SAFETY DATA SHEET

Tolnaftate Ointment Formulation

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

: None known.

: No special precautions are necessary for first aid responders.

: Treat symptomatically and supportively.

SECTION 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

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 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.

SECTION 7. HANDLING AND STORAGE

Technical measures

See Engineering measures under EXPOSURE
SAFETY DATA SHEET

Tolnaftate Ointment Formulation

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.

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>TWA (particulate)</td>
<td>10 mg/m³</td>
<td>AU OEL</td>
</tr>
<tr>
<td>Tolnaftate</td>
<td>2398-96-1</td>
<td>TWA (Total (vapour and particles))</td>
<td>150 ppm 474 mg/m³</td>
<td>AU OEL</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
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:

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

Carcinogenicity

Not classified based on available information.

Components:

Propylene glycol:
Species: Rat
Application Route: Ingestion
Exposure time: 2 Years
Result: negative

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
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
SAFETY DATA SHEET

Tolnaftate Ointment Formulation

Version 1.3   Revision Date: 09/13/2019   SDS Number: 2260142-00004   Date of last issue: 24.04.2019   Date of first issue: 29.11.2017

IATA-DGR
Not regulated as a dangerous good

IMDG-Code
Not regulated as a dangerous good

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

National Regulations

ADG
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 or notification/licensing requirements, including for carcinogens under Commonwealth, State or Territory legislation.

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

AICS: not determined
DSL: not determined
IECS: not determined

SECTION 16. OTHER INFORMATION

Further information

Revision Date: 09/13/2019

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

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 Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with
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