




SAFETY DATA SHEET

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 Eye Irrit. 2 Category 2A
Hazard statement(s) 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	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	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Ingestion	If eye irritation persists: Get medical advice/attention. Wash out mouth with water. Consult a doctor in case of complaint.

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	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 (COx).
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

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| 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

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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. |
| 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

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| 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 (<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.
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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