1. INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

1.1. Product name : Factor VIII Deficient Plasma

Catalogue No.: 110500031, 110500061

Kit components : 1) Lyophilised Human Control
2) Instruction leaflet
3) Graph Paper

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
E-mail :Sales@tulipgroup.com

1.4. In emergencies : Call your local emergency center

2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture
Classification according to regulation (EC) No. 1272/2008
The mixture is classified as non hazardous according to Regulation (EC) No .1272/2008

2.2 Label elements
Labelling according to Regulation (EC) No. 1272/2008
Hazard pictogram : None
Signal word : None
Hazard statements : None

2.3 Other hazards
None

3. COMPOSITION / INFORMATION ON INGREDIENTS

Factor VIII Deficient Plasma contains : 0.01% Thimerosal (cas No -54-64-8) (EC) No. 200-210-4
The classification of (0.01%) according to regulation (EC) no1272/2008 is H317,H413.

Data unavailable

4. FIRST AID MEASURES

Eye contact : - Rinse immediately with water for atleast 15 minutes. 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*s.*
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 fire fighting water
- Use fire fighting 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 Control parameters

Does not contain substances with exposure limit values .

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

9. PHYSICAL AND CHEMICAL PROPERTIES

Factor VIII Deficient Plasma : Pale yellow cake-form lyophilized human control
Odour : not specific
Odour threshold : No data available

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.

11. TOXICOLOGICAL INFORMATION

Thimerosal

Toxicity and effects

Acute toxicity: LD50 oral rat : 75 mg/kg
LC50 : NE

Acute effects: Harmful if swallowed
Routes of exposure
Ingestion, inhalation, eyes and skin

12. ECOLOGICAL INFORMATION

Aquatic toxicity

Thimerosal : The ecological information for the dilute thimersal has not been thoroughly investigated : however mercury and its compound are expected to significantly bio accumulate .So any waste must be handled as dangerous waste

- Effect on the ozone layer : Not dangerous for the ozone layer
- Greenhouse effect : No data available

- EFFECT ON WASTE WATER PURIFICATION: NO DATA AVAILABLE

13. WASTE DISPOSAL CONSIDERATIONS

Provisions relating to waste *:* Hazardous waste (91/689/EEC).
Packaging/container *:* Waste material code packaging (91/689/EEC, Council Decision 2001/118/EC, O.J. L47 of 16/2/2001): 15 01 10 (packaging containing residues of or contaminated by dangerous substances)

Disposal methods:

- The component must be considered as hazardous waste. It should be disposed of following local regulations.

14. TRANSPORT INFORMATION

No restrictions.

15. REGULATORY INFORMATION

No specific regulations

16. OTHER INFORMATION

The following Hazard statements refer to the classification of the components (pure substance 100 %) and not the classification of the mixture.

H300	- fatal if swallowed
H400	- Very toxic to aquatic life
H410	- Very toxic to aquatic life with long lasting effects .
EUH032	- Contact with acids liberates very toxic gas

This product is designed for use by professionals.

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 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 information provided on this SDS 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.

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