

**SAFETY DATA SHEET**  
according to the European Directive 91/155/EEC

Product: **PASTOREX<sup>®</sup> STAPH-PLUS**  
 Code: **56356** - 1 x 50 tests  
**56353** - 5 x 50 tests  
 SDF No.: **56356**

 Version: **3**

### 1. Commercial product name and supplier

**Name of product:** **PASTOREX<sup>®</sup> STAPH-PLUS**  
**Supplier**  
**Name:** *Bio-Rad*  
**Address:** *3, boulevard Raymond Poincaré*  
*92430 Marnes-la-Coquette*  
**Telephone:** *+ 33 (0)1 47 95 60 00*  
**Fax:** *+ 33 (0)1 47 41 91 33*  
**Emergency number:** *+ 33 (0)1 45 42 59 59 (in France: Orfila answering machine).*

### 2. Composition / information about ingredients

#### PREPARATIONS

#### Chemical composition:

kit components:	code 56356 50 tests	code 56353 5 x 50 tests
<b>Latex test</b> Red latex particles sensitized by fibrinogen, IgG and monoclonal antibodies directed against capsular polysaccharides of <i>Staphylococcus aureus</i> Preservative: 0,02% Thimerosal™ and < 0,1% sodium azide.	1 vial 1 x 1 ml	5 vials 5 x 1 ml
<b>Negative control</b> Latex particles sensitized by bovine albumin solution. Preservative: 0,02% Thimerosal™ and < 0,1% sodium azide.	1 vial 1 x 1 ml	5 vials 5 x 1 ml

**Hazardous acting components:** None.

**Hazardous components:**

- 0,02% Thimerosal™ - not dangerous at this concentration
- < 0.1% Sodium azide - not dangerous at this concentration.

**Use:** *In vitro* diagnostic medical device (reagent).

### 3. Hazards identification

**MAIN DANGERS:**

Product not presenting any danger according to European directives 67/548/EEC and 1999/45/EC on chemical substances and chemical preparations as well as their respective updates.

**Harmful effects on health:** Under the conditions of use recommended in the instructions and when complying with Good Laboratory Practice, this product does not present any danger for health.

**Effects on environment:** Under the conditions of use recommended in the instructions and when complying with Good Laboratory Practice, this product does not present any danger for the environment.

**Physical and chemical dangers:** Does not present any physical or chemical danger.

**Specific risks:**

- It is unwise to dispose reagents down the drains. The sodium azide can react with the copper or lead drains to form metal azides highly explosive. During elimination, rinse with large water.

### 4. First aid measures

**Inhalation:** /

**Skin contact:** Wash with soap and water.

**Eye contact:** Rinse immediately with physiological solution or water. Seek a medical advice in the case of irritation or pain and show this sheet.

**Ingestion:** / .

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### 5. Fire-fighting measures

**Suitable extinguishing media:** Usual methods used in the laboratory (H<sub>2</sub>O spray, CO<sub>2</sub>, foam, etc.).

**Specific dangers:** None.

**Special methods of intervention:** No specific methods.

**Special protective equipment:** Usual.

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### 6. Accidental release measures

**Personal precautions:** Wear disposable gloves, glasses and appropriate protective clothing.

**Environmental precautions:** Do not discard reagents and contaminated wastes down the drain.

**Methods for cleaning up:** Collect reagents with liquid absorbents or absorbent paper and then clean with water and with a detergent.

**Disposal:** Refer to Chapter 13.

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### 7. Handling and storage

#### Handling

**Technical measures** Wear disposable gloves, glasses and appropriate protective clothing.

**Precautions:** Avoid all contact with reagents even those considered not to be dangerous. Avoid spilling. Wash your hands after handling. Do not drink, eat or smoke. Do not pipet with mouth. Follow the Good Laboratory Practices.

**Instructions:** Refer to the product instruction for use.

#### Storage

**Technical measures** Keep reagents hermetically sealed.

**Storage conditions:** Follow storage recommendations stated on labels. Lot number and expiration date are stated on packaging.

**Packaging materials:** Store reagents in their original container.

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### 8. Exposure control / Personal protection

**Technical measures** Comply with Good Laboratory Practices to avoid all direct contact with reagents.

**Personal protective equipment:** Disposable gloves, protective glasses, protective clothing.

**Hygiene measures** Comply with Good Laboratory Practices. Wear disposable gloves when handling reagents and samples and wash your hands thoroughly after handling them. Carry out necessary vaccinations and biological follow-up. Also see Chapter 7.

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### 9. Physical and chemical properties

**Appearance:** Latex test reagent - red suspension  
Negative control - colorless suspension.

**Odour:** /

**pH:** /

**Density:** /

**Characteristic temperatures:** /

**Solubility:** /.

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### 10. Stability and reactivity

**Stability:** This reagent is stable, under the storage conditions recommended by the manufacturer, until the expiry date indicated on the packaging.

**Hazardous reactions:** The sodium azide can react with the copper or lead drains to form metal azides highly explosive. During elimination, rinse with large water.

**Conditions to avoid:** /

**Materials to avoid:** /

**Hazardous decomposition products:** None.

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### 11. Toxicological information

**Acute toxicity:** No known toxicological data.

**Local effects:** No known local effects.

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### 12. Ecological information

**Mobility:** /

**Degradability:** /

**Bioaccumulation:** /

**Ecotoxicity:** /

**Diverse harmful effects:** /

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### 13. Disposal considerations

**Wastes of residues** No uniform regulations have been defined concerning the elimination of chemical product and their residues in the European Community.

Chemical products and their residues must be considered to be special wastes. Their elimination is regulated by each member state. We recommend you to contact the appropriate authorities or companies specialized in the elimination of wastes, who can inform you about the ways to eliminate special wastes.

**Contaminated packaging:** Elimination in accordance with current legislation. Contaminated containers must be treated in the same way as the respective chemical product. Except in the case of specific regulations, non-contaminated containers can be eliminated in the same way as household wastes or can be recycled.

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### 14. Transport information

**Regulations:** Not regulated

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### 15. Regulatory information

**Community regulations:**

- Directive 67/548/EEC and its updated versions.

- Directive 1999/45/EC.

- Directives 91/155/EEC, 93/112/EC and 2001/58/EC.

**EC labeling:** Not applicable - not dangerous product.

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### 16. Other information

**Types of use:** Latex agglutination test for the identification of *Staphylococcus aureus*.

**Modification reason:** General modification.

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*This form completes, but does not replace the technical instructions.*

*The information indicated here is based on the current state of knowledge about the product concerned, at the time of the update and is presented in good faith. Users are also informed about the risks possibly incurred when a product is used for purposes other than those for which it is designed. The user must always be familiar with and apply all texts governing his/her particular activity. The user is solely responsible for taking the precautions related to use of the product. All of the indicated regulatory requirements are simply designed to help the user meet all of the required obligations when using a dangerous product. This list must not be considered to be exhaustive. It does not relieve the user from his/her responsibility to ensure compliance with all other obligations defined in texts other than those indicated above and governing the possession and use of the product, for which he/she is solely responsible.*

Date of creation / update:

**12 July 2002**  

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