Syphilis Fast (modified TPHA) (REF 050-051) is a latex agglutination test for the rapid assay of total anti-Treponema pallidum antibodies in human serum using the slide method.

Contents of the kit:

**LATEX**

**ADSORBED LATEX (R1)**

- 4 x 1.1 mL
- 1 x 1.1 mL

The mixture is not classified as dangerous according to Regulation 1272/2008 and European Directive 1999/45/CE and does not contain hazardous substances and/or with limit values for exposure in concentrations above the established limits.

For this mixture, according to EC Regulations 1907/2006 and 453/2010, is not necessary to develop a material safety data sheet.

**Contents:** Blue-coloured polystyrene latex particles, coated with specific stabilised and freeze-dried Treponema pallidum proteins.

**CONTROL**

**POSITIVE CONTROL**

1 x 0.5 mL

This mixture is not classified according to Regulation 1272/2008.

However, it contains substances classified as hazardous according to the Regulation and/or having occupational exposure limits for which it is required to develop of the material safety data sheet according to art. 31 of Regulation 1907/2006.

For this mixture the material safety data sheet, prepared in accordance with EC regulations 1907/2006 and 453/2010, is available below.

**Contents:** Positive human serum. The serum is calibrated to be considered highly positive. Contains sodium azide 0.09%.

**NEGATIVE CONTROL**

1 x 0.5 mL

The mixture is not classified as dangerous according to Regulation 1272/2008 and European Directive 1999/45/CE and does not contain hazardous substances and/or with limit values for exposure in concentrations above the established limits.

For this mixture, according to EC Regulations 1907/2006 and 453/2010, is not necessary to develop a material safety data sheet.

**Contents:** Serum of animal origin, totally non-reactive with the adsorbed latex. Contains fenol 0.05% and Bronidox 0.02%.
1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 PRODUCT IDENTIFIERS

    Product name: POSITIVE CONTROL
    Product number: PF 0503
    Brand: DIESSE

1.2 RELEVANT IDENTIFIED USES OF THE SUBSTANCES OR MIXTURES AND USES ADVISED AGAINST

    Identified use: Professional use as laboratory reagents.

1.3 DETAILS OF THE SUPPLIER OF THE SAFETY DATA SHEET

    Company: DIESSE Diagnostica Senese SpA
    Registered office: Via A. Solari 19
                    20144 Milan, Italy
    Tel: +39 02 4859121
    Fax: +39 02 48098530

    Production plant: Via delle Rose, 10 – Loc. Tognazza
                    53035 Monteriggioni (SI), Italy
    Tel: +39 0577 319560/61
    Fax: +39 0577 318763

1.4 EMERGENCY TELEPHONE NUMBER

    Emergency number: DIESSE Diagnostica Senese SpA
                    Tel: +39 0577 587143
                    e-mail: letiziavorai@diesse.it

2. HAZARDS IDENTIFICATION

2.1 CLASSIFICATION OF THE SUBSTANCES OR MIXTURE

    Classification according to Regulation (EC) No. 1272/2008:
    The mixtures are not classified according to Regulation 1272/2008.
    However, they contain substances classified as hazardous according to the Regulation and/or having occupational exposure limits for which it is required to develop of the material safety data sheet according to art. 31 of Regulation 1907/2006.

    Hazard statement: None

    Classification according to European Directive 67/548/EEC and 1999/45/EC:
    The mixtures are not classified according to Directives 67/548/CEE and 1999/45/CE

    R-phrases: None

2.2 LABEL ELEMENTS

    Pictograms: None
    Signal word: None
    Hazard statement(s): None
    Precautionary statement(s): None

2.3 OTHER HAZARDS

    None
3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 SUBSTANCES
Not applicable

3.2 MIXTURES

<table>
<thead>
<tr>
<th>International Chemical Identification</th>
<th>Concentration</th>
<th>Classification Directive</th>
<th>Regulation EC/1272/2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium azide</td>
<td>0.09%</td>
<td>T+ R28</td>
<td>Acute Tox. 2 H300</td>
</tr>
<tr>
<td>Cas No 26628-22-8</td>
<td></td>
<td>N R50/53</td>
<td>Aquatic Acute 1 H400</td>
</tr>
<tr>
<td>EC No 247-852-1</td>
<td></td>
<td>R32</td>
<td>Aquatic Chronic 1 H410</td>
</tr>
<tr>
<td>Index No 011-004-00-7</td>
<td></td>
<td></td>
<td>EUH032</td>
</tr>
<tr>
<td>Substance with European exposure</td>
<td></td>
<td></td>
<td>limit</td>
</tr>
</tbody>
</table>

The entire text of Hazard Statements and R-phrases is reported at Section 16 of the sheet.

