

Substrate buffer solution

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

1.1. Product identifier

Product name: Substrate buffer solution
Catalog number: ESU31
REACH Registration Number: A registration number is not available for this substance as the substance or its uses are exempted from registration, according to Article 2 (7) Regulation (EC) No. 1907/2006 [REACH], the annual tonnage does not require a registration or the registration is envisaged for a later registration deadline.

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

Use of the substance/mixture

Substrate solution for Pancreatic Elastase ELISA.

Uses advised against

None identified.

1.3. Details of the supplier of the safety data sheet

Company name: BIOSERV Diagnostics GmbH
Street: Doberaner Str. 151
Place: D-18057 Rostock
Germany
Telephone: +49 (0) 381 / 3758 2090
Telefax: +49 (0) 381 / 3758 2099
e-mail: info@bioserv-diagnostics.com
e-mail (Contact person): mail@giftnotruf.de
Internet: http://www.bioserv-diagnostics.com
Responsible Department: Advisory Center for Intoxication and Embryonic Toxicology, Berlin, Germany
+49 (0) 30 / 192 40

1.4. Emergency telephone number:

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No. 1272/2008

Hazard categories:
Reproductive toxicity: Repr. 1B
Hazard Statements:
May damage the unborn child.

2.2. Label elements

Regulation (EC) No. 1272/2008

Hazard components for labelling

N-methyl-2-pyrrolidone; 1-methyl-2-pyrrolidone

Pictograms:



Signal word: Danger

Hazard statements

H360D May damage the unborn child.

Precautionary statements

P202 Do not handle until all safety precautions have been read and understood.
P280 Wear protective gloves/protective clothing/eye protection.
P308+P313 IF exposed or concerned: Get medical advice/attention.

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P501 Dispose of contents/container to in accordance with local regulations.

Special labelling of certain mixtures

EUH208 Contains reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1). May produce an allergic reaction.

Labelling of packages where the contents do not exceed 125 ml

Pictograms:



Signal word: Danger

Hazard statements

H360D

Precautionary statements

P202-P280-P308+P313-P501

2.3. Other hazards

No information available.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Hazardous components

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	GHS Classification			
872-50-4	N-methyl-2-pyrrolidone; 1-methyl-2-pyrrolidone			5 - < 10 %
	212-828-1	606-021-00-7		
	Repr. 1B, Skin Irrit. 2, Eye Irrit. 2, STOT SE 3; H360D H315 H319 H335			
55965-84-9	reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)			< 0.1 %
	911-418-6		01-2120764691-48	
	Acute Tox. 2, Acute Tox. 2, Acute Tox. 3, Skin Corr. 1C, Eye Dam. 1, Skin Sens. 1A, Aquatic Acute 1 (M-Factor = 100), Aquatic Chronic 1 (M-Factor = 100); H330 H310 H301 H314 H318 H317 H400 H410 EUH071			

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

SECTION 4: First aid measures

4.1. Description of first aid measures

General information

When in doubt or if symptoms are observed, get medical advice.

After inhalation

Provide fresh air.

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.

After contact with eyes

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

After ingestion

If accidentally swallowed rinse the mouth with plenty of water (only if the person is conscious) and obtain immediate medical attention.

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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. Suitable extinguishing media: Water mist, Water spray, Dry extinguishing powder, Carbon dioxide (CO₂).

Unsuitable extinguishing media

None identified.

5.2. Special hazards arising from the substance or mixture

In case of fire can be released: Carbon dioxide (CO₂), Carbon monoxide, Nitrogen oxides (NO_x).

5.3. Advice for firefighters

In case of fire: Wear self-contained breathing apparatus. Co-ordinate fire-fighting measures to the fire surroundings.

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

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. 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

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

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

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

Advice on protection against fire and explosion

No special fire protection measures are necessary.

Further information on handling

Use only in accordance to the manual.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep container tightly closed. Store in a place accessible by authorized persons only. Provide adequate ventilation as well as local exhaust at critical locations. Keep cool. Protect from sunlight.

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Hints on joint storage

Do not store together with: Oxidizing agent.

Further information on storage conditions

Observe directions on the label.

storage temperature of 2 °C - 8 °C.

