

Safety Data Sheet

1. INFORMATION ON THE SUBSTANCE / PREPARATION AND COMPANY

1.1 Product Name: RedSpot -PE™

Kit	Catalog Number	Components		
RedSpot -PE™	1108230050' 1108230010	Pack Insert Set of Droppers for samples (50 nos.) Set of Droppers for test reagent (50 nos.) Set of test cards (50 nos.) Congo red reagent (1 dropper bottle) Set of sample vials/tubes (50 nos.)		

1.2 Intended Use : The **REDSPOT-PE™** Congo Red Spot Test for Pre-eclampsia Testing is an in-

vitro diagnostic kit for an early detection of Eclampsia (Preeclampsia condition) using urine

samples of pregnant females. This is a screening test.

1.3 Company : Coral Clinical Systems

(A Division of Tulip Diagnostics (Pvt) Ltd.) Plot No. M-46 & M-47, Building E, Phase III B, Verna Industrial Estate,

Verna-Goa, 403722 Tel :- +91-832-6680121 Fax :- +91-832-2887028 E-mail :- coral@tulipgroup.com

1.4 : In emergencies Call your local emergency center.

2. Composition / Information on Hazardous Ingredients

Chemical	CA 0/	%	Exposure Limits in Air				
	W/V	ACGIH	OSHA		OTHER		
Name	3#	V V / V	TLV	STEL	PEL	STEL	

Pack Insert : No Hazardous components
Set of Droppers for samples (50 nos.) : No Hazardous components
Set of Droppers for test reagent (50 nos.) : No Hazardous components
Set of test cards (50 nos.) : No Hazardous components
Congo red reagent : No Hazardous components
Set of sample vials/tubes (50 nos.) : No Hazardous components

3. Hazard Identification

According to 1999/45/EC, the preparation is classified as non-hazardous substance or mixture.

Other Information

Material of human/animal origin is not used for the preparation of this kit. No test can guarantee complete absence of viruses/infectious microorganisms, all samples used for the assay must be considered potentially infectious, therefore the assay waste must be decontaminated and disposed off, in accordance with established safety procedures.

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4. First Aid Measures

Inhalation:

Allow victim to breath fresh air. Call the physician. Allow the victim to rest.

Ingestion:

Rinse mouth. Do not induce vomiting. Obtain emergency medical attention.

Skin Contact:

Wash with plenty of soap and water. Wash contaminated clothing before reuse. If skin irritation occurs: Get medical attention immediately.

Eye Contact:

Rinse cautiously with water for several minutes. Remove contact lenses, if present and continue rinsing. If irritation persists, immediately call a doctor.

5. Fire Fighting Measures

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

Extinguishing Media:

Use fire-extinguishing media appropriate for site conditions.

Special Fire Procedures:

Use water spay or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent firefighting water from entering environment. Do not enter fire area without proper protective equipment, including respiratory protection.

Unusual Fire and Explosion Hazards:

NA.

6. Accidental Release Measures

Steps to be taken in case material is Released or Spilled:

PPE should be used: lab gloves, chemical resistant apron, boots and splash goggles. Use an absorbent material to contain / pick up the spilled solution. Place all spill residue into a suitable container, seal, label and hold for disposal.

7. Handling and Storage

Refer to packet 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:

Respiratory protection is not required under normal use of this product. If respiratory protection is needed, follow OSHA respirator regulations (29CFR1910.134) and, if necessary, wear a NIOSH approved respirator. Select respirator based on its suitability to provide worker protection for given working conditions, level of airborne concentration, and presence of sufficient oxygen.

Protective Gloves:

Wear appropriate protective gloves and Clothing to prevent skin contact.

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 products. Upon completion of work activities involving this product, wash hands thoroughly with soap and water.

9. Physical And Chemical Properties

Congo red reagent

Relative Vapour density(air = 1) :	NA	Evaporation rate(nBuAc = 1): NA
Specific Gravity (water = 1) :	NA	Freezing / Melting Point	: NA
Solubility in Water :	NA	Boiling Point	: NA
Vapour Pressure, mm Hg @ 20°C:	NA	pH	: 7.4 <u>+</u> 0.1

Odour and Appearance Information

Congo Red Reagent: Solution with Preservative

10. Stability and Reactivity

Incompatibility (Materials to Avoid): Strong oxidizers, Strong bases, metals.

Hazardous Decomposition Products: Fume.

Will Hazardous Polymerization Occur?

Hazardous polymerization will not occur.

Conditions to Avoid / Polymerization:NA

Is the Product Stable?

Yes, under normal handling and storage conditions.

Conditions to Avoid/stability

Direct sunlight, extremely high or low temperatures. Stable under normal conditions.

11. Toxicological Information

Toxicity Data:

NA

Reproductive effects:

NA

Target organ Effects:

NA

Carcinogenicity: No

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

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12. Ecological Information

Environmental Fate / Stability:NA

Effect of Material on plants or animals:NA

Effect of Chemical on Aquatic Life:NA

13. Disposal Considerations

EPA Waste Number and Proper Waste Disposal Method:

Dispose in a safe manner in accordance with local/national regulations. Dispose of contents/container to comply with local state and federal regulations

14. Transportation Information

Is this Material Hazardous? Not regulated under transportation regulations.

Proper Shipping Name: NA

Hazard Class Number: NA Packing Group: NA UN Number: NA

15. Regulatory Information NA.

16. Other Information

This product is designed for use by professionals.

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.

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