

**MATERIAL SAFETY DATA SHEET**

(According to 2001/58/EC)

Product : Quantia Fibrinogen

Doc. No. : MSDS/613

1 INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

- 1.1. Product name Quantia Fibrinogen
- Catalogue No. 10705025
10705150
- Kit components (R1) -Activation Buffer
(R2) -Fibrinogen reagent
(S) - Fibrinogen Calibrator
Package Insert
Quantia Graph Paper
- 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

Kit Component	HAZARDOUS INGREDIENT	CLASSIFICATION SUBSTANCE	EINECS NR.
R1	0.1 % Sodium azide (NaN ₃)	T+; R28-32 N; R50-53	247-852-1
R2	Material from animal origin 0.1 % Sodium azide (NaN ₃)	T+; R28-32 N; R50-53	247-852-1
S	Material from human origin 0.1 % Sodium azide (NaN ₃)	T+; R28-32 N; R50-53	247-852-1

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3 HAZARDS IDENTIFICATION

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

CLASSIFICATION PREPARATION	RISKS
Xn; R22, S23-46-61	Harmful if swallowed

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



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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 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

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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 bioaccumulative: Log Pow = NA

BCF = NA

Not Readily degradable

9 PHYSICAL AND CHEMICAL PROPERTIES

(R1) - Activation Buffer : Clear colourless liquid

(R2) - Fibrinogen reagent : Clear colourless liquid

(S) - Fibrinogen Calibrator: Lyophilized powder

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).



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Doc. No. : MSDS/613

12 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

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 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



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- 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 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 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.