



Alere BinaxNOW[®] RSV Card Device

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product name : Alere BinaxNOW[®] RSV Card Device

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/mixture : For professional use only.

1.3. Details of the supplier of the safety data sheet

Alere Scarborough, Inc.
10 Southgate Road
Scarborough, Maine 04074 - United States
T +1 (207) 730-5750
ts.scr@alere.com

1.4. Emergency telephone number

Emergency number : +1 (207) 730-5750

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification (GHS-US)

Not classified

2.2. Label elements

GHS-US labeling

No labeling applicable

2.3. Other hazards

No additional information available

2.4. Unknown acute toxicity (GHS US)

Not applicable

SECTION 3: Composition/information on ingredients

3.1. Substance

Not applicable

3.2. Mixture

Not classified

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).
First-aid measures after inhalation	: Assure fresh air breathing. Allow the victim to rest.
First-aid measures after skin contact	: Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.
First-aid measures after eye contact	: Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness persist.
First-aid measures after ingestion	: Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/injuries : Not expected to present a significant hazard under anticipated conditions of normal use.

4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Foam. Dry powder. Carbon dioxide. Water spray. Sand.

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Unsuitable extinguishing media : Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

No additional information available

5.3. Advice for firefighters

Firefighting instructions : Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Avoid (reject) fire-fighting water to enter environment.

Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures : Evacuate unnecessary personnel.

6.1.2. For emergency responders

Protective equipment : Equip cleanup crew with proper protection.

Emergency procedures : Ventilate area.

6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : On land, sweep or shovel into suitable containers. Minimize generation of dust. Store away from other materials.

6.4. Reference to other sections

See Heading 8. Exposure controls and personal protection.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapor.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Keep only in the original container in a cool, well ventilated place away from : Direct sunlight.
Keep container closed when not in use.

Incompatible products : Strong bases. strong acids.

Incompatible materials : Sources of ignition. Direct sunlight.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Alere BinaxNOW® RSV Card Device	
ACGIH	Not applicable
OSHA	Not applicable

8.2. Exposure controls

Personal protective equipment : Avoid all unnecessary exposure.

Hand protection : Wear protective gloves.

Eye protection : Chemical goggles or safety glasses.

Respiratory protection : A risk assessment is required.

Other information : When using, do not eat, drink or smoke.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Solid

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Color	: Not applicable
Odor	: Not applicable
Odor threshold	: No data available
pH	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Relative evaporation rate (butyl acetate=1)	: No data available
Flammability (solid, gas)	: No data available
Explosion limits	: No data available
Explosive properties	: No data available
Oxidizing properties	: No data available
Vapor pressure	: No data available
Relative density	: No data available
Relative vapor density at 20 °C	: No data available
Solubility	: No data available
Log Pow	: No data available
Log Kow	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

Not established.

10.3. Possibility of hazardous reactions

Not established.

10.4. Conditions to avoid

Direct sunlight. Extremely high or low temperatures.

10.5. Incompatible materials

strong acids. Strong bases.

10.6. Hazardous decomposition products

Not established.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity	: Not classified
Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Not classified
Respiratory or skin sensitization	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified

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Specific target organ toxicity (single exposure)	: Not classified
Specific target organ toxicity (repeated exposure)	: Not classified
Aspiration hazard	: Not classified
Potential Adverse human health effects and symptoms	: Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

12.1. Toxicity

No additional information available

12.2. Persistence and degradability

Alere BinaxNOW® RSV Card Device

Persistence and degradability	Not established.
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12.3. Bioaccumulative potential

Alere BinaxNOW® RSV Card Device

Bioaccumulative potential	Not established.
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12.4. Mobility in soil

No additional information available

12.5. Other adverse effects

Other information	: Avoid release to the environment.
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SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste disposal recommendations	: Dispose in a safe manner in accordance with local/national regulations.
Ecology - waste materials	: Avoid release to the environment.

