

Tolnaftate

Version: 4.0

Revision Date: 22.01.2025

SDS Number: 100000000597

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name : Tolnaftate

REACH Registration Number : NA

CAS-No. : 2398-96-1

EC-No. : 219-266-6

Unique Formula Identifier : -

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub-
stance/Mixture : Active pharmaceutical ingredients

Recommended restrictions
on use : No data available

1.3 Details of the supplier of the safety data sheet

Company : Fermion Oy

Street address : Koivu-Mankkaan tie 6 A

Post-office box: : P.O. Box 28

Postcode : 02101 Espoo, Finland

Telephone : +358 10 4261

E-mail address of person
responsible for the SDS : chemicalsafety@orion.fi

VAT Reg. No: : FI18552129

1.4 Emergency telephone number

Poison Center : +358 800 147111
+358 9 471 977

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture


Classification (REGULATION (EC) No 1272/2008)

Eye irritation, Category 2	H319: Causes serious eye irritation.
Short-term (acute) aquatic hazard, Category 1	H400: Very toxic to aquatic life.
Long-term (chronic) aquatic hazard, Category 2	H411: Toxic to aquatic life with long lasting effects.

For explanation of abbreviations see section 16.

2.2 Label elements

Labeling (REGULATION (EC) No 1272/2008)

Hazard pictograms : 

Signal Word : Warning

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Hazard Statements

H319 Causes serious eye irritation.
H400 Very toxic to aquatic life.
H411 Toxic to aquatic life with long lasting effects.

Precautionary Statements

General:

P264 Wash hands and face thoroughly after handling.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337 + P313 If eye irritation persists: Get medical advice/ attention.

Disposal:

P501 Dispose of contents according to national and local law.

2.3 Other hazards

Other hazards : No data available

PBT : No data available

vPvB : No data available

Endocrine disrupting properties : Ecological information: No data available
Toxicological information: No data available

SECTION 3: Composition/information on ingredients

3.1 Substances

Chemical name	CAS-No. EC-No. Registration-No	Concentration (% w/w)	M-Factor, SCL, ATE
Tolnaftate	2398-96-1 219-266-6 NA		M-Factor (Acute aquatic toxicity): 1

Other information : No data available

3.2 Mixtures

Not applicable

SECTION 4: First aid measures

4.1 Description of first-aid measures

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General advice	: IF exposed: Call a POISON CENTER or doctor/ physician. Helpers should ensure their own protection.
If inhaled	: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
In case of skin contact	: Remove/ Take off immediately all contaminated clothing. Wash off with soap and water.
In case of eye contact	: IF IN EYES: Rinse continuously with water for several minutes. Get medical advice/attention. Remove contact lenses, if present and easy to do. Continue rinsing.
If swallowed	: Induce vomiting. Give charcoal. Get medical advice/attention.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms	: No data available
Risks	: No data available

4.3 Indication of any immediate medical attention and special treatment needed

Treatment	: No data available
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SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media	: Carbon dioxide (CO ₂) Alcohol-resistant foam Dry chemical Water spray
Unsuitable extinguishing media	: No data available

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire fighting	: May emit toxic fumes of oxides of carbon, nitrogen and sulphur during heating or fire.
Hazardous combustion products	: No data available

5.3 Advice for firefighters

Special protective equipment for fire-fighters	: Isolating breathing apparatus eg. compressed breathing apparatus and protective clothing.
Specific extinguishing methods	: No data available
Further information	: No data available

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SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment as required.
Do not get in eyes, on skin, or on clothing.

6.2 Environmental precautions

Environmental precautions : Do not discharge into the environment.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Collect spilled powder without dusting into tight closed container.

6.4 Reference to other sections

See Section 8 and 13

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advice on safe handling : Handle in well-ventilated space.
Avoid dust formation.

7.2 Conditions for safe storage, including any incompatibilities

Packaging material : Suitable material: No data available
Unsuitable material: No data available

Further information on storage conditions : Store in a dry place.
Protect from moisture.
Store in a closed container.
See incompatible materials in section 10.5.

7.3 Specific end use(s)

Specific use(s) : No information identified.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Contains no substances with occupational exposure limit values.

8.2 Exposure controls

Engineering measures : Handle in well-ventilated space.
All exposure must be avoided.
Handle in closed systems or use an efficient local exhaust if dust, vapours or mists may release into workplace air. If technical measures cannot prevent exposure, wear personal protective equipment.

