

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

- 1.1 Product name IMMUTEX
- Catalogue No. 10810020
- Kit components Immutex Reagent (Stabilized Horse Erythrocytes)  
Positive Control  
Negative Control  
Six Circle Glass Slide  
Sample Droppers  
Mixing Stick Ladder  
Rubber Teat  
Package Insert
- 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](mailto:tulipvkn@sancharnet.in)
- 1.4 In emergencies Call your local emergency center

**2. COMPONENTS AND HAZARDOUS INGREDIENTS**

KIT COMPONENT	HAZARDOUS INGREDIENT	CLASSIFICATION SUBSTANCE	EINECS NR.
IMMUTEX RREAGENT	Material from animal origin	T+; R28-32 N; R50-53	247-852-1
POSITIVE CONTROL	0.1 % Sodium azide (NaN <sub>3</sub> )	T+; R28-32 N; R50-53	247-852-1
NEGATIVE CONTROL	Material from animal origin 0.1 % Sodium azide (NaN <sub>3</sub> )	T+; R28-32 N; R50-53	247-852-1

**3. HAZARDS IDENTIFICATION**

According to 1999/45/EG, the preparation is classified as dangerous.

CLASSIFICATION PREPARATION	RISKS
Xn; R22	Harmful if swallowed Human material is potentially infectious

#### **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 vapors, 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



## 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 waste water purification: No data available

### 12.1.1. 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.

### 13. TRANSPORT INFORMATION

No restrictions.

### 14. REGULATORY INFORMATION

Classification according to directives 67/548/EEC, 1999/45/EC.

Contains sodium azide

Xn



Harmful

- R22: Harmful if swallowed  
S23: Do not breathe vapour  
S46: If swallowed, seek medical advice immediately and show this container or label  
S61: Avoids release to the environment. Refer to special instructions/safety data sheets.

### 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 and Horse erythrocytes 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.

Risk phrases referred to in paragraph 2 & 3:

- R22: Harmful if swallowed  
R28: Very toxic if swallowed  
R32: Contact with acids liberates very toxic gas  
R50: Very toxic to aquatic organisms  
R53: May cause long-term adverse effects in the aquatic environment

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