

Phoenix Bio-Tech Corp.			
MSDS	Material Safety Data Sheet	MSDS Trep-Chek™	Version: 01
Trep-Chek™ Treponema Antibody EIA		Page 1 of 6	Date: Feb. 01, 2004

Definition: **Material Safety Data Sheet *Treponema pallidum* IgG antibody EIA**

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Revision history		
Version: V01	Effective: Feb. 01, 2004	Revision: None

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1. IDENTIFICATION OF THE PREPARATION AND OF THE COMPANY

1.1 Commercial product name: Trep-Check™ EIA, Treponema pallidum IgG Antibody
Code: TP 96 + TP960 + TP1920

1.2 Company : Phoenix Biotech Corp.
6810 Kitimat Road, Unit # 1
Mississauga, Ontario, Canada, L5N 5M2

Emergency: Tel.: +1 (905) 826-6330 Fax: +1 (905) 826-3288

2. COMPOSITION/INFORMATION ON INGREDIENTS

Product type: Chemical kit: Enzyme linked immunosorbent assay for the qualitative presumptive detection of antibodies to Treponema pallidum in human serum. Product consisting of assay plate, and preparations of different compounds. This kit contains biological materials.

Information on ingredients when in 100% concentration:

1. Human source material (in cutoff calibrators, negative and positive controls)
2. Thiomersal 5 mg/100mL (as a preservative in the controls, cutoff, conjugate, dilution buffer, CAS#: 54-64-8, S-phrase: S2-13-28-36-45, R-phrase: R26/27-33 (phrases determined at 100% concentration). *
3. Sulfuric Acid 1.0 N. (stop solution): CAS# 7664-93-9, S-phrase: S 26 R-phrase: R36/R38
4. 3,3',5,5'-Tetramethylbenzidine (TMB), CAS# 54827-17-7, Xn; R22 N; R51/53*

Warnings: Irritant (sulphuric acid in stop solution) on user label (primary and secondary packing).

Composition of components expressed in w/w %.

PC-01-1000 Positive Control: containing inactivated plasma (< 1%) demineralized water (90-95%) saline salt (< 1%), Tween-20 (< 1%) Thiomersal (5 mg/100 mL), BSA (<1%), yellow dye (<1%).

NC-01-1000 Negative Control: containing inactivated plasma (<1%), de-mineralized water (80-90%) saline salts (< 10%), Tween-20 (<1%) Thiomersal (5 mg/100 mL), BSA (<1%), performance protein (<10%), yellow dye (<1%).

CC-01-1000 Cut-off Control: containing inactivated plasma (<1%) demineralized water (90-95%) saline salt (< 1%), Tween-20 (< 1%) Thiomersal (5 mg/100 mL), BSA (<1%) and a yellow dye (<1%).

CJ-01-0013 Conjugate: highly purified proteins isolated from goat serum (antibody concentration 0.8 mg/mL) containing and horseradish roots, and 0.01 M. sodium phosphate buffer, pH 7.6, containing 0.25 M. NaCl and bovine serum (stabilizer, 15 mg/mL).

SD-01-0010 Dilution Buffer: containing demineralized water (90-95%) saline salts (<1%), Tween 20 (<1%), performance protein (< 1%), and Thiomersal (5 mg/100mL) and Bromphenol Blue (<1%).

WB-01-0100 Wash buffer: containing demineralized water (80-90 %) saline salts (<20%) Tween-20 (<1%)

SB-01-0013 TMB Substrate: containing 3,3'-5, 5'-Tetramethylbenzidine (<0.02%) dissolved in water (>95%).

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SS-01-0013 Stop Solution: Sulphuric acid 0.5 M. containing demineralized water (900-95%) and sulphuric acid (0-5%), pH < 1.0.

MP-01-1000 Microtiterplate: Recombinant *Treponema pallidum* antigens coated to Microtiterplate.

* The concentration is so low, that it does not affect the classification of the product.

3. HAZARDS IDENTIFICATION

Label precautionary statements; Irritating to eyes and skin. In case of accident or if you feel unwell, seek medical advice immediately. Dimethyl sulphoxide in TMB substrate is a hygroscopic fluid. Keep tightly closed. Sulphuric acid in low concentration is irritating to the eyes and skin.

4. FIRST AID MEASURES

General protective measures: No specific requirements known, skin and eye contact with the stop solution will cause irritation.

Eye contact: For eye contact with stop solution, flush with plenty of water for at least 15 minutes. For eye contact with test specimens, flush with plenty of water and seek medical attention.

Inhalation: Get fresh air and rest. If person feels queasy/discomfort: seek medical advice.

Skin contact: In case of skin contact with reagent or test specimens wash with soap and water.

Ingestion: For ingestion of kit reagents or any test specimens, seek immediate medical attention.

5. FIRE-FIGHTING MEASURES

Extinguishing media: Use standard fire fighting procedures depending on the source of the surrounding fire.

Thermal Decomposition: Packaging material will burn in a fire. No irritating fumes or toxins are released during fire. When heated to dryness TMB will form hazardous decomposition products.

6. ACCIDENTAL RELEASE MEASURES

After spillage: Decontaminate spill with a bleach solution or appropriate germicide prior to pick up. If material is spilled down drain, flush with a large volume of water to prevent Thiomersal buildup in copper or lead plumbing. Decontamination procedures are available on request.

Absorbent material: If stop solution spills, neutralize with soda ash, lime or a commercial available acid neutralizer.

Special measures to limit damage: No special measures.

7 HANDLING AND STORAGE

7.1 Handling: Read the package insert before use. Always follow good laboratory practices when using this product. Handle all test specimens as if capable of transmitting disease. Employee exposure to human source material is regulated under the Code of Federal Regulations 29 CFR 1910.1030. Refer to the Centers for Disease Control/ National Institutes of Health manual "Bio-Safety in Microbiological and Biomedical Laboratories".

7.2 Storage: The product should be stored in a closed room at a temperature of in between 2 an 8 °C. No special ventilation is necessary. Keep tightly closed.

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8. EXPOSURE CONTROL/PERSONAL PROTECTION

Respiratory protection: protection measures may be required as laboratory conditions indicate.

Eye protection: Goggles may be required as laboratory conditions indicate.

Hand protection: Barrier gloves (rubber).

Skin protection: Laboratory coat.

No special ventilation is necessary, however, a bio-safety cabinet, as recommended in the CDC/NIH manual, may be necessary if there is a possibility of aerosolization of test specimens or controls.

9. PHYSICAL AND CHEMICAL PROPERTIES

Properties	Sulphuric acid (>5%)	TMB (<0.02%)	Other compounds
<i>Physical state:</i>	Solution	Solution	Solution
<i>Colour:</i>	No colour	No colour	miscellaneous
<i>Odour:</i>	No odour	No odour	no odour
<i>PH value:</i>	About pH1.0	about pH 6.5	about pH 8.2
<i>Boiling point:</i>	About 100 °C	about 100 °C	about 100 °C
<i>Melting point:</i>	N.A.	Not determined	N.A.
<i>Flash point:</i>	N.A.	N.A.	N.A.
<i>Ignition temperature:</i>	N.A.	N.A.	N.A.
<i>Explosion limits:</i>	N.A.	Not determined	N.A.
<i>Vapour pressure:</i>	< 0.3	< 0.5	< 0.3
<i>Density:</i>	1.02	1.0	1.02
<i>Solubility in water:</i>	Very soluble	very soluble	very soluble
<i>Viscosity</i>	N.A.	N.A.	N.A.

All components in the kit are aqueous based solutions.

10. STABILITY AND REACTIVITY

Incompatibilities: If disposed down a drain, the Thiomersal in this kit may react with aluminum and reducing agents. Decomposition of Thiomersal can occur when exposed to light.

Hazardous reactions: hazardous polymerization will not occur. Further this product is stable. If involved in a fire, the packaging materials may produce poisonous gas. The stop solution will produce oxides and sulfur or hydrogen.

