genzyme

Corporate Headquarters
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Phone: 617-252-7500

<u>Distributor</u> **Genzyme Diagnostics**50 Gibson Drive

Kings Hill, West Malling

Kent ME19 4AF

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Phone: +44 (0) 1732 220022

Manufacturer / Distributor Genzyme Diagnostics 6659 Top Gun Street San Diego, CA 92121 USA

Phone: 858-452-3198

<u>Distributor</u> **Genzyme Diagnostics**One Kendall Square

Cambridge, MA 02139

USA

Phone: 800-332-1042

MATERIAL SAFETY DATA SHEETS

Catalog Number:	Kit Name:
190, 190E	OSOM® Influenza A&B Test

Item Number:	Component Name:	
2077	OSOM® Influenza A&B Test Extraction Buffer	

The Influenza A Positive Control Swab is an "article" and does not require an MSDS. The Influenza B Positive Control Swab is an "article" and does not require an MSDS.

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MATERIAL SAFETY DATA SHEET

OSOM® Influenza A&B Test Extraction Buffer

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: OSOM® Influenza A&B Test Extraction Buffer

Synonym(s): Extraction Buffer

Product Use: Component of OSOM® Influenza A&B Test kit (catalog # 190, 190E). For use in the

qualitative detection of influenza A and B viral antigens. For In Vitro Diagnostic Use Only.

Emergency Telephone Numbers

Genzyme (U.S.): +1 617-562-4555 CHEMTREC: (Transport-related)

-within U.S.: 1-800-424-9300

-outside U.S.: +1 703-527-3887

Description: Aqueous solution containing salts, detergent, albumin protein and bacteriocide.

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Phone: 1-800-332-1042

2. HAZARDS IDENTIFICATION

Emergency Overview:

The chemical, physical and toxicological properties of this preparation, pertaining directly to occupational exposures, have not been thoroughly characterized.

Precautionary Statements:

May be irritating to eyes and skin. Avoid contact with eyes and skin. Do not ingest or inhale. The bovine serum albumin (BSA) in this product is of US origin. The BSA was obtained from a supplier who holds a Certificate of Origin, Certificate of Analysis, and/or an EDQM Certificate of Suitability documenting the evaluation of reduction of TSE (Transmissible Spongiform Encephalopathy) risk. Preparation appearance: clear, colorless liquid.

Routes of Exposure:

Typical occupational exposure routes are eye and skin contact.

Potential Health Effects:

Inhalation Aerosol inhalation may cause sneezing, coughing or irritation of the nasal passages and throat.

Eye exposure may cause irritation, redness and watering.

Skin Skin contact may cause irritation, dryness and redness.

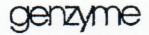
Ingestion Ingestion may produce digestive irritation or discomfort.

Chronic Effects Chronic effects from repeated or long-term occupational exposure to this preparation are

unknown.

Target Organs Unknown.

Effective Date: September 05, 2006 Date Printed: September 05, 2006



OSOM® Influenza A&B Test Extraction Buffer

Regulatory Status:

This preparation is not classified as hazardous under U.S. OSHA 29 CFR 1910.1200; E.C. Directive 1999/45/EC; Canadian R.S. 1985, c. H-3; U.K. CHIPS 2002 No. 1689; or U.N. GHS ST/SG/AC 10/30.

None of the components present in this preparation at concentrations equal to or greater than 0.1% are listed by IARC, NTP, OSHA or ACGIH as a carcinogen.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient Name	CAS#	EC#	% (w/w)
Water	7732-18-5	231-791-2	95 - 96
EC R-Phrases: None	EC Hazard Class: None		
L-Aspartic acid, monosodium salt	3792-50-5	223-264-0	2 - 3
EC R-Phrases: None	EC Hazard Class: None		
Trade Secret Detergent	Trade Secret	Trade Secret	< 1
EC R-Phrases: R36/38	EC Hazard Class: Xn		
Sodium chloride	7647-14-5	231-598-3	< 1
EC R-Phrases: R36/38	EC Hazard Class: Xi		
Sodium phosphate dibasic, anhydrous	7558-79-4	231-448-7	< 1
EC R-Phrases: R36/38	EC Hazard Class: Xi		
Bovine serum albumin	9048-46-8	232-936-2	< 1
EC R-Phrases: None	EC Hazard Class: None		
Ethylene glycol	107-21-1	203-473-3	< 1
EC R-Phrases: R22	EC Hazard Class: Xn		
Sodium azide	26628-22-8	247-852-1	< 0.1
EC R-Phrases: R28, R32, R50, R53	EC Hazard Class: T+, N		
Sodium phosphate monobasic dihydrate	13472-35-0	231-449-2	< 0.1
EC R-Phrases: None	EC Hazard Class: None		
Methylchloroisothiazolinone	26172-55-4	247-500-7	< 0.01
EC R-Phrases: R23/24/25, R34, R43, R50/53	EC Hazard Class: C, T, N		
Modified alkyl carboxylate	Not Assigned	Not Assigned	< 0.01
EC R-Phrases: None	EC Hazard Class: None		
Methylisothiazolinone	2682-20-4	220-239-6	< 0.01
EC R-Phrases: R23/24/25, R34, R43, R50/53	EC Hazard Class: C, T, N		

