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## MATERIAL SAFETY DATA SHEETS

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

Item Number:	Component Name:
<b>1004</b>	<b>Strep A Extraction Reagent (Bottle)</b>
<b>1005</b>	<b>Strep A Extraction Reagent (Ampule)</b>
<b>1003</b>	<b>Strep A CONTROL +</b>
<b>1009</b>	<b>Strep A CONTROL -</b>

Note: The page numbers on the 4 individual MSDSs for this kit are specific to each document. There are a total of 21 pages including this cover sheet.

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



# MATERIAL SAFETY DATA SHEET

## 1. Product and Company Identification

**Product name** Strep A Extraction Reagent (Bottle)  
**Synonym(s)** OSOM® Ultra Strep A Extraction Reagent Bottle  
**CAS #** Mixture  
**Kit Number:** 147  
**Product description** Aqueous, alkaline solution containing trace color indicator. The Strep A Extraction Reagent bottle contains a glass ampule. See the Strep A Extraction Reagent (Ampule) MSDS for details.  
**Product use** Component of OSOM® Ultra Strep A Test kit. For the qualitative detection of Group A Streptococcal antigen directly from throat swab specimens. For In Vitro Diagnostic Use Only.

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www.genzymediagnosics.com  
**Phone:** 858-452-3198

### Emergency Telephone Numbers

**Genzyme (U.S.):** 617-562-4555  
**CHEMTREC (U.S.):** 800-424-9300  
**CHEMTREC (Outside U.S.):** +1 703-527-3887

## 2. Hazards Identification

**Regulatory status** This preparation is classified as hazardous under U.S. OSHA 29 CFR 1910.1200.  
This medical diagnostic kit is controlled under the Canadian Food and Drugs Act and is exempt from classification, labeling and MSDS requirements under the Canadian Hazardous Products Act and Controlled Products Regulations.

**Precautionary statements** WARNING! The chemical, physical and toxicological properties of this preparation have not been thoroughly characterized. Toxic by ingestion. Avoid contact with eyes and skin. Do not ingest or inhale. Preparation appearance: clear, pink liquid.

**Potential health effects**

**Inhalation** No data available. Substantial aerosol inhalation may result in symptoms similar to those specified for ingestion.

**Eyes** No data available. Eye exposure may cause severe irritation, redness, watering, swelling and burning.

**Skin** No data available. Skin contact with sufficient chemical absorption may result in symptoms similar to those specified for ingestion.

**Ingestion** Ingestion of sodium nitrite 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 exposure to nitrites may cause headaches, visual problems and decreased blood pressure.

**Target organs** Sodium nitrite: Cardiovascular and central nervous systems.

**Potential environmental effects** See Section 12.

## 3. Composition / Information on Ingredients

Components	CAS #	Percent
Sodium nitrite	7632-00-0	12 - 14
Non-hazardous and other components below reportable levels		80 - 90

## 4. First Aid Measures

### First aid procedures

**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

### Extinguishing media

**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** Sodium nitrite is an oxidizing agent. It is not flammable itself, but it can make combustible materials more flammable if it is absorbed and dries.

**Hazardous combustion products** When heated to decomposition, may produce carbon monoxide (CO), carbon dioxide (CO<sub>2</sub>), nitrogen oxides (NO<sub>x</sub>) and sulphur oxides (SO<sub>x</sub>).

### Protection of firefighters

**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. Ensure adequate ventilation. Avoid physical contact with material and avoid aerosol inhalation. Wash hands thoroughly after handling.

**Environmental precautions** Do not let product enter drains.

**Methods for cleaning up** Absorb spill with inert material/sorbent. Decontaminate the spill site following standard procedures. Dispose of materials in accordance with all applicable federal, state, local and provincial environmental regulations, per Section 13.

## 7. Handling and Storage

**Handling** Follow good laboratory hygiene practices. See Section 8, Engineering Controls. Mixing the contents of the ampule within the Strep A Extraction Reagent bottle yields nitrous acid, which may immediately decompose into toxic nitrous gas, a short-term reaction by-product. Minimize contact and contamination of personal clothing and skin. Avoid vapor or aerosol inhalation. Wash hands thoroughly after handling.

**Storage** Store at 15 to 30°C (59 to 86°F). Keep container tightly closed in a dry and well-ventilated place. Do not store with incompatible substances; see Section 10.

## 8. Exposure Controls / Personal Protection

**Exposure guidelines** There are no ACGIH, NIOSH or OSHA occupational exposure limits currently established for this mixture or its components at concentrations equal to or greater than 1% (0.1% if carcinogen).

**Engineering controls** Minimize potential for aerosolization. Handle within a containment system or with local exhaust ventilation. Facilities storing or using this material should be equipped with an eyewash fountain and a safety shower.

### Personal protective equipment

**Respiratory protection** A respirator is not expected to be required under normal conditions of use.

**Eye / face protection** Wear appropriate protective chemical safety goggles.

**Skin protection** Wear appropriate protective clothing, such as a lab coat or other long-sleeved garment over clothing to minimize contact and contamination of clothing.

**Hand protection** Wear chemical resistant protective gloves.

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

## 9. Physical & Chemical Properties

**Physical state** Liquid.

**Color** Clear, pink

**Odor** Not available

**Chemical family** Alkaline solution

**pH** 9.0 (approximate)

**Melting point** Not applicable

**Freezing point** Not available

<b>Boiling point</b>	Not available
<b>Flash point</b>	Not available
<b>Evaporation rate</b>	Not available
<b>Flammability</b>	Not available.
<b>Flammability limits in air, upper, % by volume</b>	Not available
<b>Flammability limits in air, lower, % by volume</b>	Not available
<b>Vapor pressure</b>	Not available
<b>Vapor density</b>	Not available
<b>Specific gravity</b>	1.08
<b>Relative density</b>	1.08 g/cm <sup>3</sup>
<b>Solubility (water)</b>	Water-soluble
<b>Partition coefficient (n-octanol/water)</b>	Not available
<b>Auto-ignition temperature</b>	Not applicable
<b>Decomposition temperature</b>	Not available
<b>Viscosity</b>	Not available

## 10. Chemical Stability & Reactivity Information

<b>Reactivity</b>	Mixing Strep A Extraction Reagent bottle and ampule yields nitrous acid, which may immediately decompose into toxic nitrous gas, a short-term reaction by-product.
<b>Chemical stability</b>	Stable under ordinary conditions of use and storage. See Section 7.
<b>Possibility of hazardous reactions</b>	Hazardous polymerization will not occur.
<b>Conditions to avoid</b>	Solution is oxidized by air. Avoid high temperatures.
<b>Incompatible materials</b>	Avoid amines, ammonium salts, cyanides and reducing agents. Heat and acids will result in release of nitrous gas. Under certain conditions, nitrite compounds may react with secondary and tertiary amines to form nitrosamines, which are known carcinogens in animals.
<b>Hazardous decomposition products</b>	Thermal decomposition may lead to release of irritating gases and vapors.

## 11. Toxicological Information

<b>Routes of exposure</b>	Occupational exposure routes may include inhalation, skin absorption, and eye and skin contact.
<b>Acute effects</b>	Sodium nitrite exposure may result in a drop in blood pressure, headache, vertigo, palpitations, visual disturbances, methemoglobinemia, dyspnea and respiratory depression.

### Toxicological data

Components	Test Results
Sodium nitrite (7632-00-0)	Acute Inhalation LC50 Rat: 5.5 mg/l 4 Hours Acute Oral LD50 Rat: 85 mg/kg

<b>Skin corrosion/irritation</b>	No data available.
<b>Chronic effects</b>	No data available.
<b>Carcinogenicity</b>	No data available.
<b>Mutagenicity</b>	No data available.
<b>Reproductive effects</b>	No data available.
<b>Teratogenicity</b>	No data available.
<b>Sensitization</b>	No data available.

## 12. Ecological Information

### Ecotoxicological data

Components	Test Results
Sodium nitrite (7632-00-0)	EC50 Greasyback shrimp ( <i>Metapenaeus ensis</i> ): 16.14 - 26.61 mg/l 48 hours

## Components

Sodium nitrite (7632-00-0)

## Test Results

LC50 Channel catfish (*Ictalurus punctatus*): 0.048 mg/l 96 hours

LC50 Rainbow trout, donaldson trout (*Oncorhynchus mykiss*): 0.19 - 0.24 mg/l 96 hours

**Mobility in environmental media** No data available.

**Persistence / degradability** No data available.

**Bioaccumulation** No data available.

## 13. Disposal Considerations

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

## 14. Transport Information

### DOT

#### Basic shipping requirements:

**UN number** UN1500  
**Proper shipping name** SODIUM NITRITE SOLUTION  
**Hazard class** 5.1 (6.1)



### DOT

## 15. Regulatory Information

**US federal regulations** This preparation is a component of an FDA-regulated in vitro diagnostic device.

#### US CERCLA Hazardous Substances: Listed substance

Sodium nitrite (7632-00-0) LISTED

#### US CERCLA Hazardous Substances: Reportable quantity

Sodium nitrite (7632-00-0) 100 LBS

#### US CWA Section 311 Hazardous Substances: Listed substance

Sodium nitrite (7632-00-0) Listed.

