



SAFETY DATA SHEET

According to Regulation (EC) No. 1907/2006 (REACH), Annex II

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

- 1.1 Product identifier**
Trade name Alere Negative Control Swab
- 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**
Directive 67/548/EEC & Directive 1999/45/EC Not classified as dangerous for supply/use.
- 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 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.
- 4.3 Indication of the immediate medical attention and special treatment needed** None.

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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), phosphorous oxides (P _x O _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 the bacteria have been inactivated, the product should be handled as potentially infectious material. Refer to Directive 2000/54/EC 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. (EN166) |
|  | |
| Hand protection | Disposable gloves. (EN374) |
|  | |
| 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. |



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Body protection
Respiratory protection

Laboratory coat.
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

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. |



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| | |
|---------------------------|---|
| 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.

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. |
| European waste catalogue: | 18 01 03. |
| 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. |



SAFETY DATA SHEET

According to Regulation (EC) No. 1907/2006 (REACH), Annex II

SECTION 15: REGULATORY INFORMATION

- | | | |
|------|---|--|
| 15.1 | Safety, health and environmental regulations/legislation specific for the substance or mixture | In Vitro diagnostics medical devices directive 98/79/EC. |
| 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

Prepared by: Dr. J. J. Tobin, ChemHaz Solutions, Email: info@chemhazsolutions.com

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**
Directive 67/548/EEC & Directive 1999/45/EC Not classified as dangerous for supply/use.
- 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 and special treatment needed** None.

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SECTION 5: FIRE-FIGHTING MEASURES

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| 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

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|--|---|
| 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 Directive 2000/54/EC 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. (EN166) |
|  | |
| Hand protection | Disposable gloves. (EN374) |
|  | |
| 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. |



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Body protection
Respiratory protection

Laboratory coat.
Face mask recommended.

8.2.3 Environmental Exposure Controls

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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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11.1 Information on toxicological effects

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| 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. |



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| 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.

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. |
| European waste catalogue: | 18 01 03. |
| 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 | In Vitro diagnostics medical devices directive 98/79/EC. |
|---------------------------------------|--|



SAFETY DATA SHEET

According to Regulation (EC) No. 1907/2006 (REACH), Annex II

regulations/legislation specific for the substance or mixture

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 Regulation (EU) No 453/2010. Changes to all sections.

Supersedes: Version: 2

Prepared by: Dr. J. J. Tobin, ChemHaz Solutions, Email: info@chemhazsolutions.com

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