

According to Regulation (EC) No 1907/2006, Article 31

1. Identification of the Substance/Mixture and of the Company

1.1 Product Identifier

Trade Name: Pankrin ELISA

Product Code: BS-86-02

Kit Components:

1. Microtiterplate
2. Standard Range (4 vials, lyophilised)
3. Control (lyophilised)
4. Biotin Conjugate Dilution Buffer
5. Substrate Solution
6. Stop Solution
7. Washing Solution (10x concentrated)
8. Biotinylated Antibodies
9. Streptavidin-Peroxidase Conjugate

1.2 Relevant identified uses of the substance or mixture

Components of an in-vitro diagnostic device.

Enzyme-linked immunosorbent assay for the quantitative determination of human pancreatic elastase and other pancreatic enzymes for the diagnosis of acute pancreatitis in human serum as an aid in the diagnosis of the exocrine pancreatic function.

1.3 Details of the Supplier of the Safety Data Sheet

BIOSERV Diagnostics GmbH
Doberaner Str. 151
18057 Rostock
Germany

Phone: +49 (0) 381 / 3758 2091
Fax: +49-(0) 381 / 3758 2099
e-mail: info@bioserv-diagnostics.com
<http://www.bioserv-diagnostics.com>

1.4 Emergency Telephone Number

Advisory Center for Intoxication and Embryonic Toxicology, Berlin, Germany.
Tel.: +49 (0) 30 19240, e-mail: mail@giftnotruf.de, www.giftnotruf.de

2. Hazards Identification

2.1 Classification of the Substance or Mixture

The Substrate Solution contains substances that are classified according to EU-regulation (EG) 1272/2008, amended by (EU) 2016/1179 as reproductive toxicant (Repr. 1B, H360D).

2.2 Label Elements

The Substrate Solution has to be marked as follows:



Pictogram

Signal wording

Risk phrase

Hazard warnings

Precautionary statements

Danger!

Reproductive toxicant Repr. 1B

H360D: May damage the unborn child

P280: Wear protective gloves/protective clothing/eye protection/face protection.

2.3 Other Hazards

Results of PBT and vPvB Assessment

- PBT: Not listed

- vPvB: Not listed

3. Composition/Information on Ingredients

3.2 Mixtures

Description of the mixture:

Mixtures of hazardous and non-hazardous substances, additions listed below.

Hazardous ingredients:

Chemical name	CAS No. (EC-No.)	Amount in mixture	Classification according to Regulation (EC) No. 1272/2008 [CLP]	
			Hazard class	Hazard statement
Standard Range, Positive Control				
Sodium azide	26628-22-8 (247-852-1)	< 0,05 % w/w	Acute Tox. 2 Aquatic Acute 1 Aquatic Chronic 1	H300 H400 H410
Biotinylated Antibodies				
Thiomersal	54-64-8 (200-210-4)	< 0,05 % w/w	Acute Tox. 2 Aquatic Chronic 1	H300 H310 H330 H373 H410
Stop Solution				
Sulphuric acid	7664-93-9 (231-639-5)	< 5 % w/w	Skin Corr. 1A	H314 H290
Substrate Solution				
N-Methyl-2-pyrrolidone	872-50-4	< 5 % w/w	Repr. 1B Skin Irrit. 2	H315 H319

			Eye Irrit. 2	H360D H335
--	--	--	--------------	---------------

For the complete wording of the H-phrases refer to section 16.

4. First Aid Measures

4.1 Description of first aid measures

General information:	Consult physician. Show them MSDS.
Following inhalation:	Supply fresh air; consult doctor in case of complaints.
Following skin contact:	Wash thoroughly with soap and water.
Following eye contact:	Rinse opened eye for several minutes under running water. If symptoms persist consult a physician.
Following swallowing:	Rinse mouth, drink up to two glasses of water, consult a physician and show them MSDS.

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

No further relevant information available.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

5. Firefighting Measures

5.1 Extinguishing media

Suitable extinguishing media: no restriction, use any media suitable for extinguishing surrounding fire.

