



Safety Data Sheet

According to Annex II to REACH - Regulation 2020/878 and to Annex II to UK REACH

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

1.1. Product identifier

Code: **25RPP2000**
Product name: **MINI SYSTEM ECOSAF**

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

Intended use: **Professional laboratory use**

1.3. Details of the supplier of the safety data sheet

Name: **Biolife Italiana S.r.l.**
Full address: **Viale Monza, 272**
District and Country: **20128 Milano (Milano)**
Italia
Tel.: **0039 02 252091**
Fax: **0039 02 2576428**

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:
NHS111 in England: 111
NHS24 in Scotland: 111
NHS Direct in Wales: 111 or 0845 4647

In an emergency, if the patient has collapsed 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:

Carcinogenicity, category 1B	H350	May cause cancer.
Skin sensitization, category 1	H317	May cause an allergic skin reaction.

2.2. Label elements

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

Hazard pictograms:



Signal words: **Danger**

Hazard statements:

H350	May cause cancer.
H317	May cause an allergic skin reaction. Restricted to professional users.

Precautionary statements:



SECTION 2. Hazards identification ... / >>

P201	Obtain special instructions before use.
P280	Wear protective gloves/ protective clothing / eye protection / face protection.
P308+P313	IF exposed or concerned: Get medical advice / attention.
P261	Avoid breathing dust / fume / gas / mist / vapours / spray.
P362+P364	Take off contaminated clothing and wash it before reuse.

Contains: FORMALDEHYDE

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)
ACETIC ACID		
CAS	64-19-7	$2 \leq x < 2,5$
EC	200-580-7	Flam. Liq. 3 H226, Skin Corr. 1A H314, Eye Dam. 1 H318, Classification note according to Annex VI to the CLP Regulation: B
INDEX	607-002-00-6	Skin Corr. 1A H314: \geq 90%, Skin Corr. 1B H314: \geq 25%, Skin Irrit. 2 H315: \geq 10%, Eye Dam. 1 H318: \geq 25%, Eye Irrit. 2 H319: \geq 10%
METHANOL		
CAS	67-56-1	$0,809 \leq x < 0,909$
EC	200-659-6	Flam. Liq. 2 H225, Acute Tox. 3 H301, Acute Tox. 3 H311, Acute Tox. 3 H331, STOT SE 1 H370
INDEX	603-001-00-X	STOT SE 2 H371: \geq 3%
		STA Oral: 100 mg/kg, STA Dermal: 300 mg/kg, STA Inhalation gas: 700 ppm, STA Inhalation mists/powders: 0,501 mg/l, STA Inhalation vapours: 3 mg/l
FORMALDEHYDE		
CAS	50-00-0	$0,809 \leq x < 0,909$
EC	200-001-8	Carc. 1B H350, Muta. 2 H341, Acute Tox. 2 H330, Acute Tox. 3 H301, Acute Tox. 3 H311, Skin Corr. 1B H314, Eye Dam. 1 H318, STOT SE 3 H335, Skin Sens. 1 H317, Classification note according to Annex VI to the CLP Regulation: B, D
INDEX	605-001-00-5	Skin Corr. 1B H314: \geq 25%, Skin Irrit. 2 H315: \geq 5%, Skin Sens. 1 H317: \geq 0,2%, Eye Dam. 1 H318: \geq 25%, Eye Irrit. 2 H319: \geq 5%, STOT SE 3 H335: \geq 5%
		LD50 Oral: 100 mg/kg, LD50 Dermal: 270 mg/kg, LC50 Inhalation vapours: 0,588 mg/l/4h

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

EYES: Remove contact lenses, if present. Wash immediately with plenty of water for at least 30-60 minutes, opening the eyelids fully. Get medical advice/attention.

SKIN: Remove contaminated clothing. Rinse skin with a shower immediately. Get medical advice/attention.

INGESTION: Have the subject drink as much water as possible. Get medical advice/attention. Do not induce vomiting unless explicitly authorised by a doctor.

INHALATION: Get medical advice/attention immediately. Remove victim to fresh air, away from the accident scene. If the subject stops breathing, administer artificial respiration. Take suitable precautions for rescue workers.

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

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

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

Information not available



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.

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

Block the leakage if there is no hazard.

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 into a suitable container. Evaluate the compatibility of the container to be used, by checking section 10. Absorb the remainder with inert absorbent material.

Make sure the leakage site is well aired. 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

Keep away from heat, sparks and naked flames; do not smoke or use matches or lighters. Without adequate ventilation, vapours may accumulate at ground level and, if ignited, catch fire even at a distance, with the danger of backfire. Avoid bunching of electrostatic charges. When performing transfer operations involving large containers, connect to an earthing system and wear antistatic footwear. Vigorous stirring and flow through the tubes and equipment may cause the formation and accumulation of electrostatic charges. In order to avoid the risk of fires and explosions, never use compressed air when handling. Open containers with caution as they may be pressurised. Do not eat, drink or smoke during use. Avoid leakage of the product into the environment.

