

EU safety data sheet

Trade name: CyLyse™ FX

Current version : 4.0.0, issued: 06.09.2023

Replaced version: 3.2.1, issued: 04.09.2023

Region: GB

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

1.1 Product identifier

Trade name

CyLyse™ FX

Product no.: BD303500, AX032552

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

Relevant identified uses of the substance or mixture

For in-vitro diagnosis

Uses advised against

No data available.

1.3 Details of the supplier of the safety data sheet

Address

Sysmex Partec GmbH

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02826 Görlitz

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Information provided by / telephone

Regulatory Affairs, Tel. +49 3581 8746-0

Advice on Safety Data Sheet

sdb_info@umco.de

1.4 Emergency telephone number

For medical advice (in German and English):

+49 (0)551 192 40 (Giftinformationszentrum Nord)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification in accordance with Regulation (EC) No 1272/2008 (CLP)

Acute Tox. 4; H302

Carc. 1B; H350

Eye Irrit. 2; H319

Muta. 2; H341

Skin Irrit. 2; H315

Skin Sens. 1; H317

STOT RE 2; H373

STOT SE 2; H371

STOT SE 3; H335

Classification information

This product is assessed and classified using the methods and criteria below referred to in Article 9 of Regulation (EC) n° 1272/2008:

Physical hazards: determined through assessment data based on the methods or standards referred to in part 2 of Annex I to CLP

Health hazards and environmental hazards: determined through toxicological and ecotoxicological assessment data based on the methods or standards referred to in Part 3, 4 and 5 of Annex I to CLP.

2.2 Label elements

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

Hazard pictograms



GHS07



GHS08

Signal word

Danger

Hazardous component(s) to be indicated on label:

diethylene glycol

formaldehyde

methanol

Hazard statement(s)

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H302	Harmful if swallowed.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H341	Suspected of causing genetic defects
H350	May cause cancer.
H371	May cause damage to organs.
H373	May cause damage to organs through prolonged or repeated exposure

Precautionary statement(s)

P201	Obtain special instructions before use.
P260	Do not breathe dust/fume/gas/mist/vapours/spray.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P308+P313	IF exposed or concerned: Get medical advice/attention.

Supplemental label elements

"Restricted to professional users"

2.3 Other hazards

PBT assessment
No data available.
vPvB assessment
No data available.

SECTION 3: Composition/information on ingredients

3.1 Substances

Not applicable. The product is not a substance.

3.2 Mixtures

Hazardous ingredients

No	Substance name	Additional information	
	CAS / EC / Index / REACH no	Classification (EC) 1272/2008 (CLP)	Concentration %
1	diethylene glycol		pls. refer to footnote (2)
	111-46-6 203-872-2 603-140-00-6 01-2119457857-21	Acute Tox. 4; H302 STOT RE 2; H373	>= 20.00 - <= 30.00 wt%
2	formaldehyde		
	50-00-0 200-001-8 605-001-00-5 01-2119488953-20	Acute Tox. 3; H301 Acute Tox. 3; H311 Acute Tox. 3; H331 Carc. 1B; H350 Muta. 2; H341 Skin Corr. 1B; H314 Skin Sens. 1; H317	< 15.00 wt%
3	methanol		
	67-56-1 200-659-6 603-001-00-X 01-2119433307-44	Acute Tox. 3; H301 Acute Tox. 3; H311 Acute Tox. 3; H331 Flam. Liq. 2; H225 STOT SE 1; H370	< 5.00 wt%

Full Text for all H-phrases and EUH-phrases: pls. see section 16

(2) According to the latest state of knowledge and applying the criteria set out in annex I to Regulation (EC) No 1272/2008, the aforementioned classification is required. This classification goes beyond the classification set out in table 3, Annex VI to Regulation (CE) No 1272/2008.

No	Note	Specific concentration limits	M-factor (acute)	M-factor (chronic)
2	-	Skin Sens. 1; H317: C >= 0.2% Eye Irrit. 2; H319: C >= 5% STOT SE 3; H335: C >= 5% Skin Irrit. 2; H315: C >= 5% Skin Corr. 1B; H314: C >= 25%	-	-
3	-	STOT SE 2; H371: C >= 3% STOT SE 1; H370: C >= 10%	-	-

Acute toxicity estimate (ATE) values

No	oral	dermal	inhalative
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3		300 mg/kg bodyweight	
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SECTION 4: First aid measures

4.1 Description of first aid measures

General information

Remove contaminated clothing and shoes immediately, and launder thoroughly before reusing. In case of persisting adverse effects, consult a physician. In case of allergic symptoms, especially respiratory tract related, seek medical help immediately.

After inhalation

Remove affected persons from dangerous area by observing suitable respiratory protection measures. Ensure supply of fresh air.

After skin contact

In case of contact with skin wash off with water. Rinse with plenty of water.

After eye contact

Remove contact lenses. Rinse eye thoroughly under running water keeping eyelids wide open and protecting the unaffected eye (at least 10 to 15 minutes).

After ingestion

Rinse the mouth thoroughly with water. Do not induce vomiting. Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed

No data available.

4.3 Indication of any immediate medical attention and special treatment needed

No data available.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

Water spray jet; Foam; Carbon dioxide; Extinguishing powder

Unsuitable extinguishing media

High power water jet

5.2 Special hazards arising from the substance or mixture

In the event of fire, the following can be released: Carbon dioxide (CO₂); Carbon monoxide (CO)

5.3 Advice for firefighters

Use self-contained breathing apparatus. Wear protective clothing.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Refer to protective measures listed in sections 7 and 8.

For emergency responders

Personal protective equipment (PPE) - see section 8.

6.2 Environmental precautions

Do not discharge into the drains/surface waters/groundwater. Do not discharge into the subsoil/soil.

6.3 Methods and material for containment and cleaning up

Contain and collect spillage with non-combustible absorbent materials, e.g. sand, earth, vermiculite, diatomaceous earth and place in container for disposal according to local regulations (see section 13).

6.4 Reference to other sections

Information regarding safe handling, see section 7. Information regarding personal protective measures, see section 8. Information regarding waste disposal, see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advice on safe handling

Risks inherent to handling the product must be minimised by applying the appropriate protective and preventive measures. Working processes should - so far as possible, according to the state of the art - be designed to rule out bodily contact or the release of hazardous substances.

General protective and hygiene measures

Do not eat, drink or smoke during work time. Keep away from foodstuffs and beverages. Do not inhale vapours. Avoid contact with eyes and skin. Wash hands before breaks and after work. Remove contaminated clothing and shoes and launder thoroughly before reusing.

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7.2 Conditions for safe storage, including any incompatibilities

Technical measures and storage conditions

Keep container tightly closed and dry in a cool, well-ventilated place.

Requirements for storage rooms and vessels

Containers which are opened must be carefully closed and kept upright to prevent leakage. Always keep in containers of same material as the original.

Incompatible products

Substances to be avoided, see section 10.

7.3 Specific end use(s)

No data available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational exposure limit values

