



Safety Data Sheet

Clearview[®] RSV Extraction Reagent

Revision Date: 28 Aug 15

| I. General Information | | | |
|--|---|--|--------------------|
| Identity | Clearview[®] RSV Extraction Reagent PN ER5060 | | |
| General Use | The Clearview RSV test Extraction Reagent is a component used in the test that is intended for the rapid, qualitative detection of respiratory syncytial virus fusion protein directly from nasopharyngeal swab, and nasal aspirate specimens in children less than 6 years and adults over the age of 60. The test is intended for use as an aid in the rapid laboratory diagnosis of acute respiratory syncytial virus infection in patients with symptoms consistent with RSV infection. | | |
| | Manufactured By | Distributed by | |
| | American Bio Medica Corporation 122 Smith Rd, Kinderhook, NY 12106 Telephone: 1800 227 1243 www.abmc.com | Alere North America, LLC 30 South Keller Rd Orlando, FL 32810 Telephone: 877-441-7440 | |
| Emergency number | | Telephone: 877-441-7440 | |
| II. Hazardous Ingredients | | | |
| Hazardous Components | | Hazard Pictogram | |
| Sodium Azide | | | |
| EC Hazard Symbol | Xn | Signal Word | Warning |
| Eye Contact: May cause eye irritation. | | | |
| Skin Contact: May be harmful if absorbed through skin. | | | |
| Inhalation of Vapors: May be harmful if inhaled. Material may be destructive to the tissue of the mucous membranes and upper respiratory tract. May cause respiratory tract irritation. | | | |
| Ingestion: May be harmful if swallowed. | | | |
| Skin Contact: May be harmful if absorbed through skin. | | | |
| III. Composition | | | |
| Components | CAS # | % | TLV (units) |
| Sodium Azide | 26628-22-8 EINECS 247-852-1 | 0.20% | 2000ppm |
| Triton X 100 | 9002-03-01 | 0.13% | 13mL |
| NaOH | 1310-73-2 | N/A Adjust | |
| MOPS | 1132-61-2 | 25% | 240mL |
| B PER | 1405-20-5 | 75% | 750mL |
| IV. First Aid Procedures | | | |
| Primary Route(s) of Entry: | Dermal, Ingestion, Eyes, Inhalation | | |
| First Aid Procedures | Eye Contact: Flush with copious amounts of water to open eyes during transport to hospital. | | |
| | Skin Contact: Wash the affected area with mild soap and water for 15 minutes, seek medical attention. | | |
| | Inhalation: Move to fresh air, give artificial respiration if necessary. If breathing is difficult, administer oxygen. | | |
| | Ingestion: Wash our mouth with water provided person is conscience. Seek immediate medical attention. | | |

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| V. Fire and Explosion Hazard Data | | | |
|---|--|---------------------------|-----|
| Flash Point (Method) | N/A | Auto Ignition Temperature | N/A |
| Flammable Limits in Air (% by Volume): N/A | | | |
| Extinguishing Media: X Water Spray X CO ₂ X Foam X Dry Chemical | | | |
| Special Fire Fighting Procedures: Fight larger fires with water spray or alcohol resistant foam. | | | |
| Unusual Fire and Explosion Hazards: Sodium Azide present in this product. Contact with acidic solutions and metal compounds over time may form potentially explosive metal azides. | | | |
| VI. Accidental Release Measures | | | |
| Accidental Release, Spill Response: Contain spillage and then collect with non-combustible absorbent material, (sand, diatomaceous earth, vermiculite) and dispose of according to local regulations. | | | |
| Waste Disposal Method: Dispose in accordance with all Federal, State and Local environmental regulations. | | | |
| VII. Handling and Storage | | | |
| Handling and Storage: Avoid contact with skin and eyes. Avoid inhalation of vapor or mist. Store at 2°C – 30°C | | | |
| Other Precautions: Keep away from sources of ignition-no smoking. Keep away from combustible material. | | | |
| VIII. Exposure Controls | | | |
| Carcinogen: not identified as carcinogenic | Threshold Limit Value: Sodium Azide REL: CO 0.3mg/m ³ CO 0.1ppm TLV Short term value Co 0.29 mg/m ³ CO 0.11ppm as HN3 vapor, as NaN3 | | |
| Protection | Respiratory: Government approved respirator | | |
| | Eye: Protective eyewear, safety glasses if working directly with control | | |
| | Skin: Gloves (protective, e.g. latex, rubber, nitrile) | | |
| Ventilation Recommended | Local Exhaust: General ventilation | | |
| | Mechanical (General): N/A | | |
| Other Protective Equipment: None | | | |

