1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Tolnaftate Ointment Formulation

Manufacturer or supplier’s details
Company : MSD
Address : 199 Wenhai North Road
          HEDA, Hangzhou - Zhejiang Province - CHINA  310018
Telephone : 908-740-4000
Emergency telephone number : 86-571-87268110
E-mail address : EHSDATASTEWARD@msd.com

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

2. HAZARDS IDENTIFICATION

Emergency Overview
Appearance : ointment
Colour : No data available
Odour : No data available
Harmful to aquatic life with long lasting effects.

GHS Classification
Short-term (acute) aquatic hazard : Category 3
Long-term (chronic) aquatic hazard : Category 3

GHS label elements
Hazard pictograms : None
Signal word : None
Hazard statements : H412 Harmful to aquatic life with long lasting effects.
Precautionary statements : Prevention:
P273 Avoid release to the environment.
Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.

Physical and chemical hazards
Not classified based on available information.
SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

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SDS Number: 2260136-00005
Date of last issue: 2019/04/24
Date of first issue: 2017/11/29

Health hazards
Not classified based on available information.

Environmental hazards
Harmful to aquatic life. Harmful to aquatic life with long lasting effects.

Other hazards which do not result in classification
None known.

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>Tolnaftate</td>
<td>2398-96-1</td>
<td>&gt;= 1 -&lt; 2.5</td>
</tr>
<tr>
<td>2,6-Di-tert-butyl-p-cresol</td>
<td>128-37-0</td>
<td>&gt;= 0.25 -&lt; 1</td>
</tr>
</tbody>
</table>

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.

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.
SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

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Special protective equipment for firefighters:
Wear self-contained breathing apparatus for firefighting if necessary.
Use personal protective equipment.

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.

7. HANDLING AND STORAGE

Handling
Technical measures:
See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

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.

Avoidance of contact:
Oxidizing agents

Storage
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

Packaging material:
Unsuitable material: None known.

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>
</table>

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Tolnaftate Ointment Formulation

<table>
<thead>
<tr>
<th>Tolnaftate</th>
<th>2398-96-1</th>
<th>TWA</th>
<th>1 mg/m³ (OEB 1)</th>
<th>Internal</th>
</tr>
</thead>
<tbody>
<tr>
<td>2,6-Di-tert-butyl-p-cresol</td>
<td>128-37-0</td>
<td>TWA (Inhalable fraction and vapor)</td>
<td>2 mg/m³</td>
<td>ACGIH</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

Eye/face 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.

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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>Ointment</td>
</tr>
<tr>
<td>Colour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</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>
</tbody>
</table>
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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) : No data available
Water solubility : No data available
Partition coefficient: n-octanol/water : Not applicable
Auto-ignition temperature : No data available
Decomposition temperature : No data available
Viscosity : Not applicable
Viscosity, kinematic : Not applicable
Explosive properties : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.
Particle size : No data available

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.
11. TOXICOLOGICAL INFORMATION

Exposure routes:
- Skin contact
- Ingestion
- Eye contact

Acute toxicity:
Not classified based on available information.

Components:

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

2,6-Di-tert-butyl-p-cresol:
- Acute oral toxicity: LD50 (Rat): > 6,000 mg/kg
  Method: OECD Test Guideline 401
- Acute dermal toxicity: LD50 (Rat): > 2,000 mg/kg
  Method: OECD Test Guideline 402
  Assessment: The substance or mixture has no acute dermal toxicity

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

Components:

Tolnaftate:
- Species: Rabbit
- Result: No skin irritation

2,6-Di-tert-butyl-p-cresol:
- Species: Rabbit
- Method: OECD Test Guideline 404
- Result: No skin irritation
- Remarks: Based on data from similar materials

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

Components:

