

according to UK REACH Regulation

#### **Pepsin Solution**

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

#### 1.1. Product identifier

Pepsin Solution

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

#### Use of the substance/mixture

The product is intended for professional use.

#### 1.3. Details of the supplier of the safety data sheet

Company name: ZytoVision GmbH

Street: Fischkai 1

Place: D-27572 Bremerhaven

Telephone: +49 (0) 471/4832-300 Telefax: +49 (0) 471/4832-509

#### **SECTION 2: Hazards identification**

#### 2.1. Classification of the substance or mixture

#### **GB CLP Regulation**

This mixture is not classified as hazardous in accordance with GB CLP Regulation.

#### 2.2. Label elements

#### **GB CLP Regulation**

### Special labelling of certain mixtures

EUH208 Contains pepsin A. May produce an allergic reaction.

EUH210 Safety data sheet available on request.

#### 2.3. Other hazards

No information available.

#### **SECTION 3: Composition/information on ingredients**

#### 3.2. Mixtures

### **Hazardous components**

CAS No	Chemical name					
	EC No	Index No	REACH No			
	Classification (GB CLP Regulation)					
64-17-5	ethanol; ethyl alcohol			< 20 %		
	200-578-6	603-002-00-5	01-2119457610-43			
	Flam. Liq. 2, Eye Irrit. 2; H225 H31	Flam. Liq. 2, Eye Irrit. 2; H225 H319				
67-56-1	methanol		< 20 %			
	200-659-6	603-001-00-X				
	Flam. Liq. 2, Acute Tox. 3, Acute To H370	25 H331 H311 H301				
9001-75-6	pepsin A		< 20 %			
	232-629-3	647-008-00-6				
	Skin Irrit. 2, Eye Irrit. 2, Resp. Sens					

Full text of H and EUH statements: see section 16.



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Specific Conc. Limits, M-factors and ATE

CAS No	EC No	Chemical name	Quantity		
	Specific Conc. I	Limits, M-factors and ATE			
64-17-5	200-578-6	ethanol; ethyl alcohol	< 20 %		
	inhalation: LC5	0 = 124,7 mg/l (vapours); oral: LD50 = 10470 mg/kg			
67-56-1	200-659-6	methanol	< 20 %		
	LD50 = 15800 r	inhalation: LC50 = 128 mg/l (vapours); inhalation: ATE = 0,5 mg/l (dusts or mists); dermal: LD50 = 15800 mg/kg; oral: LD50 = 5628 mg/kg STOT SE 1; H370: >= 10 - 100 STOT SE 2; H371: >= 3 - < 10			

#### **SECTION 4: First aid measures**

#### 4.1. Description of first aid measures

#### After inhalation

Provide fresh air. If breathing is irregular or stopped, administer artificial respiration. Medical treatment necessary.

#### After contact with skin

After contact with skin, wash immediately with plenty of water and soap. Take off immediately all contaminated clothing and wash it before reuse. If skin irritation occurs: Get medical advice/attention.

#### After contact with eyes

Rinse immediately carefully and thoroughly with eye-bath or water.

#### After ingestion

Rinse mouth immediately and drink 1 glass of of water.

### 4.2. Most important symptoms and effects, both acute and delayed

No information available.

#### 4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

#### **SECTION 5: Firefighting measures**

#### 5.1. Extinguishing media

#### Suitable extinguishing media

Co-ordinate fire-fighting measures to the fire surroundings.

#### 5.2. Special hazards arising from the substance or mixture

Non-flammable.

#### 5.3. Advice for firefighters

In case of fire: Wear self-contained breathing apparatus.

#### Additional information

Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

#### **SECTION 6: Accidental release measures**

#### 6.1. Personal precautions, protective equipment and emergency procedures

#### General advice

Use personal protection equipment.

#### 6.2. Environmental precautions

Do not allow to enter into surface water or drains.

#### 6.3. Methods and material for containment and cleaning up

#### For cleaning up

Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents). Treat the recovered material as prescribed in the section on waste disposal.