| IV. Physical and Chemical Properties | | | |
|--------------------------------------|-----------------------------------|---|-------------|
| | CAS # | % | TLV (units) |
| Sodium Azide | 26628-22-8 EINECS 247-852-1 | 0.20% | 2000ppm |
| Properties | | | |
| Boiling Point | 100°C (212°F) | Solubility in water | Soluble |
| Melting Point | Not | Specific Gravity (H ₂ O = 1.0) | N/A |

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| | | | |
|-------------------------------------|----------------|---|----------------|
| | determined | | |
| Freezing Point | Not determined | Percentage Volatile by Volume | N/A |
| Vapor Pressure (mmHg @ 68°F) | Not determined | Odor | None |
| Flash Point/Flammability | Not determined | Partition Coefficient; octanol/water | N/A |
| Evaporation Rate | Not determined | Decomposition Temperature | Not determined |
| Auto Ignition Temperature | Not determined | Viscosity | Not determined |
| pH | 8.0 | Vapor Density (Air = 1) | Not determined |

X. Stability and Reactivity Data

| | | | |
|------------------|---|----------------------------|-----|
| Stability | Stable under recommended storage conditions | Conditions to Avoid | N/A |
|------------------|---|----------------------------|-----|

Incompatibility (*Materials to Avoid*): Metals and Acidic Solutions, Strong Oxidizers

| | | | |
|---------------------------------|-----|----------------------------|-----|
| Hazardous Polymerization | N/A | Conditions to Avoid | N/A |
|---------------------------------|-----|----------------------------|-----|

Hazardous Decomposition Products: None if used according to specifications.

XI. Toxicological Information

| | |
|----------------------------|--|
| Effects of Exposure | Eye Contact: May cause eye irritation. |
| | Skin Contact: May be harmful if absorbed through skin. |
| | Inhalation of Vapors: May be harmful if inhaled. Material may be destructive to the tissue of the mucous membranes and upper respiratory tract. May cause respiratory tract irritation. |
| | Ingestion: May be harmful if swallowed. |
| | Sodium Azide Oral LD50: 27mg/kg (Rat) |

XII. Ecological Information

Ecological Information: The ecological effects have been investigated but currently, none have been identified.

General Notes: Water hazard class 1 (Self Assessment) slightly hazardous for water.

XIII. Disposal Considerations

Waste Disposal Method: Dispose in accordance with all Federal, State and Local environmental regulations.

Contain spillage and then collect with non-combustible absorbent material, (sand, diatomaceous earth, vermiculite) and dispose of according to local regulations.

Avoid sewage disposal.

XIV. Transport:

DOT, Hazard Class, Land Transport, ADR/RID, Maritime Transport IMDG, Air Transport

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ICAO/IATA-DGR. No Special Handling Required.

XV. Regulatory Information

| | |
|---|--------------------------|
| SARA 311/312 Hazard Categories for Reporting | Non Hazardous |
| Minnesota Pollution Control Agency: List of Acute Hazardous Waste | Sodium Azide \geq 0.1% |
| EU Classification (90/492/EE) | N/A |
| Canadian WHMIS Classification | N/A |
| California Prop 65 | None |

XVI. Other Information

The information and recommendations set forth herein are taken from sources believed to be accurate as of the date hereof. The information provided in this SDS is based on data available to Alere from the contract manufacturer, ABMC and believed to be accurate. Alere and contract manufacturer ABMC make no warranty with respect to the accuracy of the information or the suitability of the recommendations and assume no liability to any user thereof.

