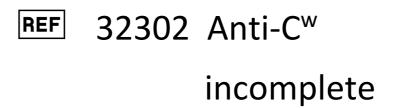


CE-Immundiagnostika GmbH

Safety Data Sheet

Decree EC No. 2015/830

Produkt | Product





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:

Reference No.:

Anti-Cw incomplete

32302; 32305

Kit components:

A 2 or 5 ml glass vial with dropper contain antibody Cw incomplete 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 s 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: <u>info@ce-immundiagnostika.com</u>

1.4 In emergencies

Call your local emergency center.

02 Componenets and hazard ingredients

Reagent Composition: Anti-Cw 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.

Sodium Azide is a toxic substance.



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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



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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

- 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

Clean-up:

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 readly degradable.

09 Physical and chemical properties

Appearance: Liquid

Color: Yellowish to brownish

Odeur: Odeurless

Odeur threshold: Not established pH-Value: $6.7 - 7.9 (25^{\circ}C)$ Initial boiling point and boiling range: Not established Melting point / Freezing point: Not established Flash point: Not established Not established **Evaporation rate:** Flammability: Not established Upper/lower flammability or explosive limits: Not applicable Not established Vapour density: Not established Relative density: Not established Vapour pressure: Not established Specific gravity: Solubility: Miscible with water Auto-ignition temperature: Not established Decomposition temperature: Not established Viscosity: Not established Not established Explosive properties: 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)



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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 LD 50 oral rat

27 ml/kg

toxicity:

LD 50 dermal rabbit 20 mg/kg

Acute Harmful if swallowed.

effects:

Chronic Carcinogenicity (TLV) A4

toxicity:

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 Not dangerous for the ozone layer

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):NoneRisk phrases:NoneSafety 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: