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### MATERIAL SAFETY DATA SHEETS

Catalog Number:	Kit Name:
<b>147</b>	<b>OSOM<sup>®</sup> Ultra Strep A Test</b>

Item Number:	Component Name:
<b>2072</b>	<b>OSOM<sup>®</sup> Ultra Strep A Extraction Reagent Bottle</b>
<b>2084</b>	<b>OSOM<sup>®</sup> Ultra Strep A Extraction Reagent Ampule</b>
<b>2075</b>	<b>OSOM<sup>®</sup> Strep A Positive Control</b>
<b>2076</b>	<b>OSOM<sup>®</sup> Strep A Negative Control</b>

Note: The page numbers on the 4 individual MSDSs for this kit are specific to each document. There are a total of 32 pages including this cover sheet.

OSOM<sup>®</sup> Ultra Strep A Test Stick is an “article” and does not require an MSDS.



**MATERIAL SAFETY DATA SHEET**  
**OSOM® Ultra Strep A Extraction Reagent Bottle**

**1. PRODUCT AND COMPANY IDENTIFICATION**

**Product Name:** OSOM® Ultra Strep A Extraction Reagent Bottle

**Synonym(s):** Ultra Strep A Extraction Reagent in Bottle; Extraction Reagent 1

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

**Description:** Aqueous solution containing color indicator and inorganic salt. The Extraction Reagent Bottle also contains a glass ampule. See the OSOM® Ultra Strep A Extraction Reagent Ampule MSDS for details.

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**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:**

WARNING! The chemical, physical and toxicological properties of this preparation have not been thoroughly characterized. Avoid contact with eyes and skin. Do not ingest or inhale. Toxic by ingestion. Harmful by inhalation and in contact with skin. May cause severe eye irritation. Preparation appearance: clear, pink liquid.

**Routes of Exposure:**

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

**Potential Health Effects:**

<b>Inhalation</b>	Substantial aerosol inhalation may result in symptoms similar to those specified for ingestion.
<b>Eye</b>	Eye exposure may cause severe irritation, redness, watering, swelling and burning.
<b>Skin</b>	Skin contact with sufficient chemical absorption may result in symptoms similar to those specified for ingestion.
<b>Ingestion</b>	Ingestion may cause gastric irritation, nausea, vomiting and abdominal pain. Significant exposure may result in a drop in blood pressure, headache, dizziness, rapid pulse and visual problems. Skin may be flushed and sweaty and then become cold. Skin and lips may turn blue.
<b>Chronic Effects</b>	Chronic effects from repeated or long-term occupational exposure to this preparation are unknown. Chronic exposure to nitrites may cause headaches, visual problems and decreased blood pressure.
<b>Target Organs</b>	Sodium nitrite: Cardiovascular and central nervous systems.

**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. Refer to Sec. 15, Regulatory Information, for details regarding hazard classification.

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:**

May be harmful for the aquatic environment.



**MATERIAL SAFETY DATA SHEET**  
**OSOM® Ultra Strep A Extraction Reagent Bottle**

**3. COMPOSITION / INFORMATION ON INGREDIENTS**

Ingredient Name	CAS #	EC #	% (wt/wt)
Water EC R-Phrases: None	7732-18-5 EC Hazard Class: None	231-791-2	84 - 88
Sodium nitrite EC R-Phrases: R8, R25, R50	7632-00-0 EC Hazard Class: T, O, N	231-555-9	12 - 14
Phenol red, free acid EC R-Phrases: None	143-74-8 EC Hazard Class: None	205-609-7	< 0.01

**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, immediately 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:**

Not considered to be 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 monoxide (CO), carbon dioxide (CO<sub>2</sub>), nitrogen oxides (NO<sub>x</sub>) and sulphur oxides (SO<sub>x</sub>).

**Standard Protective Equipment and Precautions for Firefighters:**

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



## MATERIAL SAFETY DATA SHEET

### OSOM® Ultra Strep A Extraction Reagent Bottle

#### 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:**

Do not let product enter drains.

**Methods and Materials for Containment and Clean-Up:**

Absorb spill with inert material/sorbent. 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 in a dry and well-ventilated place. Do not store with incompatible substances; see 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).

