

Trade name: CyLyse® - Leukocyte Fixation Reagent A

Product no.: 05-5010 A

Current version : 1.1.0, issued: 16.03.2015

Replaced version: 1.0.1, issued: 13.11.2014

Region: GB

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

1.1 Product identifier

Trade name

CyLyse® - Leukocyte Fixation Reagent A

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

Relevant identified uses of the substance or mixture

laboratory chemicals

1.3 Details of the supplier of the safety data sheet

Address

Sysmex Partec GmbH
Am Flugplatz 13
02828 Görlitz

Telephone no. +49 3581 8746-0

Fax no. +49 3581 8746-70

Email info@sysmex-partec.com

Information provided by / telephone

Dr. Dirk Colditz, 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)

Carc. 2; H351

Skin Sens. 1; H317

Classification in accordance with Directive 67/548/EEC or 1999/45/EC

Carc.Cat.3; R40

R43

2.2 Label elements

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

Hazard pictograms



GHS07



GHS08

Signal word

Warning

Hazardous component(s) to be indicated on label:

formaldehyde

Hazard statements

H317

May cause an allergic skin reaction.

H351

Suspected of causing cancer

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Precautionary statements

P101 If medical advice is needed, have product container or label at hand.
 P280 Wear protective gloves/eye protection/face protection.
 P302+P352 IF ON SKIN: Wash with plenty of water.
 P362+P364 Take off contaminated clothing and wash it before reuse.
 P405 Store locked up.
 P501 Dispose of contents/container in accordance with local and national regulations.

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 67/548/EEC	Classification (EC) 1272/2008 (CLP)	Concentration	%
1	formaldehyde				
	50-00-0 200-001-8 605-001-00-5 -	T; R23/24/25 C; R34 Carc.Cat.3; R40 R43	Acute Tox. 3*; H301 Acute Tox. 3*; H311 Acute Tox. 3*; H331 Carc. 2; H351 Skin Corr. 1B; H314 Skin Sens. 1; H317	> 1.00 - < 5.00	%-b.w.
2	methanol				
	67-56-1 200-659-6 603-001-00-X 01-2119433307-44	F; R11 T; R23/24/25 T; R39/23/24/25	Acute Tox. 3; H301 Acute Tox. 3; H311 Acute Tox. 3; H331 Flam. Liq. 2; H225 STOT SE 1; H370	> 0.50 - < 1.00	%-b.w.

Full Text for all R-phrases , H-phrases and EUH-phrases: pls. see section 16
 (*, **, ***, ****) Detailed explanation pls. refer to CLP regulation No. 1272/2008, annex VI, 1.2

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

Full text for the notes: pls. see section 16 "Notes relating to the identification, classification and labelling of substances ((EC) No 1272/2008, Annex VI)".

SECTION 4: First aid measures

4.1 Description of first aid measures

General information

In case of persisting adverse effects, consult a physician. Remove contaminated clothing and shoes immediately, and launder thoroughly before reusing.

After inhalation

Remove affected person from the immediate area. Ensure supply of fresh air.

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After skin contact

Wash off immediately with soap and water.

After eye contact

Separate eyelids, wash the eyes thoroughly with water (15 min.).

After ingestion

Call a doctor immediately. 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

Foam; Extinguishing powder; Carbon dioxide; Water spray jet

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

No data available. 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

Take up with absorbent material (e.g., sand, kieselguhr, universal binder). When picked up, treat material as prescribed under heading "Disposal considerations".

6.4 Reference to other sections

No data available.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advice on safe handling

Product inherent handling risks must be minimised taking the appropriate measures for protection and preventive actions. The working process should be designed to rule out the release of hazardous substances or skin contact as far as possible by the state of the art.

General protective and hygiene measures

Do not eat, drink or smoke during work time. Keep away from food, drink and animal feeding stuffs. Wash hands and skin before breaks and after work. Do not inhale vapours. Avoid contact with eyes and skin. Remove soiled or soaked clothing immediately.

Advice on protection against fire and explosion

Keep away from sources of heat and ignition. Vapours can form an explosive mixture with air.