#### US CWA Section 311 Reporting Quantities of Hazardous Substances: Listed substance

Sodium nitrite (7632-00-0) Listed.

#### US CWA Section 311 Reporting Quantities of Hazardous Substances: Reportable quantity

Sodium nitrite (7632-00-0) 100 LBS

#### US EPCRA (SARA Title III) Section 313 - Toxic Chemical: De minimis concentration

Sodium nitrite (7632-00-0) 1.0 %

#### US EPCRA (SARA Title III) Section 313 - Toxic Chemical: Listed substance

Sodium nitrite (7632-00-0) Listed.

#### US TSCA Inventory: Registration Status

Sodium nitrite (7632-00-0) Listed.

#### US TSCA Section 12(b) Export Notification: Export Notification requirement/De minimis concentration

Sodium nitrite (7632-00-0) 1.0 % TSCA Section: 5 One-Time Export Notification only.

#### US TSCA Section 5(a)(2) Final Significant New Use Rules (SNURs): Listed substance

Sodium nitrite (7632-00-0) Listed.

**US TSCA Section 5(a)(2) Final Significant New Use Rules (SNURs): Section number: 40 CFR**

Sodium nitrite (7632-00-0)

721.4740 Listed.

**CERCLA (Superfund) reportable quantity**

Sodium nitrite: 100

**Superfund Amendments and Reauthorization Act of 1986 (SARA)**

**Hazard categories** Immediate Hazard - No  
Delayed Hazard - No  
Fire Hazard - No  
Pressure Hazard - No  
Reactivity Hazard - No

**Section 302 extremely hazardous substance** No

**Section 311 hazardous chemical** No

**State regulations**

**US - California Hazardous Substances (Director's): Listed substance**

Sodium nitrite (7632-00-0)

Listed.

**16. Other Information**

**Further information**

This MSDS has been prepared in accordance with the ANSI Z400.1 format and complies with the U.S. OSHA Hazard Communication Standard 29 CFR 1910.1200.

The Product name in Section 1 has been revised.  
The Transport information in Section 14 has been revised.

**MSDS Number** 1004

**Version number** 06

**Issue date** 04-21-2010

**Revision date** 04-21-2010

**Disclaimer**

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# MATERIAL SAFETY DATA SHEET

## 1. Product and Company Identification

**Product name** Strep A Extraction Reagent (Ampule)  
**Synonym(s)** OSOM® Ultra Strep A Extraction Reagent Ampule  
**CAS #** Mixture  
**Kit Number:** 147  
**Product description** Aqueous, acidic solution. The Strep A Extraction Reagent ampule is contained in a bottle. See the Strep A Extraction Reagent (Bottle) MSDS for details.  
**Product use** Component of OSOM® Ultra Strep A Test kit. For the qualitative detection of Group A Streptococcal antigen directly from throat swab specimens. For In Vitro Diagnostic Use Only.

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## 2. Hazards Identification

**Regulatory status** This preparation is classified as hazardous under U.S. OSHA 29 CFR 1910.1200.  
 This medical diagnostic kit is controlled under the Canadian Food and Drugs Act and is exempt from classification, labeling and MSDS requirements under the Canadian Hazardous Products Act and Controlled Products Regulations.

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

**Potential health effects**

- Inhalation** Inhalation may be irritating to the nasal passages and throat.
- Eyes** Eye exposure may cause irritation, redness, watering 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.

**Potential environmental effects** None expected.

## 3. Composition / Information on Ingredients

Components	CAS #	Percent
Acetic acid	64-19-7	2
Non-hazardous and other components below reportable levels		> 90

## 4. First Aid Measures

### First aid procedures

**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

### Extinguishing media

<b>Suitable extinguishing media</b>	Use extinguishing media suitable for surrounding fire, such as carbon dioxide, chemical foam, dry chemical or water spray.
<b>Unsuitable extinguishing media</b>	Unknown.

### Specific hazards

Dilute aqueous solution not considered a fire hazard.

### Hazardous combustion products

When heated to decomposition, may produce carbon dioxide (CO<sub>2</sub>) and carbon monoxide (CO).