SECTION 14: Transport information

Department of Transportation (DOT)

In accordance with DOT
Not regulated for transport

Additional information

Other information	: No supplementary information available.
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ADR

No additional information available

Transport by sea

No additional information available

Air transport

No additional information available

SECTION 15: Regulatory information

15.1. US Federal regulations

No additional information available

15.2. International regulations

CANADA

No additional information available

EU-Regulations

No additional information available

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

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Classification according to Directive 67/548/EEC [DSD] or 1999/45/EC [DPD]

No additional information available

National regulations

No additional information available

15.3. US State regulations

No additional information available

SECTION 16: Other information

Other information : None.

SDS US (GHS HazCom 2012)

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product

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SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

- 1.1 Product identifier**
Trade name
Viral Negative Control Swab (Flu A/B, RSV, Flu A and Flu B)
- 1.2 Relevant identified uses of the substance or mixture and uses advised against**
Identified use(s)
In vitro diagnostic reagent. For professional use only.
- 1.3 Details of the supplier of the safety data sheet**
Company Identification
Alere Scarborough Inc.,
10 Southgate Road,
Scarborough,
Maine 04074, USA.
Telephone
+1 207-730-5750
E-Mail (competent person)
ts.scr@alere.com
- 1.4 Emergency telephone number**
Emergency Phone No.
+1 207-730-5750

SECTION 2: HAZARDS IDENTIFICATION

- 2.1 Classification of the substance or mixture**
OSHA Hazard Communication Standard 29 CFR 1910.1200 (HazCom 2012) / GHS
Not classified as hazardous.
- 2.2 Label elements**
No measures required.
- 2.3 Other hazards**
None anticipated.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

- 3.2 Mixtures**
Description:
In vitro diagnostic reagent. Swab impregnated with dried chemicals and heat-inactivated streptococcal bacteria (Strep A or Strep C).
- Dangerous components:
The product does not contain reportable quantities of dangerous components.

SECTION 4: FIRST AID MEASURES



- 4.1 Description of first aid measures**
- | | |
|--------------|---|
| Inhalation | Supply fresh air; consult doctor in case of complaint. |
| Skin Contact | Wash skin with soap and water. |
| Eye Contact | Rinse cautiously with water for several minutes. Consult a doctor in case of complaint. |
| Ingestion | Wash out mouth with water. Consult a doctor. |
- 4.2 Most important symptoms and effects, both acute and delayed**
None known.



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- 4.3 Indication of the immediate medical attention and special treatment needed None.

SECTION 5: FIRE-FIGHTING MEASURES

- 5.1 **Extinguishing media**
Suitable Extinguishing Media CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- 5.2 **Special hazards arising from the substance or mixture** In case of fire, the following can be released: Carbon oxides (CO_x), phosphorous oxides (P_xO_y).
- 5.3 **Advice for fire-fighters** Use fire-extinguishing methods suitable to surrounding conditions.
Wear full protective suit and self-contained breathing apparatus (SCBA) when extinguishing fires.

SECTION 6: ACCIDENTAL RELEASE MEASURES

- 6.1 **Personal precautions, protective equipment and emergency procedures** Isolate spillage and clean up immediately. Refer to Section 8 for protective measures when handling the spillage.
- 6.2 **Environmental precautions** No special requirements.
- 6.3 **Methods and material for containment and cleaning up** Collect material and dispose of as waste according to Section 13.
Swab down area with Chlorox or other disinfecting agent.
- 6.4 **Reference to other sections** 8, 13

SECTION 7: HANDLING AND STORAGE

- 7.1 **Precautions for safe handling** Although bacteria have been inactivated, the product should be handled as potentially infectious material.
Refer to Regulation 29 CFR 1910.1030 for information on handling biohazardous materials.
Avoid contact with skin and eyes.
Keep out of reach of children.
Wash hands before breaks and after work.
Clean work areas with hypochlorite or other disinfecting agent.
- 7.2 **Conditions for safe storage, including any incompatibilities** Store in the original container at 2 to 30°C.
- 7.3 **Specific end use(s)** Use as per instructions for use.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

- 8.1 **Control parameters**
- 8.1.1 **Occupational Exposure Limits** The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- 8.2 **Exposure controls**
- 8.2.1 **Appropriate engineering controls** Not relevant for this material.
- 8.2.2 **Personal protection equipment**
Eye/face protection Safety glasses recommended.



