

## MATERIAL SAFETY DATA SHEET

Revised: 18/09/2008

### 1.- IDENTIFICATION OF THE PREPARATION AND COMPANY

**Product:** SYPHILIS ELISA IgG+IgM  
**Ref:** T1060  
**Product description:** Indirect immunoenzyme assay to test IgG+IgM antibodies against *Treponema pallidum* in human serum  
**Supplier:** VIRCELL, S.L. Polígono Industrial Dos de Octubre, Plaza Domínguez Ortiz N° 1, 18320 Santa Fe, Granada. SPAIN  
 Phone: 34-958-44 12 64, Fax: 34-958-51 07 12  
 email: [vircell@vircell.com](mailto:vircell@vircell.com)  
**Distributor:** PERA MEDIKAL LTD. STL.  
 YUCE TARLA CAD. NO: 14 ZUHURATBA  
 BAKIRKOY  
 TURKEY

For *in vitro* diagnosis use only. For professional use only.

### 2.-COMPOSITION / INFORMATION ON INGREDIENTS

The product contains seven components manufactured separately:

**I.-Solid phase:** *T. pallidum* antigen coated assay strips. Although this antigen has been inactivated by a proven method, the strip should be considered potentially infectious and handled accordingly.

**II.-Serum diluent:** Buffer solution. It does not contain any hazardous ingredient in concentration >0.1% for very toxic or toxic substances, or >1% for corrosive, harmful or irritating substances.

**III.-Conjugate:** Buffer solution containing animal (non-human) antibodies conjugated with a protein with enzyme activity. It does not contain any hazardous ingredient in concentration >0.1% for very toxic or toxic substances, or >1% for corrosive, harmful or irritating substances.

**IV.-Positive/ Cutoff/ Negative controls:** Contain human serum. They do not contain any hazardous ingredient in concentration >0.1% for very toxic or toxic substances, or >1% for corrosive, harmful or irritating substances. Although they have been tested for HBs antigen, hepatitis C and HIV-I and II antibodies and found non-reactive, they should be considered as potentially infectious and handled accordingly.

**V.-Substrate:** Tetramethyl benzidine (TMB) solution. Contains 3,3',5,5'-tetramethylbenzidine (CAS#54827-17-7) and H<sub>2</sub>O<sub>2</sub>. It has not been found any information indicating that the concentration of the mix is hazardous according to the safety data sheet of the manufacturer.

**VI.-Wash solution:** Buffer solution, it does not contain any hazardous ingredient in concentration >0.1% for very toxic or toxic substances, or >1% for corrosive, harmful or irritating substances.

**VII.-Stop solution:** It contains 0.5M sulphuric acid.

Classified substances contents:

In stop solution:

Sulphuric acid	H <sub>2</sub> SO <sub>4</sub>
CAS#7664-93-9	MW: 98.08 g/mol
Concentration: <4.7%	No. CEE: 016-020-00-8
N°CE(EINECS): 231-639-5	Classification: CORROSIVE, C
	No indication for C<5%

In serum diluent:

Trypan blue	C <sub>34</sub> H <sub>24</sub> N <sub>6</sub> Na <sub>4</sub> O <sub>14</sub> S <sub>4</sub>
CAS# 72-57-1	MW: 960.8 g/mol
Concentration: 0.004%	No. CEE: -
N°CE(EINECS): 200-786-7	Classification: HARMFUL, Xn
	No indication for C<1%

In controls, conjugates, wash buffer and serum diluent:

Proclin 300	
CAS# -	MW: -
Concentration: <0.1%	No. CEE: 203-821-4
N°CE(EINECS): -	Classification: IRRITANT, Xi
	No indication for C<1%

### 3.-IDENTIFICATION OF DANGERS

Components of this kit due to the physical/chemical nature and/or the concentration of the substances present in them are classified as non significantly dangerous according to the Regulations mentioned in Section 15. Nevertheless, caution in their handling according to standard safety procedures in the laboratory is strongly recommended.

### 4.-FIRST AID

The exposure to this product is non dangerous for the user if used for the intended application. Nevertheless, should symptoms of exposure appear, take the following measurements:

#### 4.1.-General precautions:

Never provide drink or induce vomiting in the event of loss of consciousness.

#### 4.2.-Inhalation:

Remove affected person to fresh air. In the event sickness persists, seek medical assistance.

#### 4.3.-Contact with the skin:

Wash with plenty of water. Remove contaminated clothing. In the event of irritation, seek medical assistance.

#### 4.4.-Eyes:

Wash with plenty of water (for at least 15 minutes), keeping eyelids open. Seek medical assistance.

#### 4.5.-Ingestion:

Drink large amounts of water. Avoid vomiting. Seek immediate medical assistance- Do not neutralize. Substrate solution may be harmful if ingested.

## **5.- FIRE-FIGHTING**

### **5.1.-Suitable fire-extinguishing means:**

As appropriate to the environment.

### **5.2.-Fire-fighting means which must NOT be used:**

None.

### **5.3.-Special risks:**

Incombustible. In the event of fire, toxic fumes may form: SO<sub>x</sub>. Upon contact with metals hydrogen gas may form (risk of explosion!!). Burning of substrate solution may produce carbon monoxide, carbon dioxide, and nitrogen oxides.

### **5.4.-Protective equipment:**

Gas masks.