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Safety Data Sheet

Clearview® RSV Negative Control

Revision Date: 28 Aug 15

| I. General Information | | | |
|--|---|--|--------------------|
| Identity | Clearview® RSV Negative Control PN NC5060 | | |
| General Use | The Clearview RSV test Negative Reagent is a control component used for verification purposes in the test that is intended for the rapid, qualitative detection of respiratory syncytial virus fusion protein directly from nasopharyngeal swab, and nasal aspirate specimens in children less than 6 years and adults over the age of 60. The test is intended for use as an aid in the rapid laboratory diagnosis of acute respiratory syncytial virus infection in patients with symptoms consistent with RSV infection. | | |
| | Manufactured By | Distributed by | |
| | American Bio Medica Corporation 122 Smith Rd Kinderhook, NY 12106 Telephone: 1800 227 1243 www.abmc.com | Alere North America, LLC 30 South Keller Rd Orlando, FL 32810 Telephone: 877-441-7440 | |
| Emergency number | | Telephone: 877-441-7440 | |
| II. Hazardous Ingredients | | | |
| Hazardous Components | | Hazard Pictogram | |
| Sodium Azide | | | |
| EC Hazard Symbol | Xn | Signal Word | Warning |
| Eye Contact: May cause eye irritation. | | | |
| Skin Contact: May be harmful if absorbed through skin. | | | |
| Inhalation of Vapors: May be harmful if inhaled. Material may be destructive to the tissue of the mucous membranes and upper respiratory tract. May cause respiratory tract irritation. | | | |
| Ingestion: May be harmful if swallowed. | | | |
| Skin Contact: May be harmful if absorbed through skin. | | | |
| III. Composition | | | |
| Ingredients | CAS # | % | TLV (units) |
| Sodium Azide | 26628-22-8 EINECS 247-852-1 | 0.20% | 2000ppm |
| RSV Extraction Rgt | N/A | 33% | 330mL |
| Phosphate Buffered Saline | N/A | 66% | 660mL |
| Phenol Red 0.1% Soln. | 34487-61-1 | < 0.1%% | 0.4mL |
| IV. First Aid Procedures | | | |
| Primary Route(s) of Entry: | Dermal, Ingestion, Eyes, Inhalation | | |
| First Aid Procedures | Eye Contact: Flush with copious amounts of water to open eyes during transport to hospital. | | |
| | Skin Contact: Wash the affected area with mild soap and water for 15 minutes, seek medical attention. | | |
| | Inhalation: Move to fresh air, give artificial respiration if necessary. If breathing is difficult, administer oxygen. | | |
| | Ingestion: Wash our mouth with water provided person is conscience. Seek immediate medical attention. | | |

Safety Data Sheet

Clearview[®] RSV Negative Control

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| V. Fire and Explosion Hazard Data | | | |
|---|--|---|-------------|
| Flash Point (Method) | N/A | Auto Ignition Temperature | N/A |
| Flammable Limits in Air (% by Volume): N/A | | | |
| Extinguishing Media: X Water Spray X CO ₂ X Foam X Dry Chemical | | | |
| Special Fire Fighting Procedures: Fight larger fires with water spray or alcohol resistant foam. | | | |
| Unusual Fire and Explosion Hazards: Sodium Azide present in this product. Contact with acidic solutions and metal compounds over time may form potentially explosive metal azides. | | | |
| VI. Accidental Release Measures | | | |
| Accidental Release, Spill Response: Contain spillage and then collect with non-combustible absorbent material, (sand, diatomaceous earth, vermiculite) and dispose of according to local regulations. | | | |
| Waste Disposal Method: Dispose in accordance with all Federal, State and Local environmental regulations. | | | |
| VII. Handling and Storage | | | |
| Handling and Storage: Avoid contact with skin and eyes. Avoid inhalation of vapor or mist. Store at 2°C – 30°C | | | |
| Other Precautions: Keep away from sources of ignition-no smoking. Keep away from combustible material. | | | |
| VIII. Exposure Controls | | | |
| Carcinogen: not identified as carcinogenic | Threshold Limit Value: Sodium Azide REL: CO 0.3mg/m ³ CO 0.1ppm TLV Short term value Co 0.29 mg/m ³ CO 0.11ppm as HN ₃ vapor, as NaN ₃ | | |
| Protection | Respiratory: Government approved respirator | | |
| | Eye: Protective eyewear, safety glasses if working directly with control | | |
| | Skin: Gloves (protective, e.g. latex, rubber, nitrile) | | |
| Ventilation Recommended | Local Exhaust: General ventilation | | |
| | Mechanical (General): N/A | | |
| Other Protective Equipment: None | | | |
| IV. Physical and Chemical Properties | | | |
| | CAS # | % | TLV (units) |
| Sodium Azide | 26628-22-8 EINECS 247-852-1 | 0.20% | 2000ppm |
| Properties | | | |
| Boiling Point | 100°C (212°F) | Solubility in water | Soluble |
| Melting Point | Not determined | Specific Gravity (H ₂ O = 1.0) | N/A |
| Freezing Point | Not | Percentage Volatile by Volume | N/A |

