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:* Pancreatic Elastase ELISA  
*Product Code:* BS-86-01

*Kit Components:*
1. Microtiterplate
2. Standard Range (4 or 5 vials)
3. Controls
4. Substrate Solution
5. Stop Solution
6. Washing Solution (10x concentrated)
7. Extraction Buffer (10x concentrated), optionally
8. Biotinylated Elastase Antibody
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 in feces 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.: +49-30 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

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The Substrate Solution has to be marked as follows:

Pictogram
Signal wording           Danger!
Risk phrase             Reproductive toxicant Repr. 1B
Hazard warnings         H360D: May damage the unborn child
Precautionary statements 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:

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS No. (EC-No.)</th>
<th>Amount in mixture</th>
<th>Classification according to Regulation (EC) No. 1272/2008 [CLP]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard Range, Controls</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sodium azide</td>
<td>26628-22-8</td>
<td>&lt; 0,05 % w/w</td>
<td>Acute Tox. 2, Aquatic Acute 1, Aquatic Chronic 1</td>
</tr>
<tr>
<td></td>
<td>(247-852-1)</td>
<td></td>
<td>H300, H400, H410</td>
</tr>
<tr>
<td>Biotinylated Elastase Antibody</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thiomersal</td>
<td>54-64-8</td>
<td>&lt; 0,05 % w/w</td>
<td>Acute Tox. 2, Aquatic Chronic 1</td>
</tr>
<tr>
<td></td>
<td>(200-210-4)</td>
<td></td>
<td>H300, H310, H330, H373, H410</td>
</tr>
<tr>
<td>Stop Solution</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sulphuric acid</td>
<td>7664-93-9</td>
<td>&lt; 5 % w/w</td>
<td>Skin Corr. 1A</td>
</tr>
<tr>
<td></td>
<td>(231-639-5)</td>
<td></td>
<td>H314, H290</td>
</tr>
<tr>
<td>Substrate Solution</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>N-Methyl-2-pyrrolidone</td>
<td>872-50-4</td>
<td>&lt; 5 % w/w</td>
<td>Repr. 1B, Skin Irrit. 2, Eye Irrit. 2</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>H315, H319, H360D, H335</td>
</tr>
</tbody>
</table>

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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.

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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

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS No. (EC-No.)</th>
<th>MAK acc. to TRGS 900</th>
<th>BGW acc. to TRGS 903</th>
</tr>
</thead>
<tbody>
<tr>
<td>N-Methyl-2-pyrrolidon</td>
<td>872-50-4</td>
<td>82 mg/m³</td>
<td>150 mg/l Urin am Schichtende, Parameter: 5-Hydroxy-N-Methyl-2-</td>
</tr>
</tbody>
</table>

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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

<table>
<thead>
<tr>
<th>Kit component</th>
<th>Standard Range, Controls, Biotinylated Elastase Antibody, Streptavidin-Peroxidase Conjugate</th>
<th>Washing Buffer (10x), Extraction Buffer (10x)</th>
<th>Substrate Solution</th>
<th>Stop Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) Appearance:</td>
<td>Physical state (solid liquid, gas) Colour</td>
<td>Liquid, diverse colours</td>
<td></td>
<td></td>
</tr>
<tr>
<td>b) Odour</td>
<td>Not determined</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>c) Odour threshold</td>
<td>Not determined</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>d) pH</td>
<td>7.2 – 7.6, 6.5 – 7.1</td>
<td>3.6 – 3.8, &lt; 1.0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>e) Melting point / freezing point</td>
<td>0°C</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>f) Initial boiling point and boiling range</td>
<td>100°C</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>g) Flash point</td>
<td>Not applicable</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>h) Evaporation rate</td>
<td>Not determined</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>i) Flammability (solid, gas)</td>
<td>Not applicable</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>j) Upper/lower flammability or explosive limits</td>
<td>Not determined</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>k) Vapour pressure</td>
<td>Not determined</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>l) Vapour density</td>
<td>Not determined</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>m) Relative density</td>
<td>Not determined</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>n) Solubility</td>
<td>Not determined</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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### 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:

<table>
<thead>
<tr>
<th>Kit component</th>
<th>Type</th>
<th>Value</th>
<th>Species</th>
</tr>
</thead>
<tbody>
<tr>
<td>N-Methyl-2-pyrrolidone (Substrate solution)</td>
<td>LD$_{50}$ (oral)</td>
<td>3598 mg/kg</td>
<td>Rat</td>
</tr>
<tr>
<td></td>
<td>LD$_{50}$ (inhalation)</td>
<td>&gt; 5,1 mg/l</td>
<td>Rat</td>
</tr>
<tr>
<td></td>
<td>LD$_{50}$ (dermal)</td>
<td>5000 mg/kg</td>
<td>Rat</td>
</tr>
</tbody>
</table>

(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.

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12. Ecological Information

12.1 Toxicity:

N-Methyl-2-pyrrolidone:

<table>
<thead>
<tr>
<th>Species</th>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bluegill (Lepomis macrochirus)</td>
<td>LC50 (mg/l/96h)</td>
<td>832</td>
</tr>
<tr>
<td>Ide (Leuciscus idus)</td>
<td>LC50 (mg/l/96h)</td>
<td>&gt; 500</td>
</tr>
<tr>
<td>Green algae</td>
<td>IC50 (mg/l/72h)</td>
<td>&gt; 500</td>
</tr>
<tr>
<td>Invertebrates (Daphnia magna)</td>
<td>EC50 (mg/l/48h)</td>
<td>4897</td>
</tr>
</tbody>
</table>

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

14.4 Packing group
None

14.5 Environmental hazards
None

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14.6 Special precautions for user
Not applicable

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
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)
- 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
- H315: Causes skin irritation
- H319: Causes serious eye irritation

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H335: May cause respiratory irritation
H360D: May damage the unborn child

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

<table>
<thead>
<tr>
<th>Category</th>
<th>ATE Range</th>
<th>(oral in mg/ml bodyweight)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Category 1</td>
<td>$0 &lt; ATE \leq 5$</td>
<td></td>
</tr>
<tr>
<td>Category 2</td>
<td>$5 &lt; ATE \leq 50$</td>
<td></td>
</tr>
<tr>
<td>Category 3</td>
<td>$50 &lt; ATE \leq 300$</td>
<td></td>
</tr>
<tr>
<td>Category 4</td>
<td>$300 &lt; ATE \leq 2.000$</td>
<td></td>
</tr>
</tbody>
</table>