SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Tolnaftate Ointment Formulation

Manufacturer or supplier’s details
Company: MSD
Address: 26 Talavera Road, Talavera Corp Centre, Macquarie Park, New South Wales, 2113 Australia
Telephone: (61)-02-8988-8000
Emergency telephone number: (61)-02-8988-8000
E-mail address: EHSDATASTEWARD@msd.com
Telefax: 908-735-1496

Recommended use of the chemical and restrictions on use
Recommended use: Pharmaceutical

SECTION 2. HAZARDS 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:

Protection of first-aiders:

Notes to physician:

Treat symptomatically and supportively.

SECTION 5. FIREFIGHTING MEASURES

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

Unsuitable extinguishing media:

Specific hazards during fire-fighting:

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.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures:
- 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.
- 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.

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.
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>TWA (particulate)</td>
<td>10 mg/m3</td>
<td>AU OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Total (vapour and particles))</td>
<td>150 ppm 474 mg/m3</td>
<td>AU OEL</td>
</tr>
<tr>
<td>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 Material : 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
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
<table>
<thead>
<tr>
<th><strong>Tolnaftate:</strong></th>
<th></th>
</tr>
</thead>
</table>
| Genotoxicity in vitro | Test Type: Chromosome aberration test in vitro  
Result: negative |

**Carcinogenicity**

Not classified based on available information.

**Components:**

**Propylene glycol:**

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

**Reproductive toxicity**

Not classified based on available information.

**Components:**

**Propylene glycol:**

| Effects on fertility | Test Type: Three-generation reproduction toxicity study  
Species: Mouse  
Application Route: Ingestion  
Result: negative |
|---|---|
| Effects on foetal development | Test Type: Embryo-foetal development  
Species: Mouse  
Application Route: Ingestion  
Result: negative |

**Tolnaftate:**

| Effects on foetal development | Test Type: Embryo-foetal development  
Species: Mouse  
Application Route: Subcutaneous  
Developmental Toxicity: LOAEL: 1,000 mg/kg body weight  
Result: Reduced foetal weight  
Remarks: Maternal toxicity observed.  
Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Oral  
Developmental Toxicity: LOAEL: 25 mg/kg body weight  
Result: Embryo-foetal toxicity, No teratogenic effects  
Test Type: Embryo-foetal development  
Species: Mouse  
Application Route: Oral  
Developmental Toxicity: NOAEL: 2,000 mg/kg body weight  
Result: No teratogenic effects |
SAFETY DATA SHEET

Tolnaftate Ointment Formulation

Version 1.4 Revision Date: 10.10.2020 SDS Number: 2260142-00005 Date of last issue: 13.09.2019 Date of first issue: 29.11.2017

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

Prohibition/Licensing Requirements : There is no applicable prohibition, authorisation and restricted use requirements, including for carcinogens referred to in Schedule 10 of the model WHS Act and Regulations.

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

AICS : not determined

DSL : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

Further information

Revision Date : 10.10.2020


Date format : dd.mm.yyyy

Full text of other abbreviations

AU OEL : Australia. Workplace Exposure Standards for Airborne Contaminants.

AU OEL / TWA : Exposure standard - time weighted average

AICL - 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
The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

AU / EN