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MATERIAL SAFETY DATA SHEET

OSOM® Ultra Strep A Extraction Reagent Ampule

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: OSOM® Ultra Strep A Extraction Reagent Ampule

Synonym(s): Ultra Strep A Extraction Reagent in Ampule; Extraction Reagent 2

Product Use: Component of OSOM® Ultra Strep A Test kit (catalog # 147). For use in the qualitative detection of Group A Streptococcal antigen. For In Vitro Diagnostic Use Only.

Description: Aqueous, acidic solution. The Extraction Reagent Ampule is contained in a bottle. See the OSOM® Ultra Strep A Extraction Reagent Bottle MSDS for details.

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Phone: 617-252-7500

Manufacturer/Distributor
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USA
Phone: 858-452-3198

Emergency Telephone Numbers
Genzyme (U.S.): 617-562-4555
CHEMTREC (U.S.): 800-424-9300
CHEMTREC (Outside U.S.): 703-527-3887

2. HAZARDS IDENTIFICATION

Precautionary Statements:

The chemical, physical and toxicological properties of this preparation have not been thoroughly characterized. Irritating to the eyes. May be irritating to skin and respiratory system. Avoid contact with eyes and skin. Do not ingest or inhale. Preparation appearance: clear, colorless liquid.

Routes of Exposure:

Occupational exposure routes may include inhalation, eye and skin contact.

Potential Health Effects:

Inhalation	Inhalation may be irritating to the nasal passages and throat.
Eye	Eye exposure will cause immediate irritation, redness and pain.
Skin	Prolonged skin contact may cause skin irritation with discomfort and rash.
Ingestion	If large amounts are ingested, symptoms may include digestive irritation and discomfort.
Chronic Effects	Prolonged or repeated skin contact may cause chronic irritation.
Target Organs	Eyes and skin.

Regulatory Status:

This preparation is 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. CHIP 2002 No. 1689; and/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.

Potential Environmental Effects:

None expected.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient Name	CAS #	EC #	% (wt/wt)
Water	7732-18-5	231-791-2	98 - 99
EC R-Phrases: None	**EC Hazard Class:** None		

Ingredient Name	CAS #	EC #	% (wt/wt)
Acetic acid	64-19-7	200-580-7	1 - 2
EC R-Phrases: R10, R35	**EC Hazard Class:** C, F		

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 for 15 minutes while separating eyelids with fingers. Remove contact lenses if worn. Obtain immediate medical attention.

Skin Contact:

In case of contact, flush skin with cool water and remove contaminated clothing. Obtain medical attention if needed or if irritation or other symptoms develop.

Ingestion:

In case of ingestion, contact a poison control center or physician for instructions.

5. FIRE FIGHTING MEASURES

Flammable Properties:

Dilute aqueous solution not considered a fire hazard.

Suitable Extinguishing Media:

Use extinguishing media suitable for surrounding fire, such as carbon dioxide, chemical foam, dry chemical or water spray.

Unsuitable Extinguishing Media:

Unknown.

Specific Hazards Arising from the Chemical:

When heated to decomposition, may produce carbon dioxide (CO2) and carbon monoxide (CO).

Standard Protective Equipment and Precautions for Firefighters:

Firefighters should wear NIOSH-approved or equivalent Self-Contained Breathing Apparatus and full protective gear.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions:

Avoid physical contact with material and avoid aerosol inhalation. Ensure adequate ventilation. Wear Personal Protective Equipment (PPE) as indicated in Section 8. Wash hands thoroughly after handling.

Environmental Precautions:

No special environmental precautions required.

Methods and Materials for Containment and Clean-Up:

Absorb spill with inert material/sorbent or appropriate neutralizing agent. Decontaminate the spill site following standard procedures. Dispose of materials 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. See Section 8, Engineering Controls. Mixing the contents of the Strep A Extraction Reagent Ampule within the Strep A Extraction Reagent Bottle yields nitrous acid, which may immediately decompose into toxic nitrous gas, a short-term reaction by-product. Minimize contact and contamination of personal clothing and skin. Avoid vapor or aerosol inhalation. Wash hands thoroughly after handling.