Hand protection

Disposable gloves.



Material of gloves:

Latex / natural rubber, Nitrile rubber.

Penetration time of glove material:

Gloves resistance is not critical when the product is handled according to the instructions for use.

Body protection

Laboratory coat.

Respiratory protection

Face mask recommended.

8.2.3 Environmental Exposure Controls

No special measures are required.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance	Solid.
Colour	White.
Odour	No odour.
Odour Threshold (ppm)	Not applicable.
pH (Value)	Not determined.
Melting Point (°C) / Freezing Point (°C)	Not determined.
Boiling point/boiling range (°C):	Not applicable.
Flash Point (°C)	Not applicable.
Evaporation rate (BA = 1)	Not applicable.
Flammability (solid, gas)	Not determined.
Explosive limit ranges	Not applicable.
Vapour Pressure (Pascal)	Not applicable.
Vapour Density (Air=1)	Not applicable.
Density (g/ml)	Not determined.
Solubility (Water)	Not determined.
Solubility (Other)	Not determined.
Partition Coefficient (n-Octanol/water)	Not determined.
Auto Ignition Temperature (°C)	Not determined.
Decomposition Temperature (°C)	Not determined.
Viscosity (mPa.s)	Not applicable.
Explosive properties	Not explosive.
Oxidising properties	Not oxidising.

9.2 Other information

Not available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity	None known.
10.2 Chemical stability	The product is stable in accordance with the recommended storage conditions.
10.3 Possibility of hazardous reactions	None known. Hazardous polymerisation will not occur.
10.4 Conditions to avoid	None.
10.5 Incompatible materials	None known.
10.6 Hazardous Decomposition Product(s)	None known.



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SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

11.1.2 Mixtures

Acute toxicity	Based upon the available data, the classification criteria are not met.
Skin corrosion/irritation	Based upon the available data, the classification criteria are not met.
Serious eye damage/irritation	Based upon the available data, the classification criteria are not met.
Respiratory/skin sensitization	Based upon the available data, the classification criteria are not met.
Germ cell mutagenicity	No data.
Carcinogenicity	Based upon the available data, the classification criteria are not met.
Reproductive toxicity	Based upon the available data, the classification criteria are not met.
STOT-single exposure	Based upon the available data, the classification criteria are not met.
STOT-repeated exposure	Based upon the available data, the classification criteria are not met.
Aspiration hazard	Based upon the available data, the classification criteria are not met.

Health Effects and Symptoms

Skin Contact	No significant harmful effects anticipated.
Eye Contact	No significant harmful effects anticipated.
Ingestion	No significant harmful effects anticipated.

11.2 Other information Not applicable.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity	The product does not contain significant quantities of ingredients that are environmentally toxic.
12.2 Persistence and degradability	The organic part of the product is biodegradable.
12.3 Bioaccumulative potential	No data.
12.4 Mobility in soil	No data.
12.5 Results of PBT and vPvB assessment	Not applicable.
12.6 Other adverse effects	Not applicable.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods Product:

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.



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Packaging:

Disposal should be in accordance with local, state or national legislation. Contaminated packaging must be disposed of in the same manner as the product. Non-contaminated packaging materials may be recycled. Contact your local service providers for further information.

SECTION 14: TRANSPORT INFORMATION

14.1	UN number	Not applicable.
14.2	UN Proper Shipping Name	Not applicable.
14.3	Transport hazard class(es)	Not classified as dangerous for transport.
14.4	Packing Group	Not applicable.
14.5	Environmental hazards	Not applicable.
14.6	Special precautions for user	Not applicable.
14.7	Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.