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7.2 Conditions for safe storage, including any incompatibilities

Technical measures and storage conditions

Keep container tightly closed 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.

Advice on storage assembly

Do not store together with: Oxidizing agents; Acids; Bases

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	formaldehyde	50-00-0	200-001-8
List of approved workplace exposure limits (WELs) / EH40			
Formaldehyde			
	STEL	2.5 mg/m ³	2 ml/m ³
	TWA	2.5 mg/m ³	2 ml/m ³
2	methanol	67-56-1	200-659-6
List of approved workplace exposure limits (WELs) / EH40			
Methanol			
	STEL	333 mg/m ³	250 ml/m ³
	TWA	266 mg/m ³	200 ml/m ³
	Skin resorption / sensibilisation	Sk	
2006/15/EC			
Methanol			
	TWA	260 mg/m ³	200 ml/m ³
	Skin resorption / sensibilisation	Skin	

DNEL and PNEC values

DNEL values (worker)

No	Substance name	CAS / EC no	
Route of exposure	Exposure time	Effect	Value
1	methanol	67-56-1 200-659-6	
dermal	Short term (acute)	systemic	40 mg/kg/day
dermal	Long term (chronic)	systemic	40 mg/kg/day
inhalative	Short term (acute)	systemic	260 mg/m ³
inhalative	Short term (acute)	local	260 mg/m ³
inhalative	Long term (chronic)	systemic	260 mg/m ³
inhalative	Long term (chronic)	local	260 mg/m ³

DNEL value (consumer)

No	Substance name	CAS / EC no	
Route of exposure	Exposure time	Effect	Value
1	methanol	67-56-1 200-659-6	
dermal	Short term (acute)	systemic	8 mg/kg/day
dermal	Long term (chronic)	systemic	8 mg/kg/day
inhalative	Short term (acute)	systemic	50 mg/m ³
inhalative	Short term (acute)	local	50 mg/m ³
inhalative	Long term (chronic)	systemic	50 mg/m ³
inhalative	Long term (chronic)	local	50 mg/m ³

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PNEC values

No	Substance name		CAS / EC no	
	ecological compartment	Type	Value	
1	methanol		67-56-1 200-659-6	
	water	fresh water	20.80	mg/l
	water	marine water	2.08	mg/l
	water	Aqua intermittent	1540.00	mg/l
	water	fresh water sediment	77.00	mg/kg
	with reference to: dry weight			
	water	marine water sediment	7.70	mg/kg
	with reference to: dry weight			
	soil	-	3.18	mg/kg
	with reference to: dry weight			
sewage treatment plant	-	100.00	mg/l	

8.2 Exposure controls

Appropriate engineering controls

No data available.

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 (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

Normal chemical work clothing.

Environmental exposure controls

No data available.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Form/Colour	
liquid	
Odour	
No data available	
Odour threshold	
No data available	
pH value	
Value	3.7

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Boiling point / boiling range
No data available

Melting point / melting range
No data available

Decomposition point / decomposition range
No data available

Flash point
No data available

Auto-ignition temperature
No data available

Oxidising properties
No data available

Explosive properties
No data available

Flammability (solid, gas)
No data available

Lower flammability or explosive limits
No data available

Upper flammability or explosive limits
No data available

Vapour pressure
No data available

Vapour density
No data available

Evaporation rate
No data available

Relative density
No data available

Density
No data available

Solubility in water
No data available

Solubility(ies)
No data available

Partition coefficient: n-octanol/water			
No	Substance name	CAS no.	EC no.
1	formaldehyde	50-00-0	200-001-8
	log Pow		0.35
2	methanol	67-56-1	200-659-6
	log Pow		-0.77
	Source	ECHA	

Viscosity
No data available

9.2 Other information

Other information
No data available.

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SECTION 10: Stability and reactivity

10.1 Reactivity

Dangerous reactions are not expected if the product is handled according to its intended use.

10.2 Chemical stability

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

10.3 Possibility of hazardous reactions

None, if handled according to order.

10.4 Conditions to avoid

None, if handled according to intended use.

