1 INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

1.1. Product name

Turbilyte MA

Catalogue No.

11250025
11250050
11250100

Kit components

(R1) -Activation Buffer
(R2) -Latex reagent
(S) -MA Calibrator
Package Insert

1.2. Intended use

In Vitro Diagnostic Use.

1.3. Company

Tulip Diagnostics (P) Ltd.
Unit II, Ist 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

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>R1</td>
<td>0.1 % Sodium azide (NaN₃)</td>
<td>T+; R28-32 N; R50-53</td>
<td>247-852-1</td>
</tr>
<tr>
<td>R2</td>
<td>Material from Human origin</td>
<td>T+; R28-32 N; R50-53</td>
<td>247-852-1</td>
</tr>
<tr>
<td>S</td>
<td>Material from Human origin</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</th>
<th>RISKS</th>
</tr>
</thead>
<tbody>
<tr>
<td>PREPARATION</td>
<td></td>
</tr>
<tr>
<td>Xn; R22, S23-46-61</td>
<td>Harmful if swallowed</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  
- 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:
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

Sodium Azide:

<table>
<thead>
<tr>
<th></th>
<th>mg/m³</th>
<th>ppm</th>
</tr>
</thead>
<tbody>
<tr>
<td>TLV-TWA</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>TLV-STEI</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-STEI</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>
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<tr>
<td>GWBB 8h</td>
<td>-</td>
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<tr>
<td>GWBB 15min</td>
<td>-</td>
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<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>
</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

(R1) - Activation Buffer: Clear colourless liquid
(R2) - Anti-human albumin reagent: Clear colourless liquid
(S) - MA Calibrator: Clear 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
MATERIAL SAFETY DATA SHEET  
(According to 2001/58/EC)  
Product: TURBILYTE MA  
Doc. No.: MSDS/684

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

13 WASTE DISPOSAL CONSIDERATIONS


Disposal methods:  
- The positive and negative controls are potentially infectious. 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.

14 TRANSPORT INFORMATION

No restrictions.

15 REGULATORY INFORMATION

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

Contains sodium azide

Xn

R22-S23-46-61  
NaN₃  
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 human source material 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.

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.