Coral Clinical Systems
A Division of Tulip Diagnostics (P) Ltd.
Plot No. M – 46, Phase III B, Verna Ind. Estate,
Verna, Goa – 403 722, INDIA
Tel.: (0832) 6680121, Fax: (0832) 2887028

Safety Data Sheet

1. INFORMATION ON THE SUBSTANCE / PREPARATION AND COMPANY

1.1 Product Name : **Turbilyte RF (Turbidimetric Immunoassay for Determination of Rheumatoid Factor)**

Kit	Catalog No.	Components
Turbilyte RF	1112040050 1112040100	R1- Activation Buffer R2- Latex Reagent C- Calibrator

1.2 Intended Use : In Vitro Diagnostics Use.

1.3 Company : **Coral Clinical Systems**

(A Division of Tulip Diagnostics (P) Ltd.)

Plot No. M-46, Phase III B, Verna Ind. Estate,

Verna, Goa -403 722, INDIA.

Tel :- +91-832-6680121

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E-mail :- coral@tulipgroup.com

1.4 In emergencies Call your local emergency center.

2.Composition / Information on Hazardous Ingredients

Chemical Name	CAS #	% W/V	Exposure Limits in Air				
			ACGIH		OSHA		OTHER
			TLV	STEL	PEL	STEL	

Reagent 1 : No hazardous components

Calibrator : No hazardous components

3.Hazard Identification

According to regulation (EC) No. 1272/2008. The mixture is classified as non hazardous according to Regulation (EC) No. 1272/2008.

Other Information

Turbilyte RF contains uniform suspension of polystyrene latex particles coated with suitably modified Fc fraction of human IgG.

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4.First Aid Measures

Inhalation:
If breathing becomes difficult, remove victim to fresh air, Unconscious: maintain adequate airway and respiration. Seek medical attention immediately.

Ingestion:
Get medical attention if there has been ingestion of this product. Drink plenty of water.

Skin Contact:
Avoid skin contact. If skin contact occurs, rinse with water. Get medical attention immediately if irritation persists.

Eye Contact:
Immediately flush eye(s) with large volume of water for atleast 15 minutes. Do not apply neutralizing agents. Get medical attention immediately.

5.Fire Fighting Measures

Flash Point (Method used): NA **Flammable Limits – LEL: NA** **UEL:** NA

Extinguishing Media:
Use non combustible fire-extinguishing media appropriate for site conditions.

Special Fire Procedures:
Structural firefighting gear and self-contained breathing apparatus will provide adequate protection if this product is in a fire area.

Unusual Fire and Explosion Hazards:
On heating/burning: formation of small quantities of nitrous vapours, carbon monoxide, carbon dioxide.

6. Accidental Release Measures

Steps to be taken in case material is Released or Spilled:
PPE should be level D: lab gloves, chemical resistant apron, boots and splash goggles. Use an absorbent material to contain / pick up the spilled solution. Place all spill residues into a suitable container, seal, label and hold for disposal. 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:
Keep away from heat sources, acids.

Refer to pack insert for additional information on handling and storage procedures.

8.Exposure Controls and Personal Protection

Ventilation Data:
A system of local and / or general exhaust is recommended to keep employee exposures as low as possible. Local exhaust ventilation is generally preferred because it can control the emissions of the contaminant at its source.

Respiratory Protection:
If respiratory protection is needed, Select respirator based on its suitability to provide worker protection for given working conditions, level of airborne concentration, and presence of sufficient oxygen.

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Protective Gloves:
Wear appropriate protective gloves to prevent skin contact. Replace torn or punctured gloves promptly.

Other Protective Equipment:
Wear appropriate eye protection to prevent eye contact. Wear appropriate body protection to prevent skin contact.

Other Engineering Controls:
Eye wash stations and deluge showers.

Work Practices:
Good laboratory technique should be used when handling this product. Observe appropriate chemical hygiene. Avoid contact with eyes or skin. Do not place in mouth.

Hygienic Practices:
Do not eat, drink, or smoke while working with product. Upon completion of work activities involving this product, wash hands thoroughly with soap and water.

9. Physical And Chemical Properties

R_1- Activation Buffer

Relative Vapour density(air = 1)	:	NA	Evaporation rate(nBuAc = 1):		NA
Specific Gravity (water = 1)	:	NA	Freezing / Melting Point	:	NA
Solubility in Water	:	Soluble	Boiling Point	:	NA
Vapour Pressure, mm Hg @ 20^0C:		NA	pH	:	NA

R_2- Latex Reagent

Relative Vapour density(air = 1)	:	NA	Evaporation rate(nBuAc = 1):		NA
Specific Gravity (water = 1)	:	NA	Freezing / Melting Point	:	NA
Solubility in Water	:	Soluble	Boiling Point	:	NA
Vapour Pressure, mm Hg @ 20^0C:		NA	pH	:	NA

S - Calibrator

Relative Vapour density(air = 1)	:	NA	Evaporation rate(nBuAc = 1):		NA
Specific Gravity (water = 1)	:	NA	Freezing / Melting Point	:	NA
Solubility in Water	:	Soluble	Boiling Point	:	NA
Vapour Pressure, mm Hg @ 20^0C:		NA	pH	:	NA

Odour and Appearance Information
Reagent 1: Clear, Colourless liquid

Reagent 2: White Coloured Suspension

Calibrator:: Lyophilized Solid

10.Stability and Reactivity
Incompatibility (Materials to Avoid):
Keep away from metals and acid (Component contains azide)

Hazardous Decomposition Products:
No hazardous decomposition products are formed in high quantities.

Will Hazardous Polymerization Occur?
Hazardous polymerization will not occur.

Conditions to Avoid / Polymerization:
NA.

Is the Product Stable?
Yes, the product is stable until expiry date if stored in specified conditions.

Conditions to Avoid/stability
Stable Solution. Avoid acidification of solution, which may generate hydrogen cyanide gas.

11.Toxicological Information

Toxicity Data:
Sodium Azide (Undiluted): LD50 (rat and mouse, Oral)=27 mg/kg; LD50 (rabbit, skin)=20 mg/kg.

Reproductive effects:
NA.

Target organ Effects:
Eyes(redness), Skin(redness), central nervous systems(nausea/vomiting), cardiovascular systems (fall in blood pressure, change in heart rate), digestive(nausea/vomiting, diarrhea).

Carcinogenicity: No

CHEMICAL NAME	CAS #	% W/V	NTP Carcinogen		IARC	OSHA
			Known	Anticipated		
NA.						

12.Ecological Information

Environmental Fate / Stability: NA

Effect of Material on plants or animals: NA

Effect of Chemical on Aquatic Life: LC50 (96h): 0.8 mg/l (SALMO GAIRDNER/ONCORHYNCHUS MYKISS), LC50 (96h): 0.7 mg/l (LEPOMIS MACROCHIRUS), LC50 (48h): 9 mg/l (GAMMARUS SP.).

13.Disposal Considerations

EPA Waste Number and Proper Waste Disposal Method:
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.

Please consult local, state and federal regulations for additional guidance on disposal.

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14.Transportation Information

Is this Material Hazardous?
No restrictions.

Proper Shipping Name : NA		
Hazard Class Number : NA	Packing Group: NA	UN Number: NA

15.Regulatory Information: NA.

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 zoo-noses based on:
The use of BSA from sources in non-BSE countries (certificate available). But the handling of reagent, serum or plasma specimens should be in accordance with local safety procedure.

The material from human origin has been tested for HbsAg and HIV antibodies and are found to be non reactive. However handle the material as if infectious.

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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