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. Store in a cool and well ventilated place, keep far away from sources of heat, naked flames and sparks and other sources of ignition. 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	Technischen Regeln für Gefahrstoffe (TRGS 900) - Liste der Arbeitsplatzgrenzwerte und Kurzzeitwerte. MAK- und BAT-Werte-Liste 2020, Ständige Senatskommission zur Prüfung gesundheitsschädlicher Arbeitsstoffe, Mitteilung 56
ESP	España	Límites de exposición profesional para agentes químicos en España 2021
FRA	France	Valeurs limites d'exposition professionnelle aux agents chimiques en France. ED 984 - INRS
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 μεταλλαξιογόνους παράγοντες κατά την εργασία"»
HRV	Hrvatska	Pravilnik o izmjenama i dopunama Pravilnika o zaštiti radnika od izloženosti opasnim kemikalijama 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
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
GBR	United Kingdom	EH40/2005 Workplace exposure limits (Fourth Edition 2020)
EU	OEL EU	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 2020

ACETIC ACID

Threshold Limit Value

Type	Country	TWA/8h		STEL/15min		Remarks / Observations
		mg/m3	ppm	mg/m3	ppm	
AGW	DEU	25	10	50 (C)	20 (C)	
MAK	DEU	25	10	50	20	
VLA	ESP	25	10	50	20	
VLEP	FRA	25	10	50	20	
TLV	GRC	25	10	37	15	
GVI/KGVI	HRV	25	10	50	20	
VLEP	ITA	25	10	50	20	
TLV	NOR	25	10	50	20	
VLE	PRT	25	10	50	20	
NDS/NDSch	POL	25		50		
TLV	ROU	25	10	50	20	
MV	SVN	25	10	50	20	
ESD	TUR	25	10			
WEL	GBR	25	10	50	20	
OEL	EU	25	10	50	20	
TLV-ACGIH		25	10	37	15	

Health - Derived no-effect level - DNEL / DMEL

Route of exposure	Effects on consumers				Effects on workers			
	Acute local	Acute systemic	Chronic local	Chronic systemic	Acute local	Acute systemic	Chronic local	Chronic systemic
Inhalation	25		25		25		25	
	mg/m3		mg/m3		mg/m3		mg/m3	



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

METHANOL

Threshold Limit Value

Type	Country	TWA/8h		STEL/15min		Remarks / Observations
		mg/m3	ppm	mg/m3	ppm	
AGW	DEU	270	200	1080	800	SKIN
MAK	DEU	130	100	260	200	SKIN
VLA	ESP	266	200			SKIN
VLEP	FRA	260	200	1300	1000	SKIN 11
TLV	GRC	260	200	325	250	
GVI/KGVI	HRV	260	200			SKIN
VLEP	ITA	260	200			SKIN
TLV	NOR	130	100			SKIN
VLE	PRT	260	200			SKIN
NDS/NDSch	POL	100		300		SKIN
TLV	ROU	260	200			SKIN
MV	SVN	260	200	1040	800	SKIN
ESD	TUR	260	200			SKIN
WEL	GBR	266	200	333	250	SKIN
OEL	EU	260	200			
TLV-ACGIH		262	200	328	250	SKIN

FORMALDEHYDE

Threshold Limit Value

Type	Country	TWA/8h		STEL/15min		Remarks / Observations
		mg/m3	ppm	mg/m3	ppm	
AGW	DEU	0,37	0,3	0,74	0,6	
VLA	ESP	0,37	0,3	0,74	0,6	
VLEP	FRA	0,37	0,3	0,74	0,6	
TLV	GRC	0,37	0,3	0,74	0,6	
GVI/KGVI	HRV	0,37	0,3	0,74	0,6	
VLEP	ITA	0,37	0,3	0,74	0,6	
TLV	NOR	0,6	0,5	1,2 (C)	1 (C)	
VLE	PRT	0,37	0,3	0,74	0,6	
NDS/NDSch	POL	0,37		0,74		SKIN
TLV	ROU	0,37	0,3	0,74	0,6	
MV	SVN	0,62	0,5	0,62	0,5	SKIN
WEL	GBR	2,5	2	2,5	2	
OEL	EU	0,37	0,3	0,74	0,6	
TLV-ACGIH			0,1		0,3 (C)	

Legend:

(C) = CEILING ; INHAL = Inhalable Fraction ; RESP = Respirable Fraction ; THORA = Thoracic Fraction.
VND = hazard identified but no DNEL/PNEC available ; NEA = no exposure expected ; NPI = no hazard identified.

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.

The product must be used inside a closed circuit, in a well-ventilated environment and with strong localised aspiration systems in place.

