CE-Immundiagnostika GmbH

# Safety Data Sheet

Decree EC No. 2015/830

Produkt | Product

REF 23102_05 Anti-N

Clone: 1422C7

Karl-Landsteiner-Strasse 6 69151 Neckargemuend

6.8.2021

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

| | |
|---|---|
| Safety data sheet number: | 231 |
| Revision: | 00 |
| Date: 06.08.2021 | page **1** von **7** |

## 01 Identifikation of product and company

### 1.1 Product name:

**Anti-N Clone: 1422C7**

**Reference No.:**

**23102; 23105**

**Kit components:**

A 2 or 5 ml glass vial with dropper contain monoclonal antibody N (1422C7) diluted in a solution of bovine serum albumin, buffer, salts and macromolecular potentiators.

### 1.2 Intended use:

In vitro diagnostic use,
Test reagent ready for use in the identification of blood group characteristic Antigen N by the recommended techniques in the information for use described.

### 1.3 Company:

CE-Immundiagnostika GmbH
Karl-Landsteiner-Strasse 6
69151 Neckargemuend
GERMANY

Phone: + 49 (0)6223 80 09 400
Fax: + 49 (0)6223 80 09 499
eMail: info@ce-immundiagnostika.com

### 1.4 In emergencies

Call your local emergency center.

## 02 Componenets and hazard ingredients

**Reagent Composition:** Anti-N is a monoclonal reagent.

| | | |
|---|---|---|
| **Hazard ingredient:** | Material from animal origin. | < 0.1 % Sodium Azide ($NaN_3$) |
| **CAS-No.:** | - | 26628-22-8 |
| **EINECS-No.:** | - | 247-852-1 |

## 03 Hazard identification

Material from animal origin is potentially infectious.
Sodium Azide is a toxic substance.

Avoid contact with components.

## 04 First-Aid-Measure

**Eye contact:**
- Rinse immediately with water.
- Do not apply neutralizing agents.
- Consult a doctor / medical service

**Skin contact:**
- Rinse with water.
- Consult a doctor / medical service if irritation persists.

**After inhalation:**
- Remove the victim into fresh air.
- Unconscious: maintain adequate airway and respiration.
- Consult a doctor / medical service if breathing problems develop.

**After ingestion:**
- Rinse mouth and drink plenty of water.
- Never give water to an unconscious person.
- Consult a doctor / medical service if you feel unwell.

## 05 Measure to fire fight

**Suitable extinguishing media:**
- All non-combustible extinguishing media allowed
- For surrounding fires: all extinguishing media allowed.

**Unsuitable extinguishing media:**
- Do not use water jet. Direct water jet spread the fire.

**Special exposure hazards:**
- On heating/burning: formation of small quantities of nitrous vapours, carbon monoxide, carbon dioxide

**Instructions:**
- Take account of toxic firefighting water
- Use firefighting water mederately and contain it

**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.
- 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 readly degradable.

## 09 Physical and chemical properties

| | |
|---|---|
| Appearance: | Liquid |
| Color: | colorless |
| Odeur: | Odeurless |
| Odeur threshold: | Not established |
| pH-Value: | 8.3 – 8.9 (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 avaible.

## 10 Stability and reactivity

**Stability:** The component is stable until expiry date if stored in specified conditions (see label)

**Reactivity / Hazardous decompositions products:** No hazardous decomposition products are formed in high quantities.

**Conditions/Materials to avoid:** Keep away from metals and acids (Component contains azide).

## 11 Toxicology declaration

**Sodium Azide:**

**Toxicity and effects**

| | | |
|---|---|---|
| **Acute toxicity:** | LD 50 oral rat | 27 ml/kg |
| | LD 50 dermal rabbit | 20 mg/kg |
| **Acute effects:** | Harmful if swallowed. | |
| **Chronic toxicity:** | Carcinogenicity (TLV) | A4 |

**Routes of exposure**

Ingestion, inhalation, eyes and skin

⚠ Caution!

These components contain a substance that is absorbed through the skin (sodium azide).

## 12 Ecological information

**Aquatic toxicity**

Sodium azide:

| Effect dose/ -concentration | Value | Test duration | Species |
|---|---|---|---|
| LC 50 | 0.8 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.<br>- Sodium azide reacts with lead and copper plumbing forming highly explosive metal azides. |

## 14 Transport information

The reagent have to be handled with care.

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

## 15 Regulatory information

Labelling according to EU Dangerous Substances Regulations.

| | |
|---|---|
| **Symbol(s):** | None |
| **Risk phrases:** | None |
| **Safety phrases:** | None |
| **German regulations:** | 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).
This Safety Data Sheet was prepared in accordance with EC Regulation (EC) 1907/2006 (REACH),updated (EC) 2015/830 and (EC) 1272/2008 (CLP)

**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.

The information supplied here is based on data considered accurate and on our current state of knowledge. No warranty is expressed or implied regarding the accuracy of this data. Liability is expressly disclaimed for loss or injury arising out of use of this information or the use of any materials designated. It does not establish any contractual relationship.

**SDS date of creation:** 2021.08; **update:**