4. FIRST AID MEASURES

Inhalation:

If inhaled, move from exposure area to fresh air. Seek medical attention if breathing becomes difficult or if cough or other symptoms develop.

Eye Contact

Immediately flush eyes with plenty of tepid water while separating eyelids with fingers, removing contact lenses if worn. Continue to flush for at least 15 minutes. Obtain medical attention if needed or if symptoms, such as redness or irritation persist.

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Skin Contact:

In case of contact, flush skin with copious amounts of cool water and remove contaminated clothing. Wash material from skin with soap and water and rinse thoroughly with clean water. Obtain medical attention if needed or if irritation or other symptoms develop.

Ingestion:

In case of ingestion, contact a physician for instructions. If conscious and alert, rinse mouth out with water. Obtain medical attention if necessary.

5. FIRE FIGHTING MEASURES

Flammable Properties:

Aqueous solutions with these components are typically non-flammable.

Suitable Extinguishing Media:

Carbon dioxide, chemical foam, dry chemical or water spray.

Specific Hazards Arising from the Chemical:

None expected.

Standard Protective Equipment and Precautions for Firefighters:

As in any fire, firefighters should wear NIOSH-approved or equivalent Self-Contained Breathing Apparatus and full protective gear.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions:

Wear Personal Protective Equipment (PPE) as indicated in Section 8. Avoid physical contact with material. Wash hands thoroughly after handling.

Environmental Precautions:

This preparation contains a small amount of sodium azide which can react with copper, lead, brass or solder in plumbing systems and form potentially explosive metal azides. If preparation enters drain, flush with a large volume of water to prevent azide build-up.

Methods and Materials for Containment and Clean-Up:

Carefully soak up spilled liquid with a non-combustible sorbent. Scoop up spilled material and transfer to an appropriate container for disposal. After material pickup is complete, wash spill site to remove any residual material and dry completely. Dispose of spilled material and contaminated waste in accordance with all applicable federal, state, local and provincial environmental regulations, per Section 13.

7. HANDLING AND STORAGE

Handling:

Follow good laboratory hygiene practices. Wear proper Personal Protective Equipment (PPE) and employ exposure controls as indicated in Section 8. Avoid physical contact. Wash hands thoroughly after handling.

Storage:

Refer to product label and/or literature for specific storage conditions. The recommended storage temperature(s) at the time of MSDS preparation/revision is: Store at room temperature, 15 to 30°C (59 to 86°F). Do not store with incompatible substances or under avoidable conditions identified in Section 10.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

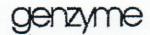
Exposure Guidelines:

There are no ACGIH, NIOSH, OSHA or country-specific occupational exposure limits currently established for components present in this preparation at concentrations equal to or greater than 1% (0.1% if carcinogen).

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Engineering Controls:

This preparation is aqueous and non-volatile and is not expected to necessitate special ventilation measures. Facilities storing or utilizing this preparation should be equipped with an eyewash fountain and a safety shower.

Personal Protective Equipment (PPE):

A respiratory protection program that meets U.S. Federal OSHA 29 CFR 1910.134 and ANSI Respiratory

> Z99.2, Canadian CSA Standard Z94.4-93, European Standard CR 529, or other applicable regulatory standards must be followed whenever exposure limits are exceeded and engineering controls are not feasible, or if insufficient ventilation or workplace conditions warrant a respirator's

Eye/Face Wear appropriate protective safety eye wear as described in the ANSI standard 787.1-2003,

OSHA's eye and face protection regulations 29 CFR 1910.133 and/or European Standard EN

Skin Wear appropriate protective clothing, such as a lab coat or other long-sleeved garment over your

clothes, to minimize contact and contamination of clothing. Change into clean clothes promptly if

clothing becomes contaminated. Remove and wash contaminated clothing before re-use.

Gloves Prevent skin exposure by wearing protective gloves impermeable to this material/preparation.

Change gloves regularly or immediately if they are contaminated, torn or punctured.