SECTION 15: REGULATORY INFORMATION

15.1	Safety, health and environmental regulations/legislation specific for the substance or mixture	OSHA Hazard Communication Standard 29 CFR 1910.1200 Consumer Product Safety Regulations 16 CFR 1600 IVD Product Labelling 21 CFR 809
	Chemical inventory listings relevant to US regulations	
	Carcinogen listings	
	IARC:	None of the ingredients is listed.
	NTP:	None of the ingredients is listed.
	ACGIH:	None of the ingredients is listed.
	OSHA:	None of the ingredients is listed.
	EPA	None of the ingredients is listed.
	Californian Proposition 65	
	Chemicals known to cause cancer:	None of the ingredients is listed.
	Chemicals known to cause reproductive toxicity:	None of the ingredients is listed.
	SARA	
	Section 355 (extremely hazardous substances):	None of the ingredients is listed.
	Section 313 (specific toxic chemical listings):	None of the ingredients is listed.
15.2	Chemical Safety Assessment	Not applicable.

SECTION 16: OTHER INFORMATION**LEGEND**

STOT Specific Target Organ Toxicity

References:

Raw material safety data sheets.

Additional Information

Reason for update:

Update in accordance with GHS.



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Supersedes:

All sections changed
Version: 2

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To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.



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SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

- 1.1 Product identifier**
Trade name Elution solution (Flu A/B, RSV, Flu A and Flu B)
- 1.2 Relevant identified uses of the substance or mixture and uses advised against**
Identified use(s) In vitro diagnostic reagent. For professional use only.
- 1.3 Details of the supplier of the safety data sheet**
Company Identification Alere Scarborough Inc.,
10 Southgate Road,
Scarborough,
Maine 04074, USA.
Telephone +1 207-730-5750
E-Mail (competent person) ts.scr@alere.com
- 1.4 Emergency telephone number**
Emergency Phone No. +1 207-730-5750

SECTION 2: HAZARDS IDENTIFICATION

- 2.1 Classification of the substance or mixture**
OSHA Hazard Communication Standard 29
CFR 1910.1200 (HazCom 2012) / GHS
Hazard statement(s) Eye Irrit. 2 Category 2A
H319: Causes serious eye irritation.
- 2.2 Label elements**
Hazard pictogram(s)

Signal word(s) WARNING
Hazard statement(s) Causes serious eye irritation.
Precautionary statement(s) Wear protective gloves/protective clothing/eye protection/face protection.
IF IN EYES: Rinse cautiously with water for several minutes.
Remove contact lenses, if present and easy to do. Continue rinsing.
If eye irritation persists: Get medical advice/attention.
- 2.3 Other hazards**
Contains isothiazolines. May produce an allergic reaction in sensitized individuals

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

- 3.2 Mixtures**
Description: In vitro diagnostic reagent. Aqueous preparation containing the hazardous components listed below.
Dangerous components:

Hazardous ingredient(s)	CAS No.	Classification code: Hazard statement(s)	%W/W
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Triton X 100	9002-93-1	Acute Tox. 4; H302 Eye Dam. 1; H318 Aquatic Chronic 2; H411	1 - 2
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3.3 Additional Information

For full text of H phrases see section 16.

► SECTION 4: FIRST AID MEASURES



4.1 Description of first aid measures

Inhalation
Skin Contact

Eye Contact

Supply fresh air; consult doctor in case of complaint.
Wash skin with soap and water. Remove contaminated clothing and wash clothing before reuse.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
If eye irritation persists: Get medical advice/attention.
Wash out mouth with water. Consult a doctor in case of complaint.

Ingestion

4.2 Most important symptoms and effects, both acute and delayed

Causes serious eye irritation.

4.3 Indication of the immediate medical attention and special treatment needed

None.

SECTION 5: FIRE-FIGHTING MEASURES

5.1 Extinguishing media

Suitable Extinguishing Media

CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

5.2 Special hazards arising from the substance or mixture

In case of fire, the following can be released: Carbon oxides (CO_x).

5.3 Advice for fire-fighters

Use fire-extinguishing methods suitable to surrounding conditions.
Wear full protective suit and self-contained breathing apparatus (SCBA) when extinguishing fires.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Refer to Section 8 for protective measures when handling the spillage.

