


SAFETY DATA SHEET

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

- 1.1 Product identifier**
Trade name Influenza A & B Test, Extraction Reagent (R1)
- 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
Hazard statement(s) Eye Irritation; Category 2A
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 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**
None anticipated.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

- 3.2 Mixtures**
Description: *In vitro* diagnostic reagent. Aqueous solution.
- Dangerous components:

Hazardous ingredient(s)	CAS No.	Classification code: Hazard statement(s)	%W/W
N-Tetradecyl-N,N-dimethyl-3-ammonio-1-propane sulfonate	14933-09-6	Skin Irrit. 2; H315 Eye Irrit. 2; H319 STOT SE 3; H335	1 - 2
Triton X100	9002-93-1	Acute Tox. 4; H302 Eye Dam. 1; H318	1 - 2

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		Aquatic Chronic 2; H411	
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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	Rinse cautiously with water for several minutes. Consult a doctor.
Ingestion	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

Suitable Extinguishing Media	CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
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5.2 Special hazards arising from the substance or mixture

In case of fire, the following can be released: Carbon oxides (COx), nitrogen oxides (NOx), sulphur oxides (SOx).

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 toweling, 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

Avoid contact with skin and eyes.
Keep out of reach of children.
Wash hands and exposed skin after use.

7.2 Conditions for safe storage, including any

Store in the original container at 4 to 30°C.

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7.3 **incompatibilities**
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.



Hand protection (Hygiene Measures)

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

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

Color

Yellow

Odor

No odor.

Odor Threshold (ppm)

Not applicable

pH (Value)

7.2

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

Vapor Pressure (Pascal)

Similar to water, approximately 23 hPa.

Vapor 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.

Oxidizing properties

Not oxidizing

9.2 **Other information**

Not available



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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	Contact with acids may liberate trace amounts of toxic gas (hydrazoic acid). Hazardous polymerization will not occur.
10.4	Conditions to avoid	None
10.5	Incompatible materials	Strong Acids, Strong Alkalis, 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) > 2000 mg/kg.
Irritation	Causes serious eye irritation.
Corrosivity	Based upon the available data, the classification criteria are not met.
Sensitization	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.
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	May cause transient irritation.
Eye Contact	Irritating to eyes.
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 information available.
12.4	Mobility in soil	No data. The product is predicted to have high mobility in soil.



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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. This must be disposed of in compliance with applicable federal, state and local waste management regulations. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information. To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent.
	Packaging:	Disposal should be in accordance with applicable federal, state and local waste management regulations. 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	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.
	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	



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Section 355 (extremely hazardous substances): Sodium azide (trace.)
Section 313 (specific toxic chemical listings): Sodium azide (trace.)

15.2 Chemical Safety Assessment

Not applicable.

► SECTION 16: OTHER INFORMATION

LEGEND

STOT Specific Target Organ Toxicity

Classification code:

Acute Tox. 4	Acute toxicity; Category 4
Eye Dam. 1	Eye damage; Category 1
Eye Irrit. 2	Eye irritation; Category 2
Skin Irrit. 2	Skin irritation; Category 2
STOT SE 3	Specific target organ toxicity — single exposure; Category 3
Aquatic Chronic 2	Aquatic chronic toxicity; Category 2

Hazard statement(s)

H302: Harmful if swallowed.
H315: Causes skin irritation.
H318: Causes serious eye damage.
H319: Causes serious eye irritation.
H335: May cause respiratory irritation.
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 sections 2, 3, 4, 11, 12, 16. ► Indicates altered section
Supersedes:	Version: 1

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

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