No	Substance name	CAS no.	EC no.		
1	diethylene glycol	111-46-6	203-872-2		
List of approved workplace exposure limits (WELs) / EH40					
2,2'-Oxydiethanol					
	WEL long-term (8-hr TWA reference period)	101	mg/m³	23	ppm
2	formaldehyde	50-00-0	200-001-8		
List of approved workplace exposure limits (WELs) / EH40					
Formaldehyde					
	WEL short-term (15 min reference period)	2.5	mg/m³	2	ppm
	WEL long-term (8-hr TWA reference period)	2.5	mg/m³	2	ppm
2004/37/EC					
Formaldehyde					
	WEL short-term (15 min reference period)	0.74	mg/m³	0.6	ppm
	WEL long-term (8-hr TWA reference period)	0.37	mg/m³	0.3	ppm
	Skin resorption / sensibilisation	dermal sensitisation (14)			
	Comments	Limit value of 0,62 mg/m3 or 0,5 ppm (3) for the health care, funeral and embalming sectors until 11 July 2024			
3	methanol	67-56-1	200-659-6		
2006/15/EC					
Methanol					
	WEL long-term (8-hr TWA reference period)	260	mg/m³	200	ppm
	Skin resorption / sensibilisation	Skin			
List of approved workplace exposure limits (WELs) / EH40					
Methanol					
	WEL short-term (15 min reference period)	333	mg/m³	250	ppm
	WEL long-term (8-hr TWA reference period)	266	mg/m³	200	ppm
	Comments	Sk			

DNEL, DMEL and PNEC values

DNEL values (worker)

DNEL values (worker)				
No	Substance name			CAS / EC no
	Route of exposure	Exposure time	Effect	Value
1	diethylene glycol			111-46-6 203-872-2
	dermal	Long term (chronic)	systemic	43 mg/kg/day
	inhalative	Long term (chronic)	local	60 mg/m³
	inhalative	Long term (chronic)	systemic	44 mg/m³
2	formaldehyde			50-00-0 200-001-8
	dermal	Long term (chronic)	systemic	240 mg/kg bw/day
	dermal	Long term (chronic)	local	37 µg/cm²
	inhalative	Long term (chronic)	systemic	9 mg/m³
	inhalative	Long term (chronic)	local	0.375 mg/m³
3	methanol			67-56-1 200-659-6
	dermal	Short term (acute)	systemic	20 mg/kg/day
	dermal	Long term (chronic)	systemic	20 mg/kg/day
	inhalative	Short term (acute)	systemic	130 mg/m³

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	inhalative	Short term (acut)	local	130	mg/m ³
	inhalative	Long term (chronic)	systemic	130	mg/m ³
	inhalative	Long term (chronic)	local	130	mg/m ³

DNEL value (consumer)

No	Substance name	Route of exposure	Exposure time	Effect	CAS / EC no	Value
1	diethylene glycol				111-46-6 203-872-2	
	dermal		Long term (chronic)	systemic	21	mg/kg/day
	inhalative		Long term (chronic)	local	12	mg/m ³
	inhalative		Long term (chronic)	systemic	12	mg/m ³
2	formaldehyde				50-00-0 200-001-8	
	oral		Long term (chronic)	systemic	4.1	mg/kg bw/day
	dermal		Long term (chronic)	systemic	102	mg/kg bw/day
	dermal		Long term (chronic)	local	12	µg/cm ²
	inhalative		Long term (chronic)	systemic	3.2	mg/m ³
	inhalative		Long term (chronic)	local	0.1	mg/m ³
3	methanol				67-56-1 200-659-6	
	oral		Long term (chronic)	systemic	4	mg/kg/day
	oral		Short term (acut)	systemic	4	mg/kg/day
	dermal		Short term (acut)	systemic	4	mg/kg/day
	dermal		Long term (chronic)	systemic	4	mg/kg/day
	inhalative		Short term (acut)	systemic	26	mg/m ³
	inhalative		Short term (acut)	local	26	mg/m ³
	inhalative		Long term (chronic)	systemic	26	mg/m ³
	inhalative		Long term (chronic)	local	26	mg/m ³

PNEC values

No	Substance name	Type	CAS / EC no	Value
1	ecological compartment		111-46-6 203-872-2	
	water	fresh water	10	mg/L
	water	marine water	1	mg/L
	water	fresh water sediment	20.9	mg/kg dry weight
	water	marine water sediment	2.09	mg/kg dry weight
	water	Aqua intermittent	10	mg/L
	soil	-	1.53	mg/kg dry weight
	sewage treatment plant	-	199.5	mg/L

8.2 Exposure controls

Appropriate engineering controls

Provide adequate ventilation. Where reasonably practicable this should be achieved by the use of local exhaust ventilation and good general extraction. If these are not sufficient to maintain concentrations of particulates and solvent vapour below the OEL (=Occupational Exposure Limit), suitable respiratory protection must be worn.

