

BIOLIFE ITALIANA S.R.L.

Revision nr.7 Dated 03/02/2025 Printed on 03/02/2025 Page n. 1 / 11 Replaced revision:6 (Dated 28/12/2021)

42185011 - BIOVITEX

Safety Data Sheet

According to Annex II to REACH - Regulation (EU) 2020/878

SECTION 1. Identification of the s	ubstance/n	nixture and of the cor	npany/undertaking
1.1. Product identifier			
Code: Product name	4218501 ⁻ BIOVITE		
1.2. Relevant identified uses of the substance	or mixture and	uses advised against	
Intended use	Supplem	ent for microbiology	
1.3. Details of the supplier of the safety data s	heet		
Name Full address District and Country	BIOLIFE Viale Mo 20128 Tel.	ITALIANA S.R.L. nza, 272 Milano Italia 0039 02 252091	(Milano)
e-mail address of the competent person responsible for the Safety Data Sheet	mktg@biolifeitaliana.it		
1.4. Emergency telephone number			
For urgent inquiries refer to	NHS24in	n England: 111 Scotland: 111 ect in Wales: 111 or 0845 4647	
	In an em	ergency, if the patient has co	llapsed or is not breathing properly, call 999

SECTION 2. Hazards identification

2.1. Classification of the substance or mixture

The product is classified as hazardous pursuant to the provisions set forth in (EC) Regulation 1272/2008 (CLP) (and subsequent amendments and supplements). The product thus requires a safety datasheet that complies with the provisions of (EU) Regulation 2020/878.

Any additional information concerning the risks for health and/or the environment are given in sections 11 and 12 of this sheet.

Hazard classification and indication:

Eye irritation, category 2	H319	Causes serious eye irritation.
Skin irritation, category 2	H315	Causes skin irritation.
Specific target organ toxicity - single exposure,	H335	May cause respiratory irritation.
category 3		

2.2. Label elements

Hazard labelling pursuant to EC Regulation 1272/2008 (CLP) and subsequent amendments and supplements.

Hazard pictograms:



Signal words:

Warning

Hazard statements: H319 H315

Causes serious eye irritation. Causes skin irritation. ΕN



SECTION 2. Hazards identification ... / >>

H335	May cause respiratory irritation.		
Precautionary statements:			
P261	Avoid breathing dust / fume / gas / mist / vapours / spray.		
P280	Wear protective gloves / eye protection / face protection.		
P312	Call a POISON CENTRE / doctor / if you feel unwell.		
P403+P233	Store in a well-ventilated place. Keep container tightly closed.		
P264	Wash thoroughly after handling.		

Contains: L-CYSTEINE HCL

2.3. Other hazards

On the basis of available data, the product does not contain any PBT or vPvB in percentage \geq than 0,1%.

The product does not contain substances with endocrine disrupting properties in concentration $\geq 0.1\%$.

SECTION 3. Composition/information on ingredients

3.2. Mixtures

Contains:

Identification		x = Conc. %	Classification (EC) 1272/2008 (CLP)
L-CYSTEINE	HCL	66 ≤ x < 70	Eve Irrit. 2 H319, Skin Irrit. 2 H315, STOT SE 3 H335
EC	200-157-7	00 = X < 70	Eye init. 2 h319, 3kin init. 2 h313, 3101 3E 3 h333
CAS	7048-04-6		
ADENINE SU	ILFATE		
INDEX		2,5 ≤ x < 3	Acute Tox. 4 H302
EC	206-286-5		ATE Oral: 500 mg/kg
CAS	321-30-2		
ACETONE			
INDEX	606-001-00-8	0,05 ≤ x < 0,1	Flam. Liq. 2 H225, Eye Irrit. 2 H319, STOT SE 3 H336, EUH066
EC	200-662-2		
CAS	67-64-1		

The full wording of hazard (H) phrases is given in section 16 of the sheet.

SECTION 4. First aid measures

4.1. Description of first aid measures

In case of doubt or in the presence of symptoms contact a doctor and show him this document.