**Engineering Controls:**

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

**Personal Protective Equipment (PPE):**

<b>Respiratory</b>	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.
<b>Eye/Face</b>	Wear appropriate protective chemical safety goggles.
<b>Skin</b>	Wear lab coat or other protective garments. Wear impervious shoe covers for spill clean-up. Remove contaminated clothing promptly.
<b>Gloves</b>	Wear chemical resistant protective gloves.
<b>General</b>	Follow company-specific safety procedures.

#### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Appearance:</b>	Clear, pink liquid	<b>pH:</b>	9 (approximate)
<b>Odor:</b>	Not available	<b>Solubility:</b>	Water-soluble



## MATERIAL SAFETY DATA SHEET

### OSOM® Ultra Strep A Extraction Reagent Bottle

<b>Specific Gravity:</b>	1.08 (approximate)	<b>Vapor Pressure:</b>	Not available
<b>Boiling Point:</b>	Not available	<b>Partition Coefficient (n-octanol/water):</b>	Not available
<b>Melting Point:</b>	Not applicable	<b>Vapor Density:</b>	Not available
<b>Freezing Point:</b>	Not available		
<b>Chemical Family:</b>	Alkaline solution		
<b>Flammability/Explosivity Limits in Air, Lower:</b>	Not available		
<b>Flammability/Explosivity Limits in Air, Upper:</b>	Not available		
<b>Auto-Ignition Temperature:</b>	Not available		
<b>Flash Point:</b>	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:**

Solution is oxidized by air. Avoid high temperatures.

**Incompatible Materials:**

Avoid amines, ammonium salts, cyanides and reducing agents. Heat and acids will result in release of nitrous gas. Under certain conditions, nitrite compounds may react with secondary and tertiary amines to form nitrosamines, which are known carcinogens in animals.

**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:**

Toxic by ingestion. Harmful by inhalation and in contact with skin. May cause severe eye irritation. Sodium nitrite exposure may result in a drop in blood pressure, headache, vertigo, palpitations, visual disturbances, methemoglobinemia, dyspnea and respiratory depression.

**Toxicology Data - Selected LD50s and LC50s**

Sodium nitrite	7632-00-0	Inhalation LC50 Rat: 5500 µg/m <sup>3</sup> /4H; Oral LD50 Rat: 88 mg/kg
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**Chronic Effects:**

No data available.

**Carcinogenicity:**

No data available.

**Mutagenicity:**

No data available.

**Teratogenicity:**

No data available.

**Reproductive Effects:**

No data available.



**MATERIAL SAFETY DATA SHEET**  
**OSOM® Ultra Strep A Extraction Reagent Bottle**

**Sensitization:**

No data available.

**12. ECOLOGICAL INFORMATION**

**Ecotoxicity:**

**Ecotoxicity - Freshwater Fish Species Data**

Sodium nitrite	7632-00-0	96 Hr LC50 <i>Oncorhynchus mykiss</i> : 0.19 mg/L [flow-through] (juvenile)
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**Persistence 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**

Sodium nitrite	7632-00-0	Toxic; Ignitable; Reactive
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**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)**

Sodium nitrite	7632-00-0	Present
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**U.S. - CERCLA/SARA - Hazardous Substances and their Reportable Quantities**

Sodium nitrite	7632-00-0	100 lb final RQ; 45.4 kg final RQ
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**U.S. - CERCLA/SARA - Section 313 - Emission Reporting**

Sodium nitrite	7632-00-0	1.0 % de minimis concentration
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# MATERIAL SAFETY DATA SHEET

