

**INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY**

- 1.1. Product Name HAV IgM (Rapid Immunochromatographic Assay for the detection of IgM antibodies to HAV in human serum/plasma)
- Catalogue no. 10501010
- Kit components Device Membrane Assembly in sealed aluminium pouch
- 1.2. Intended use In Vitro Diagnostic Use.
- 1.3. Company **Tulip Diagnostics (P) Ltd.**
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- 1.4. In emergencies Call your local emergency center

COMPONENTS AND HAZARDOUS INGREDIENTS

Kit Component	HAZARDOUS INGREDIENT	CLASSIFICATION SUBSTANCE	EINECS NR.
Antibody	Material from animal origin 0.095 % Sodium azide (NaN ₃)	T+; R28-32 N; R50-53	247-852-1

HAZARDS IDENTIFICATION

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

CLASSIFICATION PREPARATION	RISKS
Xn; R22	Harmful if swallowed Human material is potentially infectious

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

FIRE FIGHTING MEASURES

- Suitable extinguishing media:*
- All non combustible extinguishing media allowed
- Unsuitable extinguishing media:*
- For surrounding fires: all extinguishing media allowed
- Special exposure hazards:*
- No data available
 - 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

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

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

EXPOSURE CONTROLS/PERSONAL PROTECTION**8.1 Exposure limits****Sodium Azide:**

	mg/m ³	ppm
TLV-TWA	-	-
TLV-STEL	-	-
TLV-Ceiling	0.29 (NaN ₃)	0.11 (HN ₃)
OES-LTEL	-	-
OES-STEL	0.3 (NaN ₃)	-
MAK	0.2	
TRK		
MAC-TGG 8h		
MAC-TGG 15min		
MAC-Ceiling	0.3	
VMA 8h	-	-
VMA 15min	0.3	0.1
GWBB 8h	-	-
GWBB 15min	-	-
Momentary value	0.29	0.11
EC	0.1	-
EC-STEL	0.3	-

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 bio accumulative: Log Pow = NA
BCF = NA

Not Readily degradable

PHYSICAL AND CHEMICAL PROPERTIES

Antibody : Device membrane test assembly impregnated with HAV antigen colloidal gold conjugate.

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)

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).

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 wastewater purification: No data available

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:

- 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.

TRANSPORT INFORMATION

No restrictions.

REGULATORY INFORMATION

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

Contains 0.095% sodium azide

OTHER INFORMATION

This product is designed for use by professionals.

The animal source material included in this kit are considered to be free from risk for BSE/CJD & other zoonoses and judged to be non-existent based on:

The material used from animal origin are sources from non – BSE countries (Certificate available). But, handling of reagents, serum or plasma specimens should be in accordance with local safety procedures.

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 complete assurance that human blood derivatives 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

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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.