In case of more severe symptoms, ask for immediate medical aid.

EYES: Remove, if present, contact lenses if the situation allows you to do so easily. Wash immediately with plenty of water for at least 15 minutes, opening the eyelids fully. Get medical advice/attention.

SKIN: Take off contaminated clothing. Wash immediately and thoroughly with running water (and soap if possible). Get medical advice. Avoid further contact with contaminated clothing.

INGESTION: Do not induce vomiting unless explicitly authorised by a doctor. Do not give anything by mouth to an unconscious person. Get medical advice/attention.

INHALATION: Remove victim to fresh air, away from the accident scene. In the event of respiratory symptoms (coughing, wheezing, breathing difficulty, asthma) keep the victim in a comfortable position for breathing. If necessary administer oxygen. If the subject stops breathing, administer artificial respiration. Get medical advice/attention.

Rescuer protection

It is good practice for rescuers lending support to a person who has been exposed to a chemical substance or to a mixture to wear personal protective equipment. The nature of such protection depends on the hazard level of the substance or mixture, on the type of exposure and on the extent of the contamination. In the absence of other more specific indications, use of disposable gloves in the event of possible contact with body fluids is recommended. For the type of PPE suitable for the characteristics of the substance or mixture, see section 8.

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



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SECTION 4. First aid measures ... / >>

Specific information on symptoms and effects caused by the product are unknown.

DELAYED EFFECTS: Based on the information currently available, there are no known cases of delayed effects following exposure to this product.

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

Call a POISON CENTRE / doctor / . . . if you feel unwell.

Means to have available in the workplace for specific and immediate treatment

Running water for skin and eye wash.

SECTION 5. Firefighting measures

5.1. Extinguishing media

SUITABLE EXTINGUISHING EQUIPMENT The extinguishing equipment should be of the conventional kind: carbon dioxide, foam, powder and water spray. UNSUITABLE EXTINGUISHING EQUIPMENT

None in particular.

5.2. Special hazards arising from the substance or mixture

HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE

Do not breathe combustion products. The product is combustible and, when the powder is released into the air in sufficient concentrations and in the presence of a source of ignition, it can create explosive mixtures with air. Fires may start or get worse by leakage of the solid product from the container, when it reaches high temperatures or through contact with sources of ignition.

5.3. Advice for firefighters

GENERAL INFORMATION

Use jets of water to cool the containers to prevent product decomposition and the development of substances potentially hazardous for health. Always wear full fire prevention gear. Collect extinguishing water to prevent it from draining into the sewer system. Dispose of contaminated water used for extinction and the remains of the fire according to applicable regulations. SPECIAL PROTECTIVE EQUIPMENT FOR FIRE-FIGHTERS

Normal fire fighting clothing i.e. fire kit (BS EN 469), gloves (BS EN 659) and boots (HO specification A29 and A30) in combination with self-contained open circuit positive pressure compressed air breathing apparatus (BS EN 137).

SECTION 6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

If there are no contraindications, spray powder with water to prevent the formation of dust. Wear suitable protective equipment (including personal protective equipment referred to under Section 8 of the safety data sheet) to prevent any contamination of skin, eyes and personal clothing. These indications apply for both processing staff and those involved in emergency procedures.

6.2. Environmental precautions

The product must not penetrate into the sewer system or come into contact with surface water or ground water.

6.3. Methods and material for containment and cleaning up

Collect the leaked product and place it in containers for recovery or disposal. If there are no contraindications, use jets of water to eliminate product residues.

Make sure the leakage site is well aired. Evaluate the compatibility of the container to be used, by checking section 10. Contaminated material should be disposed of in compliance with the provisions set forth in point 13.

6.4. Reference to other sections

Any information on personal protection and disposal is given in sections 8 and 13.

SECTION 7. Handling and storage

7.1. Precautions for safe handling

Before handling the product, consult all the other sections of this material safety data sheet. Avoid leakage of the product into the



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SECTION 7. Handling and storage ... / >>

environment. Do not eat, drink or smoke during use. Remove any contaminated clothes and personal protective equipment before entering places in which people eat.

