

**1. INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY**

- 1.1. Product name Matrix Rh Phenotype Test Card with Anti-D
- Catalogue No. 102630024
- Kit components Matrix Rh Phenotype Card with Anti-D (24 No.), Matrix 12 card fitment (02 No.) and Package Insert (01 No.)
- 1.2. Intended use In-vitro Diagnostic Use.
- 1.3. Company Tulip Diagnostics (P) Ltd.
Plot Nos. 92/96, Phase II C,
Verna Industrial Estate,
Verna, Goa 403 722
INDIA
Telephone : +91-832-6624555
Fax : +91-832-2783511
E-mail : tulipvkn@sancharnet.in
- 1.4. In emergencies Call your local emergency center

2. COMPONENTS AND HAZARDOUS INGREDIENTS

CARD COMPOSITION	HAZARDOUS INGREDIENT	EINECS NR.
Matrix gel card with six microtubes containing specific Monoclonal Anti-C, Anti-c, Anti-D(IgM), Anti-E, Anti-e and Neutral reagent in appropriate positions.	Material from animal origin < 0.1 % Sodium azide (NaN ₃)	- 247-852-1

3. HAZARDS IDENTIFICATION

Material from animal origin is potentially infectious.

Sodium Azide is a toxic substance. Avoid contact with components.

4. FIRST AID MEASURES

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: - Never give water to an unconscious person

- Consult a doctor/medical service if you feel unwell



5. FIRE FIGHTING MEASURES

- Suitable extinguishing media:* - All non-combustible extinguishing media allowed
- For surrounding fires: all extinguishing media allowed
- Unsuitable extinguishing media:* - No data available
- 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

6. ACCIDENTAL RELEASE MEASURES

Personal protection: see 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

7. 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: see component label

Specific purposes:

- NA

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Exposure to persons

Respiratory Protection - Insufficient ventilation: wear respiratory protection

Hand Protection - Gloves

Eye Protection - Face shields

Skin Protection - Protective Clothing



8.2 Exposure to environment

Aquatic Classification: Toxic to aquatic organisms.
Ozone Classification: No data available
The substance is considered as not bioaccumulative: Log Pow = NA
BCF = NA
Not Readily degradable

9. PHYSICAL AND CHEMICAL PROPERTIES

Monoclonal Anti-C (Colourless Reagent), Anti-c (Colourless Reagent), Anti-D (Colourless Reagent), Anti-E (Colourless Reagent) ,Anti-e(Colourless Reagent) and Neutral reagent (colourless) within the Gel Matrix.

10. STABILITY AND REACTIVITY

Stability: The component is stable until expiry date if stored in specified conditions (see label)
Reactivity/Hazardous decomposition products: No hazardous decomposition products are formed in high quantities
Conditions/Materials to avoid: Keep away from metals and acids (Component contains azide)

11. TOXICOLOGICAL INFORMATION

Sodium Azide:

Toxicity and effects

Acute toxicity: LD50 oral rat : 27 mg/kg
LD50 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: - LC50 (96 h) : 0.8 mg/l (SALMO GAIRDNERI/ONCORHYNCHUS MYKISS)
- LC50 (96 h) : 0.7 mg/l (LEPOMIS MACROCHIRUS)
- LC50 (48 h) : 9 mg/l (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 forming highly explosive metal azides.

14. TRANSPORT INFORMATION

To be handled with care and keep in upright position.

15. OTHER INFORMATION

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 local safety procedure.

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