Trade name: CyLyse™ FXP Fixation Buffer

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

1.1 Product identifier

Trade name

CyLyse™ FXP Fixation Buffer

Product no.: BM900123, AE238377 (Fixation Buffer: AR134949)

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 Arndtstraße 11 a-b 02826 Görlitz

Telephone no. +49 3581 8746-0 Fax no. +49 3581 8746-70 e-mail info@sysmex-partec.com

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 Muta. 2; H341 Skin Sens. 1; H317

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





Signal word

Danger

Hazardous component(s) to be indicated on label:

formaldehyde

Hazard statement(s)

H302 Harmful if swallowed.

H317 May cause an allergic skin reaction.
H341 Suspected of causing genetic defects

H350 May cause cancer.

Precautionary statement(s)

P201 Obtain special instructions before use.

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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 /	Classification (EC) 1272/2008 (CLP)	Concentration	%
	REACH no			
1	formaldehyde			
	50-00-0	Acute Tox. 3; H301	< 5.00	wt%
	200-001-8	Acute Tox. 3; H311		
	605-001-00-5	Acute Tox. 3; H331		
	01-2119488953-20	Carc. 1B; H350		
		Muta. 2; H341		
		Skin Corr. 1B; H314		
		Skin Sens. 1; H317		
2	methanol			
	67-56-1	Acute Tox. 3; H301	< 2.50	wt%
	200-659-6	Acute Tox. 3; H311		
	603-001-00-X	Acute Tox. 3; H331		
	01-2119433307-44	Flam. Liq. 2; H225		
		STOT SE 1; H370		

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

No	Note	Specific concentration limits	M-factor (acute)	M-factor (chronic)
1	-	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%	-	-
2	-	STOT SE 2; H371: C >= 3% STOT SE 1; H370: C >= 10%	-	-

Acut	Acute toxicity estimate (ATE) values			
No	oral	dermal	inhalative	
2		300 mg/kg bodyweight		

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

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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; Extinguishing powder; Foam; Carbon dioxide

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.

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	formaldehyde	50-00-0	200-001-8

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	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		sitisation (14)		
	Comments	Limit value	of 0,62 mg/m3 c	or 0,5 ppm (3)	for the health care,
		functal and	embalming sec	toro until 11 lu	L. 0004
		iunerai anu	embalming sec	tors until 11 Ju	ly 2024
2	methanol	67-56-1	embaiming sec	200-659-6	
2	methanol 2006/15/EC		embaiming sec		
2			embaining sec		
2	2006/15/EC		mg/m³		
2	2006/15/EC Methanol	67-56-1	V	200-659-6	3
2	2006/15/EC Methanol WEL long-term (8-hr TWA reference period)	67-56-1 260	V	200-659-6	3
2	2006/15/EC Methanol WEL long-term (8-hr TWA reference period) Skin resorption / sensibilisation	67-56-1 260	V	200-659-6	3
2	2006/15/EC Methanol WEL long-term (8-hr TWA reference period) Skin resorption / sensibilisation List of approved workplace exposure limits (WELs) / EH40	67-56-1 260	V	200-659-6	3
2	2006/15/EC Methanol WEL long-term (8-hr TWA reference period) Skin resorption / sensibilisation List of approved workplace exposure limits (WELs) / EH40 Methanol	260 Skin	mg/m³	200-659-6	ppm

DNEL, DMEL and PNEC values

DNEL values (worker)

No	Substance name			CAS / EC no	
	Route of exposure	Exposure time	Effect	Value	
1	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
2	methanol			67-56-1	
				200-659-6	
	dermal	Short term (acut)	systemic	20	mg/kg/day
	dermal	Long term (chronic)	systemic	20	mg/kg/day
	inhalative	Short term (acut)	systemic	130	mg/m³
	inhalative	Short term (acut)	local	130	mg/m³
	inhalative	Long term (chronic)	systemic	130	mg/m³
	inhalative	Long term (chronic)	local	130	mg/m³

DNEL value (consumer)

No	Substance name			CAS / EC	no
	Route of exposure	Exposure time	Effect	Value	
1	formaldehyde		<u>.</u>	50-00-0	
				200-001-8	3
	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/cm²
	inhalative	Long term (chronic)	systemic	3.2	mg/m³
	inhalative	Long term (chronic)	local	0.1	mg/m³
2	methanol			67-56-1	
				200-659-6	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/m³
	inhalative	Short term (acut)	local	26	mg/m³
	inhalative	Long term (chronic)	systemic	26	mg/m³
	inhalative	Long term (chronic)	local	26	mg/m³

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.

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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.

Eve / 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

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.
-	•	

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1	formaldehyde	50	-00-0	200-001-8	
log Pow			0.35		
Reference temperature			25	°C	
Method		QSAR			
Sour	ce	ECHA			
2	methanol	67	'-56-1	200-659-6	
log P	ow		-0.77		
Sour	ce	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.

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

Acut	cute oral toxicity (result of the ATE calculation for the mixture)				
No	Product Name				
1	CyLyse™ FXP Fixation Buffer				
	Product no.: BM900123, AE238377 (Fixation B	uffer:			
	AR134949)				
ATE	(Mixture) 1921.97 mg/kg				
Meth	thod Calculation method according Regulation (EC) No 1272/2008, (CLP), anne				
		I, part 3, section 3.1.3.6.			

Acute oral toxicity

No data available

Acut	Acute dermal toxicity (result of the ATE calculation for the mixture)			
No	Product Name			
1	CyLyse™ FXP Fixation Buffer			
	Product no.: BM900123, AE238377 (Fixation E	Buffer:		
	AR134949)			
Com	ments	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).		