7.2. Conditions for safe storage, including any incompatibilities

Store only in the original container. Store the containers sealed, in a well ventilated place, away from direct sunlight. Keep containers away from any incompatible materials, see section 10 for details.

7.3. Specific end use(s)

Information not available

SECTION 8. Exposure controls/personal protection

8.1. Control parameters

Regulatory references:

DEU	Deutschland	Forschungsgemeinschaft MAK- und BAT-Werte-Liste 2022 Ständige Senatskommission zur Prüfung gesundheitsschädlicher Arbeitsstoffe Mitteilung 58
FRA	France	Valeurs limites d'exposition professionnelle aux agents chimiques en FranceDécret n° 2021-1849 du 28 décembre 2021
GRC	Ελλάδα	Π.Δ. 26/2020 (ΦΕΚ 50/Α` 6.3.2020) Εναρμόνιση της ελληνικής νομοθεσίας προς τις διατάξεις των οδηγιών 2017/2398/ΕΕ, 2019/130/ΕΕ και 2019/983/ΕΕ «για την τροποποίηση της οδηγίας 2004/37/ΕΚ "σχετικά με την προστασία των εργαζομένων από τους κινδύνους που συνδέονται με την έκθεση σε καρκινογόνους ή μεταλλαξιγόνους παράγοντες κατά την εργασία"»
HRV	Hrvatska	Pravilnik o izmjenama i dopunama Pravilnika o zaštiti radnika od izloženosti opasnimkemikalijama na radu, graničnim vrijednostima izloženosti i biološkim graničnim vrijednostima (NN 1/2021)
ITA	Italia	Decreto Legislativo 9 Aprile 2008, n.81
NOR	Norge	Forskrift om endring i forskrift om tiltaksverdier og grenseverdier for fysiske og kjemiske faktorer i arbeidsmiljøet samt smitterisikogrupper for biologiske faktorer (forskrift om tiltaks- og grenseverdier), 21. august 2018 nr. 1255
PRT	Portugal	Decreto-Lei n.º 1/2021 de 6 de janeiro, valores-limite de exposição profissional indicativos para os agentes químicos. Decreto-Lei n.º 35/2020 de 13 de julho, proteção dos trabalhadores contra os riscos ligados à exposição durante o trabalho a agentes cancerígenos ou mutagénicos
POL	Polska	Rozporządzenie ministra rozwoju, pracy i technologii z dnia 18 lutego 2021 r. Zmieniające rozporządzenie w sprawie najwyższych dopuszczalnych stężeń i natężeń czynników szkodliwych dla zdrowia w środowisku pracy
ROU	România	Hotărârea nr. 53/2021 pentru modificarea hotărârii guvernului nr. 1.218/2006, precum și pentru modificarea și completarea hotărârii guvernului nr. 1.093/2006
SWE	Sverige	Hygieniska gränsvärden, Arbetsmiljöverkets föreskrifter och allmänna råd om hygieniska gränsvärden (AFS 2018:1)
SVN	Slovenija	Pravilnik o varovanju delavcev pred tveganji zaradi izpostavljenosti kemičnim snovem pri delu (Uradni list RS, št. 100/01, 39/05, 53/07, 102/10, 43/11 – ZVZD-1, 38/15, 78/18 in 78/19)
TUR	Türkiye	Kimyasal Maddelerle Çalışmalarda Sağlık ve Güvenlik Önlemleri Hakkında Yönetmelik 12.08.2013 / 28733; 20.10.2023 / 32345.
GBR EU	United Kingdom OEL EU	EH40/2005 Workplace exposure limits (Fourth Edition 2020) Directive (EU) 2022/431; Directive (EU) 2019/1831; Directive (EU) 2019/130; Directive (EU) 2019/983; Directive (EU) 2017/2398; Directive (EU) 2017/164; Directive 2009/161/EU; Directive 2006/15/EC; Directive 2004/37/EC; Directive 2000/39/EC; Directive 98/24/EC; Directive 91/322/EEC.
	TLV-ACGIH	ACGIH 2023