### Protection of firefighters

<b>Protective equipment and precautions for firefighters</b>	Firefighters should wear NIOSH-approved or equivalent Self-Contained Breathing Apparatus and full protective gear.
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## 6. Accidental Release Measures

### Personal precautions

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

### Environmental precautions

No special environmental precautions required.

### Methods for cleaning up

Absorb spill with inert material/sorbent or appropriate neutralizing agent. Decontaminate the spill site following standard procedures. Dispose of materials in accordance with all applicable federal, state, local and provincial environmental regulations, per Section 13.

## 7. Handling and Storage

### Handling

Follow good laboratory hygiene practices. See Section 8, Engineering Controls. Mixing the contents of the ampule within the Strep A Extraction Reagent bottle yields nitrous acid, which may immediately decompose into toxic nitrous gas, a short-term reaction by-product. Avoid vapor or aerosol inhalation. 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

### Occupational exposure limits

#### ACGIH

##### Components

	Type	Value
Acetic acid (64-19-7)	STEL	15 ppm
	TWA	10 ppm

#### U.S. - OSHA

##### Components

	Type	Value
Acetic acid (64-19-7)	PEL	25 mg/m <sup>3</sup>
		10 ppm
	TWA	25 mg/m <sup>3</sup>
		10 ppm

### Engineering controls

Minimize potential for aerosolization. Handle within a containment system or with local exhaust ventilation. Facilities storing or using this preparation should be equipped with an eyewash fountain and a safety shower.

### Personal protective equipment

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

## 9. Physical & Chemical Properties

### Physical state

Liquid.

<b>Color</b>	Clear, colorless
<b>Odor</b>	Sour, pungent odor like vinegar
<b>Chemical family</b>	Acidic solution
<b>pH</b>	2.6 (approximate)
<b>Melting point</b>	Not applicable
<b>Freezing point</b>	Not available
<b>Boiling point</b>	Not available
<b>Flash point</b>	Not available
<b>Evaporation rate</b>	Not available
<b>Flammability</b>	Not available.
<b>Flammability limits in air, upper, % by volume</b>	Not available
<b>Flammability limits in air, lower, % by volume</b>	Not available
<b>Vapor pressure</b>	Not available
<b>Vapor density</b>	Not available
<b>Specific gravity</b>	Not available
<b>Relative density</b>	Not available
<b>Solubility (water)</b>	Water-soluble
<b>Partition coefficient (n-octanol/water)</b>	Not available
<b>Auto-ignition temperature</b>	Not applicable
<b>Decomposition temperature</b>	Not available
<b>Viscosity</b>	Not available

## 10. Chemical Stability & Reactivity Information

<b>Reactivity</b>	Mixing Strep A Extraction Reagent bottle and ampule yields nitrous acid, which may immediately decompose into toxic nitrous gas, a short-term reaction by-product.
<b>Chemical stability</b>	Stable under ordinary conditions of use and storage. See Section 7.
<b>Possibility of hazardous reactions</b>	Hazardous polymerization will not occur.
<b>Conditions to avoid</b>	None known.
<b>Incompatible materials</b>	Avoid strong oxidizing agents, most common metals (except aluminum), strong bases and amines.
<b>Hazardous decomposition products</b>	Thermal decomposition may lead to release of irritating gases and vapors.

## 11. Toxicological Information

<b>Routes of exposure</b>	Occupational exposure routes may include inhalation, eye and skin contact.
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### Toxicological data

#### Components

Acetic acid (64-19-7)

#### Test Results

Acute Dermal LD50 Rabbit: 1060 mg/kg

Acute Inhalation LC50 Guinea pig: 5000 mg/l 1 Hours

Acute Oral LD50 Rat: 3530 mg/kg

#### Local effects

##### Eye irritation

Acetic acid (64-19-7)

Acetic acid (64-19-7)

Eye irritation has been noted at a concentration below 10 ppm. Irritating  
Irritating

##### Skin Irritation

Acetic acid (64-19-7)

Strongly Irritating

#### Chronic effects

Prolonged or repeated skin contact may cause dermatitis.

#### Carcinogenicity

No data available.

#### Mutagenicity

No data available.

<b>Reproductive effects</b>	No data available.
<b>Teratogenicity</b>	No data available.
<b>Sensitization</b>	No data available.

## 12. Ecological Information

### Ecotoxicological data

Components	Test Results
Acetic acid (64-19-7)	EC50 Water flea (Daphnia magna): 65 mg/l 48 hours LC50 Bluegill (Lepomis macrochirus): 75 mg/l 96 hours

<b>Mobility in environmental media</b>	No data available.
<b>Persistence / degradability</b>	No data available.
<b>Bioaccumulation</b>	No data available.