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|-------------------------------------|----------------|---|----------------|
| | determined | | |
| Vapor Pressure (mmHg @ 68°F) | Not determined | Odor | None |
| Flash Point/Flammability | Not determined | Partition Coefficient; octanol/water | N/A |
| Evaporation Rate | Not determined | Decomposition Temperature | Not determined |
| Auto Ignition Temperature | Not determined | Viscosity | Not determined |
| pH | 7-8-8.0 | Vapor Density (Air = 1) | Not determined |

X. Stability and Reactivity Data

| | | | |
|---|---|----------------------------|-----|
| Stability | Stable under recommended storage conditions | Conditions to Avoid | N/A |
| Incompatibility (<i>Materials to Avoid</i>): Metals and Acidic Solutions, Strong Oxidizers | | | |
| Hazardous Polymerization | N/A | Conditions to Avoid | N/A |
| Hazardous Decomposition Products: None if used according to specifications. | | | |

XI. Toxicological Information

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|--|--|
| Effects of Exposure | Eye Contact: May cause eye irritation. |
| | Skin Contact: May be harmful if absorbed through skin. |
| | Inhalation of Vapors: May be harmful if inhaled. Material may be destructive to the tissue of the mucous membranes and upper respiratory tract. May cause respiratory tract irritation. |
| | Ingestion: May be harmful if swallowed. |
| Sodium Azide Oral LD50: 27mg/kg (Rat) | |

XII. Ecological Information

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| Ecological Information: The ecological effects have been investigated but currently, none have been identified. |
| General Notes: Water hazard class 1 (Self Assessment) slightly hazardous for water. |

XIII. Disposal Considerations

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|---|
| Waste Disposal Method: Dispose in accordance with all Federal, State and Local environmental regulations. |
| Contain spillage and then collect with non-combustible absorbent material, (sand, diatomaceous earth, vermiculite) and dispose of according to local regulations. |
| Avoid sewage disposal. |

XIV. Transport:

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|---|
| DOT, Hazard Class, Land Transport, ADR/RID, Maritime Transport IMDG, Air Transport ICAO/IATA-DGR. No Special Handling Required. |
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XV. Regulatory Information

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|--|---------------|
| SARA 311/312 Hazard Categories for Reporting | Non Hazardous |
|--|---------------|

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| | |
|---|--------------------------|
| Minnesota Pollution Control Agency: List of Acute Hazardous Waste | Sodium Azide \geq 0.1% |
| EU Classification (90/492/EE) | N/A |
| Canadian WHMIS Classification | N/A |
| California Prop 65 | None |

XVI. Other Information

The information and recommendations set forth herein are taken from sources believed to be accurate as of the date hereof. The information provided in this SDS is based on data available to Alere from the contract manufacturer, ABMC and believed to be accurate. Alere and contract manufacturer ABMC make no warranty with respect to the accuracy of the information or the suitability of the recommendations and assume no liability to any user thereof.