## OSOM® Ultra Strep A Extraction Reagent Bottle

### US State Regulations:

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

Sodium nitrite 7632-00-0 Present

### 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 - Ingredient Disclosure List**

Sodium nitrite 7632-00-0 1 %

#### **EU - Dangerous Substances Directive (67/548/EEC) - Annex I - Classification**

Sodium nitrite 7632-00-0 O;R8□T;R25□N;R50

#### **EU - Dangerous Substances Directive (67/548/EEC) - Annex I - Concentration Limits**

Sodium nitrite 7632-00-0 25%≤C: T,N; R25-50□5%≤C<25%: T; R25□1%≤C<5%: Xn; R22

#### **EU - Dangerous Substances Directive (67/548/EEC) - Annex I - Safety Phrases**

Sodium nitrite 7632-00-0 S:1/2-45-61

#### **Germany - Water Classification (VwVwS) - Annex 2 - Water Hazard Classes**

Sodium nitrite 7632-00-0 ID Number 161, hazard class 2 - hazard to waters

#### **Inventory - Australia - Inventory of Chemical Substances (AICS)**

Sodium nitrite 7632-00-0 Present

#### **Inventory - Canada - Domestic Substances List (DSL)**

Sodium nitrite 7632-00-0 Present

#### **Inventory - China**

Sodium nitrite 7632-00-0 Present

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

Sodium nitrite 7632-00-0 231-555-9

#### **Inventory - Japan Existing and New Chemical Substances (ENCS)**

Sodium nitrite 7632-00-0 1-483

#### **Inventory - Korea - Existing and Evaluated Chemical Substances**

Sodium nitrite 7632-00-0 KE-31546

### **Canadian Hazardous Products:**

**WHMIS Status** Controlled

#### **Classification**

D2B - Other Toxic Effects-TOXIC



### **European Communities Dangerous Substances/Preparations:**

**EC Hazard Class** T - Toxic

#### **Symbols**



#### **Risk Phrases**

R25 Toxic if swallowed.

#### **Safety Phrases**

S24/25 Avoid contact with skin and eyes.  
S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.  
S36/39 Wear suitable protective clothing and eye/face protection.  
S45 In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).



**MATERIAL SAFETY DATA SHEET**  
**OSOM® Ultra Strep A Extraction Reagent Bottle**

**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.

**MSDS Origination Date:** January 13, 2005

**Version #:** 4

**Revision Date:** May 02, 2008

**Disclaimer:**

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

**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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**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:**

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

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



**MATERIAL SAFETY DATA SHEET**  
**OSOM® Ultra Strep A Extraction Reagent Ampule**

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 (CO<sub>2</sub>) 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.



# MATERIAL SAFETY DATA SHEET

## OSOM® Ultra Strep A Extraction Reagent Ampule

### 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.



## MATERIAL SAFETY DATA SHEET

### OSOM® Ultra Strep A Extraction Reagent Ampule

#### Personal Protective Equipment (PPE):

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

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Appearance:</b>	Clear, colorless liquid	<b>pH:</b>	2.6 (approximate)
<b>Odor:</b>	Sour, pungent odor like vinegar	<b>Solubility:</b>	Water-soluble
<b>Boiling Point:</b>	Not available	<b>Density:</b>	Not applicable
<b>Melting Point:</b>	Not applicable	<b>Vapor Pressure:</b>	Not available
<b>Freezing Point:</b>	Not available	<b>Partition Coefficient (n-octanol/water):</b>	Not available
		<b>Vapor Density:</b>	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 handling and storage information in 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
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#### Local Effects:

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



## MATERIAL SAFETY DATA SHEET

### OSOM® Ultra Strep A Extraction Reagent Ampule

**Chronic Effects:**

Prolonged or repeated skin contact may cause dermatitis.

**Carcinogenicity:**

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.

**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
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**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
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**Ecotoxicity - Water Flea Data**

Acetic acid	64-19-7	24 Hr EC50 Daphnia magna: 95 mg/L
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**Persistence 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
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## 14. TRANSPORT INFORMATION



**MATERIAL SAFETY DATA SHEET**  
**OSOM® Ultra Strep A Extraction Reagent Ampule**

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**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

<b>15. REGULATORY INFORMATION</b>
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**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
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**U.S. - CERCLA/SARA - Hazardous Substances and their Reportable Quantities**

Acetic acid	64-19-7	5000 lb final RQ; 2270 kg final RQ
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**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)
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# MATERIAL SAFETY DATA SHEET

## OSOM® Ultra Strep A Extraction Reagent Ampule

### 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** Controlled

**Classification**

E - Corrosive



### 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.



## MATERIAL SAFETY DATA SHEET

### OSOM® Ultra Strep A Extraction Reagent Ampule

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**MSDS Origination Date:** January 13, 2005

**Version #:** 4

**Revision Date:** May 02, 2008

**Disclaimer:**

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**MATERIAL SAFETY DATA SHEET**  
**OSOM® Strep A Positive Control**

**1. PRODUCT AND COMPANY IDENTIFICATION**

**Product Name:** OSOM® Strep A Positive Control

**Synonym(s):** Strep A Positive Control; Ultra Strep A Positive Control

**Product Use:** For In Vitro Diagnostic Use Only. Component of OSOM® Strep A Test kit (catalog # 141 & 141E) and OSOM® Ultra Strep A Test kit (catalog # 147 & 149). For external quality control testing.