## **6.- MEASURES TO BE TAKEN IN THE EVENT OF ACCIDENTAL SPILLAGE**

### **6.1.-Personal measurements:**

Use protective clothes, goggles and gloves to avoid contact with the skin and eyes.

### **6.2.-Environmental measurements:**

Do not allow it to enter the drainage system. Avoid pollution of the soil, water supplies and drains.

### **6.3.-Methods for collection/cleaning:**

Collect up with absorbent materials or, if none available, dry sand or earth, and deposit in waste containers for subsequent elimination in accordance with current legislation. Clean any remains with plenty of water.

## **7.- HANDLING AND STORAGE**

It is not probable problems arise should the product be handled according to general safety and hygienic procedures.

### **7.1.-Handling:**

Controls should be considered as potentially infectious and handled accordingly. Keep containers tightly closed.

### **7.2.-Storage:**

Store at 2-8°C.

## **8.- STAFF EXPOSURE/PROTECTION CONTROLS**

### **8.1.-Technical protective measures:**

Ensure good ventilation and renewal of the air in the premises.

### **8.2.-Respiratory protection:**

In the event of the formation of fumes or aerosols, use suitable respiratory protection.

### **8.3.-Hand protection:**

Use suitable gloves.

### **8.4.-Eye protection:**

Use suitable goggles.

### **8.5.-Individual hygiene, measurements:**

Remove contaminated clothing. Use suitable work clothing. Wash hands and face before breaks and when the job is done. Never pipette by mouth.

### **8.6.-Environmental exposure controls:**

Fullfil the commitments under local environmental protection legislation.

## **9.- PHYSICAL AND CHEMICAL PROPERTIES**

Kit containing vials of reagents and coated plate. Referred to substrate solution:

### **9.1.-Appearance:**

Clear liquid, colorless to yellow tint. Odor of acetone.

### **9.2.-Other physical and chemical properties:**

Not available data.

## **10.- STABILITY AND REACTIVITY**

### **10.1.-Conditions to avoid:**

Stable until expiry date shown on package, when stored at 2-8°C. High temperatures.

### **10.2.-Material to avoid:**

Extremely oxidizing agents.

### **10.3.-Hazardous reactions/decomposition products:**

No decomposition or other reactions may be expected.

### **10.4.-Hazardous polymerization:**

Not expected.

## **11.- TOXICOLOGICAL INFORMATION**

Some product components may be harmful if ingested in large quantities.

Substrate solution effects of acute overexposure:

Inhalation: Irritant.

Ingestion: Harmful if swallowed. Irritant. May cause abdominal discomfort, nausea, vomiting and diarrhea.

Skin contact: Possible irritant.

Eye contact: Irritant. May cause stinging, discomfort and pain.

Carcinogenicity: Not reported.

Mutagenicity: Not reported.

Teratogenicity: Not reported

Controls, conjugates, serum diluent and wash solution, effects of acute overexposure:

Inhalation: Harmful. Irritations of the mucosa and high respiratory tract.

Ingestion: Harmful.

Skin contact: Harmful if absorbed.

Eye contact: Irritant.

Refer to controls:

They contain human-origin material and should be handled as potentially infectious.

## **12.-ENVIRONMENTAL INFORMATION**

Not available data.

## **13.- CONSIDERATIONS REGARDING DISPOSAL**

### **13.1.-Substance or preparation:**

Remove the material containing human serum as waste of special nature. In the European Union, there are no homogeneous standards established for disposal of chemical waste, considered waste of a special nature. Treatment and disposal is subjected to the domestic legislation of each country. In view of this, the competent authority or those companies legally authorized for the elimination of waste should be contacted.

**13.2.-Contaminated containers:**

The contaminated containers from hazardous substances should be treated such as these substances.

**14.- INFORMATION CONCERNING TRANSPORT**

The kit does not require special transport. It should be handled according to general safety procedures for chemical and potentially infectious substances.

**15.- MANDATORY INFORMATIONS**

**15.1.-Symbols:**

Not required.

**15.2.-Danger indication:**

Not required.

**15.3.-R and S phrases:**

Not required.

The product does not contain substances in concentration classified as hazardous in the Regulations about notification of new substances and classification, packing and labeling of hazardous substances (R.D. 363/95) or in R.D. 1078/93 of regulation about classification, packing and labeling of hazardous prepared or in further modifications (Order 20, february,1995), EEC regulations nor in the literature to the best of our knowledge.

They should be handled according to general safety procedures for chemical and potentially infectious substances. The regulation of identification by the EEC directives is not applied to this product.

**16.- OTHER INFORMATIONS**

**16.1.-Restrictions of use:**

This product is exclusively for use in laboratories for in vitro diagnostic testing procedures.

**16.2.-Recommendations of use:**

Handle human-containing material as potentially infectious.

**16.3.-Skill requirements:**

This product should be handled by technically qualified personnel. This safety data sheet must be consulted before use.

**16.4.-Source of key data:**

Safety data sheet of suppliers.

Spanish Service of Toxicological Information. Phone:(34 91) 562 04 20

The information in this safety data sheet is given in good faith and belief in its accuracy based on our knowledge of substance/ preparation concerned at the date of publication and according with the EEC Directives. It does not imply the acceptance of any legal liability or responsibility whatsoever by the Company for the consequences of its use or misuse in any particular circumstances.