



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

MATERIAL SAFETY DATA SHEETS

Catalog Number:	Kit Name:
141, 141E, 141E-20	OSOM[®] Strep A Test

Item Number:	Component Name:
998	OSOM[®] Strep A Extraction Reagent 1
1001	OSOM[®] Strep A Extraction Reagent 2
1003	OSOM[®] Strep A Positive Control
1009	OSOM[®] Strep A Negative Control

Note: The page numbers on the 4 individual MSDSs for this kit are specific to each document. There are a total of 30 pages including this cover sheet.

OSOM[®] Strep A Test Stick is an "article" and does not require an MSDS.



MATERIAL SAFETY DATA SHEET

OSOM® Strep A Extraction Reagent 1

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: OSOM® Strep A Extraction Reagent 1

Synonym(s): Strep A Extraction Reagent 1; Strep A Extraction Reagent

Product Use: Component of OSOM® Strep A Test kit (catalog # 141, 141E & 141E-20). For use in the qualitative detection of Group A Streptococcal antigen. For In Vitro Diagnostic Use Only.

Description: Aqueous solution containing color indicator and inorganic salt.

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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:

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:

- | | |
|------------------------|---|
| Inhalation | Substantial aerosol inhalation may result in symptoms similar to those specified for ingestion. |
| Eye | Eye exposure may cause severe irritation, redness, watering, swelling and burning. |
| Skin | Skin contact with sufficient chemical absorption may result in symptoms similar to those specified for ingestion. |
| Ingestion | 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. |
| Chronic Effects | 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. |
| Target Organs | Sodium nitrite: Cardiovascular and central nervous systems. |



MATERIAL SAFETY DATA SHEET

OSOM® Strep A Extraction Reagent 1

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.

3. COMPOSITION / INFORMATION ON INGREDIENTS

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

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 (CO₂), nitrogen oxides (NO_x) and sulphur oxides (SO_x).



MATERIAL SAFETY DATA SHEET

OSOM® Strep A Extraction Reagent 1

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:

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 Strep A Extraction Reagents 1 and 2 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):

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

9. PHYSICAL AND CHEMICAL PROPERTIES



MATERIAL SAFETY DATA SHEET
OSOM® Strep A Extraction Reagent 1

Reproductive Effects:

No data available.

Sensitization:

No data available.

12. ECOLOGICAL INFORMATION

Ecotoxicity:

Ecotoxicity - Freshwater Fish Species Data

Sodium nitrite	7632-00-0	96 Hr LC50 Oncorhynchus mykiss: 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

MATERIAL SAFETY DATA SHEET
OSOM® Strep A Extraction Reagent 1

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

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

Sodium nitrite 7632-00-0 100 lb final RQ; 45.4 kg final RQ

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

Sodium nitrite 7632-00-0 1.0 % de minimis concentration

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 Exempt

European Communities Dangerous Substances/Preparations:

EC Hazard Class T - Toxic

Symbols



Risk Phrases

R25 Toxic if swallowed.



MATERIAL SAFETY DATA SHEET

OSOM® Strep A Extraction Reagent 1

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).

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).

MSDS Origination Date: January 07, 2005

Version #: 8

Revision Date: January 05, 2009

Disclaimer:

The information above is provided in good faith. It is believed to be accurate and represents the best information currently available to us. HOWEVER, WE MAKE NO WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR OF ANY OTHER TYPE, EXPRESSED OR IMPLIED, WITH RESPECT TO PRODUCTS DESCRIBED OR DATA OR INFORMATION PROVIDED, AND WE ASSUME NO LIABILITY RESULTING FROM THE USE OF SUCH PRODUCTS, DATA OR INFORMATION. Users should make their own investigations to determine the suitability of the information for their particular purposes, and the user assumes all risk arising from their use of the material. The user is required to comply with all laws and regulations relating to the purchase, use, storage and disposal of the material, and must be familiar with and follow generally accepted safe handling procedures. In no event shall Genzyme be liable for any claims, losses, or damages of any individual or for lost profits or any special, indirect, incidental, consequential or exemplary damages, howsoever arising, even if Genzyme has been advised of the possibility of such damages.



MATERIAL SAFETY DATA SHEET

OSOM® Strep A Extraction Reagent 2

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: OSOM® Strep A Extraction Reagent 2

Synonym(s): Strep A Extraction Reagent 2

Product Use: Component of OSOM® Strep A Test kit (catalog # 141, 141E & 141E-20). For use in the qualitative detection of Group A Streptococcal antigen. For In Vitro Diagnostic Use Only.

Description: Aqueous, acidic solution.

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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:

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.



MATERIAL SAFETY DATA SHEET

OSOM® Strep A Extraction Reagent 2

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		
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.



MATERIAL SAFETY DATA SHEET

OSOM® Strep A Extraction Reagent 2

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 Strep A Extraction Reagents 1 and 2 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.



