

**KIT COMPONENTS**Product name: **PASTOREX™ STAPH-PLUS, 1 x 50 Tests**Product code: **56356**

<b>Article number</b>	<b>Description</b>	<b>Quantity</b>	<b>Symbols</b>
5637A	PASTOREX™ STAPH-PLUS - Negative Control, 1 ml	1	GHS07
5637B	PASTOREX™ STAPH-PLUS - Latex Test, 1 ml	1	GHS07

**Safety Data Sheet**  
29 CFR Part 1910.1200

Printing date 08/11/2015

Reviewed on 08/11/2015

**1 Identification**· **Product identifier**

- **Trade name: PASTOREX™ STAPH-PLUS - Negative Control, 1 ml**
  - **Article number:** 5637A
- **Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
  - **Application of the substance / the mixture** In vitro diagnostic medical device or component.

· **Details of the supplier of the safety data sheet**

- **Manufacturer/Supplier:**  
Bio-Rad  
3, Boulevard Raymond Poincaré  
F-92430 Marnes-la-Coquette  
Tel.: +33 (0)1 47 95 60 00  
Fax : +33 (0)1 47 41 91 33  
e-mail: fds-msds.fr@bio-rad.com
- **Information department:** Customer support.
- **Emergency telephone number:** See item 16

**2 Hazard(s) identification**· **Classification of the substance or mixture**

Skin Sens. 1 H317 May cause an allergic skin reaction.

· **Label elements**· **GHS label elements**

The product is classified and labeled according to the Globally Harmonized System (GHS).

- **Hazard pictograms** GHS07
- **Signal word** Warning
- **Hazard-determining components of labeling:**  
reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1)
- **Hazard statements**  
May cause an allergic skin reaction.
- **Precautionary statements**  
Wear protective gloves/protective clothing/eye protection/face protection.  
If skin irritation or rash occurs: Get medical advice/attention.  
If on skin: Wash with plenty of water.  
Dispose of contents/container in accordance with local/regional/national/international regulations.

· **Classification system:**

- **NFPA ratings (scale 0 - 4)**  
Health = 0  
Fire = 0  
Reactivity = 0
- **HMIS-ratings (scale 0 - 4)**  
Health = 0  
Fire = 0  
Reactivity = 0

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**Trade name: PASTOREX™ STAPH-PLUS - Negative Control, 1 ml**

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- **Other hazards**
- **Results of PBT and vPvB assessment**
  - **PBT:** Not applicable.
  - **vPvB:** Not applicable.

### 3 Composition/information on ingredients

- **Chemical characterization: Mixtures**
  - **Description:** Mixture containing hazardous components.

- **Dangerous components:**

57-50-1	sucrose, pure	2.5-10%
55965-84-9	reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1) 	0.01-0.1%

### 4 First-aid measures

- **Description of first aid measures**
  - **After inhalation:** Supply fresh air and to be sure call for a doctor.
  - **After skin contact:** Immediately wash with water and soap and rinse thoroughly.
  - **After eye contact:** Rinse opened eye for several minutes under running water.
  - **After swallowing:** Immediately call a doctor.
- **Information for doctor:**
  - **Most important symptoms and effects, both acute and delayed**  
No further relevant information available.
  - **Indication of any immediate medical attention and special treatment needed**  
No further relevant information available.

### 5 Fire-fighting measures

- **Extinguishing media**
  - **Suitable extinguishing agents:**  
CO<sub>2</sub>, extinguishing powder or water spray. Fight larger fires with water spray.  
Use fire fighting measures that suit the environment.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
  - **Protective equipment:** No special measures required.

### 6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**  
Wear protective clothing.  
Wear disposable gloves.
- **Environmental precautions:** Do not allow product to reach sewage system or any water course.

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**Trade name: PASTOREX™ STAPH-PLUS - Negative Control, 1 ml**

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- **Methods and material for containment and cleaning up:**  
Absorb liquid components with liquid-binding material.
- **Reference to other sections**  
See Section 7 for information on safe handling.  
See Section 8 for information on personal protection equipment.  
See Section 13 for disposal information.

**7 Handling and storage**

- **Handling:**
  - **Precautions for safe handling** Follow good laboratory practices.
  - **Information about protection against explosions and fires:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
  - **Storage:**
    - **Requirements to be met by storerooms and receptacles:** No special requirements.
    - **Information about storage in one common storage facility:** Not required.
    - **Further information about storage conditions:** None.
- **Specific end use(s)** No further relevant information available.

