

**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%.

**CONTROL -**

*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%.



**MATERIAL SAFETY DATA SHEET**  
**SYPHILIS FAST (modified TPHA)**  
**POSITIVE CONTROL**  
(According to Regulation (EC) No. 1907/2006 and 453/2010)

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**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 MIXTURE 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

<u>Registered office:</u> Via A. Solari 19 20144 Milan, Italy Tel: +39 02 4859121 Fax: +39 02 48008530	<u>Production plant:</u> Via delle Rose, 10 – Loc. Tognazza 53035 Monteriggioni (SI), Italy Tel: +39 0577 319560/61 Fax: +39 0577 318763
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**1.4 EMERGENCY TELEPHONE NUMBER**

**Emergency number:** DIESSE Diagnostica Senese SpA  
Tel: +39 0577 587143  
e-mail: [letiziarovai@diesse.it](mailto:letiziarovai@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



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### 3. COMPOSITION/INFORMATION ON INGREDIENTS

**3.1 SUBSTANCES** Not applicable

**3.2 MIXTURES**

International Chemical Identification	Concentration	Classification Directive 67/548/EEC	Regulation EC/1272/2008	
Sodium azide	0.09%	T+ R28	Acute Tox. 2	H300
Cas No 26628-22-8		N R50/53	Aquatic Acute 1	H400
EC No 247-852-1		R32	Aquatic Chronic 1	H410
Index No 011-004-00-7			EUH032	
Substance with European exposure limit				

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 (CO<sub>2</sub>, CO, NO<sub>x</sub>, SO<sub>x</sub>, 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**



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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**

**Applicable exposure limits:**

Description	Type	TWA/8h		STEL/15min	
		mg/m <sup>3</sup>	ppm	mg/m <sup>3</sup>	ppm
Sodium azidel*	D.Lgs 81/2008	0.1		0.3	

\*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.



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## 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



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12. ECOLOGICAL INFORMATION

12.1 TOXICITY

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ate a y s o s e e s o o t a m i a t e s o i l o e e t a t i o i f o m the o m p e t e t a t h o i t i e s

12.2 PERSISTENCE AND DEGRADABILITY

No data a a i l a l e

12.3 BIOACCUMULATIVE POTENTIAL

No data a a i l a l e

12.4 MOBILITY IN SOIL

No data a a i l a l e

12.5 RESULTS OF PBT AND vPvB ASSESSMENT

No data a a i l a l e

12.6 OTHER ADVERSE EFFECTS

No data a a i l a l e

13. DISPOSAL CONSIDERATIONS

13.1 WASTE TREATMENT METHODS

The p o d t a d i t s o t a i e s s h o l d e o s i d e e d s p e i a l a s t e  
The i t a s p o t a d d i s p o s a l s h o l d e p e f o m e d y a t h o i e d s p e i a l i e d o m p a i e s a o d i to the l a

14. TRANSPORT INFORMATION

Not h a a d o s o o d a o d i to the t a s p o t e l a t i o s

15. REGULATORY INFORMATION

15.1 SAFETY, HEALTH AND ENVIRONMENTAL REGULATIONS/LEGISLATION SPECIFIC FOR THE SUBSTANCE OR MIXTURE

H a a d l a e l i d e d i e t i e s 1 00 (EC) a d i t s s e e t a m e d m e t s

Leislative reference 1 00

The s e of this h e m i a l e t a i l s the o l i a t i o of R i s A s s e s s m e t y the e m p l o y e i a o d a e i t h the p o s i o s of  
the e e e A p i l 00 l a d s s e e t a m e d m e t s o e s e p o s e d to this h e m i a l a e t m s t o t d e o  
h e a l t h h e s h e t h e t h e s l t s of the i s a s s e s s m e t s h o t h a t d e p e d i o the t y p e a d a t i t y of h e m i a l a e t  
a d the m e t h o d a d f e e y of e p o s e to this a e t the e i s o l y o e L o i s to the s a f e t y a d i e l e a t t o the  
h e a l t h of the o e s a d the m e a s e s p o i d e d f o i the s a m e e e e a e s f f i e t t o e d e the i s

European Standard 1 0 00 EC

Not a p p l i a l e

index EC (Secondary)

Not a p p l i a l e

15.2 CHEMICAL SAFETY ASSESSMENT

Not p e f o m e d f o the p o d t

16. OTHER INFORMATION

This p o d t h a s t o e s e d f o d i a o s t i s e o l y y p e s o e l h o i s a l i f i e d a d t a i e d o the h a a d s s h o i this  
s a f e t y s h e e t

Text of the hazard statements present at point 3

H 00 Fatal if s a l l o e d

H 00 e y t o i t o a a t i l i f e

H 10 e y t o i t o a a t i l i f e i t h l o l a s t i e f f e t s

E H 0 C o t a t i t h a i d s l i e a t e s e y t o i a s



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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
3. Regulation (EC) 1907/2006 of the European Parliament (REACH) as amended
4. Regulation (EC) 1272/2008 of the European Parliament (CLP) as amended
5. Commission Regulation (EU) 453/2010
6. ECHA European Chemicals Agency [www.echa.europa.eu](http://www.echa.europa.eu)
7. The Merck Index
8. Handling Chemical Safety
9. NIOSH - Registry of Toxic Effects of Chemical Substances
10. INRS - Fiche Toxicologique

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