

CE-Immundiagnostika GmbH

# Safety Data Sheet

Decree EC No. 2015/830

Produkt | Product

**REF**

**37110 romelin solution**

Karl-Landsteiner-Strasse 6 69151 Neckargemuend  
16.5.2022

According to decree (EC) 1907/2006 (REACH) with update (EC) 2015/830,  
And 1272/2008 (CLP)

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**01 Identifikation of product and company****1.1 Product name:****Bromelin solution****Reference No.:****37110****Kit components:**

A 10 ml glass vial with dropper contain  
Bovine albumin 30% diluted in a solution of  
buffer, salts and macromolecular  
potentiators.

**1.2 Intended use:**

In vitro diagnostic use,  
Test reagent ready for use in the blood  
group serology as potentiator for better  
results by the recommended techniques in  
the information for use described.

**1.3. Company:**

CE-Immundiagnostika GmbH  
Karl-Landsteiner-Strasse 6  
69151 Neckargemuend  
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eMail: [info@ce-immundiagnostika.com](mailto:info@ce-immundiagnostika.com)**1.4 In emergencies**

Call your local emergency center.

**02 Componentes and hazard ingredients****Reagent Composition:**

Bromelin solution

**Hazard ingredient:**

Bromelin

**CAS-No.:**

9001-00-7

**EINECS-No.:**

-

**03 Hazard identification**

N/A

**04 First-Aid-Measure****Eye contact:**

- Immediately flush eyes with plenty of water  
the eyelids open. Remove contact

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**Skin contact:**

**After inhalation:**

**After ingestion:**

- lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get
- medical advice/attention
- Wipe off affected area and flush with plenty of soap and water.
- Remove from exposure. Remove victim to fresh air and keep at rest in a position comfortable for breathing. Keep warm and at rest. Get medical advice/attention if you feel unwell.
- Rinse mouth and drink plenty of water. In case of indisposition seek medical advice..

**05 Measure to fire fight**

**Suitable extinguishing media:**

- Non-flammable. As appropriate for surrounding fire. Water spray, foam, dry powder or CO<sub>2</sub>.

**Unsuitable extinguishing media:**

- Do not use water jet. Direct water jet spread the fire.

**Special exposure hazards:**

- Not known

**Instructions:**

- Fight fire with normal precautions from a reasonable distance

**Special protective equipment for Firefighters:**

- Heat / fire exposure: compressed air / oxygen apparatus
- Heat / fire exposure: gas-tight suit

**06 Accidental release measures**

**Personal protection:**

See point 8

**Environmental precautions:**

- Prevent soil and water pollution
- Substance must not be discharged into the sewer.
- Contain leaking substance, pump over in suitable containers.
- Plug the leak, cut off the supply.
- Dam up the liquid spill

**Clean-up:**

- Take up liquid spill into absorbent material.
- Scoop absorbed substance into closing containers.
- Carefully collect the spill /leftovers.

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- Clean contaminated surfaces with an excess of water.
- Wash clothing and equipment after handling.
- 

## 07 Handling and storage

### Handling:

- Observe normal hygiene standards.
- Do not discharge the waste into the drain.
- Remove and clean contaminated clothing.

### Storage:

- Provide for a tub to collect spills.
- Meet the legal requirements.
- Keep away from: heat sources, acids
- Storage temperature: +2 to +8°C, see component label

### Specific purpose:

- NA

## 08 Exposure controls / personal protection

### 8.1 Exposure to persons

#### Respiratory protection:

Insufficient ventilation:  
wear respiratory protection

#### Hand protection:



gloves

#### Eye Protection:



Eye protection

#### Skin protection:



Protective clothing

### 8.2 Exposures to environment

#### Aquatic classification:

Toxic to aquatic organisms

#### Ozone Classification:

No data available

#### The substance is considered as not bioaccumulative:

LogPow= NA

BCF= NA

No readily degradable.