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#### 6.4. Reference to other sections

Safe handling: see section 7

Personal protection equipment: see section 8

Disposal: see section 13

#### **SECTION 7: Handling and storage**

#### 7.1. Precautions for safe handling

#### Advice on safe handling

No special measures are necessary.

#### Advice on protection against fire and explosion

No special fire protection measures are necessary.

#### Advice on general occupational hygiene

Take off contaminated clothing. Wash hands before breaks and after work. When using do not eat, drink, smoke, sniff.

#### 7.2. Conditions for safe storage, including any incompatibilities

#### Requirements for storage rooms and vessels

Keep container tightly closed.

#### Hints on joint storage

No special measures are necessary.

#### Further information on storage conditions

Store, tightly closed, in the original vessel at conditions indicated on the label.

#### 7.3. Specific end use(s)

The product is intended for professional use.

#### **SECTION 8: Exposure controls/personal protection**

#### 8.1. Control parameters

#### **Exposure limits (EH40)**

CAS No	Substance	ppm	mg/m³	fibres/ml	Category	Origin
64-17-5	Ethanol	1000	1920	·	TWA (8 h)	WEL
67-56-1	Methanol	200	266		TWA (8 h)	WEL
		250	333		STEL (15 min)	WEL



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#### **DNEL/DMEL values**

CAS No	Substance			
DNEL type	DNEL type		Effect	Value
64-17-5	ethanol; ethyl alcohol			
Worker DNEI	_, acute	inhalation	systemic	1900 mg/m³
Worker DNEI	_, long-term	dermal	systemic	343 mg/kg bw/day
Worker DNEI	_, long-term	inhalation	systemic	950 mg/m³
67-56-1	methanol			
Worker DNEI	_, acute	inhalation	local	260 mg/m³
Worker DNEL, acute		dermal	systemic	40 mg/kg bw/day
Worker DNEI	Worker DNEL, acute		systemic	260 mg/m³
Worker DNEL, long-term		inhalation	local	260 mg/m³
Worker DNEI	Worker DNEL, long-term		systemic	40 mg/kg bw/day
Worker DNEL, long-term		inhalation	systemic	260 mg/m³

#### **PNEC** values

CAS No	Substance	
Environmental compartment		Value
64-17-5	ethanol; ethyl alcohol	
Freshwater		0,96 mg/l
Marine water		0,79 mg/l
Freshwater se	diment	3,6 mg/kg
Marine sedime	nt	2,9 mg/kg
Secondary poisoning		380 mg/kg
Micro-organisms in sewage treatment plants (STP)		580 mg/l
Soil		0,63 mg/kg
67-56-1	r-56-1 methanol	
Freshwater		20,8 mg/l
Marine water		2,08 mg/l
Freshwater sediment 77		77 mg/kg
Marine sediment 7,7		7,7 mg/kg
Micro-organisms in sewage treatment plants (STP)		100 mg/l
Soil 100 mg/k		

#### 8.2. Exposure controls

#### Individual protection measures, such as personal protective equipment

#### Eye/face protection

Wear eye/face protection.

#### **Hand protection**

When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits. The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.

#### Skin protection

Use of protective clothing.



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#### Respiratory protection

In case of inadequate ventilation wear respiratory protection.

#### **SECTION 9: Physical and chemical properties**

#### 9.1. Information on basic physical and chemical properties

Physical state: liquid Colour: colourless Odour: odourless

Test method

Melting point/freezing point: not determined not determined Boiling point or initial boiling point and

boiling range:

Flammability: not determined ISO 10156

Lower explosion limits: not determined Upper explosion limits: not determined not determined Flash point: Auto-ignition temperature: not determined Decomposition temperature: not determined not determined pH-Value: Water solubility: easily soluble

Solubility in other solvents

not determined

Partition coefficient n-octanol/water: not determined Vapour pressure: not determined Density: not determined Relative vapour density: not determined

#### 9.2. Other information

#### Information with regard to physical hazard classes

Explosive properties

The product is not: Explosive.

Oxidizing properties

The product is not: oxidising. Other safety characteristics

Evaporation rate: not determined not determined Solid content:

#### **SECTION 10: Stability and reactivity**

#### 10.1. Reactivity

No hazardous reaction when handled and stored according to provisions.