Personal protective equipment

Respiratory protection

If workplace exposure limits are exceeded, a respiration protection approved for this particular job must be worn. In case of aerosol and mist formation, take appropriate measures for breathing protection in the event workplace threshold values are not specified.

Eye / face protection

Safety glasses with side protection shield (EN 166)

Hand protection

Sufficient protection is given wearing suitable protective gloves checked according to i.e. EN 374, in the event of risk of skin contact with the product. Before use, the protective gloves should be tested in any case for its specific work-station suitability (i.e. mechanical resistance, product compatibility and antistatic properties). Adhere to the manufacturer's instructions and information relating to the use, storage, care and replacement of protective gloves. Protective gloves shall be replaced immediately when physically damaged or worn. Design operations thus to avoid permanent use of protective gloves.

Other

Chemical-resistant work clothes.

Environmental exposure controls

No data available.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

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State of aggregation			
liquid			
Form			
liquid			
Colour			
clear; colourless			
Odour			
none			
pH value			
No data available			
Boiling point / boiling range			
No data available			
Melting point/freezing point			
No data available			
Decomposition temperature			
No data available			
Flash point			
No data available			
Ignition temperature			
No data available			
Flammability			
No data available			
Lower explosion limit			
No data available			
Upper explosion limit			
No data available			
Vapour pressure			
No data available			
Relative vapour density			
No data available			
Relative density			
No data available			
Density			
No data available			
Solubility			
No data available			
Partition coefficient n-octanol/water (log value)			
No	Substance name	CAS no.	EC no.
1	formaldehyde	50-00-0	200-001-8
	log Pow	0.35	
	Reference temperature	25	°C
	Method	QSAR	
	Source	ECHA	
2	methanol	67-56-1	200-659-6
	log Pow	-0.77	
	Source	ECHA	
Kinematic viscosity			
No data available			
Particle characteristics			
No data available			

9.2 Other information

Other information
No data available.

SECTION 10: Stability and reactivity

10.1 Reactivity

No data available.

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10.2 Chemical stability

Stable under recommended storage and handling conditions (See section 7).

10.3 Possibility of hazardous reactions

Dangerous reactions are not to be expected when handling product according to its intended use.

10.4 Conditions to avoid

The product is stable and no degradation occurs under normal use. Protect against flames, sparks, overheating and against frost.

10.5 Incompatible materials

Oxidizing agents; strong acids; strong bases

10.6 Hazardous decomposition products

No data available.

SECTION 11: Toxicological information

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

Acute oral toxicity (result of the ATE calculation for the mixture)	
No	Product Name
1	CyLyse™ FX Product no.: BD303500, AX032552
ATE (Mixture)	483.33 mg/kg
Method	Calculation method according Regulation (EC) No 1272/2008, (CLP), annex I, part 3, section 3.1.3.6.

Acute oral toxicity	
No data available	

Acute dermal toxicity (result of the ATE calculation for the mixture)	
No	Product Name
1	CyLyse™ FX Product no.: BD303500, AX032552
Comments	The result of the applied calculation method according to the European Regulation (EC) 1272/2008 (CLP), Paragraph 3.1.3.6, Part 3 of Annex I is outside the values that imply a classification / labelling of this mixture according to table 3.1.1 defining the respective categories (ATE dermal > 2000 mg/kg).