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Safety Data Sheet

Clearview® RSV Positive Control

Revision Date: 28 Aug 15

| I. General Information | | | |
|--|---|--|--------------------|
| Identity | Clearview® RSV Positive Control PN PC5060 | | |
| General Use | The Clearview RSV test Positive Reagent is a control component used for verification purposes in the test that is intended for the rapid, qualitative detection of respiratory syncytial virus fusion protein directly from nasopharyngeal swab, and nasal aspirate specimens in children less than 6 years and adults over the age of 60. The test is intended for use as an aid in the rapid laboratory diagnosis of acute respiratory syncytial virus infection in patients with symptoms consistent with RSV infection. | | |
| | Manufactured By | Distributed by | |
| | American Bio Medica Corporation 122 Smith Rd, Kinderhook, NY 12106 Telephone: 1800 227 1243 www.abmc.com | Alere North America, LLC 30 South Keller Rd Orlando, FL 32810 Telephone: 877-441-7440 | |
| Emergency number | | Telephone: 877-441-7440 | |
| II. Hazardous Ingredients | | | |
| Hazardous Components | | Hazard Pictogram | |
| Sodium Azide | | | |
| Human RSV Direct Pellet | | | |
| EC Hazard Symbol | Xn | Signal Word | Warning |
| Eye Contact: May cause eye irritation. | | | |
| Skin Contact: May be harmful if absorbed through skin. | | | |
| Inhalation of Vapors: May be harmful if inhaled. Material may be destructive to the tissue of the mucous membranes and upper respiratory tract. May cause respiratory tract irritation. | | | |
| Ingestion: May be harmful if swallowed. | | | |
| Biohazard | | | |
| III. Composition | | | |
| Ingredients | CAS # | % | TLV (units) |
| Sodium Azide in RSV Negative Control | 26628-22-8 EINECS 247-852-1 | 0.20% | 2000ppm |
| Human RSV Direct Pellet | N/A | 0.14% | 1400ppm |
| IV. First Aid Procedures | | | |
| Primary Route(s) of Entry: | Dermal, Ingestion, Eyes, Inhalation | | |
| First Aid Procedures | Eye Contact: Flush with copious amounts of water to open eyes during transport to hospital. | | |
| | Skin Contact: Wash the affected area with mild soap and water for 15 minutes, seek medical attention. | | |
| | Inhalation: Move to fresh air, give artificial respiration if necessary. If breathing is difficult, administer oxygen. | | |
| | Ingestion: Wash our mouth with water provided person is conscience. Seek immediate medical attention. | | |

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Clearview[®] RSV Positive Control

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| V. Fire and Explosion Hazard Data | | | |
|---|--|---------------------------|-----|
| Flash Point (Method) | N/A | Auto Ignition Temperature | N/A |
| Flammable Limits in Air (% by Volume): N/A | | | |
| Extinguishing Media: X Water Spray X CO ₂ X Foam X Dry Chemical | | | |
| Special Fire Fighting Procedures: Fight larger fires with water spray or alcohol resistant foam. | | | |
| Unusual Fire and Explosion Hazards: Sodium Azide present in this product. Contact with acidic solutions and metal compounds over time may form potentially explosive metal azides. | | | |
| VI. Accidental Release Measures | | | |
| Accidental Release, Spill Response: Contain spillage and then collect with non-combustible absorbent material, (sand, diatomaceous earth, vermiculite) and dispose of according to local regulations. | | | |
| Waste Disposal Method: Dispose in accordance with all Federal, State and Local environmental regulations. Disinfect areas with 3% hydrogen peroxide followed by 70% alcohol. | | | |
| VII. Handling and Storage | | | |
| Handling and Storage: Avoid contact with skin and eyes. Avoid inhalation of vapor or mist. Store at 2°C – 30°C | | | |
| Other Precautions: Keep away from sources of ignition-no smoking. Keep away from combustible material. | | | |
| VIII. Exposure Controls | | | |
| Carcinogen: not identified as carcinogenic | Threshold Limit Value: Sodium Azide REL: CO 0.3mg/m ³ CO 0.1ppm TLV Short term value Co 0.29 mg/m ³ CO 0.11ppm as HN ₃ vapor, as NaN ₃ | | |
| Protection | Respiratory: Government approved respirator | | |
| | Eye: Protective eyewear, safety glasses, labcoat if working directly with control | | |
| | Skin: Gloves (protective, e.g. latex, rubber, nitrile) | | |
| Ventilation Recommended | Local Exhaust: General ventilation | | |
| | Mechanical (General): N/A | | |
| Other Protective Equipment: None | | | |