#### 10.2. Chemical stability

The product is stable under storage at normal ambient temperatures.

#### 10.3. Possibility of hazardous reactions

No known hazardous reactions.

#### 10.4. Conditions to avoid

none

#### 10.5. Incompatible materials

No information available.



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#### 10.6. Hazardous decomposition products

No known hazardous decomposition products.

#### **SECTION 11: Toxicological information**

#### 11.1. Information on hazard classes as defined in GB CLP Regulation

#### **Acute toxicity**

Based on available data, the classification criteria are not met.

#### **ATEmix calculated**

ATE (oral) 3623,2 mg/kg; ATE (dermal) 10869,6 mg/kg; ATE (inhalation vapour) 108,70 mg/l; ATE (inhalation dust/mist) 18,116 mg/l

CAS No	Chemical name							
	Exposure route	Dose		Species	Source	Method		
64-17-5	ethanol; ethyl alcohol							
	oral	LD50 mg/kg	10470	Rat	ECHA			
	inhalation (4 h) vapour	LC50 mg/l	124,7	Rat	ECHA			
67-56-1	methanol							
	oral	LD50 mg/kg	5628	Rat				
	dermal	LD50 mg/kg	15800	Rabbit				
	inhalation (4 h) vapour	LC50	128 mg/l	Rat				
	inhalation dust/mist	ATE	0,5 mg/l					

#### Irritation and corrosivity

Based on available data, the classification criteria are not met.

#### Sensitising effects

Contains pepsin A. May produce an allergic reaction.

#### Carcinogenic/mutagenic/toxic effects for reproduction

Based on available data, the classification criteria are not met.

#### STOT-single exposure

Based on available data, the classification criteria are not met.

#### STOT-repeated exposure

Based on available data, the classification criteria are not met.

#### Aspiration hazard

Based on available data, the classification criteria are not met.

#### 11.2. Information on other hazards

#### **Further information**

The mixture is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].

#### **SECTION 12: Ecological information**

#### 12.1. Toxicity

Based on available data, the classification criteria are not met.



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CAS No	Chemical name	Chemical name						
	Aquatic toxicity	Dose		[h]   [d]	Species	Source	Method	
64-17-5	ethanol; ethyl alcohol							
	Acute fish toxicity	LC50 8 mg/l	3140		Leuciscus idus (golden orfe)	IUCLID		
	Acute crustacea toxicity	EC50 9 14000 mg/l	9000-	48 h	Daphnia magna	IUCLID		
67-56-1	methanol							
	Acute fish toxicity	LC50 1 mg/l	15400	96 h	fish			
	Fish toxicity	NOEC 2 mg/l	23,75	90 d	fish			

#### 12.2. Persistence and degradability

The product has not been tested.

#### 12.3. Bioaccumulative potential

The product has not been tested.

#### Partition coefficient n-octanol/water

CAS No	Chemical name	Log Pow
64-17-5	ethanol; ethyl alcohol	-0,31

#### 12.4. Mobility in soil

The product has not been tested.

#### 12.5. Results of PBT and vPvB assessment

The substances in the mixture do not meet the PBT/vPvB criteria according to UK REACH.

The product has not been tested.

#### 12.6. Endocrine disrupting properties

This product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.

#### 12.7. Other adverse effects

No information available.

#### **Further information**

Avoid release to the environment.

#### **SECTION 13: Disposal considerations**

#### 13.1. Waste treatment methods

#### **Disposal recommendations**

Do not allow to enter into surface water or drains. Dispose of waste according to applicable legislation.

#### Contaminated packaging

Wash with plenty of water. Completely emptied packages can be recycled.

#### **SECTION 14: Transport information**

#### Land transport (ADR/RID)

14.1. UN number or ID number:No dangerous good in sense of this transport regulation.14.2. UN proper shipping name:No dangerous good in sense of this transport regulation.14.3. Transport hazard class(es):No dangerous good in sense of this transport regulation.14.4. Packing group:No dangerous good in sense of this transport regulation.

