

according to Regulation (EC) No 1907/2006

Pepsin Solution (ZUC038-060)

Print date: 07.10.2014

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

1.1. Product identifier

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

Use of the substance/mixture

in vitro-diagnostic reagent or laboratory reagent

1.3. Details of the supplier of the safety data sheet

Company name:	Zytomed Systems GmbH	
Street:	Anhaltinerstraße 16	
Place:	D-14163 Berlin	
Telephone:	+49 30 804 984 990	Telefax: +49 30 804 984 999
e-mail:	info@zytomed-systems.de	
Internet:	www.zytomed-systems.de	
1.4. Emergency telephone	+49 30 804 984 990	

number:

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Indications of danger: C - Corrosive R phrases: Causes burns.

GHS classification

This mixture is not classified as hazardous according to Regulation (EC) No. 1272/2008.

2.2. Label elements

Special labelling of certain mixtures

EUH208 Contains Pepsin A. May produce an allergic reaction.

2.3. Other hazards

No risks worthy of mention.

SECTION 3: Composition/information on ingredients

3.2. Mixtures



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Hazardous components

EC No	Chemical name	Quantity
CAS No	Classification	
Index No	GHS classification	
REACH No		
201-064-4	Tris-(hydroxymethyl)-aminomethan	<1 %
77-86-1	Xi - Irritant R36/37	
	Skin Irrit. 2, Eye Irrit. 2; H315 H319	
232-629-3	Pepsin A	<0,3 %
9001-75-6	Xi - Irritant R36/37/38-42	
647-008-00-6	Eye Irrit. 2, STOT SE 3, Skin Irrit. 2, Resp. Sens. 1; H319 H335 H315 H334	
231-595-7	hydrogen chloride	<0,2 %
7647-01-0	T - Toxic, C - Corrosive R23-35	
017-002-00-2	Acute Tox. 3, Skin Corr. 1A; H331 H314	

Full text of R and H phrases: see Section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

After inhalation

Provide fresh air.

After contact with skin

IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower. If skin irritation occurs: Get medical advice/attention.

After contact with eyes

In case of contact with eyes, rinse immediately with plenty of flowing water for 10 to 15 minutes holding eyelids apart. Subsequently consult an ophthalmologist.

After ingestion

Rinse mouth immediately and drink plenty of water. Do NOT induce vomiting. Hazards identification: Stomach perforation. Call a physician immediately. Do not allow a neutralisation agent to be drunk.

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 further informations

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

The product itself does not burn.

5.3. Advice for firefighters

Wear a self-contained breathing apparatus and chemical protective clothing. Full protective suit.

Additional information

Suppress gases/vapours/mists with water spray jet. Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

SECTION 6: Accidental release measures



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6.1. Personal precautions, protective equipment and emergency procedures

Provide adequate ventilation. Do not breathe gas/fumes/vapour/spray. Avoid contact with skin, eyes and clothes. Wear personal protection equipment. Wear 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

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

6.4. Reference to other sections

see chapter 8 and 13

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

If handled uncovered, arrangements with local exhaust ventilation have to be used. Do not breathe gas/fumes/vapour/spray. If handled uncovered, arrangements with local exhaust ventilation should be used if possible.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep container tightly closed. Keep locked up. Store in a place accessible by authorized persons only. Provide adequate ventilation as well as local exhaustion at critical locations.

7.3. Specific end use(s)

in vitro-diagnostic reagent or laboratory reagent

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure limits (EH40)

CAS No	Substance	ppm	mg/m³	fibres/ml	Category	Origin
7647-01-0	Hydrogen chloride (gas and aerosol mists)	1	2		TWA (8 h)	WEL
		5	8		STEL (15 min)	WEL

8.2. Exposure controls

Occupational exposure controls

If handled uncovered, arrangements with local exhaust ventilation have to be used. Do not breathe gas/fumes/vapour/spray.

Protective and hygiene measures

Remove contaminated, saturated clothing immediately. Protect skin by using skin protective cream. After work, wash hands and face. When using do not eat or drink.

Hand protection

Tested protective gloves are to be worn: NBR (Nitrile rubber).

