

**MATERIAL SAFETY DATA SHEET**

(According to 2001/58/EC)

Product : Tulip XL-FDP

Doc. No.: MSDS/209

1 INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

- 1.1. Product name Tulip XL-FDP
- Catalogue nrs. 10650015
- Kit components Latex particles coated with mouse monoclonal, Anti-D dimer antibody.
Positive Control
Negative Control
Six circle plastic slide
Sample droppers
Mixing stick ladder
Rubber teats
- 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
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.
XL-FDP latex reagent	Material from animal origin 0.1 % Sodium Azide (NaN ₃)	T+; R28-32 N; R50-53	247-852-1
Positive Control	Material from animal origin 0.1% Sodium Azide (NaN ₃)	T+; R28-32 N; R50-53	247-852-1
Negative Control	Material from animal origin 0.1% Sodium Azide (NaN ₃)	T+; R28-32 N; R50-53	247-852-1
Phosphate Buffer	0.1% Sodium Azide (NaN ₃)	T+; R28-32 N; R50-53	247-852-1

**3 HAZARDS IDENTIFICATION**

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

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

4 FIRST AID MEASURES

- Eye contact:* - Rinse immediately with water for at least 15 minute. Assure adequate flushing by separating the eyelids with fingers.
- 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

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 (N _a N ₃)	0.11(HN ₃)
OES-LTEL	-	-
OES-STEL	0.3 (N _a N ₃)	-
MAK	0.2	
TRK		
MAC-TGG 8h		
MAC-TGG 15 min		
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

Provide sufficient ventilation

8.2.1 Exposure to persons

Respiratory Protection - Insufficient ventilation: wear respiratory protection

Hand Protection - Gloves – compatible chemical resistant 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

Latex : Suspension
Positive, Negative Control & phosphate buffer : Liquid

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 metal and acids (Components contains azide)

11 TOXICOLOGICAL INFORMATION

Toxicity and effects

Acute toxicity: LD50 oral rat : 75 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 Azidel: - LC50 (96 h) : 0.8 mg/l (SALMO GAIRDNERI/ONCORHYNCHUS MYKISS)
- LC50 (96h) : 0.7 mg/l (LEPOMIS MACROCHIRUS)
- LC50 (48h) : 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 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 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

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.

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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