**8 Exposure controls/personal protection**

- **Additional information about design of technical systems:** No further data; see item 7.
- **Control parameters**

· **Components with limit values that require monitoring at the workplace:**

**57-50-1 sucrose, pure**

PEL	Long-term value: 15* 5** mg/m <sup>3</sup> *total dust **respirable fraction
REL	Long-term value: 10* 5** mg/m <sup>3</sup> *total dust **respirable fraction
TLV	Long-term value: 10 mg/m <sup>3</sup>

· **Additional information:** The lists that were valid during the creation were used as basis.

- **Exposure controls**
  - **Personal protective equipment:**
    - **General protective and hygienic measures:**  
Immediately remove all soiled and contaminated clothing.  
Wash hands before breaks and at the end of work.
    - **Breathing equipment:** Suitable respiratory protective device recommended.
    - **Protection of hands:** Protective gloves
    - **Eye protection:** Safety glasses

**9 Physical and chemical properties**

- **Information on basic physical and chemical properties**
  - **General Information**
    - **Appearance:**
      - **Form:** Water dispersible granulate

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**Trade name: PASTOREX™ STAPH-PLUS - Negative Control, 1 ml**

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· <b>Color:</b>	Red
· <b>Odor:</b>	Weak, characteristic
· <b>pH-value:</b>	Not determined.
· <b>Change in condition</b>	
· <b>Melting point/Melting range:</b>	Undetermined.
· <b>Boiling point/Boiling range:</b>	Undetermined.
· <b>Flash point:</b>	Not applicable.
· <b>Danger of explosion:</b>	Product does not present an explosion hazard.
· <b>Density:</b>	Not determined.
· <b>Solubility in / Miscibility with</b>	
· <b>Water:</b>	Dispersible.
· <b>Solvent content:</b>	
· <b>Solids content:</b>	10.0 %
· <b>Other information</b>	No further relevant information available.

**10 Stability and reactivity**

- **Reactivity**
  - **Chemical stability**
    - **Thermal decomposition / conditions to be avoided:**  
No decomposition if used according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known.

**11 Toxicological information**

- **Information on toxicological effects**
  - **Acute toxicity:**
    - **Sensitization:** Sensitization possible through skin contact.
  - **Additional toxicological information:**  
The product shows the following dangers according to internally approved calculation methods for preparations:  
Irritant
- **Carcinogenic categories**

· <b>IARC (International Agency for Research on Cancer)</b>
None of the ingredients is listed.

· <b>NTP (National Toxicology Program)</b>
None of the ingredients is listed.

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· **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

**12 Ecological information**

- **Toxicity**
  - **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behavior in environmental systems:**
  - **Bioaccumulative potential** No further relevant information available.
  - **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
  - **General notes:** Avoid transfer into the environment.
- **Results of PBT and vPvB assessment**
  - **PBT:** Not applicable.
  - **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

**13 Disposal considerations**

- **Waste treatment methods**
  - **Recommendation:** Must be specially treated adhering to official regulations.
- **Uncleaned packagings:**
  - **Recommendation:** Disposal must be made according to official regulations.

**14 Transport information**

- |  |                 |
|--|-----------------|
| · <b>UN-Number</b>   |                 |
| · DOT, ADR, ADN, IMDG, IATA  | Void            |
| · <b>UN proper shipping name</b>   |                 |
| · DOT, ADR, ADN, IMDG, IATA  | Void            |
| · <b>Transport hazard class(es)</b>  |                 |
| · DOT, ADR, ADN, IMDG, IATA  |                 |
| · Class  | Void            |
| · <b>Packing group</b>   |                 |
| · DOT, ADR, IMDG, IATA   | Void            |
| · <b>Environmental hazards:</b>  |                 |
| · Marine pollutant:  | No              |
| · <b>Special precautions for user</b>  | Not applicable. |
| · <b>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b> | Not applicable. |

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**Trade name: PASTOREX™ STAPH-PLUS - Negative Control, 1 ml**

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· **UN "Model Regulation":** -

**15 Regulatory information**

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**  
· **Sara**

· **Section 355 (extremely hazardous substances):**

None of the ingredient is listed.