10.5 Incompatible materials

Oxidizing agents; strong acids; strong bases

10.6 Hazardous decomposition products

None, if handled according to intended use.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute oral toxicity (result of the ATE calculation for the mixture)

No	Product Name
1	CyLyse® - Leukocyte Fixation Reagent A
Remarks	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 oral > 2000 mg/kg).

Acute oral toxicity

No data available

Acute dermal toxicity (result of the ATE calculation for the mixture)

No	Product Name
1	CyLyse® - Leukocyte Fixation Reagent A
Remarks	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	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® - Leukocyte Fixation Reagent A
Remarks	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).

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Acute inhalational toxicity
No data available
Skin corrosion/irritation
No data available
Serious eye damage/irritation
No data available
Respiratory or skin sensitisation
No data available
Germ cell mutagenicity
No data available
Reproduction toxicity
No data available
Carcinogenicity
No data available
STOT-single exposure
No data available
STOT-repeated exposure
No data available
Aspiration hazard
No data available
Delayed and immediate effects as well as chronic effects from short and long-term exposure
Inhalation of the vapours causes irritation of the respiratory tract and mucous membrane, headaches, nausea, giddiners, vomiting. Eye contact with the product may lead to irritation. Frequent persistent contact with the skin can cause skin irritation.

SECTION 12: Ecological information

12.1 Toxicity

Toxicity to fish (acute)			
No	Substance name	CAS no.	EC no.
1	methanol	67-56-1	200-659-6
LC50		15400	mg/l
Duration of exposure		96	h
Species	Lepomis macrochirus		
Method	EPA-660 / 3-7-009		
Source	ECHA		
Toxicity to fish (chronic)			
No data available			
Toxicity to Daphnia (acute)			
No	Substance name	CAS no.	EC no.
1	methanol	67-56-1	200-659-6
EC50		22200	mg/l
Duration of exposure		48	h
Species	Daphnia magna		
Method	OECD 202		
Source	ECHA		

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Toxicity to Daphnia (chronic)	
No data available	

Toxicity to algae (acute)			
No	Substance name	CAS no.	EC no.
1	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 data available	

Bacteria toxicity	
No data available	

12.2 Persistence and degradability

Biodegradability			
No	Substance name	CAS no.	EC no.
1	methanol	67-56-1	200-659-6
Type		BOD	
Value		95	%
Duration		20	day(s)
Source		ECHA	
Evaluation		readily biodegradable	

12.3 Bioaccumulative potential

Partition coefficient: n-octanol/water			
No	Substance name	CAS no.	EC no.
1	formaldehyde	50-00-0	200-001-8
log Pow		0.35	
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 Other adverse effects

No data available.

12.7 Other information

Other information
Do not discharge product unmonitored into the environment.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product

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

Residuals 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.

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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 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

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, PREPARATIONS AND ARTICLES

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

Restriction of occupation

Observe employment restrictions for child bearing mothers and nursing mothers.

Observe employment restrictions for young people.

Council Directive 96/82/EC on the control of major-accident hazards involving dangerous substances

Remarks

Annex I, part 1 + 2: not mentioned. With regard to possibly appropriate decomposition products see Chapter 10.

15.2 Chemical safety assessment

No data available.

SECTION 16: Other information

Sources of key data used to compile the data sheet:

EC Directive 67/548/EC resp. 1999/45/EC as amended in each case.

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

EC Directives 2000/39/EC, 2006/15/EC, 2009/161/EU

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 chapter.

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

R11	Highly flammable.
R23/24/25	Toxic by inhalation, in contact with skin and if swallowed.
R34	Causes burns.
R39/23/24/25	Toxic: danger of very serious irreversible effects through inhalation, in contact with skin and if swallowed.
R40	Limited evidence of a carcinogenic effect.
R43	May cause sensitisation by skin contact.
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.

Notes relating to the identification, classification and labelling of substances and mixtures ((EC) No 1272/2008, Annex VI)

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.
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'.

Department issuing safety data sheet

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This information is based on our present state of knowledge and experience.

The security data sheet describes products with a view to the security requirements.

However, it should not constitute a guarantee for any specific product properties and shall not establish a legally valid relationship.

Alterations/supplements:

Alterations to the previous edition are marked in the left-hand margin.