7.3. Specific end use(s)

Use only in accordance to the manual.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure limits (EH40)

CAS No	Substance	ppm	mg/m ³	fibres/ml	Category	Origin
872-50-4	1-Methyl-2-pyrrolidone	10	40		TWA (8 h)	WEL
		20	80		STEL (15 min)	WEL

DNEL/DMEL values

CAS No	Substance	Exposure route	Effect	Value
872-50-4	N-methyl-2-pyrrolidone; 1-methyl-2-pyrrolidone			
Worker DNEL, long-term		inhalation	systemic	14,4 mg/m ³
Worker DNEL, long-term		inhalation	local	40,0 mg/m ³
Worker DNEL, long-term		dermal	systemic	4,8 mg/kg bw/day
Consumer DNEL, long-term		inhalation	systemic	3,6 mg/m ³
Consumer DNEL, long-term		inhalation	local	4,5 mg/m ³
Consumer DNEL, long-term		dermal	systemic	2,5 mg/kg bw/day
Consumer DNEL, long-term		oral	systemic	0,85 mg/kg bw/day

PNEC values

CAS No	Substance	Value
872-50-4	N-methyl-2-pyrrolidone; 1-methyl-2-pyrrolidone	
Freshwater		0,25 mg/l
Freshwater (intermittent releases)		5 mg/l
Marine water		0,025 mg/l
Freshwater sediment		1,09 mg/kg
Marine sediment		0,109 mg/kg

8.2. Exposure controls



Appropriate engineering 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. Draw up and observe skin protection programme.

Wash hands and face before breaks and after work and take a shower if necessary. When using do not eat, drink, smoke, sniff.

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Eye/face protection

Wear eye protection.

Hand protection

Chemical protective gloves must meet the requirements of European standard EN 374. Observe the wear time limits as specified by the manufacturer.

Breakthrough time (maximum wearing time): 480 min.

Suitable material: Butyl caoutchouc (butyl rubber) (0.5 mm)

Following materials are unsuitable for protective gloves because of degradation, severe swelling or low permeation time: NR (natural rubber, natural latex), CR (polychloroprene, chloroprene rubber), NBR (Nitrile rubber), FKM (fluoro rubber), PVC (polyvinyl chloride).

Skin protection

Use of protective clothing

Respiratory protection

In case of inadequate ventilation wear respiratory protection.

Environmental exposure controls

Do not allow to enter into surface water or drains.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state:	liquid
Colour:	colourless - slightly bluish
Odour:	characteristic
pH-Value (at 25 °C):	3.5-4.0

Changes in the physical state

Melting point:	not determined
Initial boiling point and boiling range:	not determined
Flash point:	not determined

Flammability

Solid:	not applicable
Gas:	not applicable

Explosive properties

The product is not: Explosive.

Lower explosion limits:	not determined
Upper explosion limits:	not determined

Auto-ignition temperature

Solid:	not applicable
Gas:	not applicable

Decomposition temperature:	not determined
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Oxidizing properties

Not oxidising.

Vapour pressure:	not determined
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Density:	1.0030 g/cm ³
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Water solubility:	completely miscible
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Solubility in other solvents

Partition coefficient:	not determined
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Vapour density:	not determined
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Evaporation rate:	not determined
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9.2. Other information

Solid content:	not determined
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SECTION 10: Stability and reactivity

10.1. Reactivity

This material is considered to be non-reactive under normal use conditions.

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

Light-sensitive. Keep away from heat. Stable under recommended storage and handling conditions.

10.5. Incompatible materials

Avoid contact with strong oxidizing agents and metals.

10.6. Hazardous decomposition products

No known hazardous decomposition products.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity

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

CAS No.	Chemical name				
	Exposure route	Dose	Species	Source	Method
872-50-4	N-methyl-2-pyrrolidone; 1-methyl-2-pyrrolidone				
	oral	LD50 4150 mg/kg	Rat	IUCLID	OECD 401
	dermal	LD50 8000 mg/kg	Rabbit	IUCLID	OECD 402
	inhalation (4 h) aerosol	LC50 >5,1 mg/l	Rat	IUCLID	OECD 403
55965-84-9	reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)				
	oral	ATE 100 mg/kg			
	dermal	ATE 50 mg/kg			
	inhalation vapour	ATE 0,5 mg/l			
	inhalation aerosol	ATE 0,05 mg/l			

Irritation and corrosivity

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

Sensitising effects

Contains reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1). May produce an allergic reaction.

Carcinogenic/mutagenic/toxic effects for reproduction

May damage the unborn child. (N-methyl-2-pyrrolidone; 1-methyl-2-pyrrolidone)

Germ cell mutagenicity: Based on available data, the classification criteria are not met.

