

Technical package

Dossier Técnico 19/06/2023

ALPHA LIPOIC ACID

PROD)UCT	SPEC	IFICA	HON

Product Name	INCI Name	EINECS Number	CAS Code
ALPHA LIPOIC ACID	5-(dithiolan-3-yl)valeric acid	214-071-2	1077-28-7
Appearance	Slightly yellow crystal powder		
Solubility	Meets the requirements		
Identification	Meets the requirements		
Loss on drying	NMT 0,20%		
Specific rotation	-1.0~+1.0°		
Melting point	60.0	0-62.0°C	
Residue on ignition	NMt 0,10%		
Heavy metals	NMT 10ppm		
Lead	NMT 3ppm		
Arsenic	NMT 1ppm		
Cadmium	NM ⁻	Г 1ррт	
Mercury	NM ⁻	Г0,1ррт	
Limit of polymer content	Mee	ets the requirements	
Residual solvents			
Ethyl acetate	NM ⁻	Г 500ррт	
Cyclohexane	NM ⁻	Г 3880 ррт	
Toluene	NM ⁻	Г 20ррт	
Related substance			
Single impurities	NM ⁻	Γ0,1%	
Total impurities	NM ⁻	Γ2,0%	



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PRODUCT SPECIFICATION		
Assay	99.0-101.0%	
Total aerobic bacteria	NMT 1000 cfu/g	
Mold & Yeast	NMT 100 cfu/g	
E.Coli	Absence/g	
Staphylococcus aureus	Absence/g	
Salmonella	Absence/10g	
Particle size	100% through 40 mesh	
Loose bulk density	Report result	



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GENERAL PRODUCT INFORMATION	
Mesh of the product	40
Tapped density	About 0.55g/ml
Bulk density	About 0.4g/ml
Water solubility	Freely soluble in methanol, very soluble in Dimethylformamide, very slightly soluble in water.
Type of Manufacturing process (Synthesis, Fermentation, Extraction, etc.)	Synthetic
Specific Origin of the product (Animal, Vegetal, etc.)	Based on mineral oil/natural gas
Is the product FREE of GLUTEN?	Yes
Is the product suitable for vegans?	Yes
Is the product suitable for vegetarians?	Yes
Is the product free of fructose?	Yes
Is this product suitable for food?	Yes
Is this product suitable for feed of animals?	Yes
Can the product be used in baby food (according to Regulation (EU) N° 609/2013, Commission Delegated Regulation (EU) 2016/127, Commission Delegated Regulation (EU) 2021/572 and amendments)?	No
Pharmacopoeias that the product meets	EP, USP
Is this product considered Novel Food?	No
Is this product considered Novel Food Supplement?	Yes
Drug indication	Anti-diabetes, Anti diabetes neuropathy
Melting point	60.0°C~62.0°C
Country of origin of the raw material/s of the product	China
Storage conditions (in the warehouse)	Dry and cold place, suggest below 20

°C



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GENERAL PRODUCT INFORMATION

Storage conditions (during the transport/short term)

Under 25 °C



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TECHNICAL PRODUCT INFORMATION

Name of the product	Alpha Lipoic Acid
INCI Name	Alpha Lipoic Acid
Synonyms	Thioctic Acid
IUPAC name	5-(1,2-Dithiolan-3-yl)pentanoic acid
CAS	1077-28-7
EINECS	214-071-2
Molecular Formula	C8H14O2S2
Molecular mass	206.33
Physicochemical property	Slightly yellow crystal powder
Country of the factory (Manufacturing site)	China
Raw materials used for the manufacture of this product and their function	Using the starting material of adipic acid, which is a common chemical raw material.
Characterization	By IR and HPLC
Impurities	Individual impurities≤ 0.1% Total impurities≤ 2.0% Impurity B≤ 1.0%
Frequency of analysis of each batch of product:	Every batch
Frequency of analysis of each contaminant?	Every batch
Frequency of analysis of microbiology?	Every batch
Frequency of analysis of each heavy metal?	Every 6 months
Frequency of pesticide tests of this product:	N/A



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FOREIGN MATERIAL

Explanation of actions taken during the manufacturing process of this product to reduce the risk of appearance of foreign material:

Metal detector Yes Metal detector is used in the refined screening process

Sieve Yes After secondary refined drying, the product is screened by vibrating screen

Filter Yes Secondary filter silica gel, filter element aperture of 1µm



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INGREDIENTS

In accordance with the EU Regulation 1169/2011, amending EU Regulation 1924/2006 and EU Regulation 1925/2006, the following ones are the ingredients and their content (in %) in this product.

