

Thioctic acid

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
Issue date: 03/04/2023 Revision date: 02/12/2024 Supersedes version of: 03/04/2023 Version: 2.0

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

1.1. Product identifier

Product form : Substance
Substance name : Thioctic acid
Chemical name : Thioctic acid
EC-No. : 214-071-2
CAS-No. : 1077-28-7
Product code : 201600892

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

Relevant identified uses

Use of the substance/mixture : Scientific research and development
Technical testing and analysis
For professional use only
Function or use category : Laboratory chemicals

Uses advised against

Restrictions on use : Not for food, drug or home use

1.3. Details of the supplier of the safety data sheet

European Directorate for the Quality of Medicines & Healthcare
EDQM, Council of Europe
7, Allée Kastner, CS30026
F 67081 Strasbourg
France
T +33(0)388412035, F +33(0)388412771
sds@edqm.eu, www.edqm.eu

1.4. Emergency telephone number

Emergency number : +33(0)390215608

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Acute toxicity (oral), Category 4 H302
Skin corrosion/irritation, Category 2 H315
Serious eye damage/eye irritation, Category 2 H319
Skin sensitisation, category 1B H317
Hazardous to the aquatic environment – Chronic Hazard, Category 2 H411

Full text of H- and EUH-statements: see section 16

Adverse physicochemical, human health and environmental effects

Harmful if swallowed. Toxic to aquatic life with long lasting effects. Causes serious eye irritation. May cause an allergic skin reaction. Causes skin irritation.

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP) :



GHS07

GHS09

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Signal word (CLP)	: Warning
Hazard statements (CLP)	: H302 - Harmful if swallowed. H315 - Causes skin irritation. H317 - May cause an allergic skin reaction. H319 - Causes serious eye irritation. H411 - Toxic to aquatic life with long lasting effects.
Precautionary statements (CLP)	: P261 - Avoid breathing dust/fume/gas/mist/vapours/spray. P264 - Wash hands, forearms and face thoroughly after handling. P270 - Do not eat, drink or smoke when using this product. P272 - Contaminated work clothing should not be allowed out of the workplace. P273 - Avoid release to the environment. P280 - Wear protective gloves/protective clothing/eye protection/face protection/hearing protection. P301+P312 - IF SWALLOWED: Call a POISON CENTRE or doctor if you feel unwell. P302+P352 - IF ON SKIN: Wash with plenty of water. P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P321 - Specific treatment (see supplemental first aid instruction on this label). P330 - Rinse mouth. P332+P313 - If skin irritation occurs: Get medical advice/attention. P333+P313 - If skin irritation or rash occurs: Get medical advice/attention. P337+P313 - If eye irritation persists: Get medical advice/attention. P362+P364 - Take off contaminated clothing and wash it before reuse. P391 - Collect spillage. P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

Labelling according to: Exemption for inner packaging where the contents do not exceed 10ml.

No labelling required

2.3. Other hazards

Other information	: Active substance (in pharmaceutical products). Warning - substance not yet tested completely.
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SECTION 3: Composition/information on ingredients

3.1. Substances

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Thioctic acid	CAS-No.: 1077-28-7 EC-No.: 214-071-2	≤ 100	Acute Tox. 4 (Oral), H302 (ATE=500 mg/kg bodyweight) Skin Irrit. 2, H315 Eye Irrit. 2, H319 Skin Sens. 1B, H317 Aquatic Chronic 2, H411

Full text of H- and EUH-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: In all cases of doubt, or when symptoms persist, seek medical attention.
First-aid measures after inhalation	: Remove person to fresh air and keep comfortable for breathing. Allow the victim to rest. If the person feels unwell : Get medical advice/attention.
First-aid measures after skin contact	: Take off contaminated clothing. Gently wash with plenty of soap and water. If symptoms persist, call a physician. Get medical advice if skin irritation persists.

