1. INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

1.1. Product name
Rhofinal Anti-D (IgM+IgG) Monoclonal

Catalogue No.
10160005, 10160010, 10160105, 10160610, 101601000, 10191310, 10191312

Kit components
Monoclonal blood typing antibodies against D antigen.
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: 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>HAZARDOUS INGREDIENT</th>
<th>CLASSIFICATION SUBSTANCE</th>
<th>EINECS NR.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monoclonal blood typing antibodies against D antigen.</td>
<td>Material from animal origin 0.1 % Sodium azide (NaN₃)</td>
<td>T+; R28-32 N; R50-53</td>
<td>247-852-1</td>
</tr>
</tbody>
</table>

3. HAZARDS IDENTIFICATION

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

<table>
<thead>
<tr>
<th>CLASSIFICATION PREPARATION</th>
<th>RISKS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Xn; R22</td>
<td>Harmful if swallowed Human material is potentially infectious</td>
</tr>
</tbody>
</table>
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
- Storage temperature: see component label

Specific purposes:
- NA

8. 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-STEL</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-STEL</td>
<td>0.3 (NaN₃)</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-STEL</td>
<td>0.3</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.
May cause long term adverse effects in the aquatic environment
Ozone Classification: No data available
The substance is considered as not bioaccumulative: Log Pow = NA
BCF = NA
Not Readily degradable
9. PHYSICAL AND CHEMICAL PROPERTIES
Rhofinal Anti-D (IgM+IgG) Monoclonal : Colourless liquid

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

13. WASTE DISPOSAL CONSIDERATIONS


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.
MATERIAL SAFETY DATA SHEET
(According to 2001/58/EC)
Product: Rhofinal Anti-D (IgM+IgG) Monoclonal
Doc. No.: MSDS/105

14. TRANSPORT INFORMATION

No restrictions.

15. REGULATORY INFORMATION

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

Contains sodium azide

\[ \text{Xn} \]
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.

16. 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 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

The information provided on this MSDS is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text.

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.