Personal protective equipment

Respiratory protection : In open handling use respirator (P3) with a minimum protection factor of 20.
See standard working procedures/instructions or department's

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instructions for more detailed protection measures.

Eye/face protection	:	Use protective goggles.
Hand protection	:	
Remarks	:	Use protective gloves (e.g. nitrile or neopren gloves).
Skin and body protection	:	Wear protective clothing.
Protective measures	:	No data available
Environmental exposure controls	:	No data available

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Form	:	powder
Physical state	:	solid
Color	:	white, Yellowish
Odor	:	odorless
Odor Threshold	:	No data available
Melting point/range	:	110 - 112 °C
Boiling point/boiling range	:	No data available
Flammability	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Flash point	:	No data available
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Self-Accelerating decomposition temperature (SADT)	:	No data available
pH	:	No data available
Viscosity	:	
Viscosity, dynamic	:	No data available
Viscosity, kinematic	:	No data available
Flow time	:	No data available

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Solubility(ies)	
Water solubility	: insoluble
Solubility in other solvents	: Solvent: Acetone Description: soluble
Dissolution Rate	: No data available
Partition coefficient: n-octanol/water	: No data available
Dispersion Stability	: No data available
Vapor pressure	: No data available
Relative density	: No data available
Density	: No data available
Bulk density	: No data available
Relative vapor density	: No data available
Dissociation constant	: No data available
Particle characteristics	: No data available

9.2 Other information

Self-ignition	: No data available
Hygroscopic properties	: No data available
Henry's Constant	: No data available
Further information	: No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

No data available

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : Not expected to occur.

10.4 Conditions to avoid

Conditions to avoid : Dust may form explosive mixtures with air.

10.5 Incompatible materials

Materials to avoid : Acids

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Alkalis

10.6 Hazardous decomposition products

May emit toxic fumes of oxides of carbon, nitrogen and sulphur during heating or fire.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity

Health hazard information : Based on available data, the classification criteria are not met.

Acute oral toxicity : LD50 (Rat): > 6 000 mg/kg
LD50 (Mouse): 10 000 mg/kg
LD50 (dogs): > 14 000 mg/kg
LD50 (guinea pig): > 4 000 mg/kg

Acute inhalation toxicity : No data available

Acute dermal toxicity : No data available

Acute toxicity (other routes of administration) : LD50 (Rat): > 4 000 mg/kg
Target Organs: subcutaneous
LD50 (Mouse): 120 mg/kg
Target Organs: Intraperitoneal
LD50 (Mouse): 4 800 mg/kg
Target Organs: intravenous
LD50 (Mouse): > 6 000 mg/kg
Target Organs: subcutaneous
LD50 (Rabbit): >= 50 mg/kg
Target Organs: intravenous

Skin corrosion/irritation

Remarks : Skin reactions occur rarely and include irritation and dermatitis.

Serious eye damage/eye irritation

Result : Causes serious eye irritation.

Respiratory or skin sensitization

No data available

Germ cell mutagenicity

Genotoxicity in vitro : No data available

Genotoxicity in vivo : No data available

Carcinogenicity

No data available

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Reproductive toxicity

Effects on fertility : No data available

Effects on fetal development : No data available

STOT-single exposure

No data available

STOT-repeated exposure

No data available

Repeated dose toxicity

No data available

Aspiration toxicity

No data available

11.2 Information on other hazards

Endocrine disrupting properties

No data available

Experience with human exposure

General Information : No data available

Inhalation : No data available

Skin contact : No data available

Eye contact : No data available

Ingestion : No data available

Toxicology, Metabolism, Distribution

Remarks : No data available

Neurological effects

Remarks : No data available

Further information

No data available

Other Health Hazards

No data available

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SECTION 12: Ecological information

12.1 Toxicity

Toxicity to fish : No data available

Toxicity to daphnia and other aquatic invertebrates : No data available

Toxicity to algae/aquatic plants : No data available

Toxicity to fish (Chronic toxicity) : No data available

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : No data available

Toxicity to microorganisms : No data available

Toxicity to soil dwelling organisms : No data available

Plant toxicity : No data available

Sediment toxicity : No data available

Toxicity to terrestrial organisms : No data available

Ecotoxicology Assessment

Acute aquatic toxicity : Very toxic to aquatic life.
Toxic to aquatic life with long lasting effects.

