

Annexure VIII
Safety Data Sheet

Safety Data Sheet

1. INFORMATION ON THE SUBSTANCE / PREPARATION AND COMPANY

1.1 Product Name : **Bornsafe PKU**

Kit	Catalog No.	Components
Bornsafe PKU	1122010096	PKU Calibrator Level C0 to C5 PKU Control Level L1 and L2 Elution Buffer Enzyme Reagent Coenzyme Reagent Colour Reagent Colour Booster Dilution Buffer

1.2 Intended Use : For quantitative determination of Phenylalanine concentrations in neonates using blood spot samples dried on whatman S&S 903 filter collection paper.

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
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 Name	CAS #	% W/V	Exposure Limits in Air				
			ACGIH		OSHA		OTHER
			TLV	STEL	PEL	STEL	
Trichloroacetic Acid	76-03-9	3%	0.5ppm	NA	1ppm	NA	NIOSH 7mg/m ³

PKU Calibrator Level C0 to C5 - NA

PKU Control Level L1 and L2 - NA

Elution Buffer

Trichloroacetic Acid	76-03-9	3%	0.5ppm	NA	1ppm	NA	NIOSH 7mg/m ³
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Enzyme Reagent - NA

Coenzyme Reagent - NA

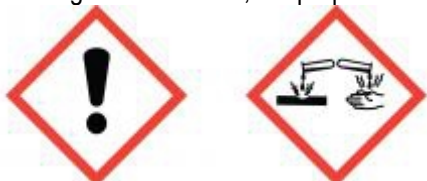
Colour Reagent - NA

Colour Booster - NA

Dilution Buffer - NA

3.Hazard Identification

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



Skin Corrosion/ Irritation,category 2; H315
Serious Eye Damage/Eye Irritation,Category 1;H318

Other Information

Material of human origin is used for the preparation of this kit.No test at present can guarantee complete absence of these viruses,all samples and reagents used for the assay must be considered potentially infectiousTherefore 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.

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 easy to do.continue rinsing.Immediately call a doctor.

5. Fire Fighting Measures

Flash Point (Method used): NA

Flammable Limits – LEL: NA

UEL: NA

Extinguishing Media:

Foam,Dry powder,Carbon dioxide,water spray,sand.

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.

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

PKU 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

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

Elution 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°C: NA	pH : NA

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 : Soluble	Boiling Point : NA
Vapour Pressure, mm Hg @ 20°C: NA	pH : NA

Coenzyme 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°C: NA	pH : NA

Colour 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°C: NA	pH : 7.0

Colour Booster

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°C: NA	pH : 7.0

Dilution 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°C: NA	pH : 10.5

Odour and Appearance Information

PKU Calibrator Level C0 to C5 : Dried blood spots

PKU Control Level L1 and L2 : Dried blood spots

Elution Buffer : Colourless liquid

Enzyme Reagent : Lyophilized Powder

Coenzyme Reagent : Lyophilized Powder

Colour Reagent : Colourless liquid

Colour Booster : Colourless liquid

Dilution Buffer : Colourless liquid

10.Stability and Reactivity

Incompatibility (Materials to Avoid):

Strong oxidizers,Strong bases,metals.

Hazardous Decomposition Products:

Fume,Carbon dioxide,Carbon monoxide.

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:

Trichloro Acetic Acid:LD50 Oral-rat-3,320mg/kg,Eyes-rabbit-Severe eye irritation-5s.

Reproductive effects:

Not classified

Target organ Effects:

Effects after skin contact:Causes skin irritation

Effects after eye contact:Causes serious eye damage.

Carcinogenicity: No

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

12.Ecological Information

Environmental Fate / Stability:Avoid release to environment.

Effect of Material on plants or animals:NA

Effect of Chemical on Aquatic Life:Very toxic to aquatic life with long lasting effects.

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: NA
Hazard Class Number : NA		

15. Regulatory Information NA.

16. Other Information

Hazard Statement and Precautionary statements referred elsewhere in the safety data sheet:

H315 -Causes skin irritation.

H318 -Causes serious eye damage.

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.

Effective Date: 22/10/19

Version No:00