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SECTION 8. Exposure controls/personal protection ... / >>

Threshold Limit Value Type Country TWA/8h STEL/15min Remarks / Observations AGW DEU 1200 500 2400 (C) 1000 (C) MAK DEU 1200 500 2400 1000 VLEP FRA 1210 500 2400 1000 VLEP ITA 1210 500 2420 1000 VLEP ITA 1210 500 200 200 200 VLE PRT 1210 500 200 200 200 200 NGV/KGV SWE 600 250 1200 (C) 500 (C) 500 (C) MV SVN 1210 500 200 (C) 500 (C) 500 (C) MV SVN 1210					ACETONE		
ng/m3 ppm mg/m3 ppm AGW DEU 1200 500 2400 (C) 1000 (C) MAK DEU 1200 500 2400 1000 VLEP FRA 1210 500 2420 1000 TLV GRC 1780 3560 3560 GVI/KGVI HRV 1210 500 2420 1000 TLV GRC 1780 3560 1000 1000 VLEP ITA 1210 500 1000 1000 1000 VLE PRT 1210 500 125 1000 1000 1000 1000 1000 1000 1000 1100 1000 1100 1000 1100 1000 1100 1000 1100 1000 1100 1000 1100 1000 1100 1100 1100 1100 1100 1100 1100 1100 1100 1100 1100 11000 11000 1100 <th colspan="5">Threshold Limit Value</th>	Threshold Limit Value						
AGW DEU 1200 500 2400 (C) 1000 (C) MAK DEU 1200 500 2400 1000 VLEP FRA 1210 500 2420 1000 TLV GRC 1780 3560	Туре	Country	TWA/8h		STEL/15min		Remarks / Observations
MAK DEU 1200 500 2400 1000 VLEP FRA 1210 500 2420 1000 TLV GRC 1780 3560			mg/m3	ppm	mg/m3	ppm	
VLEP FRA 1210 500 2420 1000 TLV GRC 1780 3560	AGW	DEU	1200	500	2400 (C)	1000 (C)	
TLV GRC 1780 3560 GVI/KGVI HRV 1210 500 VLEP ITA 1210 500 TLV NOR 295 125 VLE PRT 1210 500 NDS/NDSCh POL 600 1800 TLV ROU 1210 500 NGV/KGV SWE 600 250 NGV/KGV SWE 600 250 NGV/KGV SWE 600 250 MV SVN 1210 500 ESD TUR 1210 500 WEL GBR 1210 500	MAK	DEU	1200	500	2400	1000	
GVI/KGVI HRV 1210 500 VLEP ITA 1210 500 TLV NOR 295 125 VLE PRT 1210 500 NDS/NDSCh POL 600 1800 TLV ROU 1210 500 NGV/KGV SWE 600 250 1200 (C) 500 (C) MV SVN 1210 500 2420 1000 ESD TUR 1210 500 2420 1000 WEL GBR 1210 500 3620 1500	VLEP	FRA	1210	500	2420	1000	
VLEP ITA 1210 500 TLV NOR 295 125 VLE PRT 1210 500 NDS/NDSCh POL 600 1800 TLV ROU 1210 500 NGV/KGV SWE 600 250 1200 (C) 500 (C) MV SVN 1210 500 2420 1000 ESD TUR 1210 500 2420 1000 WEL GBR 1210 500 3620 1500	TLV	GRC	1780		3560		
TLV NOR 295 125 VLE PRT 1210 500 NDS/NDSCh POL 600 1800 TLV ROU 1210 500 NGV/KGV SWE 600 250 1200 (C) 500 (C) MV SVN 1210 500 2420 1000 ESD TUR 1210 500 3620 1500	GVI/KGVI	HRV	1210	500			
VLE PRT 1210 500 NDS/NDSCh POL 600 1800 TLV ROU 1210 500 NGV/KGV SWE 600 250 1200 (C) 500 (C) MV SVN 1210 500 2420 1000 ESD TUR 1210 500 3620 1500	VLEP	ITA	1210	500			
NDS/NDSCh POL 600 1800 TLV ROU 1210 500 NGV/KGV SWE 600 250 1200 (C) 500 (C) MV SVN 1210 500 2420 1000 ESD TUR 1210 500 3620 1500	TLV	NOR	295	125			
TLV ROU 1210 500 NGV/KGV SWE 600 250 1200 (C) 500 (C) MV SVN 1210 500 2420 1000 ESD TUR 1210 500 2420 1000 WEL GBR 1210 500 3620 1500	VLE	PRT	1210	500			
NGV/KGV SWE 600 250 1200 (C) 500 (C) MV SVN 1210 500 2420 1000 ESD TUR 1210 500 500 500 WEL GBR 1210 500 3620 1500	NDS/NDSCh	POL	600		1800		
MV SVN 1210 500 2420 1000 ESD TUR 1210 500	TLV	ROU	1210	500			
ESD TUR 1210 500 WEL GBR 1210 500 3620 1500	NGV/KGV	SWE	600	250	1200 (C)	500 (C)	
WEL GBR 1210 500 3620 1500	MV	SVN	1210	500	2420	1000	
	ESD	TUR	1210	500			
OFI FU 1210 500	WEL	GBR	1210	500	3620	1500	
	OEL	EU	1210	500			
TLV-ACGIH 250 500	TLV-ACGIH			250		500	