Alpha Lipoic Acid

Alpha Lipoic Acid



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BSE/TSE

This product does not contain and is not derived from Specified Risk Material as defined in European Commission Directive (and its amendments) and is therefore conform with the EU legislation relating to the risk of Transmission of Spongiform Encephalopathy (TSE).

GMO

The following EU regulations have been published in the Official Journal of the European Union in this subject:

- Regulation (EC) No.1829/2003 of the European Parliament and the Council of 22 September 2003 on genetically modified food and feed.
- Regulation (EC) No.1830/2003 of the European Parliament and the Council of 22 September 2003 concerning tractability and labeling on genetically modified organisms and tractability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC.

This product has not been genetically modified so there is no obligation of GMO labeling as defined by the above mentioned regulations.

NON IRRADIATION/NON IONIZED

According to directives 1992/2/EC and 1999/3/EC, we confirm that this product is not made from irradiated/ionized raw materials and that this product was not irradiated/ionized.



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PESTICIDES

To our actual knowledge of the production process, of the raw materials and of the equipment used, the potential pesticide residues in this product comply with the European legislation on pesticide residues (esp. Regulation (EC) No. 396/2005 and amendments). However, we do not test for pesticide residues on a routine basis.

RESIDUAL SOLVENTS

The product meets with:

- DIRECTIVE 2009/32/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 23 April 2009 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients
- DIRECTIVE 2010/59/EU of 26 August 2010 amending Directive 2009/32/EC of the European Parliament and of the Council on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients.

CONTAMINANTS

The product is in accordance and meets with the Commission Regulation (EU) No. 2023/915 setting maximum levels for certain contaminants in foodstuffs.

PCBS AND MELAMINE

This product is in accordance and meets with the Commission Regulation (EU) No. 2023/915 as regards the maximum levels of the contaminants Ochratoxin A, non-dioxin-like PCBS and melamine in foodstuffs.

ANTI-DOPING

As per the list of 2022 of the World Anti-Doping Agency (WADA), this product is not a doping substance or a combination of doping substances. This product is not manufactured from a doping substance.

NANOMATERIALS

According to the definition of 'Nanomaterials' of the UE Regulation No 1169/2011 of the European Parliament and of the Council of 25th of October 2011 (amending Commission Regulation (EC) 1924/2006 and Commission Regulation (EC) 1925/2006) on the provision of food information to consumers, we hereby attest that no nanomaterials are used in the manufacture, in the formulation nor in the packaging materials of this product.



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PACKING

We confirm that the packing used for this product is in compliance with:

- Regulation (EC) No. 1935/2004 of the European Parliament and of the Council of 27th of October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC
- Commission Regulation (EU) No. 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food.

ETHYLENE OXIDE (ETO) & 2-CHLORO-ETHANOL

Ethylene Oxide (& 2-Chloroethanol) is not used in any phases of the process of manufacture or storage of this product. This product does not enter in contact with Ethylene Oxide (& 2-Chloroethanol) in any phases of the process of manufacture or of storage. Therefore, this product is compliant with the limit established in Commission Regulation (EC) No. 396/2005.



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ALLERGENS

In accordance with Regulation (EU) No. 1169/2011, amending Commission Regulation (EC) No. 1924/2006 and Commission Regulation (EC) No. 1925/2006, we confirm the following information:

Does this product contain or is derived from or could be cross-contaminated by any of the following allergens?

