

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

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Hepkit Alpha Cat No. BIO60HEPA

Use of the substance/preparation: An enzyme immunoassay for the quantitative determination of human alpha glutathione S-transferase (α GST) in biological fluids such as serum and plasma, bile and tissue culture supernatants.

Company/Undertaking Identification: Biotrin International,
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2. Composition/Information on Ingredients:

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

Conjugate Concentrate: 300 μ l of anti α GST IgG conjugated to horseradish peroxidase. **Contains 0.01% Thiomersal.**

GST Calibrator**: 200 μ l purified α GST in 50% (v/v) glycerol. **Contains 0.01% Thiomersal.**

Positive Control**: 4.5ml of protein containing solution with added stabilisers. **Contains 0.01% Thiomersal and 0.01% Sodium Azide.**

Wash Concentrate: 1 x 55ml of a concentrated buffer (20x) **Contains 0.01% Thiomersal**

Substrate: 1 x 11ml of **Tetramethylbenzidine (TMB)** solution

Stop Solution 1 x 11ml of 0.5M **Sulphuric Acid (H₂SO₄) (4.9% sulphuric acid)**

**** Potentially Biohazardous Material**

3. Hazards Identification:

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.

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.

Sodium Azide is an irritant. 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. Any substrate that comes in contact with the skin should be rinsed off with water.

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 shoes and clothing.

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 attention if large quantity is ingested.

5. Fire-fighting measures:

Precautions during fire: Avoid inhalation of fumes

Suitable extinguishing media: Dry chemical powder. 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:

- Personal Precautions :** Wear Protective clothing for the prevention of skin and eye contact.
- Environmental precautions:** The Positive Control 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.
- 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 and any infected or potentially infected material should be handled as though potentially infectious.
- Storage:** Store all reagents and ELISA plate at 2-8°C
- Specific Use:** 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 (0.5M H₂SO₄) is incompatible with water and bases.

The Positive Control 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.

11. Toxicological information:

Some reagents contain thiomersal and/or sodium azide both of 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 the skin.

12. Ecological information:

No known ecological hazards

13. Disposal considerations:

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 98/79/EC (In Vitro Diagnostics Medical Devices)


16. Other information:


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

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

Signed: Mr O Connor

Date: 04/03/04

Approved: 
Quality Systems Manager

Approved: 
Health and Safety Officer

Date: 05/03/04

Date: 04/03/04