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:
145, 145E	**OSOM® Mono Test**

Item Number:	Component Name:
1053	**OSOM® Mono Test Diluent**
1054	**OSOM® Mono Test Positive Control**
1057	**OSOM® Mono Test Negative Control**

Note: The page numbers on the 3 individual MSDSs for this kit are specific to each document. There are a total of 22 pages including this cover sheet.

OSOM® Mono Test Stick is an “article” and does not require an MSDS.

Effective Date: November 12, 2008

MATERIAL SAFETY DATA SHEET

OSOM® Mono Test Diluent

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: OSOM® Mono Test Diluent

Synonym(s): Mono DILUENT

Product Use: Component of OSOM® Mono Test kit (Catalog # 145 & 145E). For use in the qualitative detection of infectious mononucleosis heterophile antibodies in serum, plasma or whole blood as an aid in the diagnosis of infectious mononucleosis. For In Vitro Diagnostic Use Only.

Description: Aqueous solution containing salts and preservative.

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Distributor

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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.

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	97 - 98
EC R-Phrases: None	**EC Hazard Class:** None		
Inorganic (buffering) salts	Mixture	Mixture	1 - 2
EC R-Phrases: None	**EC Hazard Class:** None		
Sodium azide	26628-22-8	247-852-1	0.2
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.

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
Germany - DFG - Recommended Exposure Limits - Ceilings (Peak Limitations)		
Sodium azide	26628-22-8	0.4 mg/m3 Peak (inhalable fraction)
Germany - DFG - Recommended Exposure Limits - MAK Values		
Sodium azide	26628-22-8	0.2 mg/m3 MAK (inhalable fraction)
Germany - TRGS 900 - Occupational Exposure Limits - TWAs		
Sodium azide	26628-22-8	0.2 mg/m3 TWA (exposure factor 2)
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.

Personal Protective Equipment (PPE):

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.
General	Follow company-specific safety procedures.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Clear, colorless liquid	**pH:**	7.0 (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.

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]

Persistance 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

Basic Shipping Description:

Not classified as dangerous goods. Not regulated per IATA and DOT regulations.

15. REGULATORY INFORMATION

US Federal Regulations:

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

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

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

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 13, 2005

Version #: 5

Revision Date: November 12, 2008

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® Mono Test Positive Control

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: OSOM® Mono Test Positive Control

Synonym(s): Mono CONTROL +

Product Use: Component of OSOM® Mono Test kit (Catalog # 145 & 145E). For external quality control testing. For In Vitro Diagnostic Use Only.

Description: Aqueous solution containing salt, antibodies (protein) and preservatives.

Corporate Headquarters

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500 Kendall Street
Cambridge, MA 02142
USA
Phone: 617-252-7500

Manufacturer/Distributor

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Distributor

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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. Allergic skin reaction may result in certain sensitive individuals upon exposure to the aminoglycoside antibiotic in this preparation. 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 and possible allergic reaction with itching and rash. 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.

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	97 - 99
EC R-Phrases: None	**EC Hazard Class:** None		
Rabbit anti-beef stroma antiserum	Not Assigned	Not Assigned	0.1 - 2
EC R-Phrases: None	**EC Hazard Class:** None		
Sodium azide	26628-22-8	247-852-1	0.2
EC R-Phrases: R28, R32, R50, R53	**EC Hazard Class:** T+, N		
Tris(hydroxymethyl)methylamine	77-86-1	201-064-4	0.2
EC R-Phrases: None	**EC Hazard Class:** None		
Gentamicin sulfate	1405-41-0	215-778-9	0.05
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 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.

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
Germany - DFG - Recommended Exposure Limits - Ceilings (Peak Limitations)		
Sodium azide	26628-22-8	0.4 mg/m3 Peak (inhalable fraction)
Germany - DFG - Recommended Exposure Limits - MAK Values		
Sodium azide	26628-22-8	0.2 mg/m3 MAK (inhalable fraction)
Germany - TRGS 900 - Occupational Exposure Limits - TWAs		
Sodium azide	26628-22-8	0.2 mg/m3 TWA (exposure factor 2)
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.
General	Follow company-specific safety procedures.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Clear, colorless liquid	**pH:**	7.0 (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.

Teratogenicity:

No data available.

Reproductive Effects:

No data available.

Sensitization:

Sensitization to aminoglycoside antibiotics may occur with dermal exposure.

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]

Persistance 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

Basic Shipping Description:

Not classified as dangerous goods. Not regulated per IATA and DOT regulations.

15. REGULATORY INFORMATION

US Federal Regulations:

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

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

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

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 13, 2005

Version #: 5

Revision Date: November 12, 2008

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MATERIAL SAFETY DATA SHEET

OSOM® Mono Test Negative Control

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: OSOM® Mono Test Negative Control

Synonym(s): Mono CONTROL -

Product Use: Component of OSOM® Mono Test kit (Catalog # 145 & 145E). For external quality control testing. For In Vitro Diagnostic Use Only.

Description: Aqueous solution containing salt, goat serum, and preservatives.

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. Contains animal-source material (goat serum albumin of US origin). 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.

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	99.3
EC R-Phrases: None	**EC Hazard Class:** None		
Tris(hydroxymethyl)methylamine	77-86-1	201-064-4	0.3
EC R-Phrases: None	**EC Hazard Class:** None		
Goat serum albumin	Not Assigned	Not Assigned	0.2
EC R-Phrases: None	**EC Hazard Class:** None		
Sodium azide	26628-22-8	247-852-1	0.2
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.

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
Germany - DFG - Recommended Exposure Limits - Ceilings (Peak Limitations)		
Sodium azide	26628-22-8	0.4 mg/m3 Peak (inhalable fraction)
Germany - DFG - Recommended Exposure Limits - MAK Values		
Sodium azide	26628-22-8	0.2 mg/m3 MAK (inhalable fraction)
Germany - TRGS 900 - Occupational Exposure Limits - TWAs		
Sodium azide	26628-22-8	0.2 mg/m3 TWA (exposure factor 2)
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.

Personal Protective Equipment (PPE):

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:**	8.0 (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.

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]

Persistance 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

Basic Shipping Description:

Not classified as dangerous goods. Not regulated per IATA and DOT regulations.

15. REGULATORY INFORMATION

US Federal Regulations:

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

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

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

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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

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.
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