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**09 Physical and chemical properties**

Appearance:	Liquid
Color:	colorless
Odeur:	Odeurless
Odeur threshold:	Not established
pH-Value:	4.0 – 4.5 (25°C)
Initial boiling point and boiling range:	Not established
Melting point / Freezing point:	Not established
Flash point:	Not established
Evaporation rate:	Not established
Flammability:	Not established
Upper/lower flammability or explosive limits:	Not applicable
Vapour density:	Not established
Relative density:	Not established
Vapour pressure:	Not established
Specific gravity:	Not established
Solubility:	Miscible with water
Auto-ignition temperature:	Not established
Decomposition temperature:	Not established
Viscosity:	Not established
Explosive properties:	Not established
Oxidising properties:	Not oxidizing

No other information available.

**10 Stability and reactivity**

<b>Stability:</b>	The component is stable until expiry date if stored in specified conditions (see label)
<b>Reactivity / Hazardous decomposition products:</b>	No hazardous decomposition products are formed in high quantities.
<b>Conditions/Materials to avoid:</b>	N/A

**11 Toxicology declaration**

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

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classification

criteria are

not met.

Acute

Toxicity

Estimate Mixture Calculation:

Estimate Mixture Calculation: LD50 >5000 mg/kg bw/day

LD50 >5000 mg/kg bw/day

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

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Estimate Mixture Calculation: LD50 >20 mg/l.

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Skin Contact Based on available data, the classification criteria are not met. Acute Toxicity

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Estimate Mixture Calculation: LD50 >2000 mg/kg bw/day

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Skin corrosion/irritation Based on available data, the

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Serious eye damage/irritation  
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classification criteria are not  
met.

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## 12 Ecological information

### Aquatic toxicity

Sodium azide:

Effect dose/ -concentration	Value	Test duration	Species
LC 50	100.0 mg/L	96 h	Salmo gairdneri / oncorhynchus mykiss
LC 50	0.7 mg/L	96 h	Lepomis macrochirus
LC 50	9.0 mg/L	48 h	Gammarus sp.

### Other information

Effect on the ozone layer:	Not dangerous for the ozone layer (1999/45/EC)
Greenhouse effect:	No data available.
Effect on wastewater purification:	No data available.

## 13 waste disposal considerations

Provisions relating to waste:

Hazardous waste (91/689/EEC)

Packaging / container:

Waste material code packaging (91/689/EEC, Council Decision 2001/118/EC, O.J. L47 of 16/2/2001): 15 01 10 (packaging containing residues of or contaminated by dangerous substances).

Disposal methods:

- The component must be considered as hazardous waste. It should be disposed of following local regulations.
- Sodium azide reacts with lead and copper plumbing

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forming highly explosive  
metal azides.

#### 14 Transport information

The reagent have to be handled with care.

	ADR/RID	IMDG	IATA/ICAO
<b>UN number</b>	None assigned.	None assigned.	None assign
<b>UN proper shipping name</b>	None assigned.	None assigned.	None assign
<b>Transport hazard class(es)</b>	None assigned.	None assigned.	None assign
<b>Packing group</b>	None assigned.	None assigned.	None assign
<b>Environmental hazards</b>	Not classified.	Not classified.	Not classifie
<b>Special precautions for user</b>	See Section: 2		
<b>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>	Not applicable.	Not applicable.	Not applicab
<b>Additional Information</b>	None.		

#### 15 Regulatory information

Labelling according to EU Dangerous Substances Regulations.

<b>Symbol(s):</b>	None
<b>Risk phrases:</b>	None
<b>Safety phrases:</b>	None
<b>German regulations:</b>	Warter hazard class: 1

„ Not classified as hazardous product. “

#### 16 Other notification

This product is designed for use by professionals.

The material from animal source included in this kit are considered and judged to be free from risk of BSE / CJD and other zoonoses based on:

The use of BSA from sources in non-BSE countries (certificate available). But the handling of reagent, serum or plasma specimens should be in accordance with the local safety procedure.

**References:** Existing Safety Data Sheet (SDS). Existing ECHA registration for Sodium Azide (CAS No. 26628-22-8).



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**Training advice:** Consideration should be given to the work procedures involved and the potential extent of exposure as they may determine whether a higher level of protection is required.

#### Disclaimers

Customers are urged to ensure that the product is entirely suitable for their own purpose. It is the customers' responsibility to ensure that a suitable and sufficient assessment of the risks created by the use of the product is undertaken. The use of the reagent and the interpretation of results must be carried out by properly trained and qualified personnel in accordance with the requirements of the country where the reagent is in use.

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**SDS date of creation:** 2022.05; **update:**