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MATERIALS SAFETY DATA SHEET

1. IDENTIFICATION OF THE SUBSTANCE / PREPARATION AND OF THE COMPANY / UNDERTAKING:

Product Name: Pi GST EIA

Cat No. BIO85

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

Company/Undertaking Identification: Argutus Medical LTD,
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2. COMPOSITION / INFORMATION ON INGREDIENTS:

<u>Reagent</u>	<u>Content</u>
<u>Coated Strips:</u>	12 x 8 well strips coated with IgG directed against π GST.
<u>Calibrator**:</u>	100 μ L of purified π GST. Contains Thiomersal.
<u>Sample Diluent:</u>	50mL of ready to use diluent. Contains Sodium Azide and Triton X100.
<u>Wash Concentrate:</u>	55mL of a concentrated buffer (20X). Contains Thiomersal.
<u>Positive Control**:</u>	4.5mL of purified π GST. Contains Thiomersal and Sodium Azide.
<u>Conjugate:</u>	11mL of anti- π GST HPR-IgG conjugate. Contains Thiomersal and Gentamicin.
<u>Substrate:</u>	11mL of Tetramethylbenzidine (TMB) solution.
<u>Stop Solution:</u>	11mL of 0.5M Sulphuric acid (4.9% w/w) H ₂ SO ₄
<u>Nephkit™ Urine Stabilisation Buffer:</u>	11mL of urine stabilising buffer. Contains Thiomersal and Sodium Azide.

**** Potentially Biohazardous Material**



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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.

Triton X100 is harmful. Risk of serious damage to eyes. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

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, Triton X100).



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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:

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



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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:

TMB is toxic to aquatic organisms, miscible with water, may cause long term adverse effects in the aquatic environment. Avoid emptying into waters or drains. H₂SO₄ is harmful to aquatic life in very low concentrations. It may be dangerous if it enters water intakes. Thiomersal is highly toxic to aquatic organisms and may cause long term adverse effects in the aquatic environment. Do not allow to enter waters, waste water or soil.

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:

This manufactured product is not subject to International Air Transport Association Dangerous Goods Regulations.

Not applicable



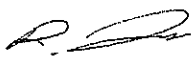
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15. REGULATORY INFORMATION AND CONSIDERATIONS:

European Union Directive 67/548/EEC;
European Union Directive 1999/45/EC;
EU Regulation 1907/2006
Directive 98/79/EC on *in vitro* diagnostic medical devices.
Products are manufactured using GMP.

16. OTHER INFORMATION:

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

Approved: 
Health and Safety Officer

Date: 31/03/09

Approved: 
Senior Management Team Member

Date: 31/03/09