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50 Gibson Drive  
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## MATERIAL SAFETY DATA SHEETS

Catalog Number:	Kit Name:
<b>145, 145E</b>	<b>OSOM<sup>®</sup> Mono Test</b>

Item Number:	Component Name:
<b>2081</b>	<b>OSOM<sup>®</sup> Mono Test Diluent</b>
<b>2082</b>	<b>OSOM<sup>®</sup> Mono Test Positive Control</b>
<b>2083</b>	<b>OSOM<sup>®</sup> Mono Test Negative Control</b>

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<sup>®</sup> Mono Test Stick is an "article" and does not require an MSDS.



## 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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**Phone:** +1 858-452-3198

**Emergency Telephone Numbers**

**Genzyme (U.S.):** +1 617-562-4555

**CHEMTREC (U.S.):** 1-800-424-9300

**CHEMTREC (Outside U.S.):** +1 703-527-3887

**Distributor**

**Genzyme Diagnostics**

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

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

#### 2. HAZARDS IDENTIFICATION

**Precautionary Statements:**

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

**Routes of Exposure:**

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

**Potential Health Effects:**

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



## MATERIAL SAFETY DATA SHEET

### OSOM® Mono Test Diluent

#### 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. CHIPS 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
<b>EC R-Phrases:</b> None	<b>EC Hazard Class:</b> None		
Inorganic (buffering) salts	Mixture	Mixture	1 - 2
<b>EC R-Phrases:</b> None	<b>EC Hazard Class:</b> None		
Sodium azide	26628-22-8	247-852-1	0.2
<b>EC R-Phrases:</b> R28, R32, R50, R53	<b>EC Hazard Class:</b> T+, N		

### 4. FIRST AID MEASURES

#### Inhalation:

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

#### Eye Contact:

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

#### Skin Contact:

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

#### Ingestion:

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

### 5. FIRE FIGHTING MEASURES

#### Flammable Properties:

Dilute aqueous solution not considered a fire hazard.

#### Suitable Extinguishing Media:

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

#### Unsuitable Extinguishing Media:

Unknown.

#### Specific Hazards Arising from the Chemical:

When heated to decomposition, may produce hydrazoic acid fumes.



## MATERIAL SAFETY DATA SHEET

### OSOM® Mono Test Diluent

#### 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:

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

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

##### EU - Occupational Exposure Directive (2000/39/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 (2000/39/EC) Indicative Occupational Exposure Limit Values (IOELV) - STELs

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

##### EU - Occupational Exposure Directive (2000/39/EC) Indicative Occupational Exposure Limit Values (IOELV) - TWAs

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

##### Germany - DFG - Recommended Exposure Limits - Ceilings (Peak Limitations)

Sodium azide 26628-22-8 0.4 mg/m<sup>3</sup> Peak (inhalable fraction)

##### Germany - DFG - Recommended Exposure Limits - MAK Values

Sodium azide 26628-22-8 0.2 mg/m<sup>3</sup> MAK (inhalable fraction)

##### Germany - TRGS 900 - Occupational Exposure Limits - TWAs

Sodium azide 26628-22-8 0.2 mg/m<sup>3</sup> TWA

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

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

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

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

#### Engineering Controls:

This preparation is aqueous and non-volatile and is not expected to require special ventilation measures. Facilities storing or utilizing 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.





## MATERIAL SAFETY DATA SHEET

### OSOM® Mono Test Diluent

#### Carcinogenicity:

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

#### ACGIH - Threshold Limits Values - Carcinogens

Sodium azide	26628-22-8	A4 - Not Classifiable as a Human Carcinogen (as sodium azide and hydrazoic acid vapor)
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#### Mutagenicity:

No data available.

#### Teratogenicity:

No data available.

#### Reproductive Effects:

No data available.

#### Sensitization:

No data available.

