

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

- 1.1. Product Name HEV IgM (Rapid Immunochromatographic Assay for the detection of IgM antibodies to HEV in human serum/plasma)
- Catalogue no. 10502010
- Kit components Device Membrane Assembly in sealed aluminium pouch
- 1.2. Intended use In Vitro Diagnostic Use.
- 1.3. Company **Tulip Diagnostics (P) Ltd.**  
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INDIA.  
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- 1.4. In emergencies Call your local emergency center

**COMPONENTS AND HAZARDOUS INGREDIENTS**

| Kit Component | HAZARDOUS INGREDIENT  | CLASSIFICATION SUBSTANCE | EINECS NR. |
|---------------|---|--------------------------|------------|
| Antibody      | Material from animal origin<br>0.095 % Sodium azide (NaN <sub>3</sub> ) | T+; R28-32<br>N; R50-53  | 247-852-1  |

**HAZARDS IDENTIFICATION**

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

| CLASSIFICATION PREPARATION | RISKS  |
|----------------------------|--|
| Xn; R22                    | Harmful if swallowed<br>Human material is potentially infectious |

**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

**FIRE FIGHTING MEASURES**

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

**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

**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

**EXPOSURE CONTROLS/PERSONAL PROTECTION****8.1 Exposure limits****Sodium Azide:**

|                 | mg/m <sup>3</sup>        | ppm                     |
|-----------------|--------------------------|-------------------------|
| TLV-TWA         | -                        | -                       |
| TLV-STEL        | -                        | -                       |
| TLV-Ceiling     | 0.29 (NaN <sub>3</sub> ) | 0.11 (HN <sub>3</sub> ) |
| OES-LTEL        | -                        | -                       |
| OES-STEL        | 0.3 (NaN <sub>3</sub> )  | -                       |
| MAK             | 0.2                      |                         |
| TRK             |                          |                         |
| MAC-TGG 8h      |                          |                         |
| MAC-TGG 15min   |                          |                         |
| MAC-Ceiling     | 0.3                      |                         |
| VMA 8h          | -                        | -                       |
| VMA 15min       | 0.3                      | 0.1                     |
| GWBB 8h         | -                        | -                       |
| GWBB 15min      | -                        | -                       |
| Momentary value | 0.29                     | 0.11                    |
| EC              | 0.1                      | -                       |
| EC-STEL         | 0.3                      | -                       |

**8.2 Control of Exposure****8.2.1 Exposure to persons**

- Respiratory Protection* - Insufficient ventilation: wear respiratory protection
- Hand Protection* - Gloves
- Eye Protection* - Face shields
- Skin Protection* - Protective Clothing

**8.2.2 Exposure to environment**

Aquatic Classification: N; R50-53 Very toxic to aquatic organisms.  
May cause long term adverse effects in the aquatic environment

Ozone Classification: No data available

The substance is considered as not bio accumulative: Log Pow = NA  
BCF = NA

Not Readily degradable

**PHYSICAL AND CHEMICAL PROPERTIES**

Antibody : Device membrane test assembly impregnated with HEV antigen colloidal gold conjugate.

**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)

**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).

**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

**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:*

- It should be disposed of following established safety procedures and local regulations.
- 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.

**TRANSPORT INFORMATION**

No restrictions.

**REGULATORY INFORMATION**

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

Contains 0.095% sodium azide

**OTHER INFORMATION**

This product is designed for use by professionals.

The animal source material included in this kit are considered to be free from risk for BSE/CJD & other zoonoses and judged to be non-existent based on:

The material used from animal origin are sources from non – BSE countries (Certificate available). But, handling of reagents, serum or plasma specimens should be in accordance with local safety procedures.

The human blood components included in this kit have been tested by European approved and/or FDA approved methods and found negative for HBsAg, anti-HCV and anti-HIV-1 and 2. No known method can offer complete assurance that human blood derivatives will not transmit hepatitis, AIDS or other infections. Therefore, handling of reagents, serum or plasma specimens should be in accordance with local safety procedures.

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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