6.2 Environmental precautions

Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Absorb with liquid-binding material (paper towelling, sand, diatomite, acid binders, universal binders, sawdust).
Dispose of contaminated material as waste according to Section 13. Rinse off area with water.

6.4 Reference to other sections

8, 13

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SECTION 7: HANDLING AND STORAGE

- | | | |
|------------|---|---|
| 7.1 | Precautions for safe handling | Avoid contact with skin and eyes.
Keep out of reach of children.
Wash hands before breaks and after work. |
| 7.2 | Conditions for safe storage, including any incompatibilities | Store in the original container at 2 to 30°C. |
| 7.3 | Specific end use(s) | Use as per instructions for use. |

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

- | | | |
|--------------|---|--|
| 8.1 | Control parameters | |
| 8.1.1 | Occupational Exposure Limits | The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace. |
| 8.2 | Exposure controls | |
| 8.2.1 | Appropriate engineering controls | Not relevant for this material. |
| 8.2.2 | Personal protection equipment | |
| | Eye/face protection | Safety glasses recommended. |
| |  | |
| | Hand protection | Disposable gloves. |
| |  | |
| | Material of gloves: | Latex / natural rubber, Nitrile rubber. |
| | Penetration time of glove material: | Gloves resistance is not critical when the product is handled according to the instructions for use. |
| | Body protection | Laboratory coat. |
| | Respiratory protection | Not normally required. |
| 8.2.3 | Environmental Exposure Controls | No special measures are required. |

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

- | | | |
|------------|--|---|
| 9.1 | Information on basic physical and chemical properties | |
| | Appearance | Clear Liquid. |
| | Colour | Colourless. |
| | Odour | No odour. |
| | Odour Threshold (ppm) | Not applicable. |
| | pH (Value) | Not available. |
| | Melting Point (°C) / Freezing Point (°C) | Similar to water, approximately 0°C. |
| | Boiling point/boiling range (°C): | Similar to water, approximately 100°C. |
| | Flash Point (°C) | Not applicable. |
| | Evaporation rate (BA = 1) | Not determined. |
| | Flammability (solid, gas) | Not applicable. |
| | Explosive limit ranges | Not applicable. |
| | Vapour Pressure (mm Hg) | Similar to water, approximately 23 hPa. |
| | Vapour Density (Air=1) | Not determined. |
| | Density (g/ml) | ~ 1.0 |
| | Solubility (Water) | Soluble. |



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	Solubility (Other)	Not determined.
	Partition Coefficient (n-Octanol/water)	Not determined.
	Auto Ignition Temperature (°C)	Not determined.
	Decomposition Temperature (°C)	Not determined.
	Viscosity (mPa.s)	Not determined.
	Explosive properties	Not explosive.
	Oxidising properties	Not oxidising.
9.2	Other information	Not available

SECTION 10: STABILITY AND REACTIVITY

10.1	Reactivity	None known.
10.2	Chemical stability	The product is stable in accordance with the recommended storage conditions.
10.3	Possibility of hazardous reactions	None anticipated. Hazardous polymerisation will not occur.
10.4	Conditions to avoid	None.
10.5	Incompatible materials	Strong acids, strong bases, strong oxidizing agents.
10.6	Hazardous Decomposition Product(s)	None known.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

11.1.2 Mixtures

Acute toxicity	Based upon the available data, the classification criteria are not met. ATE (oral) = 180,000 mg/kg
Skin corrosion/irritation	Based upon the available data, the classification criteria are not met.
Serious eye damage/irritation	Causes serious eye irritation.
Respiratory/skin sensitization	Based upon the available data, the classification criteria are not met.
Germ cell mutagenicity	No data.
Carcinogenicity	Based upon the available data, the classification criteria are not met.
Reproductive toxicity	Based upon the available data, the classification criteria are not met.
STOT-single exposure	Based upon the available data, the classification criteria are not met.
STOT-repeated exposure	Based upon the available data, the classification criteria are not met.
Aspiration hazard	Based upon the available data, the classification criteria are not met.

