

Effective Date 06.10.2021
Revision 4.0

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING
1.1. Product identifier

Trade name: Tolnaftate
CAS-number: 2398-96-1

Reach registration number: NA

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

The uses of the chemical: Active pharmaceutical ingredients
Classification of the economic activities (NACE): 212
Use categories (UC62): 41

1.3. Details of the supplier of the safety data sheet:

Manufacturer/importer: Fermion Oy
Street address: Koivu-Mankkaan tie 6 A
Post-office box: P.O. Box 28
Postcode: 02101 Espoo, Finland
Telephone number: +358 10 4261
Telefax: +358 9 452 1764
E-mail address: chemicalsafety@orion.fi
VAT Reg. No: FI18552129

1.4. Emergency telephone number

Poison Center: +358 9 471 977

SECTION 2: HAZARDS IDENTIFICATION
2.1. Classification of the substance or mixture

Classification according to regulation (EC) No 1272/2008	Eye Irrit. 2 H319, Aquatic Acute 1 H400, Aquatic Chronic 2 H411,
H Statements	Causes serious eye irritation. Very toxic to aquatic life. Toxic to aquatic life with long lasting effects.
M-Factor	M=1

Effective Date 06.10.2021
Revision 4.0

2.2. Label elements

Hazard Pictograms



Signal word

Warning

H Statements

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

P Statements

P264 Wash hands and face thoroughly after handling.
P273 Avoid release to the environment.
P280 Wear protective gloves/protective clothing/eye protection.
P305+P351+P338 IF IN EYES: Rinse continuously 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.
P501 Dispose of contents according to national and local law.

2.3. Other hazards

-

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances

Name of the ingredient	CAS-number:	EC-number	Reach registration number:
Tolnaftate	2398-96-1	219-266-6	NA

Effective Date 06.10.2021
Revision 4.0

Other information -

SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures

Special instructions	IF exposed: Call a POISON CENTER or doctor/physician. Helpers should ensure their own protection.
Inhalation	Remove victim to fresh air and keep at rest in a position comfortable for breathing.
Skin contact	Remove/Take off immediately all contaminated clothing. Wash with soap and water.
Eye contact	IF IN EYES: Rinse continuously with water for several minutes. Remove contact lenses if present and easy to do, continue rinsing.
Ingestion	Induce vomiting. Give charcoal. Get medical advice/attention.

4.2. Most important symptoms and effects, both acute and delayed

Data not available.

4.3. Indication of any immediate medical attention and special treatment needed

Data not available.

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Suitable extinguishing media	Carbon dioxide Alcohol resistant foam Dry Chemical Water spray
------------------------------	---

Effective Date 06.10.2021
Revision 4.0

5.2. Special hazards arising from the substance or mixture

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

5.3. Advice for fire-fighters

Special protective equipment for fire-fighters Isolating breathing apparatus eg. compressed breathing apparatus and protective clothing.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

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

6.2. Environmental precautions

Do not discharge into the environment.

6.3. Methods and material for containment and cleaning up

Collect spilled powder without dusting into tight closed container.

6.4. Reference to other sections

See Section 8 and 13

Effective Date 06.10.2021
Revision 4.0

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Handle in well-ventilated space.
Avoid dust formation.

7.2. Conditions for safe storage, including any incompatibilities

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)

No information identified.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

International OEL values	-
DNELs	-
PNECs	-

8.2. Exposure controls

Appropriate engineering controls

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.

Respiratory protection

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

Hand protection

Use protective gloves (e.g. nitrile or neopren gloves).

Eye protection

Effective Date 06.10.2021
Revision 4.0

Use protective goggles.

Skin protection

Wear protective clothing.

Environmental exposure controls

Releases to the environment should be avoided.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES
Appearance

Physical state	Powder
Colour	White / Yellowish
Odour	Odourless
Odour threshold	-

9.1. Information on basic physical and chemical properties

Melting point	110 - 112 °C
---------------	--------------

Water solubility	Insoluble
------------------	-----------

Solubility	Soluble in acetone
------------	--------------------

9.2. Other information

-

SECTION 10: STABILITY AND REACTIVITY
10.1.Reactivity

-

10.2. Chemical stability

Stable under normal conditions.

Effective Date 06.10.2021
Revision 4.0

10.3. Possibility of hazardous reactions

Not expected to occur.

10.4. Conditions to avoid

Dust may form explosive mixtures with air.

10.5. Incompatible materials

Acids
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 toxicological effects

Acute toxicity	Based on available data, the classification criteria are not met. LD50 = > 6000 mg/kg (rat, oral) LD50 = > 4000 mg/kg (rat, subcutaneous) LD50 = 120 mg/kg (mouse, intraperitoneal) LD50 = 10000 mg/kg (mouse, oral) LD50 = 4800 mg/kg (mouse, intravenous) LD50 = > 14000 mg/kg (dog, oral) LD = > 50 mg/kg (rabbit, intravenous) LD50 = > 4000 mg/kg (guinea pig, oral) LD50 = > 6000 mg/kg (mouse, subcutaneous)
Skin irritation and corrosion	Skin reactions occur rarely and include irritation and dermatitis.
Skin sensitization	Data not available.
Serious eye damage and irritation	Causes serious eye irritation.
Respiratory irritation	Data not available.
Respiratory sensitization	Data not available.

Effective Date 06.10.2021
Revision 4.0

Carcinogenicity	Data not available.
Germ cell mutagenicity	Data not available.
Reproductive toxicity	Data not available.
STOT-single exposure	Data not available.
STOT-repeated exposure	Data not available.
Aspiration hazard	Data not available.
Repeated dose toxicity	Data not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Aquatic toxicity

Very toxic to aquatic life.
Toxic to aquatic life with long lasting effects.

Toxic effects on other organisms

Data not available.

12.2. Persistence and degradability

The product is not expected to be biodegradable.

12.3. Bioaccumulative potential

Octanol-water partition coefficient	Data not available.
Bioconcentration factor	According to BCF value this compound is bioaccumulative.

Effective Date 06.10.2021
Revision 4.0

BCF > 2000 L/kg (QSAR)

12.4. Mobility in soil

Data not available.

12.5. Results of PBT and vPvB assessment

Data not available.

12.6. Other adverse effects

Data not available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Chemicals must be disposed of in compliance with the respective national regulations.

SECTION 14: TRANSPORT INFORMATION

14.1. UN Number

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)

9

14.4. Packing group

III

14.5. Environmental hazard

Yes

Effective Date 06.10.2021
Revision 4.0

14.6. Special precautions for user

-

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 substance or mixture

The product has not been fully tested.

15.2. Chemical Safety Assessment

No

SECTION 16: OTHER INFORMATION

Further information

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Fermion Oy shall not be held liable for any damage resulting from handling or from contact with the above product.

Sources of key data used to compile the 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