

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

Article number	Description	Quantity	Symbols
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**

GHS07

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

(Contd. on page 2)

USA

Safety Data Sheet

29 CFR Part 1910.1200

Printing date 08/11/2015

Reviewed on 08/11/2015

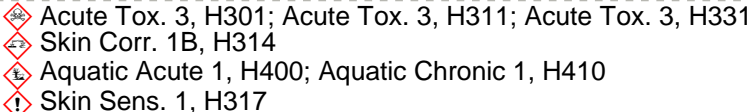
Trade name: PASTOREX™ STAPH-PLUS - Negative Control, 1 ml

(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:**
CO₂, 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.

(Contd. on page 3)

Safety Data Sheet
29 CFR Part 1910.1200

Printing date 08/11/2015

Reviewed on 08/11/2015

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

(Contd. of page 2)

- **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 ³ *total dust **respirable fraction
REL	Long-term value: 10* 5** mg/m ³ *total dust **respirable fraction
TLV	Long-term value: 10 mg/m ³

· **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

(Contd. on page 4)

Safety Data Sheet
29 CFR Part 1910.1200

Printing date 08/11/2015

Reviewed on 08/11/2015

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

(Contd. of page 3)

· Color:	Red
· Odor:	Weak, characteristic
· pH-value:	Not determined.
· Change in condition	
· Melting point/Melting range:	Undetermined.
· Boiling point/Boiling range:	Undetermined.
· Flash point:	Not applicable.
· Danger of explosion:	Product does not present an explosion hazard.
· Density:	Not determined.
· Solubility in / Miscibility with	
· Water:	Dispersible.
· Solvent content:	
· Solids content:	10.0 %
· Other information	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**

· **IARC (International Agency for Research on Cancer)**

None of the ingredients is listed.

· **NTP (National Toxicology Program)**

None of the ingredients is listed.

(Contd. on page 5)

Safety Data Sheet
29 CFR Part 1910.1200

Printing date 08/11/2015

Reviewed on 08/11/2015

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

(Contd. of page 4)

· **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

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

(Contd. on page 6)

Safety Data Sheet
29 CFR Part 1910.1200

Printing date 08/11/2015

Reviewed on 08/11/2015

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

(Contd. of page 5)

· **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

(Contd. on page 7)

Safety Data Sheet
29 CFR Part 1910.1200

Printing date 08/11/2015

Reviewed on 08/11/2015

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

(Contd. of page 6)

- 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

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 - 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

(Contd. on page 2)

USA

Safety Data Sheet

29 CFR Part 1910.1200

Printing date 08/11/2015

Reviewed on 08/11/2015

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

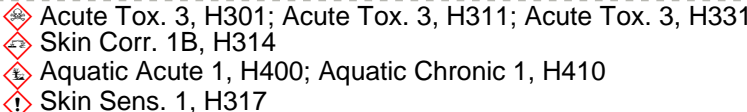



(Contd. of page 1)

- **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)  Acute Tox. 3, H301; Acute Tox. 3, H311; Acute Tox. 3, H331  Skin Corr. 1B, H314  Aquatic Acute 1, H400; Aquatic Chronic 1, H410  Skin Sens. 1, H317	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:**
CO₂, 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.

(Contd. on page 3)

Safety Data Sheet
29 CFR Part 1910.1200

Printing date 08/11/2015

Reviewed on 08/11/2015

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

(Contd. of page 2)

- **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 ³ *total dust **respirable fraction
REL	Long-term value: 10* 5** mg/m ³ *total dust **respirable fraction
TLV	Long-term value: 10 mg/m ³

· **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

(Contd. on page 4)

Safety Data Sheet
29 CFR Part 1910.1200

Printing date 08/11/2015

Reviewed on 08/11/2015

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

(Contd. of page 3)

· Color:	Red
· Odor:	Weak, characteristic
· pH-value:	Not determined.
· Change in condition	
· Melting point/Melting range:	Undetermined.
· Boiling point/Boiling range:	Undetermined.
· Flash point:	Not applicable.
· Danger of explosion:	Product does not present an explosion hazard.
· Density:	Not determined.
· Solubility in / Miscibility with	
· Water:	Dispersible.
· Solvent content:	
· Solids content:	10.0 %
· Other information	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**

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

· NTP (National Toxicology Program)
None of the ingredients is listed.

(Contd. on page 5)

Safety Data Sheet
29 CFR Part 1910.1200

Printing date 08/11/2015

Reviewed on 08/11/2015

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

(Contd. of page 4)

· **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

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

(Contd. on page 6)

Safety Data Sheet
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Trade name: PASTOREX™ STAPH-PLUS - Latex Test, 1 ml

(Contd. of page 5)

· **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

(Contd. on page 7)

Safety Data Sheet
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Trade name: PASTOREX™ STAPH-PLUS - Latex Test, 1 ml

(Contd. of page 6)

- 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