Health Effects and Symptoms

Skin Contact	May cause irritation.
Eye Contact	Causes serious eye irritation.
Ingestion	No significant harmful effects anticipated.

11.2	Other information	Not applicable.
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► SECTION 12: ECOLOGICAL INFORMATION

12.1	Toxicity	Triton X100 LC50 (Fathead minnow (Pimephales promelas)): 8.9 mg/l (96 hour) LC50 (Daphnia magna): 26 mg/l (48 hour)
12.2	Persistence and degradability	The product is poorly biodegradable.
12.3	Bioaccumulative potential	No data.
12.4	Mobility in soil	The product is predicted to have high mobility in soil.
12.5	Results of PBT and vPvB assessment	Not applicable.
12.6	Other adverse effects	Not applicable.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1	Waste treatment methods	
	Product:	Chemical residues and remains should be routinely handled as special waste. Elution solution that has been used for extraction of specimens should be disposed of as potentially infectious material. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.
	Packaging:	Disposal should be in accordance with local, state or national legislation. Contaminated packaging must be disposed of in the same manner as the product. Non-contaminated packaging materials may be recycled. Contact your local service providers for further information.

SECTION 14: TRANSPORT INFORMATION

14.1	UN number	Not applicable.
14.2	UN Proper Shipping Name	Not applicable.
14.3	Transport hazard class(es)	Not classified as dangerous for transport.
14.4	Packing Group	Not applicable.
14.5	Environmental hazards	Not applicable.
14.6	Special precautions for user	Not applicable.
14.7	Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.

SECTION 15: REGULATORY INFORMATION

15.1	Safety, health and environmental regulations/legislation specific for the substance or mixture	OSHA Hazard Communication Standard 29 CFR 1910.1200 Consumer Product Safety Regulations 16 CFR 1600 IVD Product Labelling 21 CFR 809
	Chemical inventory listings relevant to US regulations	
	Carcinogen listings	
	IARC:	None of the ingredients is listed.
	NTP:	None of the ingredients is listed.
	ACGIH:	None of the ingredients is listed.



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OSHA:	None of the ingredients is listed.
EPA	None of the ingredients is listed.
Californian Proposition 65	
Chemicals known to cause cancer:	None of the ingredients is listed.
Chemicals known to cause reproductive toxicity:	None of the ingredients is listed.
SARA	
Section 355 (extremely hazardous substances):	None of the ingredients is listed.
Section 313 (specific toxic chemical listings):	None of the ingredients is listed.

15.2 Chemical Safety Assessment Not applicable.

SECTION 16: OTHER INFORMATION

LEGEND

STOT	Specific Target Organ Toxicity
ATE	Acute toxicity estimate

Classification code:

Eye Dam. 1	Eye damage; Category 1
Acute Tox. 4	Acute toxicity; Category 4
Aquatic Chronic 2	Hazardous to the aquatic environment, Chronic, Category 2

Hazard statement(s)

H302: Harmful if swallowed.
H318: Causes serious eye damage.
H411: Toxic to aquatic life with long lasting effects.

References:

Raw material safety data sheets.

Additional Information

Reason for update:	Update in accordance with GHS. Changes to all sections.
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Supersedes:	Version: 2
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To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.



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SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

- 1.1 Product identifier**
Trade name Positive control swab (Flu A/B, RSV, Flu A and Flu B)
- 1.2 Relevant identified uses of the substance or mixture and uses advised against**
Identified use(s) In vitro diagnostic reagent. For professional use only.
- 1.3 Details of the supplier of the safety data sheet**
Company Identification Alere Scarborough Inc.,
10 Southgate Road,
Scarborough,
Maine 04074, USA.
Telephone +1 207-730-5750
E-Mail (competent person) ts.scr@alere.com
- 1.4 Emergency telephone number**
Emergency Phone No. +1 207-730-5750

SECTION 2: HAZARDS IDENTIFICATION

- 2.1 Classification of the substance or mixture**
OSHA Hazard Communication Standard 29 CFR 1910.1200 (HazCom 2012) / GHS Not classified as hazardous.
- 2.2 Label elements** No measures required.
- 2.3 Other hazards** None anticipated.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

- 3.2 Mixtures**
Description: In vitro diagnostic reagent. Swab impregnated with dried chemicals and inactivated virus (Flu A, Flu B and RSV).
- Dangerous components: The product does not contain reportable quantities of dangerous components.