Unsuitable extinguishing media: none.

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products: no further relevant information available.

5.3 Advice for firefighters

No special measures required.

6. Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Use appropriate personal protective equipment.

6.2 Environmental precautions

Dilute with plenty of water. Do not allow to enter surface or ground water.

6.3 Methods and material for containment and cleaning up

Absorb with liquid-binding material. Dispose contaminated material as waste according to section 13.

6.4 Reference to other sections

See section 8 for information on personal protection equipment.
See section 13 for disposal information.

7. Handling And Storage

7.1 Precautions for safe handling

Use all reagents in accordance with the relevant instructions for use.
Observe laboratory safety regulations.
Do not eat, drink, smoke or apply cosmetics in areas where kit reagents are handled.
Wear disposable gloves, protective glasses and clothing when handling reagents.
Handling should be done in accordance with the procedures defined by an appropriate national biohazard safety guideline or regulation.

7.2 Conditions for safe storage, including any incompatibilities

No special requirements. Store all reagents as directed in the relevant instructions for use.

7.3 Specific end use

For professional in vitro diagnostic use according to instruction manual only.

8. Exposure Controls/Personal Protection

8.1 Control parameters

Chemical name	CAS No. (EC-No.)	MAK acc. to TRGS 900	BGW acc. to TRGS 903
N-Methyl-2-pyrrolidon	872-50-4	82 mg/m ³	150 mg/l Urin am Schichtende,

			Parameter: 5-Hydroxy-N-Methyl-2-pyrrolidon
--	--	--	--

No relevant air contamination to be expected if handled according to product instructions.

8.2 Exposure controls

Pregnant women must avoid exposure by skin contact, inhalation or swallowing.

Respiratory protection: Not required if used according to instruction manual.
 Hand protection: Protective gloves Nitrile (min. 0.28 mm thickness, AQL 1.5) or Latex (min. 0.22 mm thickness, AQL 1.5).
 Eye protection: Goggles recommended during aspiration, dispensing or refilling.
 Skin protection: Lab coat.

9. Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Kit component	Standard Range, Controls, Biotinylated Elastase Antibody, Streptavidin-Peroxidase Conjugate	Washing Buffer (10x), Extraction Buffer (10x)	Substrate Solution	Stop Solution
a) Appearance: Physical state (solid liquid, gas) Colour	Liquid, diverse colours			
b) Odour	Not determined			
c) Odour threshold	Not determined			
d) pH	7,2 – 7,6	6,5 – 7,1	3,6 – 3,8	< 1,0
e) Melting point / freezing point	0°C			
f) Initial boiling point and boiling range	100°C			
g) Flash point	Not applicable			
h) Evaporation rate	Not determined			
i) Flammability (solid, gas)	Not applicable			
j) Upper/lower flammability or explosive limits	Not determined			
k) Vapour pressure	Not determined			
l) Vapour density	Not determined			

m) Relative density	Not determined
n) Solubility	Not determined
o) Partition coefficient	Not determined
p) Auto-ignition temperature	Product not self-igniting
q) Decomposition temperature	Not applicable
r) Viscosity	Not determined
s) Explosive properties	Product not explosive
t) Oxidising properties	Not determined

9.2 Other information

No other information available.

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 conditions known.

10.5 Incompatible materials

No materials known.

10.6 Hazardous decomposition products

No dangerous decomposition products known.

11. Toxicological Information

11.1 Information on toxicological effects

(a) Acute toxicity:

Kit component	Type	Value	Species
N-Methyl-2-pyrrolidone (Substrate solution)	LD ₅₀ (oral)	3598 mg/kg	Rat
	LD ₅₀ (inhalation)	> 5,1 mg/l	Rat
	LD ₅₀ (dermal)	5000 mg/kg	Rat

(b) Irritation:

Due to its low pH value Substrate Solution and Stop Solution are irritant to the eye.

(c) Corrosivity:

Sulphuric acid induces tissue injury after contact.

(d) Sensitisation:

No data available.

(e) Repeated dose toxicity:

No data available.

(f) Carcinogenicity:

No data available.

