1. INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

1.1 Product name: Erygen-ABO

Catalogue No.: 101950032

Kit components: Erygen-ABO

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: sales@tulipgroup.com

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>CAS NUMBER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Erygen-A1</td>
<td>Material from human origin</td>
<td></td>
</tr>
<tr>
<td>Erygen-B</td>
<td>Chloramphenicol</td>
<td></td>
</tr>
<tr>
<td>Erygen-O</td>
<td></td>
<td>56-75-7</td>
</tr>
</tbody>
</table>

3. HAZARDS IDENTIFICATION

Not expected to be a health hazard.

Note: this product is derived from human blood which was found non reactive for HBsAg, Anti-HIV 1/2 and Anti-HCV. No known test method can offer assurances that products derived from human blood will not transmit infectious disease

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: - Rinse mouth immediately with water
- Never give water to an unconscious person
- Consult a doctor/medical service if you feel unwell
5. FIRE FIGHTING MEASURES
Not applicable.

6. ACCIDENTAL RELEASE MEASURES

Personal protection: see 8

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
- Storage temperature: see component label

Specific purposes:
- NA

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Exposure limits
None

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

9. PHYSICAL PROPERTIES

Erygen-ABO : Reagent red cell suspension

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
11. TOXICOLOGICAL INFORMATION

Routes of exposure
Ingestion, inhalation, eyes and skin

Note: This product is manufactured from human blood and therefore must be considered capable of transmitting disease.

12. ECOLOGICAL 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

13. WASTE DISPOSAL CONSIDERATIONS

Waste Disposal methods:
- The component must be considered as hazardous waste. It should be disposed of following local regulation requirements.

14. TRANSPORT INFORMATION

No restrictions.

15. REGULATORY INFORMATION

None

OTHER INFORMATION

Labelling Information: R & S phrases not applicable

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It remains the user’s own responsibility to make sure that the information is appropriate and complete for his specific use of this product. The user is also responsible for observing any laws and applicable guidelines.

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