**Description:** Aqueous solution containing heat-inactivated bacteria and preservative.

**Corporate Headquarters**

**Genzyme Corporation**

500 Kendall Street  
Cambridge, MA 02142  
USA

**Phone:** 617-252-7500

**Manufacturer/Distributor**

**Genzyme Diagnostics**

6659 Top Gun Street  
San Diego, CA 92121  
USA

**Phone:** 858-452-3198

**Distributor**

**Genzyme Diagnostics**

50 Gibson Drive  
Kings Hill, West Malling  
Kent, ME19 4AF  
UK

**Phone:** 44 (0) 1732 220022

**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:**

CAUTION! The chemical, physical and toxicological properties of this preparation have not been thoroughly characterized. Avoid contact with eyes and skin. Do not ingest or inhale. Harmful by ingestion. Preparation appearance: clear, colorless liquid.

**Routes of Exposure:**

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

**Potential Health Effects:**

- |                        |  |
|------------------------|--|
| <b>Inhalation</b>      | Aerosol inhalation may cause coughing and sore throat.   |
| <b>Eye</b>             | Eye exposure may cause irritation, redness and watering.   |
| <b>Skin</b>            | Skin contact may cause irritation, dryness and redness. Sodium azide may be absorbed through the skin and result in systemic effects.  |
| <b>Ingestion</b>       | Ingestion of sodium azide may cause nausea, diarrhea, vomiting, headache, slight lowering of blood pressure, abdominal pain, and a general feeling of apprehension and unwellness. |
| <b>Chronic Effects</b> | No data available.   |
| <b>Target Organs</b>   | Sodium azide: Cardiovascular and central nervous system.   |



## MATERIAL SAFETY DATA SHEET

### OSOM® Strep A Positive Control

**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:**

Unknown.

### 3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient Name	CAS #	EC #	% (wt/wt)
Water	7732-18-5	231-791-2	93 - 96
<b>EC R-Phrases:</b> None	<b>EC Hazard Class:</b> None		
Non-viable Group A Streptococci	Not Assigned	Not Assigned	1 - 5
<b>EC R-Phrases:</b> None	<b>EC Hazard Class:</b> None		
Sodium azide	26628-22-8	247-852-1	0.1
<b>EC R-Phrases:</b> R28, R32, R50, R53	<b>EC Hazard Class:</b> 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 for 15 minutes while separating eyelids with fingers. Remove contact lenses if worn. Obtain medical attention if needed or if symptoms, such as redness or irritation persist.

**Skin Contact:**

In case of contact, flush skin with copious amounts of 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 hydrazoic acid fumes.



## MATERIAL SAFETY DATA SHEET

### OSOM® Strep A Positive Control

#### 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:

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. Follow proper disposal procedures.

#### Methods and Materials for Containment and Clean-Up:

Absorb spill with inert material/sorbent. 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. Minimize contact and contamination of personal clothing and skin. 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 - Ceilings (TLV-C)

Sodium azide 26628-22-8 0.29 mg/m<sup>3</sup> Ceiling (as NaN<sub>3</sub>); 0.11 ppm Ceiling (vapor, as hydrazoic acid)

##### Canada - Quebec - Occupational Exposure Limits - Ceilings

Sodium azide 26628-22-8 0.11 ppm Ceiling; 0.3 mg/m<sup>3</sup> Ceiling

##### EU - Occupational Exposure Directive (2006/15/EC) Indicative Occupational Exposure Limit Values (IOELV) - Skin Notations

Sodium azide 26628-22-8 possibility of significant uptake through the skin

##### EU - Occupational Exposure Directive (2006/15/EC) Indicative Occupational Exposure Limit Values (IOELV) - STELS

Sodium azide 26628-22-8 0.3 mg/m<sup>3</sup> STEL

##### EU - Occupational Exposure Directive (2006/15/EC) Indicative Occupational Exposure Limit Values (IOELV) - TWAs

Sodium azide 26628-22-8 0.1 mg/m<sup>3</sup> TWA

##### Israel - Occupational Exposure Limits - Ceilings

Sodium azide 26628-22-8 0.29 mg/m<sup>3</sup> Ceiling (as NaN<sub>3</sub>); 0.11 ppm Ceiling (vapor, as Hydrazoic acid)

##### Korea - Occupational Exposure Limits - Ceilings

Sodium azide 26628-22-8 0.1 ppm Ceiling; 0.3 mg/m<sup>3</sup> Ceiling

#### Engineering Controls:

This preparation is aqueous and non-volatile and is not expected to require special ventilation measures. Facilities storing or using this preparation should be equipped with an eyewash fountain.

