SAFETY DATA SHEET

Tolnaftate Ointment Formulation

Version 1.5 Revision Date: 10.10.2020 SDS Number: 2260129-00006 Date of last issue: 13.09.2019
Date of first issue: 29.11.2017

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.

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 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 (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. 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></td>
<td></td>
<td>WES-TWA (Vapour and particulates)</td>
<td>150 ppm 474 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 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
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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
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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

NZS 5433
Not regulated as a dangerous good

Section 15: Regulatory information

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

HSNO 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

AIIC - 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
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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; SADT - 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.

NZ / EN