SEKISUI

7/19/2011

IMPORTANT NOTICE CONCERNING MATERIAL SAFETY DATA SHEET/SAFETY DATA SHEET INFORMATION

Dear Valued Customer,

Sekisui Diagnostics (formerly Genzyme Diagnostics) is working to update all existing documentation in light of the change to our company name and corporate ownership. This includes the (Material) Safety Data Sheets ((M)SDSs) provided with our products.

The following contact information relative to (M)SDSs has changed effective immediately:

Corporate Headquarters:
Sekisui Diagnostics, LLC
31 New York Avenue
Framingham, MA 01701 USA
www.sekisuidiagnostics.com
Phone: 800-332-1042

Manufacturer:
Sekisui Diagnostics, LLC
6659 Top Gun Street
San Diego, CA 92121 USA
www.sekisuidiagnostics.com
Phone: 800-332-1042

Emergency Telephone Numbers:
Americas: 1-760-476-3962
Europe, Middle East & Africa: +1-760-476-3961
Asia Pacific: +1-760-476-3960
Access Code: 333512

Please feel free to use the information provided above to contact us with any questions pertaining to (M)SDSs.

MATERIAL SAFETY DATA SHEET

1. Product and Company Identification

Product name Strep A REAG 1

Synonym(s) OSOM® Strep A Extraction Reagent 1

CAS # Mixture

Kit Number: 141; 141E; 141E-20

Product description Aqueous, alkaline solution containing trace color indicator.

Product use Component of OSOM® Strep A Test kit. For the qualitative detection of Group A Streptococcal antigen from throat swabs or confirmation of presumptive Group A Streptococcal colonies recovered from culture. 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.genzymediagnostics.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.genzymediagnostics.com
Phone: 44 (0) 1732 220022

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 (CO2), nitrogen oxides (NOx) and sulphur oxides (SOx).

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 Strep A Reagents 1 and 2 yields nitrous acid, which may immediately decompose into toxic nitrous gas, a short-term reaction by-product. Minimize contact and contamination of personal clothing and skin. Avoid vapor or aerosol inhalation. Wash hands thoroughly after handling.
Storage	Store at 15 to 30°C (59 to 86°F). Keep container tightly closed in a dry and well-ventilated place. Do not store with incompatible substances; see Section 10.

8. Exposure Controls / Personal Protection

Exposure guidelines	There are no ACGIH, NIOSH 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
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	1.08
Relative density	1.08 g/cm3
Solubility (water)	Water-soluble
Partition coefficient (n-octanol/water)	Not available
Auto-ignition temperature	Not applicable
Decomposition temperature	Not available
Viscosity	Not available

10. Chemical Stability & Reactivity Information

Reactivity	Mixing Strep A Reagents 1 and 2 yields nitrous acid, which may immediately decompose into toxic nitrous gas, a short-term reaction by-product.
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	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.

11. Toxicological Information

Routes of exposure	Occupational exposure routes may include inhalation, skin absorption, and eye and skin contact.
Acute effects	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

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

12. Ecological Information

Ecotoxicological data

Components	Test Results
Sodium nitrite (7632-00-0)	EC50 Greasyback shrimp (Metapenaeus ensis): 16.14 - 26.61 mg/l 48 hours 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 998

Version number 10

Issue date 04-02-2010

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