Legend:

(C) = CEILING ; INHAL = Inhalable Fraction ; RESP = Respirable Fraction ; THORA = Thoracic Fraction.

During the risk assessment process, it is essential to take into consideration the ACGIH occupational exposure levels for particulate not otherwise classified (PNOC respirable fraction: 3 mg/m3; PNOC inhalable fraction: 10 mg/m3). For values above these limits, use a P type filter, whose class (1, 2 or 3) must be chosen according to the outcome of risk assessment. The above values are not TLVs, but guide values, to be used for particles that do not have their own TLV and that are insoluble or poorly soluble in water and have low toxicity.

8.2. Exposure controls

As the use of adequate technical equipment must always take priority over personal protective equipment, make sure that the workplace is well aired through effective local aspiration.

When choosing personal protective equipment, ask your chemical substance supplier for advice.

Personal protective equipment must be CE marked, showing that it complies with applicable standards.

Provide an emergency shower with face and eye wash station.

HAND PROTECTION

In the case of prolonged contact with the product, protect the hands with penetration-resistant work gloves (see standard EN 374). Work glove material must be chosen according to the use process and the products that may form. Latex gloves may cause sensitivity reactions.

SKIN PROTECTION

Wear category II professional long-sleeved overalls and safety footwear (see Regulation 2016/425 and standard EN ISO 20344). Wash body with soap and water after removing protective clothing.

EYE PROTECTION

Wear airtight protective goggles (see standard EN ISO 16321).

RESPIRATORY PROTECTION

Use a type P filtering facemask, whose class (1, 2 or 3) and effective need, must be defined according to the outcome of risk assessment (see standard EN 149).

ENVIRONMENTAL EXPOSURE CONTROLS

The emissions generated by manufacturing processes, including those generated by ventilation equipment, should be checked to ensure compliance with environmental standards.

SECTION 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Properties	Value
Appearance	solid powder
Colour	not available
Odour	not available
Melting point / freezing point	not available
Initial boiling point	not applicable
Flammability	not available
Lower explosive limit	not available
Upper explosive limit	not available
Flash point	not applicable
Auto-ignition temperature	not available

Information



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SECTION 9. Physical and chemical properties ... / >>

Decomposition temperature pH	
Kinematic viscosity Solubility	
Partition coefficient: n-octanol/water	
Vapour pressure Density and/or relative density	
Relative vapour density Particle characteristics	
Particle characteristics	

not available 7,0 - 7,4

not available Remark:in the complete medium Temperature: 25 °C

9.2. Other information

9.2.1. Information with regard to physical hazard classes

Information not available

9.2.2. Other safety characteristics

Information not available

SECTION 10. Stability and reactivity

10.1. Reactivity

There are no particular risks of reaction with other substances in normal conditions of use.