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

**Species:** Rabbit

**Result:** No eye irritation

**Method:** OECD Test Guideline 405

**Remarks:** Based on data from similar materials

**Respiratory or skin sensitisation**

**Skin sensitisation**
Not classified based on available information.

**Respiratory sensitisation**
Not classified based on available information.

**Components:**

### 2,6-Di-tert-butyl-p-cresol:

- **Test Type:** Human repeat insult patch test (HRIPT)
- **Exposure routes:** Skin contact
- **Species:** Humans
- **Result:** negative

**Germ cell mutagenicity**
Not classified based on available information.

**Components:**

### Tolnaftate:

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

**Genotoxicity in vivo**
- **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:** negative
- **Test Type:** Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
  - **Species:** Rat
  - **Application Route:** Ingestion
  - **Result:** negative

**Carcinogenicity**
Not classified based on available information.
Components:

2,6-Di-tert-butyl-p-cresol:
Species : Rat
Application Route : Ingestion
Exposure time : 22 Months
Result : negative

Reproductive toxicity
Not classified based on available information.

Components:

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

2,6-Di-tert-butyl-p-cresol:
Effects on fertility : Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: negative

Effects on foetal development : Test Type: Embryo-foetal development
Species: Rat
Application Route: Ingestion
Result: negative

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.

2,6-Di-tert-butyl-p-cresol:
Assessment : No significant health effects observed in animals at concentrations of 100 mg/kg bw or less.

Repeated dose toxicity

Components:

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

2,6-Di-tert-butyl-p-cresol:
Species : Rat
NOAEL : 25 mg/kg
Application Route : Ingestion
Exposure time : 22 Months
10. Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:

Tolnaftate:
Skin contact: Symptoms: Skin irritation, skin rash

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

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

M-Factor (Acute aquatic toxicity):
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
Tolnaftate Ointment Formulation

2,6-Di-tert-butyl-p-cresol:
   Toxicity to fish: LC50 (Danio rerio (zebra fish)): > 0.57 mg/l
   Exposure time: 96 h

   Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): 0.48 mg/l
   Exposure time: 48 h
   Method: OECD Test Guideline 202

   Toxicity to algae/aquatic plants: ErC50 (Pseudokirchneriella subcapitata (green algae)): > 0.24 mg/l
   Exposure time: 72 h
   Method: OECD Test Guideline 201

   NOEC (Pseudokirchneriella subcapitata (green algae)): 0.24 mg/l
   Exposure time: 72 h
   Method: OECD Test Guideline 201

   M-Factor (Acute aquatic toxicity): 1
   Toxicity to fish (Chronic toxicity): NOEC (Oryzias latipes (Japanese medaka)): 0.053 mg/l
   Exposure time: 30 d
   Method: OECD Test Guideline 210

   Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC (Daphnia magna (Water flea)): 0.316 mg/l
   Exposure time: 21 d
   Method: OECD Test Guideline 210

   M-Factor (Chronic aquatic toxicity): 1
   Toxicity to microorganisms: EC50: > 10,000 mg/l
   Exposure time: 3 h
   Method: OECD Test Guideline 209

Persistence and degradability

Components:

2,6-Di-tert-butyl-p-cresol:
   Biodegradability: Result: Not readily biodegradable.
   Biodegradation: 4.5 %
   Exposure time: 28 d
   Method: OECD Test Guideline 301C

Bioaccumulative potential

Components:

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

2,6-Di-tert-butyl-p-cresol:
Bioaccumulation: Species: Cyprinus carpio (Carp)  
  Bioconcentration factor (BCF): 330 - 1,800

Partition coefficient: n-octanol/water
  log Pow: 5.1

Mobility in soil
  No data available

Other adverse effects
  No data available

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: Not regulated as a dangerous good

  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

  GB 6944/12268: Not regulated as a dangerous good

  Special precautions for user

  Not applicable

15. REGULATORY INFORMATION

National regulatory information

  Law on the Prevention and Control of Occupational Diseases

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 : yyyy/mm/dd

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

ACGIH / TWA : 8-hour, 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 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

Disclaimer

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.

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