



MATERIAL SAFETY DATA SHEET

OSOM® Ultra Strep A Extraction Reagent Bottle

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: OSOM® Ultra Strep A Extraction Reagent Bottle

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

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

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

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

Emergency Telephone Numbers

Genzyme (U.S.): 617-562-4555

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

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

2. HAZARDS IDENTIFICATION

Precautionary Statements:

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

Routes of Exposure:

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

Potential Health Effects:

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

Regulatory Status:

This preparation is classified as hazardous under U.S. OSHA 29 CFR 1910.1200; E.C. Directive 1999/45/EC; Canadian R.S. 1985, c. H-3; U.K. CHIP 2002 No. 1689; and/or U.N. GHS ST/SG/AC 10/30. Refer to Sec. 15, Regulatory Information, for details regarding hazard classification.

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

Potential Environmental Effects:

May be harmful for the aquatic environment.



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3. COMPOSITION / INFORMATION ON INGREDIENTS

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

4. FIRST AID MEASURES

Inhalation:

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

Eye Contact:

Immediately flush eyes with plenty of tepid water for 15 minutes while separating eyelids with fingers. Remove contact lenses if worn. Obtain immediate medical attention.

Skin Contact:

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

Ingestion:

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

5. FIRE FIGHTING MEASURES

Flammable Properties:

Not considered to be a fire hazard.

Suitable Extinguishing Media:

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

Unsuitable Extinguishing Media:

Unknown.

Specific Hazards Arising from the Chemical:

When heated to decomposition, may produce carbon monoxide (CO), carbon dioxide (CO₂), nitrogen oxides (NO_x) and sulphur oxides (SO_x).

Standard Protective Equipment and Precautions for Firefighters:

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:

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

Environmental Precautions:

Do not let product enter drains.

Methods and Materials for Containment and Clean-Up:

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

7. HANDLING AND STORAGE

Handling:

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

Storage:

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

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Guidelines:

There are no ACGIH, NIOSH, OSHA or country-specific occupational exposure limits currently established for components present in this preparation at concentrations equal to or greater than 1% (0.1% if carcinogen).

Engineering Controls:

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

Personal Protective Equipment (PPE):

Respiratory	A respiratory protection program that meets U.S. Federal OSHA 29 CFR 1910.134 and ANSI Z99.2, Canadian CSA Standard Z94.4-93, European Standard CR 529, or other applicable regulatory standards must be followed whenever exposure limits may be exceeded (if applicable), engineering controls are not feasible, or if insufficient ventilation or workplace conditions warrant respirator use.
Eye/Face	Wear appropriate protective chemical safety goggles.
Skin	Wear lab coat or other protective garments. Wear impervious shoe covers for spill clean-up. Remove contaminated clothing promptly.
Gloves	Wear chemical resistant protective gloves.
General	Follow company-specific safety procedures.

9. PHYSICAL AND CHEMICAL PROPERTIES

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



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

10. STABILITY AND REACTIVITY

Chemical Stability:

Stable under ordinary conditions of use and storage. See Section 7.

Conditions to Avoid:

Solution is oxidized by air. Avoid high temperatures.

Incompatible Materials:

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

Hazardous Decomposition Products:

Thermal decomposition may lead to release of irritating gases and vapors.

Possibility of Hazardous Reactions:

Hazardous polymerization will not occur.

11. TOXICOLOGICAL INFORMATION

Acute Effects:

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

Toxicology Data - Selected LD50s and LC50s

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

No data available.

Carcinogenicity:

No data available.

Mutagenicity:

No data available.

Teratogenicity:

No data available.

Reproductive Effects:

No data available.



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Sensitization:

No data available.

12. ECOLOGICAL INFORMATION

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

Sodium nitrite

7632-00-0

96 Hr LC50 *Oncorhynchus mykiss*: 0.19 mg/L [flow-through]
(juvenile)

Persistence and Degradability:

No data available.

Bioaccumulative Potential:

No data available.

Mobility in Environmental Media:

No data available.

13. DISPOSAL CONSIDERATIONS

Methods of Disposal:

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

Waste Classification:**U.S. - California - 22 CCR - Presumed Hazardous Wastes**

Sodium nitrite

7632-00-0

Toxic; Ignitable; Reactive

14. TRANSPORT INFORMATION

Basic Shipping Description:

International Air Transport Association (IATA) Dangerous Goods Classification

UN Number: UN 3316

Proper Shipping Name: Chemical Kit

Hazard Class: 9

Hazard Label: Miscellaneous

Packing Group: PG III

Packaging Instruction: Y915

Special Provisions: A44 (excepted quantities)

U.S. Department of Transportation (DOT)

Consumer Commodity, ORM-D

15. REGULATORY INFORMATION

US Federal Regulations:

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

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

Sodium nitrite

7632-00-0

Present

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

Sodium nitrite

7632-00-0

100 lb final RQ; 45.4 kg final RQ

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

Sodium nitrite

7632-00-0

1.0 % de minimis concentration

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US State Regulations:

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

Sodium nitrite 7632-00-0 Present

International Regulations:

If approved for European Communities use, this product is regulated under the In Vitro Diagnostic Medical Devices Directive (98/79/EC).

Canada - WHMIS - Ingredient Disclosure List

Sodium nitrite 7632-00-0 1 %

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

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

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

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

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

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

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

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

Inventory - Australia - Inventory of Chemical Substances (AICS)

Sodium nitrite 7632-00-0 Present

Inventory - Canada - Domestic Substances List (DSL)

Sodium nitrite 7632-00-0 Present

Inventory - China

Sodium nitrite 7632-00-0 Present

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

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

Inventory - Japan Existing and New Chemical Substances (ENCS)

Sodium nitrite 7632-00-0 1-483

Inventory - Korea - Existing and Evaluated Chemical Substances

Sodium nitrite 7632-00-0 KE-31546

Canadian Hazardous Products:

WHMIS Status Exempt

European Communities Dangerous Substances/Preparations:

EC Hazard Class T - Toxic

Symbols



Risk Phrases

R25 Toxic if swallowed.

Safety Phrases

S24/25 Avoid contact with skin and eyes.

S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S36/39 Wear suitable protective clothing and eye/face protection.

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

16. OTHER INFORMATION

Further Information:

This MSDS has been prepared in accordance with the ANSI Z400.1 format. Every effort has been made to adhere to the hazard criteria and content requirements of the U.S. OSHA Hazard Communication Standard, Canadian Controlled Products Regulation (CPR), UK Chemical Hazard Information and Packaging Regulations, European Communities REACH Regulation, and UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS).



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Disclaimer:

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