Eye protection

Suitable eye protection: Framed glasses.



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SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state:	liquid
Colour:	colourless
Odour:	odourless

	Test method
pH-Value:	Not determined
Changes in the physical state	
Melting point:	Not determined
Initial boiling point and boiling range:	Not determined
Flash point:	Not determined
Flammability	
Solid:	Not determined
Gas:	Not determined
Lower explosion limits:	Not determined
Upper explosion limits:	Not determined
Auto-ignition temperature	
Solid:	Not determined
Gas:	Not determined
Vapour pressure:	Not determined
Density:	Not determined
Water solubility:	Not determined
Solubility in other solvents Not determined	
Partition coefficient:	Not determined
Vapour density:	Not determined
Evaporation rate:	Not determined
9.2. Other information	

No further informations

SECTION 10: Stability and reactivity

10.1. Reactivity

No data available

10.2. Chemical stability

No data available

10.3. Possibility of hazardous reactions

No data available

10.4. Conditions to avoid

No data available

10.5. Incompatible materials

No data available

10.6. Hazardous decomposition products

No data available



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Further information

No further informations

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity

CAS No	Chemical name				
	Exposure routes	Method	Dose	Species	Source
77-86-1	Tris-(hydroxymethyl)-aminomethan				
	oral	LD50	5900 mg/kg	Ratte	
7647-01-0	hydrogen chloride	-			
	inhalative vapour	ATE	3 mg/l		
	inhalative aerosol	ATE	0,5 mg/l		

Irritation and corrosivity

after ingestion: Irritation and etching. Hazards identification: Stomach perforation.

Sensitising effects

May cause sensitization by skin contact.

Additional information on tests

The classification was carried out according to the calculation method of the Preparations Directive (1999/45/EC).

SECTION 12: Ecological information

12.1. Toxicity

No data available.

12.2. Persistence and degradability

No data available.

12.3. Bioaccumulative potential

No data available.

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

No data available.

12.6. Other adverse effects

No data available.

Further information

Do not allow to enter into surface water or drains. The classification was carried out according to the calculation method of the Preparations Directive (1999/45/EC).

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Advice on disposal

Dispose of waste according to applicable legislation.

Waste disposal number of waste from residues/unused products



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160506 WASTES NOT OTHERWISE SPECIFIED IN THE LIST; gases in pressure containers and discarded chemicals; laboratory chemicals, consisting of or containing dangerous substances, including mixtures of laboratory chemicals

Classified as hazardous waste.

Contaminated packaging

Non-contaminated packages may be recycled. Handle contaminated packages in the same way as the substance itself.

SECTION 14: Transport information

Land transport (ADR/RID)

Other applicable information (land transport)

No dangerous good in sense of these transport regulations.

Inland waterways transport (ADN)

Other applicable information (inland waterways transport)

No dangerous good in sense of these transport regulations.

Marine transport (IMDG)

Other applicable information (marine transport)

No dangerous good in sense of these transport regulations.

Air transport (ICAO)

Other applicable information (air transport)

No dangerous good in sense of these transport regulations.

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: no

14.6. Special precautions for user

No further informations

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

No further informations

SECTION 15: Regulatory information

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

EU regulatory	information	
1999/13/EC (V	DC):	0,5 %
National regula	atory information	
Water contami	ating class (D):	2 - water contaminating

15.2. Chemical safety assessment

For this substance a chemical safety assessment has not been carried out.

SECTION 16: Other information

Full text of R phrases referred to under Sections 2 and 3

23	Toxic by inhalation.
34	Causes burns.
35	Causes severe burns.
36/37	Irritating to eyes and respiratory system.
36/37/38	Irritating to eyes, respiratory system and skin.
42	May cause sensitisation by inhalation.



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Full text of H statements referred to under Sections 2 and 3					
H314	Causes severe skin burns and eye damage.				
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.				
Further Info	ormation				
	This information is based on our present knowledge. No guarantee is given regarding its accuracy or comprehensiveness. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship. Zytomed Systems shall not be held liable for resulting damages from handling or from contact with the above product. Paper copies are allowed to be used for internal use only.				

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