General Consult your company's safety manager/industrial hygienist or your safety equipment

manufacturer/supplier for assistance with your selection of appropriate PPE.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:

Clear, colorless liquid

pH:

7.6 (approx.)

Odor:

Not available

Solubility:

Water-soluble

Boiling Point:

Not available

Vapor Pressure:

Not available

Melting Point:

Not applicable

Partition Coefficient

Not available

Freezing Point:

Not available

(n-octanol/water): Vapor Density:

Not available

10. STABILITY AND REACTIVITY

Chemical Stability:

Stable under ordinary conditions of use and storage; (see handling and storage information in Section 7).

Conditions to Avoid:

Do not freeze.

Incompatible Materials:

Avoid strong oxidizers, strong acids and bases, heavy metals and their salts.

Hazardous Decomposition Products:

Thermal decomposition may lead to release of irritating gases and vapors.

Possibility of Hazardous Reactions:

Hazardous polymerization will not occur.

11. TOXICOLOGICAL INFORMATION

Acute Effects:

Date Printed:

May be irritating to the eyes and skin.

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Chronic Effects:

Data indicating the presence or absence of chronic effects in humans from repeated or long-term occupational exposure to this preparation is not yet available.

12. ECOLOGICAL INFORMATION

Ecotoxicity:

No information available for product.

13. DISPOSAL CONSIDERATIONS

Methods of Disposal:

This preparation contains a small amount of sodium azide which can react with copper, lead, brass or solder in plumbing systems and form potentially explosive metal azides. If preparation enters drain, flush with a large volume of water to prevent azide build-up. Dispose of unused product, spilled material and waste in accordance with all applicable federal, state, local and provincial environmental and hazardous waste regulations.

Packaging:

Containers of this material may retain product residues. Handle contaminated packaging in the same way as the substance itself, by disposing in accordance with all applicable federal, state, local, and provincial environmental and hazardous waste regulations. If not officially specified differently, non-contaminated packaging may be treated like household waste or recycled.

Waste Classification:

Chemical waste generators must refer to the relevant hazardous waste regulations to ensure complete and accurate classification. Disposal regulations may vary according to geographic location.

14. TRANSPORT INFORMATION

Basic Shipping Description:

Not classified as dangerous goods at the time of MSDS preparation. Not regulated per IATA and DOT regulations.

15. REGULATORY INFORMATION

US Federal Regulations:

This preparation is a component of an FDA-regulated in vitro diagnostic device.

Inventory - United States - Section 8(b) Inventory (TSCA)

L-Aspartic acid, monosodium salt

3792-50-5 Present

International Regulations:

If approved for European Communities use, this product is regulated under the In Vitro Diagnostic Medical Devices Directive (98/79/EC).

Inventory - Canada - Non-Domestic Substances List (NDSL)

L-Aspartic acid, monosodium salt

3792-50-5

Present

Inventory - European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)

L-Aspartic acid, monosodium salt

3792-50-5 223-264-0

Inventory - Japan Existing and New Chemical Substances (ENCS)

L-Aspartic acid, monosodium salt

3792-50-5 2-1308

Canadian Hazardous Products:

WHMIS Status

Non-controlled

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European Communities Dangerous Substances/Preparations:

EC Hazard Class None Risk Phrases None

Safety Phrases None

16. OTHER INFORMATION

Recommended Use:

For In Vitro Diagnostic Use Only. Not for human or drug use.

Further Information:

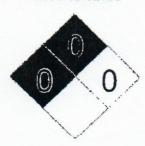
This MSDS has been prepared in accordance with the ANSI Z400.1 format. Every effort has been made to adhere to the hazard criteria and content requirements of the US OSHA Hazard Communication Standard, European Communities Safety Data Sheets Directive, Canadian Controlled Products Regulations, UK Chemical Hazard Information and Packaging Regulations, and UN Globally Harmonized System of Classification and Labelling of Chemicals.

The hazard ratings on this MSDS are for appropriately trained workers using a Hazardous Materials Identification System (HMIS®) or a National Fire Protection Association (NFPA) 704 program. The ratings are estimates and should be treated as such. The hazard rating scales range from (0) minimal hazards to (4) significant hazards or risks. Chronic (long-term) health effects are indicated in the HMIS® by an asterisk (*). HMIS® is a registered trade and service mark of the NPCA. For details on HMIS® ratings visit www.paint.org/hmis. For details on NFPA 704 visit www.nfpa.org.

HMIS® RATINGS



NFPA RATINGS



MSDS Origination Date: July 24, 2006

Version #: 2

Revision Date: September 05, 2006

Disclaimer:

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