## 12. ECOLOGICAL INFORMATION

#### Ecotoxicity:

##### Ecotoxicity - Freshwater Fish Species Data

Sodium azide	26628-22-8	96 Hr LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 Hr LC50 Lepomis macrochirus: 0.7 mg/L; 96 Hr LC50 Pimephales promelas: 5.46 mg/L [flow-through]
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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:

##### California - 22 CCR - Presumed Hazardous Wastes

Sodium azide	26628-22-8	Ignitable; Reactive
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##### 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:

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



# MATERIAL SAFETY DATA SHEET

## OSOM® Mono Test Diluent

### 15. REGULATORY INFORMATION

#### US Federal Regulations:

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

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

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

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

Sodium azide 26628-22-8 1000 lb EPCRA RQ

#### **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)

#### **CERCLA/SARA - Section 313 - Emission Reporting**

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

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

Sodium azide 26628-22-8 Present

#### US State Regulations:

#### **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 Non-controlled



## MATERIAL SAFETY DATA SHEET

### OSOM® Mono Test Diluent

#### European Communities Dangerous Substances/Preparations:

**EC Hazard Class** Xn - Harmful

**Symbols**



#### **Risk Phrases**

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

#### **Safety Phrases**

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

### 16. OTHER INFORMATION

#### **Recommended Use:**

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

#### **Further Information:**

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

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

**Version #:** 4

**Revision Date:** June 06, 2007

#### **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.

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

**Emergency Telephone Numbers**

**Genzyme (U.S.):** +1 617-562-4555

**CHEMTREC (U.S.):** 1-800-424-9300

**CHEMTREC (Outside U.S.):** +1 703-527-3887

### 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:**

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



## MATERIAL SAFETY DATA SHEET

### OSOM® Mono Test 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. CHIPS 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: R36/37/38	EC Hazard Class: Xi		
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.



## MATERIAL SAFETY DATA SHEET

### OSOM® Mono Test Positive Control

#### 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:

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

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

##### EU - Occupational Exposure Directive (2000/39/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 (2000/39/EC) Indicative Occupational Exposure Limit Values (IOELV) - STELs

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

##### EU - Occupational Exposure Directive (2000/39/EC) Indicative Occupational Exposure Limit Values (IOELV) - TWAs

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

##### Germany - DFG - Recommended Exposure Limits - Ceilings (Peak Limitations)

Sodium azide 26628-22-8 0.4 mg/m<sup>3</sup> Peak (inhalable fraction)

##### Germany - DFG - Recommended Exposure Limits - MAK Values

Sodium azide 26628-22-8 0.2 mg/m<sup>3</sup> MAK (inhalable fraction)

##### Germany - TRGS 900 - Occupational Exposure Limits - TWAs

Sodium azide 26628-22-8 0.2 mg/m<sup>3</sup> TWA

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

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

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

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

#### Engineering Controls:

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



## MATERIAL SAFETY DATA SHEET

### OSOM® Mono Test Positive Control

#### Personal Protective Equipment (PPE):

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

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Appearance:</b>	Clear, colorless liquid	<b>pH:</b>	7.0 (approximate)
<b>Odor:</b>	Not available	<b>Solubility:</b>	Water-soluble
<b>Boiling Point:</b>	Not available	<b>Vapor Pressure:</b>	Not available
<b>Melting Point:</b>	Not applicable	<b>Partition Coefficient (n-octanol/water):</b>	Not available
<b>Freezing Point:</b>	Not available	<b>Vapor Density:</b>	Not available
<b>Flammability/Explosivity Limits in Air, Lower:</b>	Not available		
<b>Flammability/Explosivity Limits in Air, Upper:</b>	Not available		
<b>Auto-Ignition Temperature:</b>	Not available		
<b>Flash Point:</b>	Not available		

### 10. STABILITY AND REACTIVITY

#### Chemical Stability:

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

#### Conditions to Avoid:

Avoid prolonged exposure to direct sunlight.

#### Incompatible Materials:

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

#### Hazardous Decomposition Products:

None expected under normal conditions of use.