Cereals containing gluten (i.e. wheat, rye, barley, oats, spelt, kamut or their hybridised strains) and products thereof	No
Crustaceans and products thereof	No
Eggs and products thereof	No
Fish and products thereof	No
Peanuts and products thereof	No
Soybeans and products thereof (with exceptions established in Annex II)	No
Milk and products thereof (including lactose) (with exceptions established in Annex II)	No
Nuts (i.e. almond, hazelnut, walnut, cashew, pecan nut, Brazil nut, pistachio nut, macadamia nut and Queensland nut) and products thereof (with exceptions established in Annex II)	No
Celery and products thereof	No
Mustard and products thereof	No
Sesame seeds and products thereof	No
Sulphur dioxide and sulphite at concentrations of more than 10 mg/kg or 10 mg/l expressed as SO2	No
Lupine and products thereof	No
Molluscs and products thereof	No



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ALBA LIST (ALLERGENS)

Note: 'Yes' means that there is contamination from

- 1) recipe contents,
- 2) other products handled on the same production line or
- 3) other products handled at same side.

	Cross contamination (mg/kg)?	Where?
Cow milk protein	No	-
Lactose	No	-
Chicken egg	No	-
Soya protein	No	-
Soya oil	No	-
Gluten	No	-
Wheat	No	-
Rye	No	-
Cattle	No	-
Pork	No	-
Chicken	No	-
Fish	No	-
Shellfish and Crustaceae	No	-
Corn	No	-
Cocoa	No	-
Leguminous plants	No	-
Nuts	No	-
Nut oil	No	-
Peanut	No	-
Peanut oil	No	-
Sesame	No	-
Sesame oil	No	-
Glutamate	No	-
Sulphide (E220 to E228)	No	-
Coriander	No	-
Celery	No	-
Carrot	No	-
Lupines	No	-



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NUTRITIONAL INFORMATION

Approximative Nutritional Information of this product is as follows:

Unit Weight 100 g

Amount Per Unit

Calories 0

Calories from fat 0

Total fat 0

- monounsaturated 0
- polyunsaturated 0
- saturated 0
- trans fat 0

Cholesterol 0

Total Carbohydrate 0

- dietary fiber 0
- sugar 0
- sugar alcohols 0
- other carbohydrates 0

Protein 0

Vitamin A (as) 0

Vitamin D (as) 0

Vitamin E (as) 0

Vitamin K 0

Thiamin (vitamin B-1) (as) 0

Riboflavin (as) 0

Niacin (as) 0

Vitamin B-6 (as) 0

Vitamin B-6 (as) 0

Folate, Folic acid or Folacin 0

Vitamin B12 (as) 0

Biotin (as) 0

Pantothenic acid (as) 0

Calcium (as) 0

Phosphorus (as) 0

lodine (as) 0

Magnesium (as) 0

Zinc (as) 0

Selenium (as) 0

Copper (as) 0

Manganese (as) 0

Molybdenum (as) 0

Chromium (as) 0

Molybdenum (as) 0



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NUTRITIONAL INFORMATION

Chloride (as) 0 Sodium (as) 0 Potassium (as) 0



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RESIDUE LIMITS (GELATIN, COLLAGEN)

We herewith certify that this product in compliance with: Commission Regulation (EU) No. 2016/355 of 11st of March 2016, amending Annex III to Commission Regulation (EC) No. 853/2004 of the European Parliament and of the Council as regards the specific requirements for gelatine, collagen and highly refined products of animal origin intended for human consumption.

HYGIENE OF FOODSTUFFS

We herewith certify that this product complies with Commission Regulation (EC) No. 852/2004 of the European Parliament on the hygiene of foodstuffs and all its amendments.

FULL TRACEABILITY

This product complies with the full traceability criteria as mentioned in Commission Regulation (EC) No. 178/2002 of the European Parliament and of the Council of 28th of January 2002, laying down the general principles and requirements of food law, establishing the European food safety authority and laying down procedures in matters of food safety.



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FACTORY ACCREDITATIONS/CERTIFICATIONS		
ISO 9001	Yes	
ISO 22000	No	
HACCP	Yes	
GMP	No	
FAMIQS	No	
BRC	No	
Other accreditations/certifications	Kosher, Halal	



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NON ANIMAL TESTING

We certify that the product has not been tested on animals.