SECTION 4: FIRST AID MEASURES



- 4.1 Description of first aid measures**
- | | |
|--------------|---|
| Inhalation | Supply fresh air; consult doctor in case of complaint. |
| Skin Contact | Wash skin with soap and water. |
| Eye Contact | Rinse cautiously with water for several minutes. Consult a doctor in case of complaint. |
| Ingestion | Wash out mouth with water. Consult a doctor. |
- 4.2 Most important symptoms and effects, both acute and delayed** None known.
- 4.3 Indication of the immediate medical attention** None.



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and special treatment needed

SECTION 5: FIRE-FIGHTING MEASURES

- | | |
|--|---|
| 5.1 Extinguishing media
Suitable Extinguishing Media | CO ₂ , powder or water spray. Fight larger fires with water spray or alcohol resistant foam. |
| 5.2 Special hazards arising from the substance or mixture | In case of fire, the following can be released: Carbon oxides (CO _x), nitrogen oxides (NO _x). |
| 5.3 Advice for fire-fighters | Use fire-extinguishing methods suitable to surrounding conditions.
Wear full protective suit and self-contained breathing apparatus (SCBA) when extinguishing fires. |

SECTION 6: ACCIDENTAL RELEASE MEASURES

- | | |
|--|---|
| 6.1 Personal precautions, protective equipment and emergency procedures | Isolate spillage and clean up immediately. Refer to Section 8 for protective measures when handling the spillage. |
| 6.2 Environmental precautions | No special requirements. |
| 6.3 Methods and material for containment and cleaning up | Collect material and dispose of as waste according to Section 13.
Swab down area with Chlorox or other disinfecting agent. |
| 6.4 Reference to other sections | 8, 13 |

SECTION 7: HANDLING AND STORAGE

- | | |
|---|--|
| 7.1 Precautions for safe handling | Although the virus has been inactivated, the product should be handled as potentially infectious material.
Refer to Regulation 29 CFR 1910.1030 for information on handling biohazardous materials.
Avoid contact with skin and eyes.
Keep out of reach of children.
Wash hands before breaks and after work.
Clean work areas with hypochlorite or other disinfecting agent. |
| 7.2 Conditions for safe storage, including any incompatibilities | Store in the original container at 2 to 30°C. |
| 7.3 Specific end use(s) | Use as per instructions for use. |

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

- | | |
|---|--|
| 8.1 Control parameters | |
| 8.1.1 Occupational Exposure Limits | The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace. |
| 8.2 Exposure controls | |
| 8.2.1 Appropriate engineering controls | Not relevant for this material. |
| 8.2.2 Personal protection equipment
Eye/face protection | Safety glasses recommended. |



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Hand protection



Disposable gloves.

Material of gloves:

Penetration time of glove material:

Latex / natural rubber, Nitrile rubber

Gloves resistance is not critical when the product is handled according to the instructions for use.

Body protection

Laboratory coat.

Respiratory protection

Face mask recommended.

8.2.3 Environmental Exposure Controls

No special measures are required.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance

Solid.

Colour

White.

Odour

No odour.

Odour Threshold (ppm)

Not applicable.

pH (Value)

Not determined.

Melting Point (°C) / Freezing Point (°C)

Not determined.

Boiling point/boiling range (°C):

Not applicable.

Flash Point (°C)

Not applicable.

Evaporation rate (BA = 1)

Not applicable.

Flammability (solid, gas)

Not determined.

Explosive limit ranges

Not applicable.

