



1.INFORMATION OF THE SUBSTANCE /PREPARATION AND COMPANY

- 1.1 Product name Insight HBsAb (Device)
Catalogue No. 10505010

- Kit components Insight HBsAb Device
Sample Applicator
Desiccant pouch
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
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- 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

INSIGHT HBSAB Device : Membrane test assembly impregnated with colloidal gold conjugated to HBsAg monoclonal and mouse IgG antibodies , HbsAg antigen and goat anti mouse IgG at the respective regions.

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 7

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

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

Appearance	White nitrocellulose membrane on a plastic backup
Odour	Odourless

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

Acute effects: Harmful if swallowed

Routes of exposure:

Ingestion, inhalation, eyes and skin

Caution! These components contain a substance that is absorbed through the skin

Acute toxicity: LC50 : Not Known

12. ECOLOGICAL 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.

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 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 material used from animal origin are source from non-BSE countries (certificate available). But the handling of reagent, serum or plasma specimens should be in accordance with local safety procedure.

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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