Acute dermal toxicity			
No	Substance name	CAS no.	EC no.
1	diethylene glycol	111-46-6	203-872-2
LD50		13300	mg/kg bodyweight
Species	rabbit		
Source	ECHA		
2	methanol	67-56-1	200-659-6
LD50		17100	mg/kg bodyweight
Species	rabbit		
Source	ECHA		

Acute inhalational toxicity (result of the ATE calculation for the mixture)	
No	Product Name
1	CyLyse™ FX Product no.: BD303500, AX032552
Comments	The result of the applied calculation method according to the European Regulation (EC) 1272/2008 (CLP), Paragraph 3.1.3.6, Part 3 of Annex I is outside the values that imply a classification / labelling of this mixture according to table 3.1.1 defining the respective categories (ATE for inhalation: > 20.000 ppmV (gases), > 20 mg/l (vapours), > 5 mg/l (dusts/mists).

Acute inhalational toxicity			
No	Substance name	CAS no.	EC no.
1	diethylene glycol	111-46-6	203-872-2
LC50		4.6	mg/l
Duration of exposure		4	h
State of aggregation	Dust/mist		
Species	rat		
Source	ECHA		
Evaluation/classification	Based on available data, the classification criteria are not met.		

Skin corrosion/irritation		
No	Substance name	EC no.

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1	diethylene glycol	111-46-6	203-872-2
Species	rabbit		
Source	ECHA		
Evaluation	non-irritant		
2	formaldehyde	50-00-0	200-001-8
Species	rabbit		
Method	OECD 404		
Source	ECHA		
Evaluation	corrosive		
Evaluation/classification	Based on available data, the classification criteria are met.		
Serious eye damage/irritation			
No	Substance name	CAS no.	EC no.
1	diethylene glycol	111-46-6	203-872-2
Species	rabbit		
Source	ECHA		
Evaluation	non-irritant		
Respiratory or skin sensitisation			
No	Substance name	CAS no.	EC no.
1	diethylene glycol	111-46-6	203-872-2
Route of exposure	Skin		
Species	guinea pig		
Method	67/548/EEC, B.6		
Source	ECHA		
Evaluation	non-sensitizing		
2	formaldehyde	50-00-0	200-001-8
Route of exposure	Skin		
Species	guinea pig		
Method	OECD 406		
Source	ECHA		
Evaluation	sensitizing		
Evaluation/classification	Based on available data, the classification criteria are met.		
Germ cell mutagenicity			
No	Substance name	CAS no.	EC no.
1	diethylene glycol	111-46-6	203-872-2
Source	ECHA		
Evaluation/classification	Based on available data, the classification criteria are not met.		
2	formaldehyde	50-00-0	200-001-8
Type of examination	in vitro gene mutation study in bacteria		
Species	Salmonella typhimurium		
Method	OECD 471		
Source	ECHA		
Evaluation/classification	Based on available data, the classification criteria are met.		
Reproduction toxicity			
No	Substance name	CAS no.	EC no.
1	diethylene glycol	111-46-6	203-872-2
Source	ECHA		
Evaluation/classification	Based on available data, the classification criteria are not met.		
Carcinogenicity			
No	Substance name	CAS no.	EC no.
1	diethylene glycol	111-46-6	203-872-2
Source	ECHA		
Evaluation/classification	Based on available data, the classification criteria are not met.		
2	formaldehyde	50-00-0	200-001-8
Route of exposure	inhalational		
Species	Human		
Source	ECHA		
Evaluation/classification	Based on available data, the classification criteria are met.		
STOT - single exposure			
No data available			
STOT - repeated exposure			
No data available			
Aspiration hazard			
No data available			

11.2 Information on other hazards

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Endocrine disrupting properties
No data available.

Other information
No data available.

