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 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.genzymediagnostics.com
Phone: 858-452-3198

Distributor

Genzyme Diagnostics
50 Gibson Drive
Kings Hill, West Malling
Kent ME19 4AF UK
www.genzymediagnostics.com
Phone: 44 (0) 1732 220022

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 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	Type	Value
Sodium azide (26628-22-8)	Ceiling TWA	0.11 ppm 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	
Incompatiblities (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.

Reproductive effects	No data available.
Teratogenicity	No data available.
Sensitization	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

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

13. Disposal Considerations

Disposal instructions 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.

14. Transport Information

DOT

Not regulated as hazardous goods.

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 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)

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 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
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