· **Section 313 (Specific toxic chemical listings):**

None of the ingredients is listed.

· **TSCA (Toxic Substances Control Act):**

57-50-1 sucrose, pure

56-40-6 Glycine

7647-14-5 sodium chloride

7732-18-5 water, distilled, conductivity or of similar purity

· **Proposition 65**

· **Chemicals known to cause cancer:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

· **Chemicals known to cause developmental toxicity:**

None of the ingredients is listed.

· **Carcinogeny categories**

· **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

· **TLV (Threshold Limit Value established by ACGIH)**

57-50-1 sucrose, pure

A4

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients is listed.

· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

**16 Other information**

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Department issuing SDS:**

SDS / FDS Administr.

Bio-Rad

Marnes-la-Coquette, France

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**Trade name: PASTOREX™ STAPH-PLUS - Negative Control, 1 ml**

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**- Contact:**

Customer Support  
Phone : +33 (0)1 47 95 60 91  
USA  
Bio-Rad Laboratories  
6565 185th Avenue NE  
Redmond, WA 98052-5039

Phone Number: 1-800-2BIORAD (1-800-224-6723) or (425) 881-8300 (daytime PST)

· **Date of preparation / last revision** 08/11/2015 / 2· **Abbreviations and acronyms:**

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)  
IMDG: International Maritime Code for Dangerous Goods  
DOT: US Department of Transportation  
IATA: International Air Transport Association  
ACGIH: American Conference of Governmental Industrial Hygienists  
EINECS: European Inventory of Existing Commercial Chemical Substances  
ELINCS: European List of Notified Chemical Substances  
CAS: Chemical Abstracts Service (division of the American Chemical Society)  
NFPA: National Fire Protection Association (USA)  
HMIS: Hazardous Materials Identification System (USA)  
Acute Tox. 3: Acute toxicity, Hazard Category 3  
Skin Corr. 1B: Skin corrosion/irritation, Hazard Category 1B  
Skin Sens. 1: Sensitisation - Skin, Hazard Category 1  
Aquatic Acute 1: Hazardous to the aquatic environment - AcuteHazard, Category 1  
Aquatic Chronic 1: Hazardous to the aquatic environment - Chronic Hazard, Category 1

USA



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29 CFR Part 1910.1200

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Reviewed on 08/11/2015

**1 Identification**· **Product identifier**

- **Trade name: PASTOREX™ STAPH-PLUS - Latex Test, 1 ml**
  - **Article number:** 5637B
- **Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
  - **Application of the substance / the mixture** In vitro diagnostic medical device or component.

· **Details of the supplier of the safety data sheet**· **Manufacturer/Supplier:**

Bio-Rad  
3, Boulevard Raymond Poincaré  
F-92430 Marnes-la-Coquette  
Tel.: +33 (0)1 47 95 60 00  
Fax : +33 (0)1 47 41 91 33  
e-mail: fds-msds.fr@bio-rad.com

- **Information department:** Customer support.
- **Emergency telephone number:** See item 16

**2 Hazard(s) identification**· **Classification of the substance or mixture**

Skin Sens. 1 H317 May cause an allergic skin reaction.

· **Label elements**· **GHS label elements**

The product is classified and labeled according to the Globally Harmonized System (GHS).

- **Hazard pictograms** GHS07
- **Signal word** Warning

· **Hazard-determining components of labeling:**

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1)

· **Hazard statements**

May cause an allergic skin reaction.

· **Precautionary statements**

Wear protective gloves/protective clothing/eye protection/face protection.

If skin irritation or rash occurs: Get medical advice/attention.

If on skin: Wash with plenty of water.

Dispose of contents/container in accordance with local/regional/national/international regulations.

· **Classification system:**· **NFPA ratings (scale 0 - 4)**

Health = 0

Fire = 0

Reactivity = 0

· **HMIS-ratings (scale 0 - 4)**

Health = 0

Fire = 0

Reactivity = 0

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**Trade name: PASTOREX™ STAPH-PLUS - Latex Test, 1 ml**

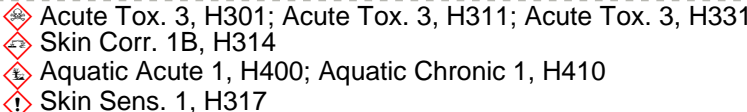
(Contd. of page 1)

- **Other hazards**
- **Results of PBT and vPvB assessment**
  - **PBT:** Not applicable.
  - **vPvB:** Not applicable.

