

**MATERIAL SAFETY DATA SHEET**

(According to 2001/58/EC)

Product : Quantia RF

Doc. No. : MSDS/601

1 INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

- 1.1. Product name Quantia RF
- Catalogue No. 10710050
10710150
- Kit components (R1) -Activation Buffer
(R2) -Latex reagent
(S) - RF 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 human 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: - Consult a doctor/medical service if irritation persists
- Rinse with water

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

Clean-up:



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- 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
EC	0.1	-
EC-STEL	0.3	-



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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) - Latex reagent : White colour suspension

(S) - RF 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).

12 ECOLOGICAL INFORMATION

Aquatic toxicity

Sodium azide: - LC50 (96 h) : 0.8 mg/l (SALMO GAIRDNERI/ONCORHYNCHUS MYKISS)



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- 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
- 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



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This product is designed for use by professionals.

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

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