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First-aid measures after eye contact	: Rinse immediately and thoroughly, pulling the eyelids well away from the eye (15 minutes minimum). Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention if pain, blinking or redness persists.
First-aid measures after ingestion	: Rinse mouth out with water (only if the person is conscious). Never give anything by mouth to an unconscious person. Immediately call a POISON CENTER/doctor.

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

Symptoms/effects after skin contact	: May cause an allergic skin reaction. Causes skin irritation.
Symptoms/effects after eye contact	: Causes serious eye irritation. Redness, pain.

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

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	: Use extinguishing media appropriate for surrounding fire. Carbon dioxide. Water spray. Dry powder. Extinguishing blanket.
Unsuitable extinguishing media	: Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire	: Incomplete combustion releases dangerous carbon monoxide, carbon dioxide and other toxic gases. Toxic fumes may be released.
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5.3. Advice for firefighters

Firefighting instructions	: Prevent fire fighting water from entering the environment.
Protection during firefighting	: Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures	: Avoid contact with skin, eyes and clothing.
For non-emergency personnel	
Emergency procedures	: Evacuate unnecessary personnel.
For emergency responders	
Protective equipment	: Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Avoid release to the environment. Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

For containment	: Absorb with an inert material and place in an appropriate waste disposal container.
Methods for cleaning up	: Clean contaminated surfaces with an excess of water. Clean with the help of detergents.

6.4. Reference to other sections

See Section 13 for disposal information.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling	: Avoid all unnecessary exposure. Ensure good ventilation of the work station.
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Hygiene measures : Do not eat, drink or smoke when using this product. Contaminated work clothing should not be allowed out of the workplace. Wash hands before work breaks and after finishing work.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a well-ventilated place. Keep container tightly closed. Keep away from heat and direct sunlight.

Packaging materials : Keep in original containers.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Appropriate engineering controls

Appropriate engineering controls:

Ensure good ventilation of the work station. Both local exhaust and general room ventilation are usually required. Material should be handled in a laboratory hood whenever possible.

Personal protection equipment

Eye and face protection

Eye protection:

Wear eye protection. Safety glasses with side shields. (EN 166)

Skin protection

Skin and body protection:

Wear suitable protective clothing. Laboratory use : Lab coat. (EN 13034)

Hand protection:

Wear suitable gloves. Chemically resistant protective gloves. (EN 374)

Respiratory protection

Respiratory protection:

In case of dust formation use respirator with filter: P3

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Colour	: Yellow.
Appearance	: Crystalline powder.
Molecular mass	: 206.33 g/mol
Odour	: Not available
Odour threshold	: Not available
Melting point	: ≈ 61 °C
Freezing point	: Not available
Boiling point	: 160 – 165 °C
Flammability	: Not available
Lower explosion limit	: Not applicable
Upper explosion limit	: Not applicable
Flash point	: Not applicable
Auto-ignition temperature	: Not applicable
Decomposition temperature	: Not available
pH	: Not available
pH solution	: Not available

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Viscosity, kinematic	: Not applicable
Solubility	: Water: 0.1 – 1 g/l
Partition coefficient n-octanol/water (Log Kow)	: Not available
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Density	: Not available
Relative density	: Not available
Relative vapour density at 20°C	: Not applicable
Particle size	: Not available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

No additional information available

10.3. Possibility of hazardous reactions

No additional information available

10.4. Conditions to avoid

No additional information available

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

No additional information available

SECTION 11: Toxicological information

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

Acute toxicity (oral)	: Harmful if swallowed.
Acute toxicity (dermal)	: Not classified (Lack of data)
Acute toxicity (inhalation)	: Not classified (Lack of data)

Thioctic acid (1077-28-7)

LD50 oral rat	> 300 – < 2000 mg/kg (estimated value)
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Skin corrosion/irritation	: Causes skin irritation.
Serious eye damage/irritation	: Causes serious eye irritation.
Respiratory or skin sensitisation	: May cause an allergic skin reaction.
Germ cell mutagenicity	: Not classified (Based on available data, the classification criteria are not met)
Carcinogenicity	: Not classified (Lack of data)
Reproductive toxicity	: Not classified (Based on available data, the classification criteria are not met)
STOT-single exposure	: Not classified (Lack of data)
STOT-repeated exposure	: Not classified (Based on available data, the classification criteria are not met)
Aspiration hazard	: Not classified (Lack of data)