Storage:

Store at 15 to 30°C (59 to 86°F). Keep container tightly closed. Do not store with incompatible substances; see Section 10.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Guidelines:

ACGIH - Threshold Limits Values - Short Term Exposure Limits (TLV-STEL)		
Acetic acid	64-19-7	15 ppm STEL
ACGIH - Threshold Limits Values - Time Weighted Averages (TLV-TWA)		
Acetic acid	64-19-7	10 ppm TWA
Australia - Occupational Exposure Standards - STELs		
Acetic acid	64-19-7	15 ppm STEL; 37 mg/m3 STEL
Australia - Occupational Exposure Standards - TWAs		
Acetic acid	64-19-7	10 ppm TWA; 25 mg/m3 TWA
Canada - Quebec - Occupational Exposure Limits - STEVs		
Acetic acid	64-19-7	15 ppm STEV; 37 mg/m3 STEV
Canada - Quebec - Occupational Exposure Limits - TWAEVs		
Acetic acid	64-19-7	10 ppm TWAEV; 25 mg/m3 TWAEV
China - Occupational Exposure Limits - Permissible Concentration-Short Term (PC-STEL)		
Acetic acid	64-19-7	20 mg/m3 STEL
China - Occupational Exposure Limits - Permissible Concentration-Time Weighted Average (PC-TWA)		
Acetic acid	64-19-7	10 mg/m3 TWA
EU - Occupational Exposure Directive (2006/15/EC) Indicative Occupational Exposure Limit Values (IOELV) - TWAs		
Acetic acid	64-19-7	10 ppm TWA; 25 mg/m3 TWA
Israel - Occupational Exposure Limits - STELs		
Acetic acid	64-19-7	15 ppm STEL
Israel - Occupational Exposure Limits - TWAs		
Acetic acid	64-19-7	10 ppm TWA
Japan - Recommended Exposure Limits - TWAs		
Acetic acid	64-19-7	10 ppm OEL; 25 mg/m3 OEL
Korea - Occupational Exposure Limits - STELs		
Acetic acid	64-19-7	15 ppm STEL; 37 mg/m3 STEL
Korea - Occupational Exposure Limits - TWAs		
Acetic acid	64-19-7	10 ppm TWA; 25 mg/m3 TWA
U.S. - OSHA - Final PELs - Time Weighted Averages (TWAs)		
Acetic acid	64-19-7	10 ppm TWA; 25 mg/m3 TWA

Engineering Controls:

Provide adequate ventilation by means of mechanical exhaust, to keep airborne concentrations low. Facilities storing or using this preparation should be equipped with an eyewash fountain.

Personal Protective Equipment (PPE):

Respiratory A respiratory protection program that meets U.S. Federal OSHA 29 CFR 1910.134 and ANSI Z99.2, Canadian CSA Standard Z94.4-93, European Standard CR 529, or other applicable regulatory standards must be followed whenever exposure limits may be exceeded (if applicable), engineering controls are not feasible, or if insufficient ventilation or workplace conditions warrant respirator use. In such cases an air purifying respirator equipped with an organic vapor/acid gas cartridge is recommended.

Personal Protective Equipment (PPE):

Eye/Face	Wear appropriate protective chemical safety goggles.
Skin	Wear lab coat or other protective garments. Remove contaminated clothing promptly.
Gloves	Wear chemical resistant protective gloves.
General	Follow company-specific safety procedures.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Clear, colorless liquid	**pH:**	2.6 (approximate)
Odor:	Sour, pungent odor like vinegar	**Solubility:**	Water-soluble
Boiling Point:	Not available	**Density:**	Not applicable
Melting Point:	Not applicable	**Vapor Pressure:**	Not available
Freezing Point:	Not available	**Partition Coefficient (n-octanol/water):**	Not available
		Vapor Density:	Not available

Chemical Family: Acidic solution

Flammability/Explosivity Limits in Air, Lower: Not available

Flammability/Explosivity Limits in Air, Upper: Not available

Auto-Ignition Temperature: Not available

Flash Point: Not available

10. STABILITY AND REACTIVITY

Chemical Stability:

Stable under ordinary conditions of use and storage. See Section 7.

Conditions to Avoid:

None known.

Incompatible Materials:

Avoid strong oxidizing agents, most common metals (except aluminum), strong bases and amines.

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:

Toxicology Data - Selected LD50s and LC50s

Acetic acid	64-19-7	Inhalation LC50 Rat: 11.4 mg/L/1H; Oral LD50 Rat:3310 mg/kg; Dermal LD50 Rabbit:1060 mg/kg

Local Effects:

Causes eye irritation and may cause skin and respiratory tract irritation.

Chronic Effects:

Prolonged or repeated skin contact may cause dermatitis.

Carcinogenicity:

No data available.