4. FIRST AID MEASURES

4.1 DESCRIPTION OF FIRST AID MEASURES

General advice: Move the person from the exposure to open air. Consult a physician immediately and show this Material Safety Datasheet.

Skin contact: Wear off the contaminated clothes and wash with copious amounts of water.

Eye contact: If present, remove immediately contact lenses. Wash with plenty of water at least 15 minutes, keeping eyelids opened. Consult an oculist if the irritation persists.

Inhalation: Consult a physician

Ingestion: Rinse mouth immediately and drink a copious amounts of water. Do not cause vomiting or emesis. Call a physician immediately.

4.2 MOST IMPORTANT SYMPTOMS AND EFFECTS
No data available

4.3 INDICATION OF ANY IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED
No data available

5. FIREFIGHTING MEASURES

5.1 EXTINGUISH MEDIA

Suitable extinguishing media: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment

Not Suitable extinguishing media: None

5.2 SPECIAL HAZARDS ARISING FROM THE SUBSTANCE OR MIXTURE

The mixture is not flammable, however in case of fire may release irritating and/or toxic gases (CO₂, CO, NOₓ, SOₓ, HCl).

5.3 ADVICE FOR FIREFIGHTERS

In case of fire wear self-contained breathing apparatus. Avoid that fire extinguishing water contaminates surface water and/or groundwater.

6. ACCIDENTAL RELEASE MEASURES

6.1 PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES

Keep people not involved in the intervention operations away. Avoid inhalation contact with vapors/aerosols. Ensure an adequate ventilation of the affected area.

Do not handle damaged containers or the leaked product before wearing appropriate protective outfit.

6.2 ENVIRONMENTAL PRECAUTIONS
Avoid the contamination of surface water, soil and the dispersion in the air. Do not let product enter into drains. Discharge into the environment must be avoided.

6.3 METHODS AND MATERIALS FOR CONTAINMENT AND CLEANING UP

Contain the leakages with earth and sand. Collect the spilled material with mechanical means avoiding raising of dust and store it in suitable containers for disposal. Use water only to remove residuals, to avoid the danger of spill of product into the sewers.

6.4 REFERENCE TO OTHER SECTIONS

For further information see section 8 and 13

7. HANDLING AND STORAGE

7.1 PRECAUTION FOR SAFE HANDLING

Work in well ventilated areas and in the presence of ventilation systems or personal protective equipment. Do not inhale vapors or mists. Avoid contact with eyes and skin.

7.2 CONDITION FOR SAFE STORAGE, INCLUDING ANY INCOMPATIBILITIES

Keep the containers tightly closed and labeled in a cool, well-ventilated area, away from heat sources and from direct sunlight. Keep the containers vertically avoiding the possibility of falls and leakage.

7.3 SPECIFIC END USE

None

8. EXPOSURE CONTROL/PERSONAL PROTECTION

8.1 CONTROL PARAMETERS

<table>
<thead>
<tr>
<th>Description</th>
<th>Type</th>
<th>TWA/8h mg/m³</th>
<th>STEL/15min mg/m³</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium azide*</td>
<td>D.Lgs 81/2008</td>
<td>0.1</td>
<td>0.3</td>
</tr>
</tbody>
</table>

*Note: Skin

Other information: None

8.2 EXPOSURE CONTROLS

Work and handle according to the usual precautionary measures for handling chemicals. Do not eat, drink or smoke while handling the product; wash hands thoroughly with soap and water before meals and after the work shift. Immediately remove all contaminated clothing.

Appropriate engineering controls:

Ensure an adequate ventilation of the working area.

Personal Protective Equipment:

The suggestions on the use of specific PPE are indicative. Their choice should be made according to the use of the product and the instructions given by the supplier of the device.

- Hand protections:
  Chemical-resistant gloves, compliant with EN 374.
  Suitable material: nitrile rubber (thickness: 0.11 mm).
  Gloves have to be checked by the user, before using.
  Dispose the used gloves according to good laboratory practices and to law.
  Clean and dry the hands after the use.

- Eye protections:
  Side Shields Safety Goggles compliant with EN 166

- Body protections:
  Work outfits.

- Respiratory protections:
  Based on the results of the risk assessment the use a full face mask with combined filter type AP (EN 14387) may be need.