HAND PROTECTION

Protect hands with category III work gloves (see standard EN 374).

The following should be considered when choosing work glove material: compatibility, degradation, failure time and permeability.

The work gloves' resistance to chemical agents should be checked before use, as it can be unpredictable. The gloves' wear time depends on the duration and type of use.

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 166).

RESPIRATORY PROTECTION

If the threshold value (e.g. TLV-TWA) is exceeded for the substance or one of the substances present in the product, use a mask with a type A filter whose class (1, 2 or 3) must be chosen according to the limit of use concentration. (see standard EN 14387). In the presence of gases or vapours of various kinds and/or gases or vapours containing particulate (aerosol sprays, fumes, mists, etc.) combined filters are required.

Respiratory protection devices must be used if the technical measures adopted are not suitable for restricting the worker's exposure to the



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

threshold values considered. The protection provided by masks is in any case limited.

If the substance considered is odourless or its olfactory threshold is higher than the corresponding TLV-TWA and in the case of an emergency, wear open-circuit compressed air breathing apparatus (in compliance with standard EN 137) or external air-intake breathing apparatus (in compliance with standard EN 138). For a correct choice of respiratory protection device, see standard EN 529.

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	Information
Appearance	liquid	
Colour	colourless	
Odour	Not available	
Melting point / freezing point	Not available	
Initial boiling point	Not available	
Flammability	Not available	
Lower explosive limit	Not available	
Upper explosive limit	Not available	
Flash point	> 63 °C	
Auto-ignition temperature	Not available	
pH	4,5	
Kinematic viscosity	Not available	
Solubility	Not available	
Partition coefficient: n-octanol/water	Not available	
Vapour pressure	Not available	
Density and/or relative density	1,03	
Relative vapour density	Not available	
Particle characteristics	Not applicable	

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.

FORMALDEHYDE

Decomposes under the effect of heat.

Aqueous solutions are stabilised with methanol but tend to polymerise over time.

10.2. Chemical stability

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

10.3. Possibility of hazardous reactions

The vapours may also form explosive mixtures with the air.

ACETIC ACID

Risk of explosion on contact with: chromium (VI) oxide, potassium permanganate, sodium peroxide, perchloric acid, phosphorus chloride, hydrogen peroxide. May react dangerously with: alcohols, bromine pentafluoride, chlorosulphuric acid, dichromate-sulphuric acid, ethane diamine, ethylene glycol, potassium hydroxide, strong bases, sodium hydroxide, strong oxidising agents, nitric acid, ammonium nitrate, potassium tert-butoxide, oleum. Forms explosive mixtures with: air.

FORMALDEHYDE

Risk of explosion on contact with: nitromethane, nitrogen dioxide, hydrogen peroxide, phenoles, performic acid, nitric acid. May polymerise



SECTION 10. Stability and reactivity ... / >>

on contact with: strong oxidising agents,alkalis.May react dangerously with: hydrochloric acid,magnesium carbonate,sodium hydroxide,perchloric acid,aniline.Forms explosive mixtures with: air.

10.4. Conditions to avoid

Avoid overheating. Avoid bunching of electrostatic charges. Avoid all sources of ignition.

ACETIC ACID

Avoid exposure to: sources of heat,naked flames.

FORMALDEHYDE

Avoid exposure to: light,sources of heat,naked flames.

10.5. Incompatible materials

ACETIC ACID

Incompatible with: carbonates,hydroxides,phosphates,oxidising substances,bases.

FORMALDEHYDE

Incompatible with: acids,alkalis,ammonia,tannin,strong oxidants,phenoles,copper salts,silver,iron.

10.6. Hazardous decomposition products

In the event of thermal decomposition or fire, gases and vapours that are potentially dangerous to health may be released.

FORMALDEHYDE

When heated to decomposition releases: methanol,carbon monoxide.

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

Metabolism, toxicokinetics, mechanism of action and other information

Information not available

Information on likely routes of exposure

METHANOL

WORKERS: inhalation; contact with the skin.

POPULATION: ingestion of contaminated food or water; contact with the skin of products containing the substance.

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

METHANOL

The minimum lethal dose for humans by ingestion is considered to be in the range from 300 to 1000 mg/kg. Ingestion of 4-10 ml of the substance may cause permanent blindness in adult humans (IPCS).