Chronic aquatic toxicity : No data available

Toxicity Data on Soil : No data available

Other organisms relevant to the environment : No data available

12.2 Persistence and degradability

Biodegradability : Result: Not biodegradable

Biochemical Oxygen Demand (BOD) : No data available

Chemical Oxygen Demand (COD) : No data available

BOD/COD : No data available

ThOD : No data available

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BOD/ThOD	:	No data available
Dissolved organic carbon (DOC)	:	No data available
Physico-chemical removability	:	No data available
Stability in water	:	No data available
Impact on Sewage Treatment	:	No data available
Photodegradation	:	No data available

12.3 Bioaccumulative potential

Bioaccumulation	:	Bioconcentration factor (BCF): > 2 000 L/kg (QSAR) According to BCF value this compound is bioaccumulative.
Partition coefficient: n-octanol/water	:	No data available

12.4 Mobility in soil

Mobility	:	No data available
Distribution among environmental compartments	:	No data available
Stability in soil	:	No data available

12.5 Results of PBT and vPvB assessment

Assessment	:	No data available
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12.6 Endocrine disrupting properties

No data available

12.7 Other adverse effects

Environmental fate and pathways	:	No data available
Adsorbed organic bound halogens (AOX)	:	No data available
Ozone-Depletion Potential	:	No data available
Additional ecological information	:	No data available

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SECTION 13: Disposal considerations

13.1 Waste treatment methods

Chemical incinerator equipped with an afterburner and scrubber is the recommended method of disposal for this material. Observe all local and national regulations when disposing of this material.

SECTION 14: Transport information

14.1 UN number

ADR/RID: UN 3077

IMDG: UN 3077

IATA: UN 3077

14.2 UN proper shipping name

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Tolnaftate)

14.3 Transport hazard class(es) (ADR/RID, IMDG, ICAO/IATA)

ADR/RID: 9

IMDG: 9

IATA: 9

14.4 Packing group

ADR/RID: III

IMDG: III

IATA: III

14.5 Environmental hazards

ADR/RID: Yes

IMDG: Yes

IATA: Yes

14.6 Special precautions for user

Tunnel restriction code : No data available

Further information for transport : No data available

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC code

Not applicable

SECTION 15: Regulatory information

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

The product has not been fully tested.

15.2 Chemical Safety Assessment

No

SECTION 16: Other information

Full text of H-Statements

H319

Causes serious eye irritation.

H400

Very toxic to aquatic life.

H411

Toxic to aquatic life with long lasting effects.

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Full text of other abbreviations

Eye Irrit.	:	Eye irritation
Aquatic Acute	:	Short-term (acute) aquatic hazard
Aquatic Chronic	:	Long-term (chronic) aquatic hazard

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways

ADR - Agreement concerning the International Carriage of Dangerous Goods by Road

AIIC - Australian Inventory of Industrial Chemicals

ASTM - American Society for the Testing of Materials

bw - Body weight

CLP - Classification Labelling Packaging Regulation

Regulation (EC) No 1272/2008

CMR - Carcinogen, Mutagen or Reproductive Toxicant

DIN - Standard of the German Institute for Standardisation

DSL - Domestic Substances List (Canada)

ECHA - European Chemicals Agency

EC-Number - European Community number

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

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)

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MARPOL - International Convention for the Prevention of Pollution from Ships

n.o.s. - Not Otherwise Specified

NO(A)EC - No Observed (Adverse) Effect Concentration

NO(A)EL - No Observed (Adverse) Effect Level

NOELR - No Observable Effect Loading Rate

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

RID - Regulations concerning the International Carriage of Dangerous Goods by Rail

SADT - Self-Accelerating Decomposition Temperature

SDS - Safety Data Sheet

SVHC - substance of very high concern

TCSI - Taiwan Chemical Substance Inventory

TECI - Thailand Existing Chemicals Inventory

TRGS - Technical Rule for Hazardous Substances

TSCA - Toxic Substances Control Act (United States)

UN - United Nations

vPvB - Very Persistent and Very Bioaccumulative

Further information

Other information : No data available

Sources of key data used to compile the Material Safety Data Sheet : Information provided by the supplier

Information which has been added, deleted or revised : Updated section / sections:
2, 4, 6, 8, 11, 12, 14

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 given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.