#### Possibility of Hazardous Reactions:

Hazardous polymerization will not occur.

### 11. TOXICOLOGICAL INFORMATION

#### Acute Effects:

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

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

#### Local Effects:

No data available.

#### Chronic Effects:

No data available.



## MATERIAL SAFETY DATA SHEET

### OSOM® Mono Test Positive Control

#### Carcinogenicity:

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

#### ACGIH - Threshold Limits Values - Carcinogens

Sodium azide	26628-22-8	A4 - Not Classifiable as a Human Carcinogen (as sodium azide and hydrazoic acid vapor)
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#### 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 <i>Oncorhynchus mykiss</i> : 0.8 mg/L; 96 Hr LC50 <i>Lepomis macrochirus</i> : 0.7 mg/L; 96 Hr LC50 <i>Pimephales promelas</i> : 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:

##### California - 22 CCR - Presumed Hazardous Wastes

Sodium azide	26628-22-8	Ignitable; Reactive
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##### 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:

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



# MATERIAL SAFETY DATA SHEET

## OSOM® Mono Test Positive Control

### 15. REGULATORY INFORMATION

#### US Federal Regulations:

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

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

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

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

Sodium azide 26628-22-8 1000 lb EPCRA RQ

#### **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)

#### **CERCLA/SARA - Section 313 - Emission Reporting**

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

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

Sodium azide 26628-22-8 Present

#### US State Regulations:

#### **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 Non-controlled



# MATERIAL SAFETY DATA SHEET

## OSOM® Mono Test 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.

### 16. OTHER INFORMATION

**Recommended Use:**

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

**Further Information:**

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

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

**Version #:** 4

**Revision Date:** June 06, 2007

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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:** +1 617-252-7500

**Manufacturer/Distributor**

**Genzyme Diagnostics**

6659 Top Gun Street  
San Diego, CA 92121  
USA

**Phone:** +1 858-452-3198

**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.):** +1 617-562-4555

**CHEMTREC (U.S.):** 1-800-424-9300

**CHEMTREC (Outside U.S.):** +1 703-527-3887

### 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:**

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

**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. CHIPS 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® Mono Test Negative Control

### Potential Environmental Effects:

Unknown.

### 3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient Name	CAS #	EC #	% (wt/wt)
Water	7732-18-5	231-791-2	99.3
<b>EC R-Phrases:</b> None	<b>EC Hazard Class:</b> None		
Tris(hydroxymethyl)methylamine	77-86-1	201-064-4	0.3
<b>EC R-Phrases:</b> R36/37/38	<b>EC Hazard Class:</b> Xi		
Goat serum albumin	Not Assigned	Not Assigned	0.2
<b>EC R-Phrases:</b> None	<b>EC Hazard Class:</b> None		
Sodium azide	26628-22-8	247-852-1	0.2
<b>EC R-Phrases:</b> R28, R32, R50, R53	<b>EC Hazard Class:</b> T+, N		

### 4. FIRST AID MEASURES

#### Inhalation:

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

#### Eye Contact:

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

#### Skin Contact:

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

#### Ingestion:

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

### 5. FIRE FIGHTING MEASURES

#### Flammable Properties:

Dilute aqueous solution not considered a fire hazard.

#### Suitable Extinguishing Media:

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

#### Unsuitable Extinguishing Media:

Unknown.

#### Specific Hazards Arising from the Chemical:

When heated to decomposition, may produce hydrazoic acid fumes.