ACETONE

Decomposes under the effect of heat.

10.2. Chemical stability

The product is stable in normal conditions of use and storage.

10.3. Possibility of hazardous reactions

The powders are potentially explosive when mixed with air.

ACETONE

Risk of explosion on contact with: bromine trifluoride,fluorine dioxide,hydrogen peroxide,nitrosyl chloride,2-methyl-1,3 butadiene,nitromethane,nitrosyl perchlorate.May react dangerously with: potassium tert-butoxide,alkaline hydroxides,bromine,bromoform,isoprene,sodium,sulphur dioxide,chromium trioxide,chromyl chloride,nitric acid,chloroform,peroxymonosulphuric acid,phosphoryl oxychloride,chromosulphuric acid,fluorine,strong oxidising agents,strong reducing agents.Develops flammable gas on contact with: nitrosyl perchlorate.

10.4. Conditions to avoid

Avoid environmental dust build-up.

ACETONE

Avoid exposure to: sources of heat, naked flames.

10.5. Incompatible materials

ACETONE

Incompatible with: acids,oxidising substances.

10.6. Hazardous decomposition products

ACETONE

May develop: ketenes, irritant substances.

SECTION 11. Toxicological information

In the absence of experimental data for the product itself, health hazards are evaluated according to the properties of the substances it contains, using the criteria specified in the applicable regulation for classification.

It is therefore necessary to take into account the concentration of the individual hazardous substances indicated in section 3, to evaluate the toxicological effects of exposure to the product.

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



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SECTION 11. Toxicological information ... / >>

Metabolism, toxicokinetics, mechanism of action and other information

Information not available

Information on likely routes of exposure

Information not available

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Information not available

Interactive effects

Information not available

ACUTE TOXICITY

ATE (Inhalation) of the mixture: ATE (Oral) of the mixture: ATE (Dermal) of the mixture:

> ADENINE SULFATE ATE (Oral):

Not classified (no significant component) >2000 mg/kg Not classified (no significant component)

500 mg/kg estimate from table 3.1.2 of Annex I of the CLP (figure used for calculation of the acute toxicity estimate of the mixture)

SKIN CORROSION / IRRITATION

Causes skin irritation

SERIOUS EYE DAMAGE / IRRITATION

Causes serious eye irritation

RESPIRATORY OR SKIN SENSITISATION

Does not meet the classification criteria for this hazard class

GERM CELL MUTAGENICITY

Does not meet the classification criteria for this hazard class

CARCINOGENICITY

Does not meet the classification criteria for this hazard class

REPRODUCTIVE TOXICITY

Does not meet the classification criteria for this hazard class

STOT - SINGLE EXPOSURE

May cause respiratory irritation

STOT - REPEATED EXPOSURE

Does not meet the classification criteria for this hazard class

ASPIRATION HAZARD

Does not meet the classification criteria for this hazard class

11.2. Information on other hazards

Based on the available data, the product does not contain substances listed in the main European lists of potential or suspected endocrine disruptors with human health effects under evaluation.

ΕN



SECTION 12. Ecological information

Use this product according to good working practices. Avoid littering. Inform the competent authorities, should the product reach waterways or contaminate soil or vegetation.

12.1. Toxicity

Information not available

12.2. Persistence and degradability

ACETONE Rapidly degradable

12.3. Bioaccumulative potential

ACETONE Partition coefficient: n-octanol/water BCF

-0,23 3

12.4. Mobility in soil

Information not available

12.5. Results of PBT and vPvB assessment

On the basis of available data, the product does not contain any PBT or vPvB in percentage \geq than 0,1%.

12.6. Endocrine disrupting properties

Based on the available data, the product does not contain substances listed in the main European lists of potential or suspected endocrine disruptors with environmental effects under evaluation.

12.7. Other adverse effects

Information not available

SECTION 13. Disposal considerations

13.1. Waste treatment methods

Reuse, when possible. Product residues should be considered special hazardous waste. The hazard level of waste containing this product should be evaluated according to applicable regulations.

