

CytoLyse

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830 Date of issue: 16 Jun 2024 Version: Rev 0, 2024-06

SECTION 1: Identification of the su	bstance/mixture	and of the company/undertaking		
1.1. Product identifier				
Product form	: Mixture, Liquid			
Product name	: CytoLyse			
Product code	: CYTO-3001			
1.2. Relevant identified uses of the sul	ostance or mixture a	nd uses advised against		
1.2.1. Relevant identified uses				
Main use category	: Professional U	se		
Use of the substance/mixture	: Health Care. S	cientific and industrial laboratory use.		
1.2.2. Uses advised against				
No additional information available				
1.3. Details of the supplier of the safet	y data sheet			
Cytomark, a division of Caltag Medsystems Whiteleaf Business Centre 11 Little Balmer Buckingham, MK18 1TF - United Kingdom T +44 1280 827460 <u>Support@cytomark.co.uk</u>				
1.4. Emergency telephone number				
Emergency number : +44 (0)1280 827460				
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SECTION 2: Hazards identification				
2.1. Classification of the substance or	mixture			
The product has been classified according to the legis	slation in force.			
Classification according to Regulation (EC) No 12	72/2008 as amended.			
Health Hazards				
Acute toxicity (Oral)	Category 4	H302: Harmful if swallowed.		
Acute toxicity (Dermal)	Category 4	H312: Harmful in contact with skin.		
Acute toxicity (Inhalation - vapor)	Category 4	H332: Harmful if inhaled.		
Skin irritation	Category 2	H315: Causes skin irritation.		
Serious eye irritation Skin sensitizer	Category 2	H319: Causes serious eye irritation.		
	Category 1	H317: May cause an allergic skin reaction.		
Germ Cell Mutagenicity	Category 2	H341: Suspected of causing genetic defects.		
Carcinogenicity	Category 1B	H350: May cause cancer.		
Specific Target Organ Toxicity - Single Exposure Specific Target Organ Toxicity - Single Exposure	Category 2 Category 3	H371: May cause damage to organs. H335: May cause respiratory irritation.		
Specific Target Organ Toxicity - Repeated Exposure	Category 2 (Kidney)	H373: May cause damage to organs through prolonged or repeated exposure.		
2.2. Label elements	3 7 1 1			
Labelling according to Regulation (EC) No. 1272/2 Contains: Diethylene glycol Formaldehyde	008 [CLP]			

Signal Word: Hazard Statement(s): Danger H302+H312+H332: Harmful if swallowed, in contact with skin or if inhaled. H315: Causes skin irritation. H319: Causes serious eye irritation. H317: May cause an allergic skin reaction. H341: Suspected of causing genetic defects. H350: May cause cancer. H371: May cause cancer. H335: May cause respiratory irritation. H337: May cause damage to organs through prolonged or repeated exposure. according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

Precautionary Statements	
Prevention:	P201: Obtain special instructions before use.
	P202: Do not handle until all safety precautions have been read and understood.
	P260: Do not breathe dust/fume/gas/mist/vapors/spray.
	P264: Wash thoroughly after handling.
	P272: Contaminated work clothing should not be allowed out of the workplace.
	P280: Wear protective gloves/protective clothing/eye protection/face protection.
Response:	
	P333+P313: If skin irritation or rash occurs: Get medical advice/attention.
	P337+P313: If eye irritation persists: Get medical advice/attention.
	P308+P313: IF exposed or concerned: Get medical advice/attention.
	P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.
	P312: Call a POISON CENTRE/doctor if you feel unwell.

2.3. Other hazards

Endocrine Disruption-Toxicity

The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Endocrine Disruption-Ecotoxicity

The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Formaldehyde	(CAS-No.) 50-00-0 (EC-No.) 200-001-8 (EC Index-No.) 605-001-00-5 (REACH-no) 01-2119488953-20	<1	Acute Tox. 3 (Oral), H301 Acute Tox. 3 (Dermal), H311 Acute Tox. 3 (Inhalation), H331 Skin Corr. 1B, H314 Skin Sens. 1, H317 Muta. 2, H341 Carc. 1B, H350
Diethylene Glycol	(CAS-No.) 111-46-6 (EC-No.) 203-872-2 (EC Index-No.) (REACH-no)	<4	H302

Specific concentration limits:

Name	Product identifier	Specific concentration limits
Formaldehyde	(CAS-No.) 50-00-0 (EC-No.) 200-001-8 (EC Index-No.) 605-001-00-5 (REACH-no) 01-2119488953-20	(0.2 = <c 1,="" 100)="" <="" h317<br="" sens.="" skin="">(5 =<c 100)="" 3,="" <="" h335<br="" se="" stot="">(5 =<c 2,="" 25)="" <="" eye="" h319<br="" irrit.="">(5 =<c 2,="" 25)="" <="" h315<br="" irrit.="" skin="">(25 =<c 100)="" 1b,="" <="" corr.="" h314<="" skin="" td=""></c></c></c></c></c>

Note B : Some substances (acids, bases, etc.) are placed on the market in aqueous solutions at various concentrations and, therefore, these solutions require different classification and labelling since the hazards vary at different concentrations. In Part 3 entries with Note B have a general designation of the following type: 'nitric acid ... %'. In this case the supplier must state the percentage concentration of the solution on the label. Unless otherwise stated, it is assumed that the percentage concentration is calculated on a weight/weight basis.

Note D : Certain substances which are susceptible to spontaneous polymerisation or decomposition are generally placed on the market in a stabilised form. It is in this form that they are listed in Part 3. However, such substances are sometimes placed on the market in a non-stabilised form. In this case, the supplier must state on the label the name of the substance followed by the words 'non-stabilised'.

Full text of H-statements: see section 16

SECTION 4: First aid measures	
4.1. Description of first aid measures	
First-aid measures general	: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).
First-aid measures after inhalation	: If experiencing respiratory symptoms: Remove person to fresh air and keep comfortable for breathing. Allow the victim to rest.
First-aid measures after skin contact	If skin irritation or rash occurs: Gently wash with plenty of soap and water. Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse. Get medical advice/attention. Wash contaminated clothing before reuse.
First-aid measures after eye contact	: Rinse immediately with plenty of water. If eye irritation persists: Get medical advice/attention.
First-aid measures after ingestion	: If you feel unwell, seek medical advice. Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention.
44 hrs 0004	

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

	and effects, both acute and delayed
Symptoms/effects	: May cause cancer.
Symptoms/effects after inhalation	: May cause respiratory irritation.
Symptoms/effects after skin contact	: May cause an allergic skin reaction.
Symptoms/effects after eye contact	: May cause eye irritation.
Symptoms/effects after ingestion	: Ingestion may cause nausea, vomiting and diarrhea.
4.3. Indication of any immediate	e medical attention and special treatment needed
Treat symptomatically.	
SECTION 5: Firefighting mea	sures
5.1. Extinguishing media	
Suitable extinguishing media	: Use extinguishing media appropriate for surrounding fire.
Unsuitable extinguishing media	: Do not use a heavy water stream.
5.2. Special hazards arising fro	om the substance or mixture
Fire hazard	: The product is not flammable.
Explosion hazard	: Product is not explosive.
Hazardous decomposition products ir	
fire	heated may give off formaldehyde gas.
5.3. Advice for firefighters	
Precautionary measures fire	: Exercise caution when fighting any chemical fire.
Firefighting instructions	: Prevent fire fighting water from entering the environment. Use water spray or fog for cooling
	exposed containers.
Protection during firefighting	: Do not enter fire area without proper protective equipment, including respiratory protection.
SECTION 6: Accidental releas	se measures
6.1. Personal precautions, prot	ective equipment and emergency procedures
General measures	: Ensure adequate ventilation. Avoid breathing vapour or mist. Avoid contact with skin and eyes
6.1.1. For non-emergency persor	
6.1.1. For non-emergency persor Protective equipment	: Do not attempt to take action without suitable protective equipment. For further information
i lotective equipment	refer to section 8: "Exposure controls/personal protection".
Emergency procedures	: Evacuate unnecessary personnel.
6.1.2. For emergency responders	
· · · · · · · · · · · · · · · · · · ·	
Protective equipment	 Equip cleanup crew with proper protection. For further information refer to section 8: "Exposu controls/personal protection".
Emergency procedures	: Ventilate area.
0	
6.2. Environmental precautions	
, ,	ters. Notify authorities if liquid enters sewers or public waters.
6.3. Methods and material for c	containment and cleaning up
For containment	: Absorb spillage.
Methods for cleaning up	: Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents).
6.4. Reference to other section	S
	8: "Exposure controls/personal protection". For disposal of solid materials or residues refer to section 13:
SECTION 7: Handling and sto	
7.1. Precautions for safe handli	
Precautions for safe handling	: Avoid contact with skin and eyes. Always wash hands after handling the product. Wash hand
	and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour. Avoid breathing fume, mist, spray, vapours. Do not handle until all safety precautions have been read and understood.
Hygiene measures	: Always wash hands after handling the product. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reuse.