Material Safety Data Sheet

Documento MSDS 19/04/2023

ALPHA LIPOIC ACID

MSDS (Material Safety Data Sheet)

1. Identification of the substance/preparation AND the company:

Product Name: ALPHA LIPOIC ACID

CAS Number: 1077-28-7

Supplier Information:
Productos Quimicos Gonmisol S.A.
Camino de la Verneda 47-49
08930 - San Adrian del Besos
Barcelona - Spain
Phone +34 933136118
Fax +34 933147427
www.gonmisol.com

2: HAZARD IDENTIFICATION

2.1 Classification of the substance or mixture
Acute toxicity, Category 4, oral
Skin corrosion/irritation, Category 2
Skin sensitization, Category 1
Serious eye damage/irritation, Category 2
Toxic to aquatic life with long lasting effects, Category 2
2.2 GHS Label elements, including precautionary statements
Pictograms:







Material Safety Data Sheet

Documento MSDS 19/04/2023

ALPHA LIPOIC ACID

MSDS (Material Safety Data Sheet)

Single word: Warning

Hazard statements: 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.

Prevention: P264 Wash hands and \dots thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.

P280 Wear protective gloves/protective clothing/eye protection/face

P261 Avoid breathing dust/fume/gas/mist/vapors/spray.

P272 Contaminated work clothing should not be allowed out of the workplace.

P273 Avoid release to the environment.

Response: P301+P317 IF SWALLOWED: Get medical help.

P330 Rinse mouth.

P302+P352 IF ON SKIN: Wash with plenty of water.

P321 Specific treatment (see ... on this label).

P332+P317 If skin irritation occurs: Get medical help.

P362+P364 Take off contaminated clothing and wash it before reuse.

P333+P317 If skin irritation or rash occurs: Get medical help.

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+P317 If eye irritation persists: Get medical help.

P391 Collect spillage.

Storage: None

Disposal: P501 Dispose of contents/container to an appropriate treatment and

disposal facility in accordance with applicable laws and regulations,

and product characteristics at time of disposal.

2.3 Other hazards which do not result in classification

No data available.

3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Common name Alpha Lipoic Acid

Formula C8H14O2S2

CAS No. 1077-28-7

Concentration ≥99%

Chemical name 5-(Dithiolan-3-yl)valeric acid



Material Safety Data Sheet

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Molecular weight 206.3 EC No. 214-071-2

4: FIRST-AID MEASURES

4.1 Description of the first aid measures If inhaled: Move the victim into fresh air.

In case of skin contact: Take off immediately all contaminated clothing, wash off with soap and plenty of water. If feel unwell, get medical help.

In case of eye contact: Rinse with flowing water or saline. Get medical help immediately. If swallowed: Rinse mouth with water, do not induce vomiting. Get medical help immediately. 4.2 Most important symptoms/effects, acute and delayed

No data available.

4.3 Indication of immediate medical attention and special treatment needed, if necessary General advice to rescuer: Move the victim out of dangerous area. Consult a physician. Show this safety data sheet to the doctor in attendance.

General advice to doctor: None.

5: FIRE-FIGHTING MEASURES

5.1 Suitable extinguishing media

Use water spray, dry chemical, foam or carbon dioxide fire extinguisher. Avoid using oncethrough water, which may cause splashing of flammable liquid and spread the fire.

5.2 Special hazards arising from the chemical

No data available.

5.3 Specific protective actions for fire-fighters

Fire-fighters should wear self-contained breathing apparatus and full body fire-fighting suit, and fight fire upwind.

6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures Emergency personnel are advised to wear self-contained breathing apparatus, antistatic clothes, and rubber oil-resistant gloves. Do not touch or across leakage. All equipment used should be earthed. Cut off the origin of leakage as possible. Eliminate all sources of ignition. Mark out contaminated areas with signs, prevent unauthorized access, and evacuate irrelevant personnel from crosswind or upwind to safety zone.