#### Personal Protective Equipment (PPE):

- |                    |  |
|--------------------|--|
| <b>Respiratory</b> | A respirator is not required under normal conditions of use.                       |
| <b>Eye/Face</b>    | Wear appropriate protective chemical safety glasses.                               |
| <b>Skin</b>        | Wear lab coat or other protective garments. Remove contaminated clothing promptly. |
| <b>Gloves</b>      | Wear chemical resistant protective gloves.   |



## MATERIAL SAFETY DATA SHEET

### OSOM® Strep A Positive Control

#### Personal Protective Equipment (PPE):

**General** Follow company-specific safety procedures.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Appearance:</b>	Clear, colorless liquid	<b>pH:</b>	7.2 (approximate)
<b>Odor:</b>	Not available	<b>Solubility:</b>	Water-soluble
<b>Boiling Point:</b>	Not available	<b>Vapor Pressure:</b>	Not available
<b>Melting Point:</b>	Not applicable	<b>Partition Coefficient (n-octanol/water):</b>	Not available
<b>Freezing Point:</b>	Not available	<b>Vapor Density:</b>	Not available
<b>Flammability/Explosivity Limits in Air, Lower:</b>	Not available		
<b>Flammability/Explosivity Limits in Air, Upper:</b>	Not available		
<b>Auto-Ignition Temperature:</b>	Not available		
<b>Flash Point:</b>	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:

Avoid prolonged exposure to direct sunlight.

#### Incompatible Materials:

Avoid strong oxidizing agents, acids, heavy metals and their salts.

#### Hazardous Decomposition Products:

None expected under normal conditions of use.

#### Possibility of Hazardous Reactions:

Hazardous polymerization will not occur.

### 11. TOXICOLOGICAL INFORMATION

#### Acute Effects:

##### Toxicology Data - Selected LD50s and LC50s

Sodium azide 26628-22-8 Oral LD50 Rat: 27 mg/kg; Dermal LD50 Rabbit: 20 mg/kg

#### Local Effects:

No data available.

#### Chronic Effects:

No data available.

#### Carcinogenicity:

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.

##### ACGIH - Threshold Limits Values - Carcinogens

Sodium azide 26628-22-8 A4 - Not Classifiable as a Human Carcinogen

##### Canada - Manitoba - Occupational Exposure Limits - Carcinogens

Sodium azide 26628-22-8 A4 - Not Classifiable as a Human Carcinogen



**MATERIAL SAFETY DATA SHEET**  
**OSOM® Strep A Positive Control**

**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**

Sodium azide

26628-22-8

96 Hr LC50 *Oncorhynchus mykiss*: 0.8 mg/L; 96 Hr LC50  
*Lepomis macrochirus*: 0.7 mg/L; 96 Hr LC50 *Pimephales*  
*promelas*: 5.46 mg/L [flow-through]

**Persistence and Degradability:**

No data available.

**Bioaccumulative Potential:**

No data available.

**Mobility in Environmental Media:**

No data available.

**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.

**Waste Classification:**

**U.S. - California - 22 CCR - Presumed Hazardous Wastes**

Sodium azide

26628-22-8

Ignitable; Reactive

**U.S. - RCRA (Resource Conservation & Recovery Act) - P Series Wastes - Acutely Toxic Wastes**

Sodium azide

26628-22-8

waste number P105

**14. TRANSPORT INFORMATION**



## MATERIAL SAFETY DATA SHEET

### OSOM® Strep A Positive Control

#### 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)**

Sodium azide 26628-22-8 Present

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

Sodium azide 26628-22-8 1000 lb final RQ; 454 kg final RQ

#### **U.S. - CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs**

Sodium azide 26628-22-8 1000 lb EPCRA RQ

#### **U.S. - CERCLA/SARA - Section 302 Extremely Hazardous Substances TPQs**

Sodium azide 26628-22-8 500 lb TPQ (This material is a reactive solid. The TPQ does not default to 10000 pounds for non-powder, non-molten, non-solvent form)