Mutagenicity:

No data available.

Teratogenicity:

No data available.

Reproductive Effects:

No data available.

Sensitization:

No data available.

12. ECOLOGICAL INFORMATION

Ecotoxicity:

Ecotoxicity - Freshwater Fish Species Data		
Acetic acid	64-19-7	96 Hr LC50 Pimephales promelas: 88 mg/L [static]; 96 Hr LC50 Lepomis macrochirus: 75 mg/L
Ecotoxicity - Microtox Data		
Acetic acid	64-19-7	5 min EC50 Photobacterium phosphoreum: 8.8 mg/L; 15 min EC50 Photobacterium phosphoreum: 8.8 mg/L; 25 min EC50 Photobacterium phosphoreum: 8.8 mg/L
Ecotoxicity - Water Flea Data		
Acetic acid	64-19-7	24 Hr EC50 Daphnia magna: 95 mg/L

Persistance and Degradability:

No data available.

Bioaccumulative Potential:

No data available.

Mobility in Environmental Media:

No data available.

13. DISPOSAL CONSIDERATIONS

Methods of Disposal:

Dispose of unused product, spilled material and waste in accordance with all applicable federal, state, local and provincial environmental and hazardous waste regulations.

Waste Classification:

U.S. - California - 22 CCR - Presumed Hazardous Wastes		
Acetic acid	64-19-7	Toxic; Corrosive; Ignitable

14. TRANSPORT INFORMATION

Basic Shipping Description:

International Air Transport Association (IATA) Dangerous Goods Classification
UN Number: UN 3316
Proper Shipping Name: Chemical Kit
Hazard Class: 9
Hazard Label: Miscellaneous
Packing Group: PG III
Packaging Instruction: Y915
Special Provisions: A44 (excepted quantities)

U.S. Department of Transportation (DOT)
Consumer Commodity, ORM-D

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)

Acetic acid	64-19-7	Present

U.S. - CERCLA/SARA - Hazardous Substances and their Reportable Quantities

Acetic acid	64-19-7	5000 lb final RQ; 2270 kg final RQ

US State Regulations:

U.S. - California - 8 CCR Section 339 - Director's List of Hazardous Substances

Acetic acid	64-19-7	Present (exempt in solutions of less than 10% or when present in food or beverages)

International Regulations:

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

Canada - WHMIS - Classifications of Substances		
Acetic acid	64-19-7	B3, E (including 56%, 80%, 84%, 92%); E (30%, 36%); D2B (3%)
Canada - WHMIS - Ingredient Disclosure List		
Acetic acid	64-19-7	1 %
EU - Dangerous Substances Directive (67/548/EEC) - Annex I - Classification		
Acetic acid	64-19-7	R10; C;R35
EU - Dangerous Substances Directive (67/548/EEC) - Annex I - Concentration Limits		
Acetic acid	64-19-7	90%<=C: C; R35 25%<=C<90%: C; R34: 10%<=C<25%: Xi; R36/38
EU - Dangerous Substances Directive (67/548/EEC) - Annex I - Safety Phrases		
Acetic acid	64-19-7	S:1/2-23-26-45
Germany - Water Classification (VwVwS) - Annex 2 - Water Hazard Classes		
Acetic acid	64-19-7	ID Number 93, hazard class 1 - low hazard to waters
Inventory - Australia - Inventory of Chemical Substances (AICS)		
Acetic acid	64-19-7	Present
Inventory - Canada - Domestic Substances List (DSL)		
Acetic acid	64-19-7	Present
Inventory - Canada - Non-Domestic Substances List (NDSL)		
Acetic acid	64-19-7	Present
Inventory - China		
Acetic acid	64-19-7	Present
Inventory - European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)		
Acetic acid	64-19-7	200-580-7
Inventory - Japan Existing and New Chemical Substances (ENCS)		
Acetic acid	64-19-7	2-688
Inventory - Korea - Existing and Evaluated Chemical Substances		
Acetic acid	64-19-7	KE-00013

Canadian Hazardous Products:

WHMIS Status Exempt

European Communities Dangerous Substances/Preparations:

EC Hazard Class Exempt

Risk Phrases None

Safety Phrases None

16. OTHER INFORMATION

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 U.S. OSHA Hazard Communication Standard, Canadian Controlled Products Regulation (CPR), UK Chemical Hazard Information and Packaging Regulations, European Communities REACH Regulation, and UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS).

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OSOM® Ultra Strep A Extraction Reagent Ampule

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