### 3 Composition/information on ingredients

- **Chemical characterization: Mixtures**
  - **Description:** Mixture containing hazardous components.

- **Dangerous components:**

57-50-1	sucrose, pure	2.5-10%
55965-84-9	reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1) 	0.01-0.1%

### 4 First-aid measures

- **Description of first aid measures**
  - **After inhalation:** Supply fresh air and to be sure call for a doctor.
  - **After skin contact:** Immediately wash with water and soap and rinse thoroughly.
  - **After eye contact:** Rinse opened eye for several minutes under running water.
  - **After swallowing:** Immediately call a doctor.
- **Information for doctor:**
  - **Most important symptoms and effects, both acute and delayed**  
No further relevant information available.
  - **Indication of any immediate medical attention and special treatment needed**  
No further relevant information available.

### 5 Fire-fighting measures

- **Extinguishing media**
  - **Suitable extinguishing agents:**  
CO<sub>2</sub>, extinguishing powder or water spray. Fight larger fires with water spray.  
Use fire fighting measures that suit the environment.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
  - **Protective equipment:** No special measures required.

### 6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**  
Wear protective clothing.  
Wear disposable gloves.
- **Environmental precautions:** Do not allow product to reach sewage system or any water course.

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**Trade name: PASTOREX™ STAPH-PLUS - Latex Test, 1 ml**

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- **Methods and material for containment and cleaning up:**  
Absorb liquid components with liquid-binding material.
- **Reference to other sections**  
See Section 7 for information on safe handling.  
See Section 8 for information on personal protection equipment.  
See Section 13 for disposal information.

**7 Handling and storage**

- **Handling:**
  - **Precautions for safe handling** Follow good laboratory practices.
  - **Information about protection against explosions and fires:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
  - **Storage:**
    - **Requirements to be met by storerooms and receptacles:** No special requirements.
    - **Information about storage in one common storage facility:** Not required.
    - **Further information about storage conditions:** None.
- **Specific end use(s)** No further relevant information available.

**8 Exposure controls/personal protection**

- **Additional information about design of technical systems:** No further data; see item 7.
- **Control parameters**

· **Components with limit values that require monitoring at the workplace:**

**57-50-1 sucrose, pure**

PEL	Long-term value: 15* 5** mg/m <sup>3</sup> *total dust **respirable fraction
REL	Long-term value: 10* 5** mg/m <sup>3</sup> *total dust **respirable fraction
TLV	Long-term value: 10 mg/m <sup>3</sup>

· **Additional information:** The lists that were valid during the creation were used as basis.

- **Exposure controls**
  - **Personal protective equipment:**
    - **General protective and hygienic measures:**  
Immediately remove all soiled and contaminated clothing.  
Wash hands before breaks and at the end of work.
    - **Breathing equipment:** Suitable respiratory protective device recommended.
    - **Protection of hands:** Protective gloves
    - **Eye protection:** Safety glasses

**9 Physical and chemical properties**

- **Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

· **Form:** Water dispersible granulate

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**Trade name: PASTOREX™ STAPH-PLUS - Latex Test, 1 ml**

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· <b>Color:</b>	Red
· <b>Odor:</b>	Weak, characteristic
· <b>pH-value:</b>	Not determined.
· <b>Change in condition</b>	
· <b>Melting point/Melting range:</b>	Undetermined.
· <b>Boiling point/Boiling range:</b>	Undetermined.
· <b>Flash point:</b>	Not applicable.
· <b>Danger of explosion:</b>	Product does not present an explosion hazard.
· <b>Density:</b>	Not determined.
· <b>Solubility in / Miscibility with</b>	
· <b>Water:</b>	Dispersible.
· <b>Solvent content:</b>	
· <b>Solids content:</b>	10.0 %
· <b>Other information</b>	No further relevant information available.

**10 Stability and reactivity**

- **Reactivity**
  - **Chemical stability**
    - **Thermal decomposition / conditions to be avoided:**  
No decomposition if used according to specifications.
  - **Possibility of hazardous reactions** No dangerous reactions known.
  - **Conditions to avoid** No further relevant information available.
  - **Incompatible materials:** No further relevant information available.
  - **Hazardous decomposition products:** No dangerous decomposition products known.