#### **U.S. - CERCLA/SARA - Section 313 - Emission Reporting**

Sodium azide 26628-22-8 1.0 % de minimis concentration

#### US State Regulations:

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

Sodium azide 26628-22-8 Present



# MATERIAL SAFETY DATA SHEET

## OSOM® Strep A Positive Control

### 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

Sodium azide 26628-22-8 D1A

#### Canada - WHMIS - Ingredient Disclosure List

Sodium azide 26628-22-8 1 %

#### EU - Dangerous Substances Directive (67/548/EEC) - Annex I - Classification

Sodium azide 26628-22-8 T+;R28□R32□N;R50-53

#### EU - Dangerous Substances Directive (67/548/EEC) - Annex I - Safety Phrases

Sodium azide 26628-22-8 S:1/2-28-45-60-61

#### Germany - Water Classification (VwVwS) - Annex 2 - Water Hazard Classes

Sodium azide 26628-22-8 ID Number 636, hazard class 2 - hazard to waters

#### Inventory - Australia - Inventory of Chemical Substances (AICS)

Sodium azide 26628-22-8 Present

#### Inventory - Canada - Domestic Substances List (DSL)

Sodium azide 26628-22-8 Present

#### Inventory - China

Sodium azide 26628-22-8 Present

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

Sodium azide 26628-22-8 247-852-1

#### Inventory - Japan Existing and New Chemical Substances (ENCS)

Sodium azide 26628-22-8 1-482

#### Inventory - Korea - Existing and Evaluated Chemical Substances

Sodium azide 26628-22-8 KE-31357

### Canadian Hazardous Products:

WHMIS Status Non-controlled

### European Communities Dangerous Substances/Preparations:

EC Hazard Class Xn - Harmful

Symbols



#### Risk Phrases

R22 Harmful if swallowed.  
R32 Contact with acids liberates very toxic gas.

#### Safety Phrases

S35 This material and its container must be disposed of in a safe way.

## 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 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.



## MATERIAL SAFETY DATA SHEET

### OSOM® Strep A Positive Control

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**MSDS Origination Date:** January 07, 2005

**Version #:** 4

**Revision Date:** May 02, 2008

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# MATERIAL SAFETY DATA SHEET

## OSOM® Strep A Negative Control

### 1. PRODUCT AND COMPANY IDENTIFICATION

**Product Name:** OSOM® Strep A Negative Control

**Synonym(s):** Strep A Negative Control; Ultra Strep A Negative Control

**Product Use:** For In Vitro Diagnostic Use Only. Component of OSOM® Strep A Test kit (catalog # 141 & 141E) and OSOM® Ultra Strep A Test kit (catalog # 147 & 149). For external quality control testing.

**Description:** Aqueous solution containing heat-inactivated bacteria and preservative.

**Corporate Headquarters**

**Genzyme Corporation**

500 Kendall Street  
Cambridge, MA 02142  
USA

**Phone:** 617-252-7500

**Manufacturer/Distributor**

**Genzyme Diagnostics**

6659 Top Gun Street  
San Diego, CA 92121  
USA

**Phone:** 858-452-3198

**Distributor**

**Genzyme Diagnostics**

50 Gibson Drive  
Kings Hill, West Malling  
Kent, ME19 4AF  
UK

**Phone:** 44 (0) 1732 220022

**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:**

CAUTION! The chemical, physical and toxicological properties of this preparation have not been thoroughly characterized. Avoid contact with eyes and skin. Do not ingest or inhale. Harmful by ingestion. Preparation appearance: clear, colorless liquid.

**Routes of Exposure:**

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

**Potential Health Effects:**

<b>Inhalation</b>	Aerosol inhalation may cause coughing and sore throat.
<b>Eye</b>	Eye exposure may cause irritation, redness and watering.
<b>Skin</b>	Skin contact may cause irritation, dryness and redness. Sodium azide may be absorbed through the skin and result in systemic effects.
<b>Ingestion</b>	Ingestion of sodium azide may cause nausea, diarrhea, vomiting, headache, slight lowering of blood pressure, abdominal pain, and a general feeling of apprehension and unwellness.
<b>Chronic Effects</b>	No data available.
<b>Target Organs</b>	Sodium azide: Cardiovascular and central nervous system.