MATERIAL SAFETY DATA SHEET

OSOM® Strep A Extraction Reagent 2

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.
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



MATERIAL SAFETY DATA SHEET

OSOM® Strep A Extraction Reagent 2

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.

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
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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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MATERIAL SAFETY DATA SHEET
OSOM® Strep A Extraction Reagent 2

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
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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® Strep A Extraction Reagent 2

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).



MATERIAL SAFETY DATA SHEET

OSOM® Strep A Extraction Reagent 2

MSDS Origination Date: January 07, 2005

Version #: 8

Revision Date: January 05, 2009

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: Component of OSOM® Strep A Test kit (catalog # 141, 141E & 141E-20) and OSOM® Ultra Strep A Test kit (catalog # 147 & 149). For external quality control testing. For In Vitro Diagnostic Use Only.

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:

Inhalation	Aerosol inhalation may cause coughing and sore throat.
Eye	Eye exposure may cause irritation, redness and watering.
Skin	Skin contact may cause irritation, dryness and redness. Sodium azide may be absorbed through the skin and result in systemic effects.
Ingestion	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.
Chronic Effects	No data available.
Target Organs	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
EC R-Phrases: None	EC Hazard Class: None		
Non-viable Group A Streptococci	Not Assigned	Not Assigned	1 - 5
EC R-Phrases: None	EC Hazard Class: None		
Sodium azide	26628-22-8	247-852-1	0.1
EC R-Phrases: R28, R32, R50, R53	EC Hazard Class: 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/m³ Ceiling (as NaN₃); 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/m³ 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/m³ STEL

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

Sodium azide 26628-22-8 0.1 mg/m³ TWA

Israel - Occupational Exposure Limits - Ceilings

Sodium azide 26628-22-8 0.29 mg/m³ Ceiling (as NaN₃); 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/m³ 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):

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

Appearance:	Clear, colorless liquid	pH:	7.2 (approximate)
Odor:	Not available	Solubility:	Water-soluble
Boiling Point:	Not available	Vapor Pressure:	Not available
Melting Point:	Not applicable	Partition Coefficient (n-octanol/water):	Not available
Freezing Point:	Not available	Vapor Density:	Not available
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:

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:

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

Mutagenicity:

No data available.



MATERIAL SAFETY DATA SHEET

OSOM® Strep A Positive Control

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]
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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:

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

Sodium azide	26628-22-8	waste number P105
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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



MATERIAL SAFETY DATA SHEET

OSOM® Strep A Positive Control

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

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 Exempt



MATERIAL SAFETY DATA SHEET

OSOM® Strep A Positive Control

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.
S45 In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

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).

MSDS Origination Date: January 07, 2005

Version #: 8

Revision Date: January 05, 2009

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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: Component of OSOM® Strep A Test kit (catalog # 141, 141E & 141E-20) and OSOM® Ultra Strep A Test kit (catalog # 147 & 149). For external quality control testing. For In Vitro Diagnostic Use Only.

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:

Inhalation	Aerosol inhalation may cause coughing and sore throat.
Eye	Eye exposure may cause irritation, redness and watering.
Skin	Skin contact may cause irritation, dryness and redness. Sodium azide may be absorbed through the skin and result in systemic effects.
Ingestion	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.
Chronic Effects	No data available.
Target Organs	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
EC R-Phrases: None	EC Hazard Class: None		
Non-viable Group C Streptococci	Not Assigned	Not Assigned	1 - 5
EC R-Phrases: None	EC Hazard Class: None		
Sodium azide	26628-22-8	247-852-1	0.1
EC R-Phrases: R28, R32, R50, R53	EC Hazard Class: 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/m³ Ceiling (as NaN₃); 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/m³ 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/m³ STEL

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

Sodium azide 26628-22-8 0.1 mg/m³ TWA

Israel - Occupational Exposure Limits - Ceilings

Sodium azide 26628-22-8 0.29 mg/m³ Ceiling (as NaN₃); 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/m³ 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):

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



MATERIAL SAFETY DATA SHEET

OSOM® Strep A Negative Control

Personal Protective Equipment (PPE):

General Follow company-specific safety procedures.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Clear, colorless liquid	pH:	7.2 (approximate)
Odor:	Not available	Solubility:	Water-soluble
Boiling Point:	Not available	Vapor Pressure:	Not available
Melting Point:	Not applicable	Partition Coefficient (n-octanol/water):	Not available
Freezing Point:	Not available	Vapor Density:	Not available
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:

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:

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

Mutagenicity:

No data available.



MATERIAL SAFETY DATA SHEET
OSOM® Strep A Negative Control

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]
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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:

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

Sodium azide	26628-22-8	waste number P105
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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



MATERIAL SAFETY DATA SHEET

OSOM® Strep A Negative Control

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

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 Exempt



MATERIAL SAFETY DATA SHEET

OSOM® Strep A Negative Control

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.
S45 In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

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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