**11 Toxicological information**

- **Information on toxicological effects**
  - **Acute toxicity:**
    - **Sensitization:** Sensitization possible through skin contact.
  - **Additional toxicological information:**  
The product shows the following dangers according to internally approved calculation methods for preparations:  
Irritant
  - **Carcinogenic categories**

· <b>IARC (International Agency for Research on Cancer)</b>
None of the ingredients is listed.

· <b>NTP (National Toxicology Program)</b>
None of the ingredients is listed.

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· **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

**12 Ecological information**

- **Toxicity**
  - **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behavior in environmental systems:**
  - **Bioaccumulative potential** No further relevant information available.
  - **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
  - **General notes:** Avoid transfer into the environment.
- **Results of PBT and vPvB assessment**
  - **PBT:** Not applicable.
  - **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

**13 Disposal considerations**

- **Waste treatment methods**
  - **Recommendation:** Must be specially treated adhering to official regulations.
- **Uncleaned packagings:**
  - **Recommendation:** Disposal must be made according to official regulations.

**14 Transport information**

- |  |                 |
|--|-----------------|
| · <b>UN-Number</b>   |                 |
| · DOT, ADR, ADN, IMDG, IATA  | Void            |
| · <b>UN proper shipping name</b>   |                 |
| · DOT, ADR, ADN, IMDG, IATA  | Void            |
| · <b>Transport hazard class(es)</b>  |                 |
| · DOT, ADR, ADN, IMDG, IATA  |                 |
| · Class  | Void            |
| · <b>Packing group</b>   |                 |
| · DOT, ADR, IMDG, IATA   | Void            |
| · <b>Environmental hazards:</b>  |                 |
| · Marine pollutant:  | No              |
| · <b>Special precautions for user</b>  | Not applicable. |
| · <b>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b> | Not applicable. |

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**Trade name: PASTOREX™ STAPH-PLUS - Latex Test, 1 ml**

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· **UN "Model Regulation":** -

**15 Regulatory information**

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**  
· **Sara**

· **Section 355 (extremely hazardous substances):**

None of the ingredient is listed.

· **Section 313 (Specific toxic chemical listings):**

None of the ingredients is listed.

· **TSCA (Toxic Substances Control Act):**

57-50-1	sucrose, pure
56-40-6	Glycine
7647-14-5	sodium chloride
25952-53-8	Carbodiimide
7732-18-5	water, distilled, conductivity or of similar purity

· **Proposition 65**

· **Chemicals known to cause cancer:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

· **Chemicals known to cause developmental toxicity:**

None of the ingredients is listed.

· **Carcinogeny categories**

· **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

· **TLV (Threshold Limit Value established by ACGIH)**

57-50-1	sucrose, pure	A4
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· **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients is listed.

· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

**16 Other information**

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Department issuing SDS:**

SDS / FDS Administr.

Bio-Rad

Marnes-la-Coquette, France

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**Trade name: PASTOREX™ STAPH-PLUS - Latex Test, 1 ml**

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**- Contact:**

Customer Support  
Phone : +33 (0)1 47 95 60 91  
USA  
Bio-Rad Laboratories  
6565 185th Avenue NE  
Redmond, WA 98052-5039

Phone Number: 1-800-2BIORAD (1-800-224-6723) or (425) 881-8300 (daytime PST)

· **Date of preparation / last revision** 08/11/2015 / 2· **Abbreviations and acronyms:**

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)  
IMDG: International Maritime Code for Dangerous Goods  
DOT: US Department of Transportation  
IATA: International Air Transport Association  
ACGIH: American Conference of Governmental Industrial Hygienists  
EINECS: European Inventory of Existing Commercial Chemical Substances  
ELINCS: European List of Notified Chemical Substances  
CAS: Chemical Abstracts Service (division of the American Chemical Society)  
NFPA: National Fire Protection Association (USA)  
HMIS: Hazardous Materials Identification System (USA)  
Acute Tox. 3: Acute toxicity, Hazard Category 3  
Skin Corr. 1B: Skin corrosion/irritation, Hazard Category 1B  
Skin Sens. 1: Sensitisation - Skin, Hazard Category 1  
Aquatic Acute 1: Hazardous to the aquatic environment - AcuteHazard, Category 1  
Aquatic Chronic 1: Hazardous to the aquatic environment - Chronic Hazard, Category 1

USA