



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 Elution Buffer
- 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. Aqueous preparation containing the hazardous components listed below.
- Dangerous components:

EC Classification No. 1272/2008

Hazardous ingredient(s)	CAS No.	EC No.	REACH Registration No.	Classification code: Hazard statement(s)	%W/W
Triton X100	9002-93-1	-	Not available	Acute Tox. 4; H302 Eye Dam. 1; H318 Aquatic Chronic 2; H411	0.1 - 0.2

EC Classification No. 67/548/EEC

Hazardous ingredient(s)	CAS No.	EC No.	REACH Registration No.	EC Classification and Risk Phrases	%W/W
Triton X100*	9002-93-1	-	Not available	Xn (Xi); R22-41-51/53	0.1 - 0.2

- 3.3 Additional Information** For full text of R/H phrases see section 16.

SECTION 4: FIRST AID MEASURES





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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. Remove contaminated clothing and wash clothing before reuse.
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 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.

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), sulphur oxides (SO _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	Refer to Section 8 for protective measures when handling the spillage.
6.2 Environmental precautions	No special measures are required.
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

SECTION 7: HANDLING AND STORAGE

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.

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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)

8.0

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 (Pascal)

Similar to water, approximately 23 hPa.

Vapour Density (Air=1)

Not determined.

Density (g/ml)

~ 1.0

Solubility (Water)

Soluble.

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.



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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	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.
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SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity	Triton X100 LC50 (Fathead minnow (<i>Pimephales promelas</i>)): 8.9 mg/l (96 hour) LC50 (<i>Daphnia magna</i>): 26 mg/l (48 hour)
12.2 Persistence and degradability	The product is poorly biodegradable. Contains a candidate substance of very high concern- Triton X100
12.3 Bioaccumulative potential	No information available.
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.



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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.

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



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LEGEND

STOT Specific Target Organ Toxicity

Eye Dam. 1	Eye damage; Category 1
Acute Tox. 4	Acute toxicity; Category 4

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

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 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**

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.

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



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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



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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.



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SECTION 14: TRANSPORT INFORMATION

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	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.

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

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