6.2 Environmental precautions

Handling leakage to avoid environmental pollution. Prevent leakage into drains, surface and ground water.

6.3 Methods and materials for containment and cleaning up

Small leakage: Collect the leaking liquid in a sealable container as far as possible. Absorb with sandy soil, activated carbon or other inert materials and transfer to a safe place. Do not



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MSDS (Material Safety Data Sheet)

flush down the drains.

A large number of leak: Build a causeway or trenching asylum. Seal off the drainage pipe. Cover with foam to inhibit evaporation. Transfer to tank car or special collector with explosion-proof pump, recycle or transport to waste disposal site.

7: HANDLING AND STORAGE

7.1 Precautions for safe handing

Operators should be trained and strictly follow the operating procedures. Handling in a well ventilated place. Keep away from fire and heat. Avoid contact with incompatible materials such as oxidants etc. (incompatible materials refer to Section 10). Avoid formation of dust and aerosols. Prevent fire caused by electrostatic discharge steam. by electrostatic discharge steam. Wear suitable protective clothing, avoid eye and skin contact, and steam inhalation, personal protection measures refer to Section 8. Eating, drinking and smoking in work areas is prohibited. Wash thoroughly after handing. Remove contaminated clothing and protective equipment before entering eating areas.

7.2 Conditions for safe storage, including any incompatibilities

Store in a cool, dark, dry and well-ventilated warehouse, where temperature should not exceed 20°C. Keep the container airtight. Keep away from fire and heat. Store separately from oxidants and edible chemicals, and avoid mixing (incompatible materials refer to Section 10). The warehouse must be equipped with lightning protection equipment. The exhaust system should be equipped with a grounding device for removing static electricity. Adopt explosionproof lighting and ventilation settings. Do not use devices or tools that may generate sparks. The storage area should be equipped with emergency equipment leakage and suitable holding materials.

8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Occupational exposure limits (OELs): No data available.

Biological limit values: No data available.

8.2 Appropriate engineering controls

The workplace is recommended to be separated from other workplaces. Closed operation to prevent leakage. Improve ventilation. Set up automatic alarm device and accident ventilation facilities. Set up emergency exit channels and necessary drainage areas. Set up

red zone warning lines, warning signs and warning instructions, and set up a communication alarm system. Equipped with safe showers and eye washing facilities.

8.3 Individual protection measures, such as personal protective equipment (PPE)

Respiratory protection: Wear a filter gas mask (half mask) when the concentration in the air exceeds the standard. In case of emergency rescue or evacuation, wear a self-contained breathing apparatus.

Hand protection: Wear rubber oil-resistant gloves.

Eye protection: Wear chemical safety glasses.



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Skin and body protection: Wear permeable protective clothing.

9. Physical AND Chemical Properties

For this information, please, refer directly to the Certificate of Analysis OR Specifications

10: STABILITY AND REACTIVITY

- 10.1 Reactivity: No data available.
- 10.2 Chemical stability: Stable under recommended storage conditions.
- 10.3 Possibility of hazardous reactions: No data available.
- 10.4 Conditions to avoid: Avoid electrostatic discharge, heat, and humidity, etc.
- 10.5 Incompatible materials: Strong oxidizing agents.
- 10.6 Hazardous decomposition products: No data available.

11: TOXICOLOGICAL INFORMATION

Acute toxicity: Oral LD50: 1190 ~ 1210 mg/kg/body weight (rat).

Skin corrosion/irritation: No data available.

Serious eye damage/irritation: No data available.

Respiratory or skin sensitization: No data available.

Germ cell mutagenicity: No data available.

Carcinogenicity: No data available.

Reproductive toxicity: No data available.

STOT-single exposure: No data available.

STOT-repeated exposure: No data available.

Aspiration hazard: No data available.

12: ECOLOGICAL INFORMATION

12.1 Toxicity

Toxicity to fish: LC50 (4 days): 43~96mg/L, LC0 (4 days) 19 mg/L, LC100 (4 days) 96 mg/L;

Toxicity to daphnia: No data available;

Toxicity to algae and cyanobacteria: EC50 (72hours): 1.23~5.51mg/L, LOEC (72hours):

477μg/L, EC10 (72hours): 583μg/L;

Toxicity to microorganisms: No data available.

