



SAFETY DATA SHEET

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

- 1.1 Product identifier**
Trade name Alere i Strep A Test Base
- 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.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

- 3.2 Mixtures**
Description: In vitro diagnostic reagent. Lyophilised pellet.
- Dangerous components: The product does not contain reportable quantities of dangerous components.

SECTION 4: FIRST AID MEASURES



- 4.1 Description of first aid measures**
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|--------------|---|
| Inhalation | Not relevant for this material. |
| Skin Contact | Wash skin with soap and water. |
| Eye Contact | Rinse cautiously with water for several minutes. |
| Ingestion | Wash out mouth with water. Consult a doctor in case of complaint. |
- 4.2 Most important symptoms and effects, both acute and delayed** None.
- 4.3 Indication of the immediate medical attention and special treatment needed** None.

SAFETY DATA SHEET

SECTION 5: FIRE-FIGHTING MEASURES

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|--|---|
| 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: Hazardous fumes. |
| 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 | 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. |
| 6.4 Reference to other sections | 8, 13 |

SECTION 7: HANDLING AND STORAGE

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|---|--|
| 7.1 Precautions for safe handling | Specimens should be handled as potentially infectious materials.
Refer to OSHA Regulation 29 CFR 1910.1030 for 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

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| 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 | Safety glasses recommended. |
| 
Eye/face protection | |
| 
Hand protection | Disposable gloves. |
| Material of gloves: | Latex / natural rubber, Nitrile rubber. |



SAFETY DATA SHEET

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	Solid.
Colour	White.
Odour	Odourless.
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)	Soluble.
Solubility (Other)	Not determined.
Partition Coefficient (n-Octanol/water)	Not applicable.
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	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



SAFETY DATA SHEET

Sensitisation	not met. Based upon the available data, the classification criteria are not met.
Repeated dose toxicity	Based upon the available data, the classification criteria are not met.
Carcinogenicity	Based upon the available data, the classification criteria are not met.
Mutagenicity	Based upon the available data, the classification criteria are not met.
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 product is readily biodegradable.
12.3 Bioaccumulative potential	The product has no potential for bioaccumulation.
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:	Dispose of as potentially biohazardous waste. Disposal should be in accordance with local, state or national legislation. 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.



SAFETY DATA SHEET

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
	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.

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