## 13. Disposal Considerations

<b>Disposal instructions</b>	Dispose of unused product, spilled material and waste in accordance with all applicable federal, state, local and provincial environmental and hazardous waste regulations.
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## 14. Transport Information

### DOT

Not regulated as hazardous goods.

## 15. Regulatory Information

<b>US federal regulations</b>	This preparation is a component of an FDA-regulated in vitro diagnostic device.
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### US CAA Section 111 Volatile Organic Compounds: Listed substance

Acetic acid (64-19-7) Listed.

### US CERCLA Hazardous Substances: Listed substance

Acetic acid (64-19-7) LISTED

### US CERCLA Hazardous Substances: Reportable quantity

Acetic acid (64-19-7) 5000 LBS

### US CWA Section 311 Hazardous Substances: Listed substance

Acetic acid (64-19-7) Listed.

### US CWA Section 311 Reporting Quantities of Hazardous Substances: Listed substance

Acetic acid (64-19-7) Listed.

### US CWA Section 311 Reporting Quantities of Hazardous Substances: Reportable quantity

Acetic acid (64-19-7) 5000 LBS

### US OSHA Hazard Communication Standard: Listed substance

Acetic acid (64-19-7) Listed.

### US TSCA Inventory: Registration Status

Acetic acid (64-19-7) Listed.

### CERCLA (Superfund) reportable quantity

Acetic acid: 5000

### Superfund Amendments and Reauthorization Act of 1986 (SARA)

<b>Hazard categories</b>	Immediate Hazard - No Delayed Hazard - No Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No
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**Section 302 extremely hazardous substance** No

**Section 311 hazardous chemical** No

### State regulations

#### US - California Hazardous Substances (Director's): Listed substance

Acetic acid (64-19-7) Listed.

## 16. Other Information

### Further information

This MSDS has been prepared in accordance with the ANSI Z400.1 format and complies with the U.S. OSHA Hazard Communication Standard 29 CFR 1910.1200.

The Product name in Section 1 has been revised.  
The Transport information in Section 14 has been revised.

### MSDS Number

1005

### Version number

06

### Issue date

04-21-2010

### Revision date

04-21-2010

### Disclaimer

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# MATERIAL SAFETY DATA SHEET

## 1. Product and Company Identification

**Product name** Strep A CONTROL +  
**Synonym(s)** OSOM® Strep A Positive Control  
**CAS #** Mixture  
**Kit Number:** 141; 141E; 141E-20; 147; 149  
**Product description** Aqueous solution containing heat-inactivated bacteria and preservative.  
**Product use** Component of OSOM® Strep A Test and OSOM® Ultra Strep A Test. For external quality control testing. For In Vitro Diagnostic Use Only.

### Corporate Headquarters

**Genzyme Corporation**  
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**Phone:** 617-252-7500

### Manufacturer/Distributor

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### Emergency Telephone Numbers

**Genzyme (U.S.):** 617-562-4555  
**CHEMTREC (U.S.):** 800-424-9300  
**CHEMTREC (Outside U.S.):** +1 703-527-3887

### Distributor

**Genzyme Diagnostics**  
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Kent ME19 4AF UK  
www.genzymediagnosics.com  
**Phone:** 44 (0) 1732 220022

## 2. Hazards Identification

**Regulatory status** This preparation is not classified as hazardous under U.S. OSHA 29 CFR 1910.1200.

This medical diagnostic kit is controlled under the Canadian Food and Drugs Act and is exempt from classification, labeling and MSDS requirements under the Canadian Hazardous Products Act and Controlled Products Regulations.

**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. Preparation appearance: clear, colorless liquid.

### **Potential health effects**

**Inhalation** No data available.  
**Eyes** No data available. Eye exposure may cause irritation, redness and watering.  
**Skin** No data available. 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.

**Potential environmental effects** See Section 12.

## 3. Composition / Information on Ingredients

Components	CAS #	Percent
Sodium azide	26628-22-8	0.1
Non-hazardous and other components below reportable levels		> 90

## 4. First Aid Measures

### **First aid procedures**

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

<b>Eye contact</b>	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.
<b>Skin contact</b>	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.
<b>Ingestion</b>	In case of ingestion, contact a poison control center or physician for instructions.

## 5. Fire Fighting Measures

### Extinguishing media

<b>Suitable extinguishing media</b>	Use extinguishing media suitable for surrounding fire, such as carbon dioxide, chemical foam, dry chemical or water spray.
<b>Unsuitable extinguishing media</b>	Unknown.