: Always wash hands after handling the product. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reuse.

7.2.	Conditions for safe storage, including any incompatibilities			
Techn	cal measures	Does not require any specific or particular technical measures.		
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according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

Storage conditions	: Keep only in the original container in a cool, well ventilated place away from : Direct sunlight. Keep container closed when not in use.
Incompatible products	: Strong bases. Strong acids.
Incompatible materials	: Sources of ignition. Direct sunlight.

7.3. Specific end use(s)

No additional information available

SECTI	ON 8: Exposure controls/personal protection
8.1.	Control parameters

Sodium Citrate (6132-04-3)

No additional information avaliable

Diethylene glycol (111-46-6)			
nited Kingdom WEL	L TWA	101 mg/m ³	23 ppm
nited Kingdom WEL	L TWA	101 mg/m ³	23 ppm

forma	formaldehyde (50-00-0)		
United	l Kingdom	WEL TWA	2.5 mg/m ³ 2 ppm
United	l Kingdom	WEL STEL	2.5 mg/m ³ 2 ppm
8.2.	Exposure controls		

Appropriate engineering controls:

Ensure adequate ventilation.

Personal protective equipment:

Avoid all unnecessary exposure.

Hand protection:

Wear chemically resistant protective gloves. Standard EN 374 - Protective gloves against chemicals.

Eye protection:

Chemical goggles or safety glasses. Standard EN 166 - Personal eye-protection - specifications

Skin and body protection:

Wear suitable protective clothing

Respiratory protection:

Wear respiratory protection.

Other information:

Do not eat, drink or smoke during use.

SECTION 9: Physical and chemical properties					
9.1. Information on basic physical and chemical properties					
Physical state	: Liquid				
Colour	: Colourless				
Odour	: Odourless				
Odour threshold	: No data available				
рН	: 8.0				
Relative evaporation rate (butylacetate=1)	: No data available				
Melting point	: No data available				
Freezing point	: No data available				
Boiling point	: No data available				
Flash point	: No data available				
Auto-ignition temperature	: No data available				
Decomposition temperature	: No data available				
Flammability (solid, gas)	: No data available				
Vapour pressure	: No data available				
Relative vapour density at 20 °C	: No data available				
Relative density	: 1.0				

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

: Fully miscible
: No data available

9.2. Other information

No additional information available

SECTI	ON 10: Stability and reactivity			
10.1.	Reactivity			
The proc	duct is non-reactive under normal conditions of use, storage and transport.			
10.2.	Chemical stability			
Stable u	inder normal conditions.			
10.3.	Possibility of hazardous reactions			
None un	None under normal use.			
10.4.	Conditions to avoid			
None un	nder normal use.			
10.5.	Incompatible materials			
Strong acids. Strong bases. Peroxides. Other metals or alloys.				
10.6.	Hazardous decomposition products			

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information			
11.1. Information on toxicological effects			
Acute toxicity	: Not classified		
formaldehyde (50-00-0)			
LD50 oral	100 mg/kg bodyweight		
LD50 dermal	270 mg/kg bodyweight		
LC50 inhalation rat (Dust/Mist - mg/l/4h)	497 mg/l		
Sodium Citrate (6132-04-3)			
LD50 oral rat	6730 mg/kg bodyweight		
Skin corrosion/irritation	: Not classified		
	pH: 7 - 7.4		
Additional information	: Based on available data, the classification criteria are not met		
Serious eye damage/irritation	: Not classified		
	pH: 7 - 7.4		
Additional information	: Based on available data, the classification criteria are not met		
Respiratory or skin sensitisation	: May cause an allergic skin reaction.		
Germ cell mutagenicity	: Not classified		
	Based on available data, the classification criteria are not met		
Carcinogenicity	: May cause cancer.		
Reproductive toxicity	: Not classified		
Additional information	: Based on available data, the classification criteria are not met		
STOT-single exposure	: Not classified		
Additional information	: Based on available data, the classification criteria are not met		
STOT-repeated exposure	: Not classified		
Additional information	: Based on available data, the classification criteria are not met		
Aspiration hazard	: Not classified		
Additional information	: Based on available data, the classification criteria are not met		