11. TOXICOLOGICAL INFORMATION

Occupational exposure to this product is not expected to produce adverse human health effects following prudent workplace practices. The human serum components used in the preparation of this chemical kit have been tested by an FDA approved method for the presence of the antibody to HIV 1&2, Hepatitis C and Hepatitis B surface antigen and found to be negative. Because no test method can offer complete assurance that HIV, Hepatitis C, Hepatitis B virus or other infectious agents are absent, specimens and human based reagents should be handled as if capable of transmitting infectious agents. The test wells are coated with Recombinant Treponema Antigens.

Note: The Centre for Disease Control and Centre for Devices and Radiological Health recommend that potentially infectious agents be handled at the Bio-safety level 2.

The following toxicological information concerns the most potentially hazardous ingredients;

1. Sulphuric acid solution (stop solution) is a poison and causes irritation. The oral LD50 (oral rat) for sulfuric acid is 2140 mg/kg (25% solution). LC50 (inhalation rat): 510 mg/m³/2h (calculated on the basis of pure compound).

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2. Thiomersal (controls and buffers <0.05% w/w); LD50: 75 mg/ kg, oral rat, reproductive impairment is demonstrated. No evidence of carcinogenic properties.

3. 3,3,5,5-Tetramethylbenzidine (Substrate solution, <0.02% w/w); The active compound may be absorbed through ingestion. May give irritation to the eyes and skin. May give irritation of the gastrointestinal tract. TMB has shown a possible mutagenic effect in experimental animals (mice).

12. ECOLOGICAL INFORMATION

Water hazard class: Accordance with local regulations should be observed. Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system. TMB is toxic to aquatic organisms. (EC50: 1-10 mg/l.). TMB is not readily biodegradable. May cause long-term adverse effects in the aquatic environment. Bio-accumulative potential of TMB: Log Kow: 4.11.

13. DISPOSAL CONSIDERATIONS

Dispose of through authority facilities or pass to chemical disposal company. Disposable ignitable materials must be incinerated; liquid waste and non-ignitable materials must be decontaminated with sodium hypochlorite at a final concentration of 3 % for at least half an hour. Liquid waste containing acid must be neutralized before treatment. A minimum of one hour at 121 °C is usually considered adequate, though the users must check the effectiveness of their decontamination cycle by initially validating it and routinely using indicators. TMB: EWC code: 16 05 08

14. TRANSPORT INFORMATION

UN Number: -

Proper shipping name: In vitro diagnostic

Package group: Not applicable

Class or division: -

The kit contains small amounts of one or more compatible items of dangerous goods, which are used for medical, analytical or testing purposes. The goods are however in too low quantities to be classified as dangerous.

15. REGULATORY INFORMATION

This product does not require special labeling, in accordance with the appropriate international transport regulations (in addition as described in section 14).

The compounds Thiomersal and 3,3,5,5-tetramethylbenzidine are in low quantities (<0.02%) present in the preparations. No additional information is needed on the user label according to national legislation. The LD50 value of the preparation is calculated according to section 3.6.1.7.1 of the IATA manual and considered not dangerous.

The compound sulphuric acid is known to cause irritation to the eyes and in low-level quantities (1N. 0.5 M). The label "Irritant" is used on the user labels (primary and secondary packing).

Risk phrases: R36/R38: Irritating to eyes and skin

Safety Phrases: S 26: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

The compound 3,3'-5,5' TMB in substrate preparation;

Risk phrases: R22: Harmful if swallowed, R51/R53: Toxic to aquatic organisms, may cause long-term effects in the aquatic environment.

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Symbol on the user-label (Stop solution and kit-package):

Xi



16. OTHER INFORMATION

This product is intended for in vitro diagnostic use only. Not for use in humans.

The information herein is believed to be correct as of the date hereof and excludes any guarantee related with the final use given to the product, being the recipient the last responsible for observing the local laws applicable in any case.

Department issuing MSDS: Quality Assurance
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