**Specific hazards** Dilute aqueous solution not considered a fire hazard.

**Hazardous combustion products** When heated to decomposition, may produce hydrazoic acid fumes.

### Protection of firefighters

**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 and avoid aerosol inhalation. 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 for cleaning 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). Do not store with incompatible substances; see Section 10.

## 8. Exposure Controls / Personal Protection

### Occupational exposure limits

#### ACGIH

Components	Type	Value
Sodium azide (26628-22-8)	Ceiling	0.11 ppm
	TWA	0.29 mg/m3

#### U.S. - OSHA

Components	Type	Value
Sodium azide (26628-22-8)	Ceiling	0.1 ppm
		0.3 mg/m3

**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 and a safety shower.

### Personal protective equipment

**Respiratory protection** A respirator is not expected to be required under normal conditions of use.

**Eye / face protection** Wear appropriate protective chemical safety glasses or goggles.

**Skin protection** Wear lab coat or other protective garments. Remove contaminated clothing promptly.

**Hand protection** Wear chemical resistant protective gloves.

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

## 9. Physical & Chemical Properties

Physical state	Liquid.
Color	Clear, colorless
Odor	Not available
pH	7.2 (approximate)
Melting point	Not applicable
Freezing point	Not available
Boiling point	Not available
Flash point	Not available
Evaporation rate	Not available
Flammability	Not available.
Flammability limits in air, upper, % by volume	Not available
Flammability limits in air, lower, % by volume	Not available
Vapor pressure	Not available
Vapor density	Not available
Specific gravity	Not available
Relative density	Not available
Solubility (water)	Water-soluble
Partition coefficient (n-octanol/water)	Not available
Auto-ignition temperature	Not available
Decomposition temperature	Not available
Viscosity	Not available

## 10. Chemical Stability & Reactivity Information

Reactivity	Unknown.
Chemical stability	Stable under ordinary conditions of use and storage. See Section 7.
Possibility of hazardous reactions	Hazardous polymerization will not occur.
Conditions to avoid	None known.
Incompatible materials	
Incompatibilities (NIOSH)	
Sodium azide (26628-22-8)	Acids, metals, water [Note: Over a period of time, sodium azide may react with copper, lead, brass, or solder in plumbing systems to form an accumulation of the HIGHLY EXPLOSIVE compounds of lead azide & copper azide.]
Hazardous decomposition products	None expected under normal conditions of use.

## 11. Toxicological Information

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

### Toxicological data

#### Components

#### Test Results

Sodium azide (26628-22-8)

Acute Dermal LD50 Rabbit: 20 mg/kg

Acute Oral LD50 Mouse: 27 mg/kg

Acute Oral LD50 Rat: 27 mg/kg

**Local effects** No data available.

**Chronic effects** No data available.

**Carcinogenicity** No data available.

**Mutagenicity** No data available.

<b>Reproductive effects</b>	No data available.
<b>Teratogenicity</b>	No data available.
<b>Sensitization</b>	No data available.

## 12. Ecological Information

### Ecotoxicological data

Components	Test Results
Sodium azide (26628-22-8)	EC50 Water flea (Daphnia pulex): 2.8 - 6.2 mg/l 48 hours LC50 Bluegill (Lepomis macrochirus): 0.68 mg/l 96 hours

<b>Mobility in environmental media</b>	No data available.
<b>Persistence / degradability</b>	No data available.
<b>Bioaccumulation</b>	No data available.

## 13. Disposal Considerations

<b>Disposal instructions</b>	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.
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## 14. Transport Information

### DOT

Not regulated as hazardous goods.

## 15. Regulatory Information

<b>US federal regulations</b>	This preparation is a component of an FDA-regulated in vitro diagnostic device.
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### US CERCLA Hazardous Substances: Listed substance

Sodium azide (26628-22-8) LISTED

### US CERCLA Hazardous Substances: Reportable quantity

Sodium azide (26628-22-8) 1000 LBS

### US EPCRA (SARA Title III) Section 302 - Extremely Hazardous Spill: Reportable quantity

Sodium azide (26628-22-8) 1000 LBS

### US EPCRA (SARA Title III) Section 302 - Extremely Hazardous Substance: Listed substance

Sodium azide (26628-22-8) Listed.

### US EPCRA (SARA Title III) Section 312 - Extremely Hazardous: Reporting threshold quantity, lower

Sodium azide (26628-22-8) 500 LBS

### US EPCRA (SARA Title III) Section 313 - Toxic Chemical: De minimis concentration

Sodium azide (26628-22-8) 1.0 %

### US EPCRA (SARA Title III) Section 313 - Toxic Chemical: Listed substance

Sodium azide (26628-22-8) Listed.