## MATERIAL SAFETY DATA SHEET

### OSOM® Strep A Negative Control

#### 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:

Unknown.

### 3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient Name	CAS #	EC #	% (wt/wt)
Water	7732-18-5	231-791-2	93 - 96
<b>EC R-Phrases:</b> None	<b>EC Hazard Class:</b> None		
Non-viable Group C Streptococci	Not Assigned	Not Assigned	1 - 5
<b>EC R-Phrases:</b> None	<b>EC Hazard Class:</b> None		
Sodium azide	26628-22-8	247-852-1	0.1
<b>EC R-Phrases:</b> R28, R32, R50, R53	<b>EC Hazard Class:</b> 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 for 15 minutes while separating eyelids with fingers. Remove contact lenses if worn. Obtain medical attention if needed or if symptoms, such as redness or irritation persist.

#### Skin Contact:

In case of contact, flush skin with copious amounts of 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 hydrazoic acid fumes.



## MATERIAL SAFETY DATA SHEET

### OSOM® Strep A Negative Control

#### 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:

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. Follow proper disposal procedures.

#### Methods and Materials for Containment and Clean-Up:

Absorb spill with inert material/sorbent. 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. Minimize contact and contamination of personal clothing and skin. 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 - Ceilings (TLV-C)

Sodium azide 26628-22-8 0.29 mg/m<sup>3</sup> Ceiling (as NaN<sub>3</sub>); 0.11 ppm Ceiling (vapor, as hydrazoic acid)

##### Canada - Quebec - Occupational Exposure Limits - Ceilings

Sodium azide 26628-22-8 0.11 ppm Ceiling; 0.3 mg/m<sup>3</sup> Ceiling

##### EU - Occupational Exposure Directive (2006/15/EC) Indicative Occupational Exposure Limit Values (IOELV) - Skin Notations

Sodium azide 26628-22-8 possibility of significant uptake through the skin

##### EU - Occupational Exposure Directive (2006/15/EC) Indicative Occupational Exposure Limit Values (IOELV) - STELS

Sodium azide 26628-22-8 0.3 mg/m<sup>3</sup> STEL

##### EU - Occupational Exposure Directive (2006/15/EC) Indicative Occupational Exposure Limit Values (IOELV) - TWAs

Sodium azide 26628-22-8 0.1 mg/m<sup>3</sup> TWA

##### Israel - Occupational Exposure Limits - Ceilings

Sodium azide 26628-22-8 0.29 mg/m<sup>3</sup> Ceiling (as NaN<sub>3</sub>); 0.11 ppm Ceiling (vapor, as Hydrazoic acid)

##### Korea - Occupational Exposure Limits - Ceilings

Sodium azide 26628-22-8 0.1 ppm Ceiling; 0.3 mg/m<sup>3</sup> Ceiling

#### Engineering Controls:

This preparation is aqueous and non-volatile and is not expected to require special ventilation measures. Facilities storing or using this preparation should be equipped with an eyewash fountain.

#### Personal Protective Equipment (PPE):

- |                    |  |
|--------------------|--|
| <b>Respiratory</b> | A respirator is not required under normal conditions of use.                       |
| <b>Eye/Face</b>    | Wear appropriate protective chemical safety glasses.                               |
| <b>Skin</b>        | Wear lab coat or other protective garments. Remove contaminated clothing promptly. |
| <b>Gloves</b>      | Wear chemical resistant protective gloves.   |



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#### Personal Protective Equipment (PPE):

**General** Follow company-specific safety procedures.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Appearance:</b>	Clear, colorless liquid	<b>pH:</b>	7.2 (approximate)
<b>Odor:</b>	Not available	<b>Solubility:</b>	Water-soluble
<b>Boiling Point:</b>	Not available	<b>Vapor Pressure:</b>	Not available
<b>Melting Point:</b>	Not applicable	<b>Partition Coefficient (n-octanol/water):</b>	Not available
<b>Freezing Point:</b>	Not available	<b>Vapor Density:</b>	Not available
<b>Flammability/Explosivity Limits in Air, Lower:</b>	Not available		
<b>Flammability/Explosivity Limits in Air, Upper:</b>	Not available		
<b>Auto-Ignition Temperature:</b>	Not available		
<b>Flash Point:</b>	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:

Avoid prolonged exposure to direct sunlight.