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SECTION 12: Ecological information			
12.1. Toxicity			
Sodium Citrate (6132-04-3)			
EC50 Daphnia 1	655-825.9 mg/l		
formaldehyde (50-00-0)			
LC50 fish 1	6.7 mg/l		
EC50 other aquatic organisms 1	5.8 mg/l waterflea	l	
EC50 other aquatic organisms 2	3.48 mg/l		
12.2. Persistence and degradability			
Cytolyse			
Persistence and degradability	Not established.		
12.3. Bioaccumulative potential			
Cytolyse			
Bioaccumulative potential	Not established.		
formaldehyde (50-00-0)	-		
Log Pow	0.779		
12.4. Mobility in soil	·		
No additional information available			
2.5. Results of PBT and vPvB assessmen	nt		
No additional information available			
2.6. Other adverse effects			
Additional information	:		
SECTION 13: Disposal consideration	S		
13.1. Waste treatment methods			
Product/Packaging disposal recommendations	contents/contair		vith local/national regulations. Dispose of I waste collection point, in accordance with local, Ilation.
Ecology - waste materials	: Avoid release to	the environment.	
SECTION 14: Transport information			
n accordance with ADR / RID / IMDG / IATA / AD)N		
			PID

ADR	IMDG	ΙΑΤΑ	ADN	RID
14.1. UN number				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.2. UN proper sh	ipping name			I
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.3. Transport ha	zard class(es)			
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.4. Packing grou	ip			
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.5. Environment	al hazards			
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
No supplementary	information available			·

14.6. Special precautions for user

- Overland transport

Not applicable

- Transport by sea

Not applicable

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

- Air transport

Not applicable

- Inland waterway transport Not applicable

- Rail transport

Not applicable

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

Regulation 1005/2009/EC on substances that deplete the ozone layer, Annex I, Controlled Substances:

none Regulation 1005/2009/EC on substances that deplete the ozone layer, Annex II, New Substances:

none

EU. REACH Annex XIV, Substances Subject to Authorization: none

EU. Regulation 2019/1021/EU on persistent organic pollutants (POPs) (recast), as amended:

none EU. Directive 2010/75/EU on Industrial Emissions (IPPC), Annex II, L 334/17:

none **Regu** none

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 1 as amended:

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 2 as amended:

none Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 3 as amended:

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex V as amended:

none

none

none

EU. REACH Candidate List of Substances of Very High Concern for Authorization (SVHC):

Regulation (EC) No. 1907/2006 Annex XVII Substances subject to restriction on marketing and use:

The packaging shall be visibly, legibly and indelibly marked as follows:

Restricted to professional users.

Chemical Name	CAS-No.	Concentration
Formaldehyde	50-00-0	<1%

Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens and mutagens at work.:

Chemical Name	CAS-No.	Concentration
Formaldehyde	50-00-0	<1%

Directive 92/85/EEC: on the safety and health of pregnant workers and workers who have recently given birth or are breast feeding.:

Chemical Name	CAS-No.	Concentration
Formaldehyde	50-00-0	<1%

EU. Directive 2012/18/EU (SEVESO III) on major accident hazards involving dangerous substances, Annex I: Not applicable

EU. Regulation No. 166/2006 PRTR (Pollutant Release and Transfer Registry), Annex II: Pollutants: none

Directive 98/24/EC on the protection of workers from the risks related to chemical agents at work:

Chemical Name	CAS-No.	Concentration
Formaldehyde	50-00-0	<1%
Diethylene	111-46-6	<4%
Glycol		

15.1.2. National regulations

No additional information available

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according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

15.2. **Chemical safety assessment**

No chemical safety assessment has been carried out

SECTION 16: Other information

: REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

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Data sources

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Other information	: None.
Full text of H- and EUH-statements:	
Acute Tox. 3 (Dermal)	Acute toxicity (dermal), Category 3
Acute Tox. 3 (Inhalation)	Acute toxicity (inhal.), Category 3
Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
Carc. 1B	Carcinogenicity, Category 1B
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Muta. 2	Germ cell mutagenicity, Category 2
Skin Corr. 1B	Skin corrosion/irritation, Category 1B
Skin Irrit. 2	Skin corrosion/irritation, Category 2
Skin Sens. 1	Skin sensitisation, Category 1
STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation
H301	Toxic if swallowed.
H302	Harmful if swallowed
H311	Toxic in contact with skin.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation
H331	Toxic if inhaled.
H335	May cause respiratory irritation.
H341	Suspected of causing genetic defects.
H350	May cause cancer.

SDS EU (REACH Annex II) -

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.