



**Works:**  
Plot Nos. M 46 - 47, Phase III B, Verna Industrial Estate,  
Verna, Goa - 403 722, INDIA.  
Tel.: (0832) 6624502 / 6682000, Fax: (0832) 6680156.  
E-mail: zephyr@tulipgroup.com

## MATERIAL SAFETY DATA SHEET

### 1. INFORMATION ON THE SUBSTANCE / PREPARATION AND COMPANY

1.1 Product Name : **BornSafe TSH**

Kit	Components
<b>BornSafe TSH</b>	TSH Calibrator Level C0 to C5 TSH Control Level L1 and L2 TSH Enzyme Reagent Extraction Reagent Substrate Solution Stop Solution Wash Solution Coated Microwells Sealing tape Pack insert Protocol sheet Microwell Holder

1.2 Intended Use : **Born Safe™** Neonatal TSH Screening ELISA is an enzyme immunoassay for the quantitative determination of human thyroid stimulating hormone in dried blood samples spotted on Whatman 903 filter paper. This kit is particularly suitable for screening for primary hypothyroidism in newborns. Elevated results indicate the need for further study to assess congenital hypothyroidism.

1.3 Company : **ZEPHYR BIOMEDICALS**  
  
(A Division of Tulip Diagnostics (P) Ltd.)  
  
Plot Nos. M 46-47, Phase III B,  
  
Verna Industrial Estate,  
  
Verna, Goa- 403 722, INDIA,  
  
Phone: 91 832 6682000  
  
Fax : 91 832 6680156  
  
Email: [zephyr@tulipgroup.com](mailto:zephyr@tulipgroup.com)





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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	

**TSH Calibrator Level C0 to C5:** No Hazardous components

**TSH Control Level L1 and L2:** No Hazardous components

**TSH Enzyme Reagent:** No Hazardous components

**Extraction Reagent:** No Hazardous components

**Substrate Solution:** No Hazardous components

**Stop Solution:** No Hazardous components

**Wash Solution:** No Hazardous components

**Coated Microwells:** No Hazardous components

**Sealing tape:** No Hazardous components

**Pack insert:** No Hazardous components

**Protocol sheet:** No Hazardous components

**Microwell Holder:** 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 used for the preparation of this kit. No test can guarantee complete absence of these viruses, all samples and reagents 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.

**4. First Aid Measures**

**Inhalation:**

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





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**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 spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire fighting 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.







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

**9. Physical And Chemical Properties**

**TSH Calibrator Level C0 to C5**

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 : NA	
Blood tested negative for anit-HIV, anti-HCV and HBsAg.	

**TSH Control Level L1 and L2**

Relative Vapour density(air = 1) : NA	Evaporation
rate( nBuAc = 1): NA	
Specific Gravity (water = 1) : NA	Freezing / Melting
Point : NA	





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Solubility in Water	: NA	Boiling
Point	: NA	
Vapour Pressure, mm Hg @ 20°C:	NA	
pH	: NA	
Blood tested negative for anit-HIV, anti-HCV and HBsAg.		

### TSH Enzyme 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	: 6.6	

### Extraction 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	: 7.3 to 7.4	

### Substrate Solution

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	: <4.0	

### Stop Solution

Relative Vapour density(air = 1)	: NA	Evaporation
rate( nBuAc = 1):	NA	
Specific Gravity (water = 1)	: NA	Freezing / Melting
Point	: NA	







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Solubility in Water	: NA	Boiling
Point	: NA	
Vapour Pressure, mm Hg @ 20°C:	NA	
pH	: <3.0	

**Wash Solution**

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	: 8.7 to 8.9	

**Coated Microwells**

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	: NA	

**Odour and Appearance Information**

**TSH Calibrator Level C0 to C5:** Dried Blood Spots

**TSH Control Level L1 and L2:** Dried Blood Spots

**TSH Enzyme Reagent:** Solution with Protein stabilizers and Preservative

**Extraction Reagent:** Solution with Protein stabilizers and Preservative

**Substrate Solution:** Aromatic solution containing TMB

**Stop Solution:** Diluted mineral acid

**Wash Solution :** Buffer Solution with preservative and surfactant

**Coated Microwells :** No Hazardous components





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**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 #	% 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:NA**



**Zephyr Biomedicals**  
A Division of Tulip Diagnostics (P) Ltd.

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Corporate Office: Gitanjali, Tulip Block, Dr. Antonio Do Rego Bagh, Bambolim Complex  
Post Office, Goa - 403 202, INDIA. Tel.: (0832) 2458546-51, Fax: (0832) 2458544.  
E-mail: sales@tulipgroup.com, Website: www.tulipgroup.com



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