Disposal must be performed through an authorised waste management firm, in compliance with national and local regulations. The management of waste arising from the use or dispersal of this product must be organised in accordance with occupational safety regulations. See section 8 for possible need for PPE.

CONTAMINATED PACKAGING

Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.

SECTION 14. Transport information

The product is not dangerous under current provisions of the Code of International Carriage of Dangerous Goods by Road (ADR) and by Rail (RID), of the International Maritime Dangerous Goods Code (IMDG), and of the International Air Transport Association (IATA) regulations.

14.1. UN number or ID number

not applicable

ΕN



ΕN

SECTION 14. Transport information ... / >>

14.2. UN proper shipping name

not applicable

14.3. Transport hazard class(es)

not applicable

14.4. Packing group

not applicable

14.5. Environmental hazards

not applicable

14.6. Special precautions for user

not applicable

14.7. Maritime transport in bulk according to IMO instruments

Information not relevant

SECTION 15. Regulatory information

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

Seveso Category - Directive 2012/18/EU:

Restrictions relating to the product or contained substances pursuant to Annex XVII to EC Regulation 1907/2006

None

Product Point 40 Contained substance Point 75

Regulation (EU) 2019/1148 - on the marketing and use of explosives precursors not applicable

Substances in Candidate List (Art. 59 REACH) On the basis of available data, the product does not contain any SVHC in percentage \geq than 0,1%.

Substances subject to authorisation (Annex XIV REACH)

None

Substances subject to exportation reporting pursuant to Regulation (EU) 649/2012: None

Substances subject to the Rotterdam Convention:

None

Substances subject to the Stockholm Convention: None

Healthcare controls

Workers exposed to this chemical agent must not undergo health checks, provided that available risk-assessment data prove that the risks related to the workers' health and safety are modest and that the 98/24/EC directive is respected.

15.2. Chemical safety assessment

A chemical safety assessment has not been performed for the preparation/for the substances indicated in section 3.



SECTION 16. Other information

Text of hazard (H) indications mentioned in section 2-3 of the sheet:

Flam. Liq. 2 Acute Tox. 4 Eye Irrit. 2 Skin Irrit. 2 STOT SE 3 H225 H302 H319 H315 H335 H336	Flammable liquid, category 2 Acute toxicity, category 4 Eye irritation, category 2 Skin irritation, category 2 Specific target organ toxicity - single exposure, category 3 Highly flammable liquid and vapour. Harmful if swallowed. Causes serious eye irritation. Causes skin irritation. May cause respiratory irritation.
H335 H336 EUH066	May cause respiratory irritation. May cause drowsiness or dizziness. Repeated exposure may cause skin dryness or cracking.

LEGEND:

- ADR: European Agreement concerning the carriage of Dangerous goods by Road
- ATE: Acute Toxicity Estimate
- CAS: Chemical Abstract Service Number
- CE50: Effective concentration (required to induce a 50% effect)
- CE: Identifier in ESIS (European archive of existing substances)
- CLP: Regulation (EC) 1272/2008
- DNEL: Derived No Effect Level
- EmS: Emergency Schedule
- GHS: Globally Harmonized System of classification and labeling of chemicals
- IATA DGR: International Air Transport Association Dangerous Goods Regulation
- IC50: Immobilization Concentration 50%
- IMDG: International Maritime Code for dangerous goods
- IMO: International Maritime Organization
- INDEX: Identifier in Annex VI of CLP
- LC50: Lethal Concentration 50%
- LD50: Lethal dose 50%
- OEL: Occupational Exposure Level
- PBT: Persistent, bioaccumulative and toxic
- PEC: Predicted environmental Concentration
- PEL: Predicted exposure level
- PMT: Persistent, mobile and toxic
- PNEC: Predicted no effect concentration
- REACH: Regulation (EC) 1907/2006
- RID: Regulation concerning the international transport of dangerous goods by train
- TLV: Threshold Limit Value
- TLV CEILING: Concentration that should not be exceeded during any time of occupational exposure.
- TWA: Time-weighted average exposure limit
- TWA STEL: Short-term exposure limit
- VOC: Volatile organic Compounds
- vPvB: Very persistent and very bioaccumulative
- vPvM: Very persistent and very mobile
- WGK: Water hazard classes (German).