(g) Mutagenicity:

No data available.

(h) Toxicity for reproduction:

N-Methyl-2-Pyrrolidone (Substrate solution): May damage the unborn child (Repr. 1B).

Quantitative toxicological data is not available. Toxicity is calculated according to EG1272/2008, Annex I, refer to section 15.1. Further dangerous properties cannot be

excluded. However, if used according to safety instructions the risk to the operator is minimal.

12. Ecological Information

12.1 Toxicity:

N-Methyl-2-pyrrolidone:

Species	Type	Value
Bluegill (<i>Lepomis macrochirus</i>)	LC ₅₀ (mg/l/96h)	832
Ide (<i>Leuciscus idus</i>)	LC ₅₀ (mg/l/96h)	> 500
Green algae	IC ₅₀ (mg/l/72h)	> 500
Invertebrates (<i>Daphnia magna</i>)	EC ₅₀ (mg/l/48h)	4897

12.2 Persistence and degradability:

N.Methyl-2-pyrrolidone: > 90 % / 20 d easily biodegradable.

12.3 Bioaccumulative potential:

N-Methyl-2-pyrrolidone: log POW ≤ 4, no bioaccumulation to be expected.

12.4 Mobility in soil: No further relevant information available.

12.5 Results of PBT and vPvB assessment: Not listed as PBT or vPVB.

12.6 Other adverse effects: No further relevant information available.

13. Disposal Considerations

13.1 Waste treatment methods

Product:

Recommendation: Dispose of waste according to applicable local, state, and federal regulations.

Uncleaned packaging:

Recommendation: Dispose of waste according to applicable local, state, and federal regulations.

Recommended cleansing agents: Water, if necessary together with cleansing agents.

14. Transport Information

This product is not subject to official transport regulations.

14.1 UN number

None

14.2 UN proper shipping name

None

14.3 Transport hazard class(es)

None

<u>14.4 Packing group</u>	None
<u>14.5 Environmental hazards</u>	None
<u>14.6 Special precautions for user</u>	Not applicable
<u>14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code</u>	Not applicable

15. Regulatory Information

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

1907/2006/EC	Registration, evaluation and authorization of chemicals regulation (REACH)
1272/2008/EC	Classification, labelling and packaging regulation (CLP, globally harmonized system GHS) replaces 67/548/EEC and 1999/45/EC amending 1907/2006/EC
2016/1179/EU	Commission regulation amending Regulation (EC) 1272/2008
453/2010/EC	Compilation of safety data sheets regulation (SDS), amending 1907/2006/EC

Further regulations, restrictions and prohibition ordinances:

Substance of very high concern (SVHC) according to EG 1907/2006 (REACH): N-Methyl-2-pyrrolidone (CAS 872-50-4).

Calculated acute toxicity according to 1272/2008/EC Annex I: 65.000 mg/kg bodyweight, no classification (refer to section 16).

Classified as not water-hazardous according to 1272/2008/EC and WGK1 according to VwVwS.

15.2 Chemical safety assessment

No data available.

16. Other Information

Hazard statements according to GHS used in this Safety Data Sheet

H300:	Fatal if swallowed
H310:	Fatal in contact with skin
H330:	Fatal if inhaled
H373:	May cause damage to organs through prolonged or repeated exposure
H400:	Very toxic to aquatic life
H410:	Very toxic to aquatic life with long lasting effects
H290:	May be corrosive to metals
H314:	Causes severe skin burns and eye damage

Pankrin ELISA
(BS-86-02)

H315: Causes skin irritation
H319: Causes serious eye irritation
H335: May cause respiratory irritation
H360D: May damage the unborn child

Categories of Acute Toxicity according to 1272/2008/EC:

Category 1	$0 < ATE \leq 5$	(oral in mg/ml bodyweight)
Category 2	$5 < ATE \leq 50$	(oral in mg/ml bodyweight)
Category 3	$50 < ATE \leq 300$	(oral in mg/ml bodyweight)
Category 4	$300 < ATE \leq 2.000$	(oral in mg/ml bodyweight)