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

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



# MATERIAL SAFETY DATA SHEET

## OSOM® Mono Test Negative Control

### 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:

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

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

##### EU - Occupational Exposure Directive (2000/39/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 (2000/39/EC) Indicative Occupational Exposure Limit Values (IOELV) - STELs

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

##### EU - Occupational Exposure Directive (2000/39/EC) Indicative Occupational Exposure Limit Values (IOELV) - TWAs

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

##### Germany - DFG - Recommended Exposure Limits - Ceilings (Peak Limitations)

Sodium azide 26628-22-8 0.4 mg/m<sup>3</sup> Peak (inhalable fraction)

##### Germany - DFG - Recommended Exposure Limits - MAK Values

Sodium azide 26628-22-8 0.2 mg/m<sup>3</sup> MAK (inhalable fraction)

##### Germany - TRGS 900 - Occupational Exposure Limits - TWAs

Sodium azide 26628-22-8 0.2 mg/m<sup>3</sup> TWA

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

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

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

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

#### Engineering Controls:

This preparation is aqueous and non-volatile and is not expected to require special ventilation measures. Facilities storing or utilizing 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.



## MATERIAL SAFETY DATA SHEET

### OSOM® Mono Test Negative Control

#### Personal Protective Equipment (PPE):

<b>Gloves</b>	Wear chemical resistant protective gloves.
<b>General</b>	Follow company-specific safety procedures.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Appearance:</b>	Clear, colorless liquid	<b>pH:</b>	8.0 (approximate)
<b>Odor:</b>	Not available	<b>Solubility:</b>	Water-soluble
<b>Boiling Point:</b>	Not available	<b>Vapor Pressure:</b>	Not available
<b>Melting Point:</b>	Not applicable	<b>Partition Coefficient (n-octanol/water):</b>	Not available
<b>Freezing Point:</b>	Not available	<b>Vapor Density:</b>	Not available
<b>Flammability/Explosivity Limits in Air, Lower:</b>	Not available		
<b>Flammability/Explosivity Limits in Air, Upper:</b>	Not available		
<b>Auto-Ignition Temperature:</b>	Not available		
<b>Flash Point:</b>	Not available		

### 10. STABILITY AND REACTIVITY

#### Chemical Stability:

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

#### Conditions to Avoid:

Avoid prolonged exposure to direct sunlight.

#### Incompatible Materials:

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

#### Hazardous Decomposition Products:

None expected under normal conditions of use.

#### Possibility of Hazardous Reactions:

Hazardous polymerization will not occur.

### 11. TOXICOLOGICAL INFORMATION

#### Acute Effects:

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

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

#### Local Effects:

No data available.

#### Chronic Effects:

No data available.

#### Carcinogenicity:

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

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

Sodium azide 26628-22-8 A4 - Not Classifiable as a Human Carcinogen (as sodium azide and hydrazoic acid vapor)



## MATERIAL SAFETY DATA SHEET

### OSOM® Mono Test Negative Control

**Mutagenicity:**

No data available.

**Teratogenicity:**

No data available.

**Reproductive Effects:**

No data available.

**Sensitization:**

No data available.

### 12. ECOLOGICAL INFORMATION

**Ecotoxicity:****Ecotoxicity - Freshwater Fish Species Data**

Sodium azide

26628-22-8

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

**Persistence and Degradability:**

No data available.

**Bioaccumulative Potential:**

No data available.

**Mobility in Environmental Media:**

No data available.

### 13. DISPOSAL CONSIDERATIONS

**Methods of Disposal:**

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

**Waste Classification:****California - 22 CCR - Presumed Hazardous Wastes**

Sodium azide

26628-22-8

Ignitable; Reactive

**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.



# MATERIAL SAFETY DATA SHEET

## OSOM® Mono Test Negative Control

### 15. REGULATORY INFORMATION

#### US Federal Regulations:

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

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

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

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

Sodium azide 26628-22-8 1000 lb EPCRA RQ

#### **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)

#### **CERCLA/SARA - Section 313 - Emission Reporting**

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

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

Sodium azide 26628-22-8 Present

#### US State Regulations:

#### **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 Non-controlled



## MATERIAL SAFETY DATA SHEET

### OSOM® Mono Test 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.

### 16. OTHER INFORMATION

#### **Recommended Use:**

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

#### **Further Information:**

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

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

**Version #:** 4

**Revision Date:** June 06, 2007

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