Interactive effects

Information not available

ACUTE TOXICITY

ATE (Inhalation - mists / powders) of the mixture:	> 5 mg/l
ATE (Inhalation - vapours) of the mixture:	> 20 mg/l
ATE (Inhalation - gas) of the mixture:	> 20000 mg/l
ATE (Oral) of the mixture:	>2000 mg/kg
ATE (Dermal) of the mixture:	>2000 mg/kg

ACETIC ACID

LD50 (Oral):	3310 mg/kg Rat
LD50 (Dermal):	1060 mg/kg Rabbit
LC50 (Inhalation vapours):	11,4 mg/l/4h Rat

METHANOL

STA (Oral):	100 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)
STA (Dermal):	300 mg/kg estimate from table 3.1.2 of Annex I of the CLP



SECTION 11. Toxicological information ... / >>

STA (Inhalation mists/powders):	(figure used for calculation of the acute toxicity estimate of the mixture) 0,501 mg/l estimate from table 3.1.2 of Annex I of the CLP
STA (Inhalation vapours):	(figure used for calculation of the acute toxicity estimate of the mixture) 3 mg/l estimate from table 3.1.2 of Annex I of the CLP
STA (Inhalation gas):	(figure used for calculation of the acute toxicity estimate of the mixture) 700 ppm estimate from table 3.1.2 of Annex I of the CLP (figure used for calculation of the acute toxicity estimate of the mixture)
FORMALDEHYDE	
LD50 (Oral):	100 mg/kg Rat
LD50 (Dermal):	270 mg/kg Rabbit
LC50 (Inhalation vapours):	0,588 mg/l/4h Rat

SKIN CORROSION / IRRITATION

Does not meet the classification criteria for this hazard class

SERIOUS EYE DAMAGE / IRRITATION

Does not meet the classification criteria for this hazard class

RESPIRATORY OR SKIN SENSITISATION

Sensitising for the skin

Respiratory sensitization

Information not available

Skin sensitization

Information not available

GERM CELL MUTAGENICITY

Does not meet the classification criteria for this hazard class

CARCINOGENICITY

May cause cancer

REPRODUCTIVE TOXICITY

Does not meet the classification criteria for this hazard class

Adverse effects on sexual function and fertility

Information not available

Adverse effects on development of the offspring

Information not available

Effects on or via lactation

Information not available

STOT - SINGLE EXPOSURE

Does not meet the classification criteria for this hazard class

Target organ

Information not available

Route of exposure

Information not available



SECTION 11. Toxicological information ... / >>

STOT - REPEATED EXPOSURE

Does not meet the classification criteria for this hazard class

Target organ

Information not available

Route of exposure

Information not available

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.

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

ACETIC ACID	
Solubility in water	> 10000 mg/l
Rapidly degradable	
METHANOL	
Solubility in water	1000 - 10000 mg/l
Rapidly degradable	
FORMALDEHYDE	
Solubility in water	55000 mg/l
Rapidly degradable	

12.3. Bioaccumulative potential

ACETIC ACID	
Partition coefficient: n-octanol/water	-0,17
METHANOL	
Partition coefficient: n-octanol/water	-0,77
BCF	0,2
FORMALDEHYDE	
Partition coefficient: n-octanol/water	0,35
BCF	< 1

12.4. Mobility in soil

ACETIC ACID	
Partition coefficient: soil/water	1,153
FORMALDEHYDE	
Partition coefficient: soil/water	1,202



SECTION 12. Ecological information ... / >>

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.

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

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:

None



SECTION 15. Regulatory information ... / >>

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

<u>Product</u>		
Point	3 - 40	
<u>Contained substance</u>		
Point	75	
Point	69	METHANOL
Point	28-72	FORMALDEHYDE

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 health-dangerous chemical agent must undergo sanitary checks carried out in compliance with 2004/37/EC directive.

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	Flammable liquid, category 2
Carc. 1B	Carcinogenicity, category 1B
Muta. 2	Germ cell mutagenicity, category 2
Acute Tox. 2	Acute toxicity, category 2
Acute Tox. 3	Acute toxicity, category 3
STOT SE 1	Specific target organ toxicity - single exposure, category 1
Skin Corr. 1A	Skin corrosion, category 1A
STOT SE 3	Specific target organ toxicity - single exposure, category 3
Skin Sens. 1	Skin sensitization, category 1
H225	Highly flammable liquid and vapour.
H350	May cause cancer.
H341	Suspected of causing genetic defects.
H330	Fatal if inhaled.
H301	Toxic if swallowed.
H311	Toxic in contact with skin.
H370	Causes damage to organs.
H314	Causes severe skin burns and eye damage.
H335	May cause respiratory irritation.
H317	May cause an allergic skin reaction.

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



SECTION 16. Other information ... / >>

- 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 as REACH Regulation
- PEC: Predicted environmental Concentration
- PEL: Predicted exposure level
- 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 as for REACH Regulation
- 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)
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)

- 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.



Biolife Italiana S.r.l.
25RPP2000 - MINI SYSTEM ECOSAF

Revision nr.5
Dated 13/06/2023
Printed on 13/06/2023
Page n. 13 / 13
Replaced revision:4 (Dated 12/06/2023)

EN

SECTION 16. Other information ... / >>

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:
09.