11.2. Information on other hazards

No additional information available

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SECTION 12: Ecological information

12.1. Toxicity

Hazardous to the aquatic environment, short-term (acute) : Not classified (Based on available data, the classification criteria are not met)

Hazardous to the aquatic environment, long-term (chronic) : Toxic to aquatic life with long lasting effects.

Thioctic acid (1077-28-7)	
LC50 - Fish [1]	≥ 43 – ≤ 96 mg/l (96 Hours, Brachydanio rerio (zebra-fish)) (OECD 203 method)
EC50 - Crustacea [1]	10.2 mg/l (48 Hours, Daphnia magna (Water flea)) (OECD 202 method)
ErC50 algae	1.67 mg/l (72 Hours, Pseudokirchneriella subcapitata (Green algae)) (OECD 201 method)

12.2. Persistence and degradability

Thioctic acid (1077-28-7)	
Persistence and degradability	Rapidly degradable

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Endocrine disrupting properties

No additional information available

12.7. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

No additional information available

SECTION 14: Transport information

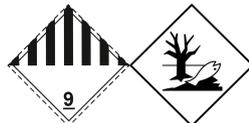
In accordance with ADR / IMDG / IATA

ADR	IMDG	IATA
14.1. UN number or ID number		
UN 3077	UN 3077	UN 3077
14.2. UN proper shipping name		
ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.	Environmentally hazardous substance, solid, n.o.s.

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ADR	IMDG	IATA
Transport document description		
UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S., 9, III, (-)	UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S., 9, III, MARINE POLLUTANT	UN 3077 Environmentally hazardous substance, solid, n.o.s., 9, III
14.3. Transport hazard class(es)		
9	9	9
		
14.4. Packing group		
III	III	III
14.5. Environmental hazards		
Dangerous for the environment: Yes	Dangerous for the environment: Yes Marine pollutant: Yes EmS-No. (Fire): F-A EmS-No. (Spillage): S-F	Dangerous for the environment: Yes
No supplementary information available		

14.6. Special precautions for user

Overland transport

Classification code (ADR)	: M7
Special provisions (ADR)	: 274, 335, 375, 601
Limited quantities (ADR)	: 5kg
Excepted quantities (ADR)	: E1
Packing instructions (ADR)	: P002, IBC08, LP02, R001
Special packing provisions (ADR)	: PP12, B3
Mixed packing provisions (ADR)	: MP10
Portable tank and bulk container instructions (ADR)	: T1, BK1, BK2, BK3
Portable tank and bulk container special provisions (ADR)	: TP33
Tank code (ADR)	: SGAV, LGBV
Vehicle for tank carriage	: AT
Transport category (ADR)	: 3
Special provisions for carriage - Packages (ADR)	: V13
Special provisions for carriage - Bulk (ADR)	: VC1, VC2
Special provisions for carriage - Loading, unloading and handling (ADR)	: CV13
Hazard identification number (Kemler No.)	: 90
Orange plates	: 

Tunnel restriction code (ADR) : -

Transport by sea

Special provisions (IMDG)	: 274, 335, 966, 967, 969
Limited quantities (IMDG)	: 5 kg
Excepted quantities (IMDG)	: E1
Packing instructions (IMDG)	: LP02, P002
Special packing provisions (IMDG)	: PP12
IBC packing instructions (IMDG)	: IBC08
IBC special provisions (IMDG)	: B3
Tank instructions (IMDG)	: BK1, BK2, BK3, T1

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Tank special provisions (IMDG) : TP33
Stowage category (IMDG) : A
Stowage and handling (IMDG) : SW23