Vapour Pressure (Pascal)

Not applicable.

Vapour Density (Air=1)

Not applicable.

Density (g/ml)

Not determined.

Solubility (Water)

Not determined.

Solubility (Other)

Not determined.

Partition Coefficient (n-Octanol/water)

Not determined.

Auto Ignition Temperature (°C)

Not determined.

Decomposition Temperature (°C)

Not determined.

Viscosity (mPa.s)

Not applicable.

Explosive properties

Not explosive.

Oxidising properties

Not oxidising.

9.2 Other information

Not available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

None known.

10.2 Chemical stability

The product is stable in accordance with the recommended storage conditions.

10.3 Possibility of hazardous reactions

None known. Hazardous polymerisation will not occur.

10.4 Conditions to avoid

None.

10.5 Incompatible materials

None known.

10.6 Hazardous Decomposition Product(s)

None known.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects



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11.1.2 Mixtures

Acute toxicity	Based upon the available data, the classification criteria are not met.
Irritation	Based upon the available data, the classification criteria are not met.
Corrosivity	Based upon the available data, the classification criteria are not met.
Sensitisation	Based upon the available data, the classification criteria are not met.
Repeated dose toxicity	No data
Carcinogenicity	Based upon the available data, the classification criteria are not met.
Mutagenicity	No data.
Toxicity for reproduction	Based upon the available data, the classification criteria are not met.
STOT-single exposure	Based upon the available data, the classification criteria are not met.
STOT-repeated exposure	Based upon the available data, the classification criteria are not met.
Aspiration hazard	Based upon the available data, the classification criteria are not met.

Health Effects and Symptoms

Skin Contact	No significant harmful effects anticipated.
Eye Contact	No significant harmful effects anticipated.
Ingestion	No significant harmful effects anticipated.

11.2 Other information	Not applicable.
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SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity	The product does not contain significant quantities of ingredients that are environmentally toxic.
12.2 Persistence and degradability	The organic part of the product is biodegradable.
12.3 Bioaccumulative potential	No data.
12.4 Mobility in soil	No data.
12.5 Results of PBT and vPvB assessment	Not applicable.
12.6 Other adverse effects	Not applicable.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods	
Product:	Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.
Packaging:	Disposal should be in accordance with local, state or national legislation. Contaminated packaging must be disposed of in the same manner as the product. Non-contaminated packaging materials may be recycled. Contact your local service providers for further information.



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SECTION 14: TRANSPORT INFORMATION

14.1	UN number	Not applicable.
14.2	UN Proper Shipping Name	Not applicable.
14.3	Transport hazard class(es)	Not classified as dangerous for transport.
14.4	Packing Group	Not applicable.
14.5	Environmental hazards	Not applicable.
14.6	Special precautions for user	Not applicable.
14.7	Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.

SECTION 15: REGULATORY INFORMATION

15.1	Safety, health and environmental regulations/legislation specific for the substance or mixture	OSHA Hazard Communication Standard 29 CFR 1910.1200 Consumer Product Safety Regulations 16 CFR 1600 IVD Product Labelling 21 CFR 809
	Chemical inventory listings relevant to US regulations	
	Carcinogen listings	
	IARC:	None of the ingredients is listed.
	NTP:	None of the ingredients is listed.
	ACGIH:	None of the ingredients is listed.
	OSHA:	None of the ingredients is listed.
	EPA	None of the ingredients is listed.
	Californian Proposition 65	
	Chemicals known to cause cancer:	None of the ingredients is listed.
	Chemicals known to cause reproductive toxicity:	None of the ingredients is listed.
	SARA	
	Section 355 (extremely hazardous substances):	None of the ingredients is listed.
	Section 313 (specific toxic chemical listings):	None of the ingredients is listed.
15.2	Chemical Safety Assessment	Not applicable.

SECTION 16: OTHER INFORMATION

LEGEND

STOT Specific Target Organ Toxicity

References:

Raw material safety data sheets.

Additional Information

Reason for update:	Update in accordance with GHS. All sections changed
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