Carcinogenicity: 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.

Additional information on tests

The mixture is classified as hazardous according to regulation (EC) No 1272/2008 [CLP].

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Further information

May cause sensitization by inhalation.

SECTION 12: Ecological information

12.1. Toxicity

The product is not: Ecotoxic.

CAS No	Chemical name					
	Aquatic toxicity	Dose	[h] [d]	Species	Source	Method
872-50-4	N-methyl-2-pyrrolidone; 1-methyl-2-pyrrolidone					
	Acute fish toxicity	LC50 832 mg/l	96 h	rainbow trout	IUCLID	Static fish toxicity test according to BBA-bulletin No. 33, 2. edition, September 1975
	Acute algae toxicity	ErC50 600,5 mg/l	72 h	green algae	ECHA	DIN 38412 / part 9
	Acute crustacea toxicity	EC50 ca. 4897 mg/l	48 h	Daphnia magna	IUCLID	DIN 38412 / part 11
	Algae toxicity	NOEC 92,6 mg/l	3 d	green algae	ECHA	DIN 38412 / part 9
	Crustacea toxicity	NOEC 21,5 mg/l	21 d	Daphnia magna (Big water flea)	ECHA	OECD 211
	Acute bacteria toxicity	(100 mg/l)	0 h	Activated sludge	Actra hydrochim. hydrobiol. 9(5), 555-57	

12.2. Persistence and degradability

Biodegradable.

CAS No	Chemical name			
	Method	Value	d	Source
	Evaluation			
872-50-4	N-methyl-2-pyrrolidone; 1-methyl-2-pyrrolidone			
	OECD 301C	73 %	28	MITI
	Does not bioaccumulate.			

12.3. Bioaccumulative potential

No indication of bioaccumulation potential.

Partition coefficient n-octanol/water

CAS No	Chemical name	Log Pow
872-50-4	N-methyl-2-pyrrolidone; 1-methyl-2-pyrrolidone	-0,46

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 REACH, annex XIII.

12.6. Other adverse effects

No information available.

Further information

Avoid release to the environment. There are no data available on the mixture itself.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

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Disposal recommendations

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

List of Wastes Code - residues/unused products

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

List of Wastes Code - used product

160508 WASTES NOT OTHERWISE SPECIFIED IN THE LIST; gases in pressure containers and discarded chemicals; discarded organic chemicals consisting of or containing hazardous substances; hazardous waste

List of Wastes Code - contaminated packaging

150102 WASTE PACKAGING; ABSORBENTS, WIPING CLOTHS, FILTER MATERIALS AND PROTECTIVE CLOTHING NOT OTHERWISE SPECIFIED; packaging (including separately collected municipal packaging waste); plastic packaging

Contaminated packaging

Hazardous waste according to Directive 2008/98/EC (waste framework directive). Handle contaminated packages in the same way as the substance itself.

SECTION 14: Transport information

Land transport (ADR/RID)

14.1. UN 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:	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.

Marine transport (IMDG)

14.1. UN 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.

Air transport (ICAO-TI/IATA-DGR)

14.1. UN 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. Transport in bulk according to Annex II of Marpol and the IBC Code

No dangerous good in sense of this transport regulation.

SECTION 15: Regulatory information

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

EU regulatory information

Authorisations (REACH, annex XIV):

Substances of very high concern, SVHC (REACH, article 59):

N-methyl-2-pyrrolidone; 1-methyl-2-pyrrolidone

Restrictions on use (REACH, annex XVII):

Entry 30: N-methyl-2-pyrrolidone; 1-methyl-2-pyrrolidone

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

National regulatory information

Employment restrictions:

Observe restrictions to employment for juvenils according to the 'juvenile work protection guideline' (94/33/EC). Observe employment restrictions under the Maternity Protection Directive (92/85/EEC) for expectant or nursing mothers.

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

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%

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

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IBC: Intermediate Bulk Container

SVHC: Substance of Very High Concern

For abbreviations and acronyms, see table at <http://abbrev.esdscom.eu>

Relevant H and EUH statements (number and full text)

H301	Toxic if swallowed.
H310	Fatal in contact with skin.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H330	Fatal if inhaled.
H335	May cause respiratory irritation.
H360D	May damage the unborn child.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
EUH071	Corrosive to the respiratory tract.
EUH208	Contains reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1). May produce an allergic reaction.

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