- 12.2 Persistence and degradability: No data available.
- 12.3 Bioaccumulative potential: No data available.
- 12.4 Mobility in soil: No data available.
- 12.5 Other adverse effects: No data available.

13: DISPOSAL CONSIDERATIONS

13.1 Disposal methods

Product: Recycle as possible, if not, disposal by burning but not drainage.



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Contaminated packaging: Return the container to the manufacturer or disposal in accordance with prevailing country, federal, state and local regulations.

Disposal cautions: Prevailing country, federal, state and local regulations should be referred to before disposal. Personnel safety precautions refer to Section 8.

14: TRANSPORT INFORMATION

14.1 UN number

ADR/RID: Not dangerous goods; IMDG: Not dangerous goods; IATA: Not dangerous goods.

14.2 UN proper shipping name

ADR/RID: Not dangerous goods; IMDG: Not dangerous goods; IATA: Not dangerous goods.

14.3 Transport hazard class(es)

ADR/RID: Not dangerous goods; IMDG: Not dangerous goods; IATA: Not dangerous goods.

14.4 Packing group, if applicable

ADR/RID: Not dangerous goods; IMDG: Not dangerous goods; IATA: Not dangerous goods.

14.5 Environmental hazards

ADR/RID: Yes; IMDG: Yes; IATA: Yes. 14.6 Special precautions for user

No data available.

14.7 Transport in bulk according to IMO instruments

No data available.

15: REGULATORY INFORMATION

15.1 Safety, health and environmental regulations specific for the product in question

Name Alpha Lipoic Acid CAS No. 1077-28-7

Regulations Remark Listed

Chinese Chemical Inventory of Existing Chemical Substances (China IECSC)

European Inventory of Existing Commercial Chemical Substances (EINECS)

EC Inventory

Remark Not Listed

China Catalog of Hazardous chemicals (2015)

China Catalogue of Occupational Hazardous Factors (2015)

China List of Easy-made Explosive Dangerous Chemicals (2017)

China List of Key Hazardous Chemicals for Environmental Management

United States Toxic Substances Control Act (TSCA) Inventory

16: OTHER INFORMATION

Information on revision

Date of preparation: Dec. 26, 2022



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MSDS (Material Safety Data Sheet)

Version number: 1.0

Abbreviations and acronyms

CAS: Chemical Abstracts Service LD50: Lethal Dose 50% LC50: Lethal Concentration 50% LC0: Lethal Concentration 0%

LC100: Lethal Concentration 100% EC50: Effective Concentration 50%

LOEC: Lowest Observed Effect Concentration EC10: Effective Concentration 10%

ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road

RID: Regulation concerning the International Carriage of Dangerous Goods by Rail

IMDG: International Maritime Dangerous Goods IATA: International Air Transportation Association

Literature references

Internal Labour Organization (ILO) - International Chemical Safety Cards (ICSCs), website:

http://www.ilo.org/dyn/icsc/showcard.home;

IARC - International Agency for Research on Cancer, website: http://www.iarc.fr/;

ECHA - European Chemicals Agency, website: https://echa.europa.eu/it/home;

US EPA - US Environmental Protection Agency: CompTox Chemicals Dashboard, website: https://comptox.epa.gov/dashboard/;

eChemPortal - The Global Portal to Information on Chemical Substances by OECD, website: https://www.echemportal.org/echemportal/;

NIH – National Library of Medicine: PubChem, website: https://pubchem.ncbi.nlm.nih.gov/; ERG - Emergency Response Guidebook by U.S. Department of Transportation, website:

http://www.phmsa.dot.gov/hazmat/library/erg.

Disclaimer

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. This SDS only applies to the above product, and does not apply to mixtures of the above product with other substances unless otherwise specified. This SDS only provides safety information to properly trained users, who should make independent judgement due to the suitability of the SDS, of the product. The author of this SDS shall not be held liable for any damage resulting from using the SDS.