

1. Identification of the substance/preparation and of the company:

Product Name: Pi GST EIA

Cat No. BIO85

Intended Use: An enzyme immunoassay for the quantitative detection of Pi glutathione S-transferase (π GST) in human plasma and urine.

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2. Composition/Information on Ingredients:

Coated Strips: 12 x 8 well strips coated with IgG directed against π GST.

Calibrator:** 1 x 100 μ l of purified π GST in 50% (v/v) glycerol (5 mg/L). **Contains 0.0095% thiomersal.**

Sample Diluent: 1 x 50 ml of protein containing solution with added stabilisers. **Contains 0.02% sodium azide.**

Wash Concentrate: 1 x 55 ml of phosphate buffered saline/ Tween 20 (PBST, 20X). **Contains 0.01% thiomersal.**

Positive Control:** 1 x 4.5 ml of π GST in protein containing solution with added stabilisers (4.5 ml). **Contains 0.01% thiomersal and 0.01% sodium azide.**

Conjugate: 1 x 11 ml of anti- π GST IgG conjugated to horseradish peroxidase. **Contains 0.01% thiomersal and 0.01% gentamicin.**

Substrate: 1 x 11 ml of stabilised liquid TMB (3,3'-5,5' tetramethylbenzidine) solution.

Stop Solution 1 x 11 ml of 0.5 M sulphuric Acid (H_2SO_4).

NephkitTM Urine Stabilising Buffer: 1x 11 ml of urine stabilising buffer

**** Potentially Biohazardous Material**

3. Hazards Identification:

Thiomersal is toxic by inhalation, in contact with skin and if swallowed. It is irritating to eyes, respiratory system and skin. It is a possible mutagen which may affect kidneys and nerves. There is danger of cumulative effects

Sulphuric acid Corrosive, Causes burns.

Avoid contact with the skin and eyes. If contact occurs rinse immediately with water and seek medical advice

Sodium Azide Avoid contact with components containing azide. Do not ingest or inhale. Harmful if swallowed. Contact with acids liberates very toxic gas.

TMB (3,3',5,5' – tetramethylbenzidine) may irritate the skin and mucous membranes. It is a possible mutagen. Any substrate that comes in contact with the skin should be rinsed off with water.

Gentamicin is toxic. It is harmful by inhalation, in contact with skin and if swallowed. Target organs are kidneys and ears.

Reagents marked with ** are considered POTENTIALLY BIOHAZARDOUS MATERIAL. The calibrator and positive control contains material of different human origin, which has been tested and found to be negative for Hepatitis B, DNA, HCV RNA and HIV RNA. However, no test method can offer complete assurance that infectious agents are absent.

4. First Aid Measures: Applicable for all kit components

Inhalation: If exposure is severe remove to fresh air.

Skin: Wash skin with copious amounts of water. Remove contaminated clothing and shoes.

Eye: Flush eyes with copious amounts of water for at least 15 minutes. Assure adequate flushing of the eyes by separating the eyelids. If any irritation persists, obtain medical assistance.

Ingestion: Wash out mouth with copious amounts of water. Give plenty of water to drink. Obtain medical assistance if large quantity is ingested.

5. Fire-fighting measures:

Precautions during fire: Avoid inhalation of fumes

Suitable extinguishing media: Use media suitable to extinguish the supporting or surrounding fire. Do not use water on sodium azide containing components.

Special exposure hazards: Some components may decompose and emit toxic fumes under fire conditions (Sodium Azide, TMB, Thiomersal).

Special fire-fighting procedures: Self-contained breathing apparatus may be required if heavy fumes are emitted. It is advisable for protective clothing to be worn to prevent contact with skin and eyes.

6. Accidental release measures:

Environmental precautions: The Positive Control and Sample Diluent contains sodium azide which may form potentially explosive metal azides with lead and copper plumbing. For disposal, reagent should be flushed with large volumes of water to prevent azide build up in drains.

Methods for cleaning up: Wipe up spills with absorbent paper, then clean area with a concentrated chlorine solution, 0.5% available chlorine (0.5% hypochlorite). Discard all materials used to wipe up spills using biohazard waste facilities.
Residues of chemicals, preparations and kit components are generally considered as hazardous waste. All such materials should be disposed of in accordance with established safety procedures.

7. Handling and storage:

Handling: All clinical specimens, Calibrator and Positive Control should be handled as though potentially infectious.

Storage: Store all reagents and ELISA plate at 2-8°C

Specific Use: This product is for laboratory use only.

8. Exposure controls/personal protection:

The Calibrator, Positive Control and all patient specimens are considered potentially biohazardous materials. They should be handled at the Biosafety Level 2 as recommended for any potentially infectious human serum or blood specimen in the CDC/NIH manual "Biosafety in Microbiological and Biomedical Laboratories", 1998.

Some of the reagents in this kit contain toxic or irritant components (Refer to section 3). Wear protective clothing, disposable latex gloves and eye protection while handling specimens and performing the assay. Wash hands thoroughly when finished.

9. Physical and chemical properties:

Not Applicable

10. Stability and reactivity:

The stop solution (0.5 M H₂SO₄) is incompatible with water and bases.

The Positive Control and Sample Diluent contains sodium azide which may form potentially explosive metal azides with lead and copper plumbing. Sodium azide explodes when heated and may form hazardous combustion or decomposition products.

Substrate (TMB solution) is incompatible with strong oxidizing agents.

Thiomersal is incompatible with strong oxidising agents, strong acids and strong bases.

Gentamicin may form hazardous combustion or decomposition products.

11. Toxicological information:

Some reagents contain Thiomersal, Sodium Azide and Gentamicin which are toxic by inhalation, in contact with skin and if swallowed.

The substrate Tetramethylbenzidine (TMB) is a possible mutagen. It is harmful if swallowed, inhaled or absorbed through skin.

12. Ecological information:

No known ecological hazards

13. Disposal considerations:

Dispose of all clinical specimens, infected or potentially infected material in accordance with good laboratory practice. All such material should be handled and disposed of as if potentially infectious.

Residues of chemicals, preparations and kit components are generally considered as hazardous waste. All such materials should be disposed of in accordance with established safety procedures.

14. Transport information:

Not applicable

15. Regulatory information:

Directive 2001/58/EC
Directive 1999/45/EC
Directive 98/79/EC on *in vitro* diagnostic medical devices.


16. Other information:


Training: This product should be used by technically qualified individuals only. Individuals should be trained in handling potentially biohazardous material. The contents of this MSDS should be known before use.

Restrictions on Use: This product is for laboratory use only.

Signed: Mr O Connor

Date: 14/04/04

Approved: 

Approved: 

Quality Systems Manager

Health and Safety Officer