Air transport

PCA Excepted quantities (IATA) : E1
PCA Limited quantities (IATA) : Y956
PCA limited quantity max net quantity (IATA) : 30kgG
PCA packing instructions (IATA) : 956
PCA max net quantity (IATA) : 400kg
CAO packing instructions (IATA) : 956
CAO max net quantity (IATA) : 400kg
Special provisions (IATA) : A97, A158, A179, A197, A215
ERG code (IATA) : 9L

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

SECTION 15: Regulatory information

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

EU-Regulations

REACH Annex XVII (Restriction List)

Not listed on REACH Annex XVII

REACH Annex XIV (Authorisation List)

Not listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Not listed on the REACH Candidate List

Ozone Regulation (1005/2009)

Not listed on the Ozone Depletion list (Regulation EU 1005/2009)

Council Regulation (EC) for the control of dual-use items

Not listed on the COUNCIL REGULATION (EC) of dual-use items.

Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

15.2. Chemical safety assessment

No additional information available

SECTION 16: Other information

Indication of changes

Section	Changed item	Comments
	Supersedes version of	Added
	Revision date	Added
1.1	EC-No.	Added
1.1	CAS-No.	Added

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Indication of changes		
Section	Changed item	Comments
1.2	Main use category	Removed
1.2	Restrictions on use	Modified
1.2	Use of the substance/mixture	Modified
2.1	Adverse physicochemical, human health and environmental effects	Modified
2.1	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Modified
2.2	Hazard statements (CLP)	Modified
2.2	Hazard pictograms (CLP)	Modified
2.2	Precautionary statements (CLP)	Modified
2.3	Other information	Added
4.1	First-aid measures after skin contact	Modified
4.1	First-aid measures after eye contact	Modified
4.1	First-aid measures after ingestion	Added
4.1	First-aid measures after inhalation	Added
4.1	First-aid measures general	Added
4.2	Symptoms/effects after skin contact	Added
4.2	Symptoms/effects after eye contact	Added
5.1	Suitable extinguishing media	Modified
5.1	Unsuitable extinguishing media	Added
5.2	Fire hazard	Removed
5.2	Hazardous decomposition products in case of fire	Added
5.3	Firefighting instructions	Modified
5.3	Protection during firefighting	Added
6.1	Emergency procedures	Modified
6.1	Protective equipment	Added
6.1	General measures	Added
6.2	Environmental precautions	Added
6.3	For containment	Added
6.3	Methods for cleaning up	Added
6.4	Reference to other sections (8, 13)	Added
7.1	Hygiene measures	Added
7.1	Precautions for safe handling	Added
7.2	Packaging materials	Added
7.2	Storage conditions	Added
7.3	Specific end uses	Removed
8.2	Skin and body protection	Modified
8.2	Appropriate engineering controls	Modified

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Indication of changes		
Section	Changed item	Comments
8.2	Hand protection	Modified
8.2	Respiratory protection	Added
8.2	Eye protection	Added
9	Molecular mass	Added
9	Melting point	Added
9	Colour	Added
9	Boiling point	Added
9	Appearance	Modified
10.1	Reactivity	Removed
10.3	Possibility of hazardous reactions	Removed
10.5	Incompatible materials	Removed
10.6	Hazardous decomposition products	Removed
11.1	ATE CLP (oral)	Modified
11.1	LD50 oral rat	Modified
12.1	Ecology - general	Removed
12.1	ErC50 algae	Added
12.1	EC50 - Crustacea [1]	Added
12.1	LC50 - Fish [1]	Added
14	Transport information	Modified

Full text of H- and EUH-statements:	
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Aquatic Chronic 2	Hazardous to the aquatic environment – Chronic Hazard, Category 2
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
H302	Harmful if swallowed.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H411	Toxic to aquatic life with long lasting effects.
Skin Irrit. 2	Skin corrosion/irritation, Category 2
Skin Sens. 1B	Skin sensitisation, category 1B

Safety Data Sheet (SDS), EU

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