

CE-Immundiagnostika GmbH

Safety Data Sheet

Decree EC No. 2015/830

Produkt | Product

REF Kel-coom-0005-xx
Anti-Kell
coombsreactive

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

Safety data sheet number:

103V

Revision:

00

Date: 01.07.2021

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01 Identifikation of product and company

1.1 Product name:

Anti-Kell coombsreactive

Reference No.:

Kel-coom-0005-xx

Kit components:

A 5 or 10 ml glass vial with dropper contain monoclonal antibody Kell coombsreactive 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 K by the recommended techniques in the information for use described.

1.3 Company:

CE-Immundiagnostika GmbH
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69151 Neckargemuend
GERMANY

Phone: + 49 (0)6223 80 09 400

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1.4 In emergencies

Call your local emergency center.

02 Componentes and hazard ingredients

Reagent Composition:

Anti-Kell is a coombsreactive reagent.

Hazard ingredient:

Material < 0.1 % Sodium Azide (NaN₃)
from
animal
origin.

CAS-No.:

- 26628-22-8

EINECS-No.:

- 247-852-1

03 Hazard identification

Material from animal origin is potentially infectious.

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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 moderately and contain it
- Special protective equipment for Firefighters:**
- Heat / fire exposure: compressed air / oxygen apparatus
 - Heat / fire exposure: gas-tight suit

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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

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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.

09 Physical and chemical properties

Appearance:	Liquid
Color:	Yellowish to brownish
Odeur:	Odeurless
Odeur threshold:	Not established
pH-Value:	6.6 – 7.8 (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

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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.

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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 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.

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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.

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