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

1.1 Product identifier

Trade name

CyLyse® - 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

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.

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 it is 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.

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/m³	2	ml/m³
	TWA	2.5	mg/m³	2	ml/m³
2	**methanol**	**67-56-1**		**200-659-6**	
	List of approved workplace exposure limits (WELs) / EH40				
	Methanol				
	STEL	333	mg/m³	250	ml/m³
	TWA	266	mg/m³	200	ml/m³
	Skin resorption / sensibilisation	Sk			
	2006/15/EC				
	Methanol				
	TWA	260	mg/m³	200	ml/m³
	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 (acut)	systemic	40	mg/kg/day
	dermal	Long term (chronic)	systemic	40	mg/kg/day
	inhalative	Short term (acut)	systemic	260	mg/m³
	inhalative	Short term (acut)	local	260	mg/m³
	inhalative	Long term (chronic)	systemic	260	mg/m³
	inhalative	Long term (chronic)	local	260	mg/m³

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 (acut)	systemic	8	mg/kg/day
	dermal	Long term (chronic)	systemic	8	mg/kg/day
	inhalative	Short term (acut)	systemic	50	mg/m³
	inhalative	Short term (acut)	local	50	mg/m³
	inhalative	Long term (chronic)	systemic	50	mg/m³
	inhalative	Long term (chronic)	local	50	mg/m³

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

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.

SECTION 10: Stability and reactivity

10.1 Reactivity
Dangerous reactions are not expecting handling the product 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 order.

10.5 Incompatible materials
Oxidizing agents; strong acids; strong bases

10.6 Hazardous decomposition products
None, if handled according to order

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® - 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® - 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® - 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).

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			

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.

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

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.

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.