| IV. Physical and Chemical Properties | | | |
|--------------------------------------|-----------------------------------|---|-------------|
| | CAS # | % | TLV (units) |
| Sodium Azide | 26628-22-8 EINECS 247-852-1 | 0.20% | 2000ppm |
| Properties | | | |
| Boiling Point | 100°C (212°F) | Solubility in water | Soluble |
| Melting Point | Not | Specific Gravity (H ₂ O = 1.0) | N/A |

Safety Data Sheet

Clearview[®] RSV Positive Control

Revision Date: 28 Aug 15

| | | | |
|-------------------------------------|----------------|---|----------------|
| | determined | | |
| Freezing Point | Not determined | Percentage Volatile by Volume | N/A |
| Vapor Pressure (mmHg @ 68°F) | Not determined | Odor | None |
| Flash Point/Flammability | Not determined | Partition Coefficient; octanol/water | N/A |
| Evaporation Rate | Not determined | Decomposition Temperature | Not determined |
| Auto Ignition Temperature | Not determined | Viscosity | Not determined |
| pH | 7-8-8.0 | Vapor Density (Air = 1) | Not determined |

X. Stability and Reactivity Data

| | | | |
|---|---|----------------------------|-----|
| Stability | Stable under recommended storage conditions | Conditions to Avoid | N/A |
| Incompatibility (<i>Materials to Avoid</i>): Metals and Acidic Solutions, Strong Oxidizers | | | |
| Hazardous Polymerization | N/A | Conditions to Avoid | N/A |
| Hazardous Decomposition Products: None if used according to specifications. | | | |

XI. Toxicological Information

| | |
|----------------------------|--|
| Effects of Exposure | Eye Contact: May cause eye irritation. |
| | Skin Contact: May be harmful if absorbed through skin. |
| | Inhalation of Vapors: May be harmful if inhaled. Material may be destructive to the tissue of the mucous membranes and upper respiratory tract. May cause respiratory tract irritation. |
| | Ingestion: May be harmful if swallowed. |
| | Sodium Azide Oral LD50: 27mg/kg (Rat) |

XII. Ecological Information

| |
|--|
| Ecological Information: The ecological effects have been investigated but currently, none have been identified. Avoid release to environment. |
| General Notes: Water hazard class 1 (Self Assessment) slightly hazardous for water. |

XIII. Disposal Considerations

| |
|---|
| Waste Disposal Method: Dispose in accordance with all Federal, State and Local environmental regulations. |
| Contain spillage and then collect with non-combustible absorbent material, (sand, diatomaceous earth, vermiculite) and dispose of according to local regulations. |
| Disinfect material before disposal. 10% bleach may be used for disinfection. |
| Avoid sewage disposal. |

XIV. Transport:

| |
|--|
| DOT, Hazard Class, Land Transport, ADR/RID, Maritime Transport IMDG, Air Transport |
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Safety Data Sheet

Clearview[®] RSV Positive Control

Revision Date: 28 Aug 15

ICAO/IATA-DGR. No Special Handling Required.

XV. Regulatory Information

| | |
|---|--------------------------|
| SARA 302/304/311/312 Hazard Categories for Reporting | Hazardous |
| Minnesota Pollution Control Agency: List of Acute Hazardous Waste | Sodium Azide \geq 0.1% |
| EU Classification (90/492/EE) | N/A |
| Canadian WHMIS Classification | Class D, Div. 3 |
| California Prop 65 | None |
| OSHA Hazard | Biohazardous |

XVI. Other Information

The information and recommendations set forth herein are taken from sources believed to be accurate as of the date hereof. The information provided in this SDS is based on data available to Alere from the contract manufacturer, ABMC and believed to be accurate. Alere and contract manufacturer ABMC make no warranty with respect to the accuracy of the information or the suitability of the recommendations and assume no liability to any user thereof.

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