#### Incompatible Materials:

Avoid strong oxidizing agents, acids, heavy metals and their salts.

#### Hazardous Decomposition Products:

None expected under normal conditions of use.

#### Possibility of Hazardous Reactions:

Hazardous polymerization will not occur.

### 11. TOXICOLOGICAL INFORMATION

#### Acute Effects:

##### Toxicology Data - Selected LD50s and LC50s

Sodium azide 26628-22-8 Oral LD50 Rat: 27 mg/kg; Dermal LD50 Rabbit: 20 mg/kg

#### Local Effects:

No data available.

#### Chronic Effects:

No data available.

#### Carcinogenicity:

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.

##### ACGIH - Threshold Limits Values - Carcinogens

Sodium azide 26628-22-8 A4 - Not Classifiable as a Human Carcinogen

##### Canada - Manitoba - Occupational Exposure Limits - Carcinogens

Sodium azide 26628-22-8 A4 - Not Classifiable as a Human Carcinogen



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**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**

Sodium azide

26628-22-8

96 Hr LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 Hr LC50  
Lepomis macrochirus: 0.7 mg/L; 96 Hr LC50 Pimephales  
promelas: 5.46 mg/L [flow-through]

**Persistence and Degradability:**

No data available.

**Bioaccumulative Potential:**

No data available.

**Mobility in Environmental Media:**

No data available.

**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.

**Waste Classification:**

**U.S. - California - 22 CCR - Presumed Hazardous Wastes**

Sodium azide

26628-22-8

Ignitable; Reactive

**U.S. - RCRA (Resource Conservation & Recovery Act) - P Series Wastes - Acutely Toxic Wastes**

Sodium azide

26628-22-8

waste number P105

**14. TRANSPORT INFORMATION**



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#### 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)**

Sodium azide 26628-22-8 Present

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

Sodium azide 26628-22-8 1000 lb final RQ; 454 kg final RQ

#### **U.S. - CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs**

Sodium azide 26628-22-8 1000 lb EPCRA RQ

#### **U.S. - CERCLA/SARA - Section 302 Extremely Hazardous Substances TPQs**

Sodium azide 26628-22-8 500 lb TPQ (This material is a reactive solid. The TPQ does not default to 10000 pounds for non-powder, non-molten, non-solvent form)

#### **U.S. - CERCLA/SARA - Section 313 - Emission Reporting**

Sodium azide 26628-22-8 1.0 % de minimis concentration

#### US State Regulations:

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

Sodium azide 26628-22-8 Present



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## OSOM® Strep A Negative Control

### 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

Sodium azide 26628-22-8 D1A

#### Canada - WHMIS - Ingredient Disclosure List

Sodium azide 26628-22-8 1 %

#### EU - Dangerous Substances Directive (67/548/EEC) - Annex I - Classification

Sodium azide 26628-22-8 T+;R28□R32□N;R50-53

#### EU - Dangerous Substances Directive (67/548/EEC) - Annex I - Safety Phrases

Sodium azide 26628-22-8 S:1/2-28-45-60-61

#### Germany - Water Classification (VwVwS) - Annex 2 - Water Hazard Classes

Sodium azide 26628-22-8 ID Number 636, hazard class 2 - hazard to waters

#### Inventory - Australia - Inventory of Chemical Substances (AICS)

Sodium azide 26628-22-8 Present

#### Inventory - Canada - Domestic Substances List (DSL)

Sodium azide 26628-22-8 Present

#### Inventory - China

Sodium azide 26628-22-8 Present

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

Sodium azide 26628-22-8 247-852-1

#### Inventory - Japan Existing and New Chemical Substances (ENCS)

Sodium azide 26628-22-8 1-482

#### Inventory - Korea - Existing and Evaluated Chemical Substances

Sodium azide 26628-22-8 KE-31357

### Canadian Hazardous Products:

WHMIS Status Non-controlled

### European Communities Dangerous Substances/Preparations:

EC Hazard Class Xn - Harmful

Symbols



#### Risk Phrases

R22 Harmful if swallowed.  
R32 Contact with acids liberates very toxic gas.

#### Safety Phrases

S35 This material and its container must be disposed of in a safe way.

## 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 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.



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**Revision Date:** May 02, 2008

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