SECTION 12: Ecological information

12.1 Toxicity

Toxicity to fish (acute)			
No	Substance name	CAS no.	EC no.
1	diethylene glycol	111-46-6	203-872-2
LC50		75200	mg/l
Duration of exposure		96	h
Species	Pimephales promelas		
Source	ECHA		
2	formaldehyde	50-00-0	200-001-8
LC50		24.1	mg/l
Duration of exposure		96	h
Species	Pimephales promelas		
Method	OECD 203		
Source	ECHA		
Evaluation/classification	Based on available data, the classification criteria are not met.		
3	methanol	67-56-1	200-659-6
LC50		15400	mg/l
Duration of exposure		96	h
Species	Lepomis macrochirus		
Method	EPA-660 / 3-75-009		
Source	ECHA		
Toxicity to fish (chronic)			
No data available			
Toxicity to Daphnia (acute)			
No	Substance name	CAS no.	EC no.
1	formaldehyde	50-00-0	200-001-8
EC50		5.8	mg/l
Duration of exposure		48	h
Species	Daphnia magna		
Method	OECD 202		
Source	ECHA		
Evaluation/classification	Based on available data, the classification criteria are not met.		
2	methanol	67-56-1	200-659-6
EC50		22200	mg/l
Duration of exposure		48	h
Species	Daphnia magna		
Method	OECD 202		
Source	ECHA		
Toxicity to Daphnia (chronic)			
No data available			
Toxicity to algae (acute)			
No	Substance name	CAS no.	EC no.
1	formaldehyde	50-00-0	200-001-8
EC50		3.48	mg/l
Duration of exposure		72	h
Species	Desmodesmus subspicatus		
Method	OECD 201		
Source	ECHA		
Evaluation/classification	Based on available data, the classification criteria are not met.		
2	methanol	67-56-1	200-659-6
EC50	appr.	22000	mg/l
Duration of exposure		96	h
Species	Pseudokirchneriella subcapitata		
Method	OECD 201		
Source	ECHA		
Toxicity to algae (chronic)			
No	Substance name	CAS no.	EC no.
1	diethylene glycol	111-46-6	203-872-2
NOEC		2700	mg/l

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Duration of exposure	8	day(s)	
Species	Scenedesmus quadricauda		
Source	ECHA		
Bacteria toxicity			
No	Substance name	CAS no.	EC no.
1	diethylene glycol	111-46-6	203-872-2
EC20	>	1.995	mg/l
Duration of exposure		0.5	h
Species	activated sludge		
Method	ISO 8192		
Source	ECHA		

12.2 Persistence and degradability

Biodegradability			
No	Substance name	CAS no.	EC no.
1	diethylene glycol	111-46-6	203-872-2
Type	DOC decrease		
Value	90	- 100	%
Duration		28	day(s)
Method	OECD 301 B		
Source	ECHA		
Evaluation	readily biodegradable		
2	formaldehyde	50-00-0	200-001-8
Type	aerobic biodegradation		
Value		99	%
Duration		28	d
Method	OECD 301 A		
Source	ECHA		
Evaluation	readily biodegradable		
3	methanol	67-56-1	200-659-6
Type	BOD		
Value		95	%
Duration		20	day(s)
Source	ECHA		
Evaluation	readily biodegradable		

12.3 Bioaccumulative potential

Bioconcentration factor (BCF)			
No	Substance name	CAS no.	EC no.
1	diethylene glycol	111-46-6	203-872-2
BCF		100	
Species	Leuciscus idus		
Source	ECHA		
Partition coefficient n-octanol/water (log value)			
No	Substance name	CAS no.	EC no.
1	formaldehyde	50-00-0	200-001-8
log Pow		0.35	
Reference temperature		25	°C
Method	QSAR		
Source	ECHA		
2	methanol	67-56-1	200-659-6
log Pow		-0.77	
Source	ECHA		

12.4 Mobility in soil

No data available.

12.5 Results of PBT and vPvB assessment

Results of PBT and vPvB assessment	
PBT assessment	No data available.
vPvB assessment	No data available.

12.6 Endocrine disrupting properties

No data available.

12.7 Other adverse effects

No data available.