#### Inland waterways transport (ADN)

14.1. UN number or ID number: No dangerous good in sense of this transport regulation.



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14.2. UN proper shipping name:No dangerous good in sense of this transport regulation.14.3. Transport hazard class(es):No dangerous good in sense of this transport regulation.14.4. Packing group:No dangerous good in sense of this transport regulation.

Marine transport (IMDG)

14.1. UN number or ID number:No dangerous good in sense of this transport regulation.14.2. UN proper shipping name:No dangerous good in sense of this transport regulation.14.3. Transport hazard class(es):No dangerous good in sense of this transport regulation.14.4. Packing group:No dangerous good in sense of this transport regulation.

Segregation group: 1 - acids

Air transport (ICAO-TI/IATA-DGR)

14.1. UN number or ID number:No dangerous good in sense of this transport regulation.14.2. UN proper shipping name:No dangerous good in sense of this transport regulation.14.3. Transport hazard class(es):No dangerous good in sense of this transport regulation.14.4. Packing group:No dangerous good in sense of this transport regulation.

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: No

14.6. Special precautions for user

No dangerous good in sense of this transport regulation.

14.7. Maritime transport in bulk according to IMO instruments

No dangerous good in sense of this transport regulation.

#### **SECTION 15: Regulatory information**

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

#### **EU regulatory information**

Restrictions on use (REACH, annex XVII):

Entry 40, Entry 69, Entry 75

Information according to 2012/18/EU Not subject to 2012/18/EU (SEVESO III)

(SEVESO III):

**National regulatory information** 

Water hazard class (D): 1 - slightly hazardous to water

Skin resorption/Sensitization: Causes allergic hypersensitivity reactions.

#### 15.2. Chemical safety assessment

Chemical safety assessments for substances in this mixture were not carried out.

#### **SECTION 16: Other information**

#### Changes

This data sheet contains changes from the previous version in section(s):

1,2,4,5,6,7,8,9,10,11,12,13,14,15,16.

#### Abbreviations and acronyms

CLP: Classification, labelling and Packaging

REACH: Registration, Evaluation and Authorization of Chemicals

GHS: Globally Harmonised System of Classification, Labelling and Packaging of Chemicals

**UN: United Nations** 

CAS: Chemical Abstracts Service
DNEL: Derived No Effect Level
DMEL: Derived Minimal Effect Level
PNEC: Predicted No Effect Concentration

ATE: Acute toxicity estimate LC50: Lethal concentration, 50%



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LD50: Lethal dose, 50% LL50: Lethal loading, 50% EL50: Effect loading, 50%

EC50: Effective Concentration 50%

ErC50: Effective Concentration 50%, growth rate NOEC: No Observed Effect Concentration

BCF: Bio-concentration factor

PBT: persistent, bioaccumulative, toxic vPvB: very persistent, very bioaccumulative

ADR: Accord européen sur le transport des marchandises dangereuses par Route

(European Agreement concerning the International Carriage of Dangerous Goods by Road)

RID: Regulations concerning the international carriage of dangerous goods by rail

ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways (Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures)

IMDG: International Maritime Code for Dangerous Goods

EmS: Emergency Schedules MFAG: Medical First Aid Guide

IATA: International Air Transport Association ICAO: International Civil Aviation Organization

MARPOL: International Convention for the Prevention of Marine Pollution from Ships

IBC: Intermediate Bulk Container SVHC: Substance of Very High Concern

For abbreviations and acronyms, see: ECHA Guidance on information requirements and chemical safety

assessment, chapter R.20 (Table of terms and abbreviations).

#### Relevant H and EUH statements (number and full text)

H225	Highly flammable liquid and vapour.
H301	Toxic if swallowed.
H311	Toxic in contact with skin.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H331	Toxic if inhaled.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335	May cause respiratory irritation.
H370	Causes damage to organs.
EUH208	Contains pepsin A. May produce an allergic reaction.
EUH210	Safety data sheet available on request.

#### **Further Information**

The information is based on the present level of our knowledge. It does not, however, give assurance of product properties and establishes no contract legal rights. The receiver of our product is singularly responsible for adhering to existing laws and regulations. The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.

(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)