr>
<td>Developmental Toxicity: LOAEL: 25 mg/kg body weight</td>
<td></td>
</tr>
<tr>
<td>Result: Embryo-foetal toxicity, No teratogenic effects</td>
<td></td>
</tr>
</tbody>
</table>

Test Type: Embryo-foetal development
Species: Mouse
Application Route: Oral
Developmental Toxicity: NOAEL: 2,000 mg/kg body weight
Result: No teratogenic effects
STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
Not classified based on available information.

Components:

Tolnaftate:
Assessment : No significant health effects observed in animals at concentrations of 100 mg/kg bw or less.

Repeated dose toxicity

Components:

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

Tolnaftate:
Species : Mouse
NOAEL : 2,500 mg/kg
Application Route : Oral
Exposure time : 14 d
Remarks : No significant adverse effects were reported

Species : Dog
NOAEL : 500 mg/kg
Application Route : Oral
Exposure time : 30 Days
Remarks : No significant adverse effects were reported

Species : Rabbit
NOAEL : 2,500 mg/kg
Application Route : Oral
Exposure time : 91 Days
Remarks : No significant adverse effects were reported

Species : Rabbit
NOAEL : 30 mg/kg
Application Route : Skin contact
Exposure time : 30 d
Remarks : No significant adverse effects were reported

Species : Rat
Application Route : Inhalation
Exposure time : 3 Weeks
Remarks : No significant adverse effects were reported

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

**Components:**

**Tolnaftate:**

- **Skin contact**
  - Symptoms: Skin irritation, skin rash

Section 12: Ecological information

**Ecotoxicity**

**Components:**

**Propylene glycol:**

- Toxicity to fish: LC50 (Oncorhynchus mykiss (rainbow trout)): 40,613 mg/l
  - Exposure time: 96 h

- Toxicity to daphnia and other aquatic invertebrates: EC50 (Ceriodaphnia dubia (water flea)): 18,340 mg/l
  - Exposure time: 48 h

- Toxicity to algae/aquatic plants: ErC50 (Skeletonema costatum (marine diatom)): 19,300 mg/l
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201

- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC (Ceriodaphnia dubia (water flea)): 13,020 mg/l
  - Exposure time: 7 d

- Toxicity to microorganisms: NOEC (Pseudomonas putida): > 20,000 mg/l
  - Exposure time: 18 h

**Tolnaftate:**

- Toxicity to fish: LC50 (Menidia beryllina (Silverside)): > 2 mg/l
  - Exposure time: 96 h
  - Remarks: No toxicity at the limit of solubility

- Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 2.5 mg/l
  - Exposure time: 48 h
  - Method: OECD Test Guideline 202
  - Remarks: No toxicity at the limit of solubility
  
  LC50 (Americamysis): > 2.5 mg/l
  - Exposure time: 96 h
  - Remarks: No toxicity at the limit of solubility

- Toxicity to algae/aquatic plants: EC50 (Pseudokirchneriella subcapitata (green algae)): 0.55 mg/l
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201

  NOEC (Pseudokirchneriella subcapitata (green algae)): 0.16 mg/l
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201
Toxicity to microorganisms:
EC50: > 1,000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209
Remarks: No toxicity at the limit of solubility

NOEC: 1,000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209
Remarks: No toxicity at the limit of solubility

Persistence and degradability

Components:

Propylene glycol:
Biodegradability: Result: Readily biodegradable.
Biodegradation: 98.3 %
Exposure time: 28 d
Method: OECD Test Guideline 301F

Bioaccumulative potential

Components:

Propylene glycol:
Partition coefficient: n-octanol/water: log Pow: -1.07

Tolnaftate:
Partition coefficient: n-octanol/water: log Pow: 4.53

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:
Not regulated as a dangerous good
Section 15: Regulatory information

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

HSNOS Approval Number
HSR100425 Pharmaceutical Active Ingredients Group Standard 2017

HSW Controls
Certified handler certificate not required.
Tracking hazardous substance not required.
Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

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

Section 16: Other information

Further information
Date format : dd.mm.yyyy

Full text of other abbreviations
NZ OEL : New Zealand. Workplace Exposure Standards for Atmospheric Contaminants
NZ OEL / WES-TWA : Workplace Exposure Standard - Time Weighted average

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
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NZ / EN