GENERAL BIBLIOGRAPHY

- 1. Regulation (EC) 1907/2006 (REACH) of the European Parliament
- 2. Regulation (EC) 1272/2008 (CLP) of the European Parliament
- 3. Regulation (EU) 2020/878 (II Annex of REACH Regulation)
- 4. Regulation (EC) 790/2009 (I Atp. CLP) of the European Parliament
- 5. Regulation (EU) 286/2011 (II Atp. CLP) of the European Parliament
- 6. Regulation (EU) 618/2012 (III Atp. CLP) of the European Parliament
- 7. Regulation (EU) 487/2013 (IV Atp. CLP) of the European Parliament
- 8. Regulation (EU) 944/2013 (V Atp. CLP) of the European Parliament
- 9. Regulation (EU) 605/2014 (VI Atp. CLP) of the European Parliament
- 10. Regulation (EU) 2015/1221 (VII Atp. CLP) of the European Parliament
- 11. Regulation (EU) 2016/918 (VIII Atp. CLP) of the European Parliament
- 12. Regulation (EU) 2016/1179 (IX Atp. CLP)
- 13. Regulation (EU) 2017/776 (X Atp. CLP)
- 14. Regulation (EU) 2018/669 (XI Atp. CLP)
- 15. Regulation (EU) 2019/521 (XII Atp. CLP)



SECTION 16. Other information ... / >>

- 16. Delegated Regulation (UE) 2018/1480 (XIII Atp. CLP)
- 17. Regulation (EU) 2019/1148
- 18. Delegated Regulation (UE) 2020/217 (XIV Atp. CLP)
- 19. Delegated Regulation (UE) 2020/1182 (XV Atp. CLP)
- 20. Delegated Regulation (UE) 2021/643 (XVI Atp. CLP)
- 21. Delegated Regulation (UE) 2021/849 (XVII Atp. CLP)
- 22. Delegated Regulation (UE) 2022/692 (XVIII Atp. CLP)
- 23. Delegated Regulation (UE) 2023/707
- 24. Delegated Regulation (UE) 2023/1434 (XIX Atp. CLP)
- 25. Delegated Regulation (UE) 2023/1435 (XX Atp. CLP)
- 26. Delegated Regulation (UE) 2024/197 (XXI Atp. CLP)
- The Merck Index. 10th Edition
- Handling Chemical Safety
- INRS Fiche Toxicologique (toxicological sheet)
- Patty Industrial Hygiene and Toxicology
- N.I. Sax Dangerous properties of Industrial Materials-7, 1989 Edition
- IFA GESTIS website
- ECHA website
- Database of SDS models for chemicals Ministry of Health and ISS (Istituto Superiore di Sanità) Italy

Note for users:

The information contained in the present sheet are based on our own knowledge on the date of the last version. Users must verify the suitability and thoroughness of provided information according to each specific use of the product.

This document must not be regarded as a guarantee on any specific product property.

The use of this product is not subject to our direct control; therefore, users must, under their own responsibility, comply with the current health and safety laws and regulations. The producer is relieved from any liability arising from improper uses.

Provide appointed staff with adequate training on how to use chemical products.

CALCULATION METHODS FOR CLASSIFICATION

Chemical and physical hazards: Product classification derives from criteria established by the CLP Regulation, Annex I, Part 2. The data for evaluation of chemical-physical properties are reported in section 9.

Health hazards: Product classification is based on calculation methods as per Annex I of CLP, Part 3, unless determined otherwise in Section 11.

Environmental hazards: Product classification is based on calculation methods as per Annex I of CLP, Part 4, unless determined otherwise in Section 12.

Changes to previous review: The following sections were modified: 01 / 04 / 08 / 09 / 11 / 13 / 16.