MATERIAL SAFETY DATA SHEET
(According to 2001/58/EC)
Product: HEV IgM (Rapid Immunochromatographic Assay for the detection of IgM antibodies to HEV in human serum/plasma)
Doc. No.: MSDS/912

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.
Unit II, First Floor,
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

COMPONENTS AND HAZARDOUS INGREDIENTS

<table>
<thead>
<tr>
<th>Kit Component</th>
<th>HAZARDOUS INGREDIENT</th>
<th>CLASSIFICATION SUBSTANCE</th>
<th>EINECS NR.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antibody</td>
<td>Material from animal origin</td>
<td>T+; R28-32 N; R50-53</td>
<td>247-852-1</td>
</tr>
<tr>
<td>0.095 % Sodium azide (NaN₃)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

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 develope

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
- 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

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

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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

<table>
<thead>
<tr>
<th>Sodium Azide:</th>
<th>mg/m³</th>
<th>ppm</th>
</tr>
</thead>
<tbody>
<tr>
<td>TLV-TWA</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>TLV-STE (0.29 (NaN₃))</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TLV-Ceiling</td>
<td>0.29 (NaN₃)</td>
<td>0.11 (HN₃)</td>
</tr>
<tr>
<td>OES-LTEL</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>OES-STE (0.3 (NaN₃))</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MAK</td>
<td>0.2</td>
<td>-</td>
</tr>
<tr>
<td>TRK</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>MAC-TGG 8h</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>MAC-TGG 15min</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>MAC-Ceiling</td>
<td>0.3</td>
<td>-</td>
</tr>
<tr>
<td>VMA 8h</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>VMA 15min</td>
<td>0.3</td>
<td>0.1</td>
</tr>
<tr>
<td>GWBB 8h</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>GWBB 15min</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Momentary value</td>
<td>0.29</td>
<td>0.11</td>
</tr>
<tr>
<td>EC</td>
<td>0.1</td>
<td>-</td>
</tr>
<tr>
<td>EC-STE (0.3)</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

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.
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


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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