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 Ultra Strep A REAG B

Synonym(s) OSOM® Ultra Strep A Extraction Reagent B

CAS # Mixture

Kit Number: 149

Product description Aqueous, acidic solution.

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.

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

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

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 carbon dioxide (CO2) and carbon monoxide (CO).

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	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 Strep A Reagents A and B 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/m3
		10 ppm
	TWA	25 mg/m3
		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

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 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	Sour, pungent odor like vinegar
Chemical family	Acidic solution
pH	2.6 (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 applicable
Decomposition temperature	Not available
Viscosity	Not available

10. Chemical Stability & Reactivity Information

Reactivity	Mixing Strep A Reagents A and B 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	None known.
Incompatible materials	Avoid strong oxidizing agents, most common metals (except aluminum), strong bases and amines.
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, eye and skin contact.

Toxicological data

Components	Test Results
Acetic acid (64-19-7)	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)	Eye irritation has been noted at a concentration below 10 ppm. Irritating
Acetic acid (64-19-7)	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.
Reproductive effects	No data available.

Teratogenicity	No data available.
Sensitization	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

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

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 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)

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

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	1007
Version number	06
Issue date	04-22-2010
Revision date	04-22-2010
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.