### US OSHA Hazard Communication Standard: Listed substance

Sodium azide (26628-22-8) Listed.

### US TSCA Inventory: Registration Status

Sodium azide (26628-22-8) Listed.

### CERCLA (Superfund) reportable quantity

Sodium azide: 1000

### Superfund Amendments and Reauthorization Act of 1986 (SARA)

<b>Hazard categories</b>	Immediate Hazard - No Delayed Hazard - No Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No
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<b>Section 302 extremely hazardous substance</b>	No
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**Section 311 hazardous chemical** No

**State regulations**

**US - California Hazardous Substances (Director's): Listed substance**  
Sodium azide (26628-22-8) Listed.

**16. Other Information**

**Further information** This MSDS has been prepared in accordance with the ANSI Z400.1 format and complies with the U.S. OSHA Hazard Communication Standard 29 CFR 1910.1200.

The Product name in Section 1 has been revised.  
The Transport information in Section 14 has been revised.

**MSDS Number** 1003

**Version number** 10

**Issue date** 04-02-2010

**Revision date** 04-02-2010

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# MATERIAL SAFETY DATA SHEET

## 1. Product and Company Identification

**Product name** Strep A CONTROL -  
**Synonym(s)** OSOM® Strep A Negative Control  
**CAS #** Mixture  
**Kit Number:** 141; 141E; 141E-20; 147; 149  
**Product description** Aqueous solution containing heat-inactivated bacteria and preservative.  
**Product use** Component of OSOM® Strep A Test and OSOM® Ultra Strep A Test. For external quality control testing. For In Vitro Diagnostic Use Only.

### Corporate Headquarters

**Genzyme Corporation**  
500 Kendall Street  
Cambridge, MA 02142 USA  
www.genzyme.com  
**Phone:** 617-252-7500

### Manufacturer/Distributor

**Genzyme Diagnostics**  
6659 Top Gun Street  
San Diego, CA 92121 USA  
www.genzymediagnosics.com  
**Phone:** 858-452-3198

### Emergency Telephone Numbers

**Genzyme (U.S.):** 617-562-4555  
**CHEMTREC (U.S.):** 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  
www.genzymediagnosics.com  
**Phone:** 44 (0) 1732 220022

## 2. Hazards Identification

**Regulatory status** This preparation is not classified as hazardous under U.S. OSHA 29 CFR 1910.1200.

This medical diagnostic kit is controlled under the Canadian Food and Drugs Act and is exempt from classification, labeling and MSDS requirements under the Canadian Hazardous Products Act and Controlled Products Regulations.

**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. Preparation appearance: clear, colorless liquid.

### **Potential health effects**

**Inhalation** No data available.  
**Eyes** No data available. Eye exposure may cause irritation, redness and watering.  
**Skin** No data available. 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.

**Potential environmental effects** See Section 12.

## 3. Composition / Information on Ingredients

Components	CAS #	Percent
Sodium azide	26628-22-8	0.1
Non-hazardous and other components below reportable levels		> 90

## 4. First Aid Measures

### **First aid procedures**

**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** 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

### Extinguishing media

**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** Dilute aqueous solution not considered a fire hazard.

**Hazardous combustion products** When heated to decomposition, may produce hydrazoic acid fumes.

### Protection of firefighters

**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 and avoid aerosol inhalation. 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 for cleaning 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). Do not store with incompatible substances; see Section 10.

## 8. Exposure Controls / Personal Protection

### Occupational exposure limits

#### ACGIH

##### Components

Components	Type	Value
Sodium azide (26628-22-8)	Ceiling	0.11 ppm
	TWA	0.29 mg/m3

#### U.S. - OSHA

##### Components

Components	Type	Value
Sodium azide (26628-22-8)	Ceiling	0.1 ppm
		0.3 mg/m3

### 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 and a safety shower.

### Personal protective equipment

**Respiratory protection** A respirator is not expected to be required under normal conditions of use.

**Eye / face protection** Wear appropriate protective chemical safety glasses or goggles.

**Skin protection** Wear lab coat or other protective garments. Remove contaminated clothing promptly.

**Hand protection** Wear chemical resistant protective gloves.

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

## 9. Physical & Chemical Properties

Physical state	Liquid.
Color	Clear, colorless
Odor	Not available
pH	7.2 (approximate)
Melting point	Not applicable
Freezing point	Not available
Boiling point	Not available
Flash point	Not available
Evaporation rate	Not available
Flammability	Not available.
Flammability limits in air, upper, % by volume	Not available
Flammability limits in air, lower, % by volume	Not available
Vapor pressure	Not available
Vapor density	Not available
Specific gravity	Not available
Relative density	Not available
Solubility (water)	Water-soluble
Partition coefficient (n-octanol/water)	Not available
Auto-ignition temperature	Not available
Decomposition temperature	Not available
Viscosity	Not available