Acut	Acute dermal toxicity					
No	Substance name	CA	S no.	EC no.		
1	methanol	67·	-56-1	200-659-6		
LD50			17100	mg/kg bodyweight		
Spec		rabbit				
Sour	ce	ECHA				

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

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No	Product Name					
1	CyLyse™ FXP Fixation Buffer Product no.: BM900123, AE238377 (Fixation B AR134949)	Buffer:				
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).				
Acut	Acute inhalational toxicity					
No d	lo data available					

No data available

Skin	Skin corrosion/irritation						
No	Substance name	CAS no.	EC no.				
1	formaldehyde	50-00-0	200-001-8				
Spec	ies	rabbit					
Method		OECD 404					
Source		ECHA					
Evaluation		corrosive					
Evalu	uation/classification	Based on available data, the classification crite	eria are met.				

Serious eye damage/irritation

No data available

Resp	Respiratory or skin sensitisation						
No	Substance name	CAS no. EC	no.				
1	formaldehyde	50-00-0 200-	-001-8				
Rout	e of exposure	Skin					
Species		guinea pig					
Meth	od	OECD 406					
Source		ECHA					
Evaluation		sensitizing					
Evalu	uation/classification	Based on available data, the classification criteria are	re met.				

Gern	Germ cell mutagenicity						
No	Substance name	CAS no.	EC no.				
1	formaldehyde	50-00-0	200-001-8				
Type of examination		in vitro gene mutation study in bacteria					
Spec	ies	Salmonella typhimurium					
Meth	od	OECD 471					
Sour	ce	ECHA					
Evalu	uation/classification	Based on available data, the classification crit	eria are met.				

Reproduction toxicity

No data available

Carc	Carcinogenicity						
No	Substance name	CAS no.	EC no.				
1	formaldehyde	50-00-0	200-001-8				
Route	e of exposure	inhalational					
Species		Human					
Sour	ce	ECHA					
Evalu	uation/classification	Based on available data, the classification crite	ria are met.				

STOT - single exposure No data available

STOT - repeated exposure

No data available

spiration hazard
o data available
o data available

11.2 Information on other hazards

Endocrine disrupting properties

No data available.

Other information

No data available.

SECTION 12: Ecological information

12.1 Toxicity

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Toxi	city to fish (acute)				
No	Substance name	CAS no.		EC no.	
1	formaldehyde	50-00-0		200-001-8	
LC50			24.1	mg/l	
Dura	tion of exposure		96	h	
Spec	ies	Pimephales promelas			
Meth	od	OECD 203			
Sour	ce	ECHA			
Eval	uation/classification	Based on available data, the classification criteria are not met.			
2	methanol	67-56-1 200-659-6		200-659-6	
LC50			15400	mg/l	
Dura	tion of exposure		96	h	
Species		Lepomis macrochirus			
Method		EPA-660 / 3-75-009			
Sour	ce	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	
EC5)		5.8	mg/l	
Dura	tion of exposure		48	h ¯	
Spec	ies	Daphnia magna			
Meth	od	OECD 202			
Sour	ce	ECHA			
Eval	uation/classification	Based on available data, the classification criteria are not met.			
2	methanol	67-56-1		200-659-6	
EC5)		22200	mg/l	
Dura	tion of exposure		48	h ¯	
Spec	ies	Daphnia magna			
Meth	od	OECD 202			
Sour	ce	ECHA			

Toxicity to Daphnia (chronic)

No data available

Toxi	Toxicity to algae (acute)					
No	Substance name	CAS no.		EC no.		
1	formaldehyde	50-00-0		200-001-8		
EC5)		3.48	mg/l		
Dura	tion of exposure		72	h		
Spec	cies	Desmodesmus subspicatus				
Meth	od	OECD 201				
Sour	ce	ECHA				
Eval	uation/classification	Based on available data, the classification criteria are not met.				
2	methanol	67-56-1		200-659-6		
EC5)	appr.	22000	mg/l		
Duration of exposure			96	h		
Species		Pseudokirchneriella subcapitata				
Method		OECD 201				
Sour	ce	ECHA				

Toxicity to algae (chronic) No data available

Bacteria toxicity

No data available

2.2 Persistence and degradability							
_	Biodegradability						
No	Substance name	CAS no.	EC no.				
1	formaldehyde	50-00-0	200-001-8				
Туре		aerobic biodegradation					
Valu	e		99 %				
Dura	ition		28 d				
Meth	nod	OECD 301 A					
Sour	ce	ECHA					
Eval	uation	readily biodegradable					
2	methanol	67-56-1	200-659-6				
Туре		BOD					

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Value		95	%
Duration		20	day(s)
Source	ECHA		
Evaluation	readily biod	egradable	

12.3 Bioaccumulative potential

Parti	Partition coefficient n-octanol/water (log value)						
No	Substance name		CAS no.		EC no.		
1	formaldehyde		50-00-0		200-001-8		
log P	Pow			0.35			
Refe	Reference temperature			25	°C		
Meth	od	QSAR					
Sour	ce	ECHA					
2	methanol		67-56-1		200-659-6		
log P	Pow		_	-0.77			
Sour		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

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

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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	200-00	1-8	28, 72, 75, 77	
2	methanol	67-56-1	200-65	9-6	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.

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

UMCO GmbH - D-21107 Hamburg, Georg-Wilhelm-Strasse 187, Tel.: +49(40)555 546 300, Fax: +49(40)555 546 357, e-mail: umco@umco.de

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.

Alterations/supplements:

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

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