



1. INFORMATION OF THE SUBSTANCE /PREPARATION AND COMPANY

- 1.1 Product name Plasmatrol H-II
Catalogue No. 11041061
Kit components Lyophilised Human Control Level II
Package Insert
Assay value sheet
- 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

Plasmatrol H-II derived from human source plasma are potentially biohazardous material.
CAS Registry Number : Not applicable

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 swallowed* :- wash out mouth with plenty of water. Drink plenty of water. Call a Doctor or medical service .



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
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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



8.2.1 Exposure to persons

<i>Respiratory Protection</i>	- Insufficient ventilation: wear respiratory protection
<i>Hand Protection</i>	- Gloves
<i>Eye Protection</i>	- Face shields
<i>Skin Protection</i>	- Protective Clothing

9. PHYSICAL AND CHEMICAL PROPERTIES

Plasmatrol H-II : stabilized and freeze dried preparation of selected human plasma

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

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

The ecological information for the dilute thimerosal has not been thoroughly investigated : however mercury and its compounds are expected to significantly bioaccumulate . So any waste must be handled as dangerous waste .

Other information

- 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.

- Labels - none required due to dilution
- H317 - May cause an allergic skin reaction
- H413 - May cause long lasting harmful effects to aquatic life

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.

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SDS established : 2021-09-16

Revision number : 02