SECTION 13: Disposal considerations

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13.1 Waste treatment methods

Product

Disposal of the product should be carried out in accordance with all applicable regulations following consultation with the responsible local authority and the disposal company in an authorised and suitable disposal facility.

Allocation of a waste code number, according to the European Waste Catalogue, should be carried out in agreement with the regional waste disposal company.

Packaging

Residues must be removed from packaging and when emptied completely disposed of in accordance with the regulations for waste removal. Incompletely emptied packaging must be disposed of in the form of disposal specified by the regional disposer.

SECTION 14: Transport information

14.1 Transport ADR/RID/ADN

The product is not subject to ADR/RID/ADN regulations.

14.2 Transport IMDG

The product is not subject to IMDG regulations.

14.3 Transport ICAO-TI / IATA

The product is not subject to ICAO-TI / IATA regulations.

14.4 Other information

No data available.

14.5 Environmental hazards

Information on environmental hazards, if relevant, please see 14.1 - 14.3.

14.6 Special precautions for user

No data available.

14.7 Maritime transport in bulk according to IMO instruments

Not relevant

SECTION 15: Regulatory information

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

EU regulations

Regulation (EC) No 1907/2006 (REACH) Annex XIV (List of substances subject to authorisation)

According to the data available and/or specifications supplied by upstream suppliers, this product does not contain any substances considered as substances requiring authorisation as listed on Annex XIV of the REACH regulation (EC) 1907/2006.

REACH candidate list of substances of very high concern (SVHC) for authorisation

According to available data and the information provided by preliminary suppliers, the product does not contain substances that are considered substances meeting the criteria for inclusion in annex XIV (List of Substances Subject to Authorisation) as laid down in Article 57 and article 59 of REACH (EC) 1907/2006.

Regulation (EC) No 1907/2006 (REACH) Annex XVII: RESTRICTIONS ON THE MANUFACTURE, PLACING ON THE MARKET AND USE OF CERTAIN DANGEROUS SUBSTANCES, MIXTURES AND ARTICLES

The product is considered being subject to REACH regulation (EC) 1907/2006 annex XVII.

No 3

The product contains following substance(s) that are considered being subject to REACH regulation (EC) 1907/2006 annex XVII.

No	Substance name	CAS no.	EC no.	No
1	formaldehyde	50-00-0	200-001-8	28, 72, 75, 77
2	methanol	67-56-1	200-659-6	69, 75

Directive 2012/18/EU on the control of major-accident hazards involving dangerous substances

This product is not subject to Part 1 or 2 of Annex I.

Other regulations

Adhere to the national sanitary and occupational safety regulations when using this product.

15.2 Chemical safety assessment

A chemical safety assessment has not been carried out for this mixture.

SECTION 16: Other information

Sources of key data used to compile the data sheet:

Regulation (EC) No 1907/2006 (REACH), 1272/2008 (CLP) as amended in each case.

Directives 2000/39/EC, 2006/15/EC, 2009/161/EU, (EU) 2017/164.

National Threshold Limit Values of the corresponding countries as amended in each case.

Transport regulations according to ADR, RID, IMDG, IATA as amended in each case.

The data sources used to determine physical, toxic and ecotoxic data, are indicated directly in the corresponding section.

EU safety data sheet

Trade name: CyLyse™ FX

Current version : 4.0.0, issued: 06.09.2023

Replaced version: 3.2.1, issued: 04.09.2023

Region: GB

Full text of the H- and EUH- phrases drawn up in sections 2 and 3 (provided not already drawn up in these sections)

H225	Highly flammable liquid and vapour.
H301	Toxic if swallowed.
H311	Toxic in contact with skin.
H314	Causes severe skin burns and eye damage.
H331	Toxic if inhaled.
H370	Causes damage to organs.

Creation of the safety data sheet

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This information is based on our present knowledge and experience.

The safety data sheet describes products with a view to safety requirements.

It does not however, constitute a guarantee for any specific product properties and shall not establish a legally valid contractual relationship.

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