## 10. Chemical Stability & Reactivity Information

Reactivity	Unknown.
Chemical stability	Stable under ordinary conditions of use and storage. See Section 7.
Possibility of hazardous reactions	Hazardous polymerization will not occur.
Conditions to avoid	None known.
Incompatible materials	
Incompatibilities (NIOSH)	
Sodium azide (26628-22-8)	Acids, metals, water [Note: Over a period of time, sodium azide may react with copper, lead, brass, or solder in plumbing systems to form an accumulation of the HIGHLY EXPLOSIVE compounds of lead azide & copper azide.]
Hazardous decomposition products	None expected under normal conditions of use.

## 11. Toxicological Information

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

### Toxicological data

#### Components

#### Test Results

Sodium azide (26628-22-8)

Acute Dermal LD50 Rabbit: 20 mg/kg

Acute Oral LD50 Mouse: 27 mg/kg

Acute Oral LD50 Rat: 27 mg/kg

**Local effects** No data available.

**Chronic effects** No data available.

**Carcinogenicity** No data available.

**Mutagenicity** No data available.

<b>Reproductive effects</b>	No data available.
<b>Teratogenicity</b>	No data available.
<b>Sensitization</b>	No data available.

## 12. Ecological Information

### Ecotoxicological data

Components	Test Results
Sodium azide (26628-22-8)	EC50 Water flea (Daphnia pulex): 2.8 - 6.2 mg/l 48 hours LC50 Bluegill (Lepomis macrochirus): 0.68 mg/l 96 hours

<b>Mobility in environmental media</b>	No data available.
<b>Persistence / degradability</b>	No data available.
<b>Bioaccumulation</b>	No data available.

## 13. Disposal Considerations

<b>Disposal instructions</b>	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.
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## 14. Transport Information

### DOT

Not regulated as hazardous goods.

## 15. Regulatory Information

<b>US federal regulations</b>	This preparation is a component of an FDA-regulated in vitro diagnostic device.
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### US CERCLA Hazardous Substances: Listed substance

Sodium azide (26628-22-8) LISTED

### US CERCLA Hazardous Substances: Reportable quantity

Sodium azide (26628-22-8) 1000 LBS

### US EPCRA (SARA Title III) Section 302 - Extremely Hazardous Spill: Reportable quantity

Sodium azide (26628-22-8) 1000 LBS

### US EPCRA (SARA Title III) Section 302 - Extremely Hazardous Substance: Listed substance

Sodium azide (26628-22-8) Listed.

### US EPCRA (SARA Title III) Section 312 - Extremely Hazardous: Reporting threshold quantity, lower

Sodium azide (26628-22-8) 500 LBS

### US EPCRA (SARA Title III) Section 313 - Toxic Chemical: De minimis concentration

Sodium azide (26628-22-8) 1.0 %

### US EPCRA (SARA Title III) Section 313 - Toxic Chemical: Listed substance

Sodium azide (26628-22-8) Listed.

### US OSHA Hazard Communication Standard: Listed substance

Sodium azide (26628-22-8) Listed.

### US TSCA Inventory: Registration Status

Sodium azide (26628-22-8) Listed.

### CERCLA (Superfund) reportable quantity

Sodium azide: 1000

### Superfund Amendments and Reauthorization Act of 1986 (SARA)

<b>Hazard categories</b>	Immediate Hazard - No Delayed Hazard - No Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No
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<b>Section 302 extremely hazardous substance</b>	No
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**Section 311 hazardous chemical** No

**State regulations**

**US - California Hazardous Substances (Director's): Listed substance**  
Sodium azide (26628-22-8) Listed.

**16. Other Information**

**Further information**

This MSDS has been prepared in accordance with the ANSI Z400.1 format and complies with the U.S. OSHA Hazard Communication Standard 29 CFR 1910.1200.

The Product name in Section 1 has been revised.  
The Transport information in Section 14 has been revised.

**MSDS Number**

1009

**Version number**

10

**Issue date**

04-02-2010

**Revision date**

04-02-2010

**Disclaimer**

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