1 INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

1.1. Product name
Fibroquant

Catalogue No.
10641020

Kit components

<table>
<thead>
<tr>
<th>Kit</th>
<th>(1) Bovine Thrombin Reagent.</th>
</tr>
</thead>
<tbody>
<tr>
<td>(2) Lyophilised Human Fibrinogen Calibrator.</td>
<td></td>
</tr>
<tr>
<td>(3) Owren’s Buffer.</td>
<td></td>
</tr>
<tr>
<td>(4) Package Insert.</td>
<td></td>
</tr>
<tr>
<td>(5) Graph Paper.</td>
<td></td>
</tr>
</tbody>
</table>

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 : tulipykn@sancharnet.in

1.4. In emergencies
Call your local emergency center

2 COMPONENTS AND HAZARDOUS INGREDIENTS

<table>
<thead>
<tr>
<th>Kit Component</th>
<th>INGREDIENT</th>
<th>EINECS NR.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bovine Thrombin Reagent.</td>
<td>Material from animal origin.</td>
<td></td>
</tr>
<tr>
<td>Lyophilised Human Fibrinogen Calibrator.</td>
<td>Material from human origin.</td>
<td>200-210-4</td>
</tr>
<tr>
<td>Owren’s Buffer</td>
<td>0.01 % Thimerosal.</td>
<td></td>
</tr>
</tbody>
</table>

3 HAZARDS IDENTIFICATION

Data unavailable.
4 FIRST AID MEASURES

Eye contact: - Rinse immediately with water for at least 15 minutes. Assure adequate flushing by separating the eyelids with fingers.
- 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
- Wash out mouth with water provided person is conscious.
- Do not induce vomiting
- 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
- Storage temperature: see component label

Specific purposes:  - NA

8 EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Exposure limits
Data unavailable.

8.2 Control of Exposure
Provide sufficient ventilation

8.2.1 Exposure to persons

Respiratory Protection  - Insufficient ventilation: wear respiratory protection
Hand Protection  - Gloves – compatible chemical resistant gloves
Eye Protection  - Face shields
Skin Protection  - Protective Clothing

8.2.2 Exposure to environment

Aquatic Classification:  Data unavailable.

Ozone Classification:  Data unavailable

The substance is considered as not bioaccumulative:  Data unavailable

9 PHYSICAL AND CHEMICAL PROPERTIES

Fibroquant:  White lyophilised thrombin reagent powder, pale yellow cake-form lyophilised
human fibrinogen calibrator and owren’s buffer which is a liquid form.

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

11 TOXICOLOGICAL INFORMATION

**Toxicity and effects**
*Acute toxicity:* Data unavailable

*Chronic toxicity:* Data unavailable

**Routes of exposure**
Ingestion, inhalation, eyes and skin

12 ECOLOGICAL INFORMATION

**Aquatic toxicity**
Data unavailable

**Other information**
- Effect on the ozone layer: Data unavailable
- Greenhouse effect: Data unavailable
- Effect on waste water purification: Data unavailable

13 WASTE DISPOSAL CONSIDERATIONS

**Provisions relating to waste:** Data unavailable

**Disposal methods:**
The human fibrinogen calibrator is potentially infectious. It should be disposed of following local regulations.

14 TRANSPORT INFORMATION

No restrictions.

15 REGULATORY INFORMATION

Data unavailable
OTHER INFORMATION

This product is designed for use by professionals.

The human source 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 completed assurance that human blood derivative will not transmit hepatitis, AIDS or other infections. Therefore, handling of reagents, serum or plasma specimens should be in accordance with local safety procedures.

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.
Therefore, handling of reagents, serum or plasma specimens should be in accordance with local safety procedures.

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