8.3 ENVIRONMENTAL EXPOSURE CONTROLS:

Do not discard residuals in the environment. Discard the empty containers as hazardous waste.
9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES

- **Appearance**: Liquid
- **Odor**: Odorless
- **Odor threshold**: Not pertinent
- **pH**: No data available
- **Melting point/freezing point**: No data available
- **Initial boiling point and boiling range**: No data available
- **Flash point**: Not pertinent
- **Evaporation rate**: Not pertinent
- **Flammability**: Not pertinent
- **Upper/lower flammability or explosive limit**: Not pertinent
- **Vapor pressure**: No data available
- **Vapor density**: No data available
- **Relative density**: No data available
- **Water solubility**: Soluble in water
- **Partition coefficient: n-octano/water**: No data available
- **Autoignition temperature**: Not pertinent
- **Decomposition temperature**: No data available
- **Viscosity**: No data available
- **Explosive properties**: Not explosive
- **Oxidizing properties**: No data available

9.2 OTHER SAFETY INFORMATION

- None

10. STABILITY AND REACTIVITY

10.1 REACTIVITY

- No data available

10.2 CHEMICAL STABILITY

- Stable under the recommended transport, handling and storage conditions

10.3 POSSIBILITY OF HAZARDOUS REACTIONS

- No data available

10.4 CONDITIONS TO AVOID

- Avoid the strong heating of the mixture.
- **Sodium azide**: Contact with acids liberates very toxic gas.

10.5 INCOMPATIBLE MATERIALS

- Agenti ossidanti forti ed agenti riducenti

10.6 HAZARDOUS DECOMPOSITION PRODUCTS

- When heated or in case of fire, vapors potentially dangerous to health may be produced.

11. TOXICOLOGICAL INFORMATION

11.1 INFORMATION ON TOXICOLOGICAL EFFECTS

- There is no information on toxicological effects of exposure to mixtures. These, however, might cause health effects in sensitive individuals.
- In any case, it is recommended to handle them in accordance with the rules of good industrial hygiene.

- **Acute toxicity**: No data available
- **Skin irritation/corrosion**: No data available
- **Eye lesions/severe eye irritation**: No data available
- **Respiratory/skin sensitization**: No data available
- **Mutagenicity for germ cells**: No data available
- **Carcinogenicity**: No data available
- **Reproductive toxicity**: No data available
- **Toxicity for target organs (single and repeated exposures)**: No data available
- **Hazards in case of inhalation**: No data available
- **Additional information**: No data available
12. ECOLOGICAL INFORMATION

12.1 Toxicity


12.2 Persistence and Degradability

No data available

12.3 Bioaccumulative Potential

No data available

12.4 Mobility in Soil

No data available

12.5 Residue of PBT and vPvB Assessment

No data available

12.6 Other Adverse Effects

No data available

13. DISPOSAL CONSIDERATIONS

13.1 Waste Treatment Methods

The product and its container should be considered special waste. Their transport and disposal should be performed by authorized specialized companies according to the law.

14. TRANSPORT INFORMATION

Not hazardous good according to the transport regulations.

15. REGULATORY INFORMATION

15.1 Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Hazard labeling under directives 1272/2008 (EC) and its subsequent amendments.

Decree 81/2008:
The use of this chemical entails the obligation of "Risk Assessment" by the employer in accordance with the provisions of the Decree April 9, 2008 n. 81 and subsequent amendments. Workers exposed to this chemical agent must not undergo health checks whether the results of the risk assessment show that, depending on the type and quantity of chemical agent and the method and frequency of exposure to this agent, there is only one "Low risk to the safety and irrelevant to the health" of the workers and the measures provided for in the same Decree are sufficient to reduce the risk.

European Standard 1907/2006/EC:
Not applicable

Directive 96/82/EC (Seveso Directive):
Not applicable

15.2 Chemical Safety Assessment

Not performed for the product

16. OTHER INFORMATION

This product has to be used for diagnostic use only by personnel who is qualified and trained on the hazards shown in this safety sheet.

Text of the hazard statements present at point 3

H 00 Fatal if inhaled

H 00 Eye to i to ail life

H 00 Eye to i to ail life ith lo lastic effe ts

EU: H 00 Co t i th a d id i et es ey to i as
Text of the Risk phrases present at point 3
R28  Very toxic if swallowed
R32  Contact with acids liberates very toxic gas
R50/53 Very toxic to aquatic organisms. May cause long-term adverse effects in the aquatic environment

REFERENCES:
1. Directive 1999/45/EC and following amendments
2. Directive 67/548/EEC and following amendments and technical adjustments
7. The Merck Index
8. Handling Chemical Safety
9. NIOSH - Registry of Toxic Effects of Chemical Substances
10. INRS - Fiche Toxique

DIESSE Diagnostica Senese SpA declares that the information contained in this data sheet is based on the knowledge available to us on the date of the last version. Users must verify the suitability and accuracy of the provided information according to the specific use of the product. The document has not be accepted as a guarantee of any specific product property. Because of the use of this product is not subject to our direct control the users under their own responsibility must observe the laws and regulations relating to health and safety. We accept no responsibility for improper use.

This data sheet supersedes each previous edition.