

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 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.

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

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 (NO_x) and sulphur oxides (SO_x).

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

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 Extraction Reagent bottle and ampule 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 (<i>Metapenaeus ensis</i>): 16.14 - 26.61 mg/l 48 hours

Components**Test Results**

Sodium nitrite (7632-00-0)

LC50 Channel catfish (*Ictalurus punctatus*): 0.048 mg/l 96 hoursLC50 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.

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

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.

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.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	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.

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 (<i>Daphnia pulex</i>): 2.8 - 6.2 mg/l 48 hours LC50 Bluegill (<i>Lepomis macrochirus</i>): 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

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.

1. Product and Company Identification

Material name	Strep A CONTROL +
Version #	01
Issue date	09-05-2012
Revision date	-
Supersedes date	-
CAS #	Mixture
Kit number	141; 141E; 141E-20; 147; 149
Product use	For external quality control testing.
Manufacturer information	
Corporate Headquarters	Sekisui Diagnostics, LLC 31 New York Avenue, Framingham, MA 01701 USA www.sekisuidiagnostics.com Phone: 800-332-1042 Americas 1-760-476-3962
Emergency Telephone Numbers	Europe, Middle East & Africa +1-760-476-3961 Asia Pacific +1-760-476-3960 Access code 333512

2. Hazards Identification

Physical state	Liquid.
Appearance	Colorless liquid.
Emergency overview	Physical and health hazard information on reagent mixtures have not been determined.
OSHA regulatory status	This product is not hazardous according to OSHA 29CFR 1910.1200.
Potential health effects	
Routes of exposure	Skin contact. Eye contact.
Eyes	May cause eye irritation.
Skin	May cause skin irritation.
Inhalation	In high concentrations, vapors may be irritating to the respiratory system.
Ingestion	May cause discomfort if swallowed.
Target organs	Eyes.
Chronic effects	No data available.
Signs and symptoms	Ingestion may cause irritation and malaise.
Potential environmental effects	The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

3. Composition / Information on Ingredients

Components	CAS #	Percent
Non-viable Group A Streptococci	N/A	1 - 5
Sodium azide	26628-22-8	< 0.2

Composition comments	All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.
-----------------------------	--

4. First Aid Measures

First aid procedures	
Eye contact	In case of contact, immediately flush eyes with fresh water for at least 15 minutes while holding the eyelids open. Remove contact lenses if worn. Get medical attention if irritation persists.

Skin contact	Wash skin thoroughly with soap and water. Get medical attention if irritation develops and persists.
Inhalation	Move to fresh air. Call a physician if symptoms develop or persist.
Ingestion	Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person. Get medical attention if irritation develops and persists.
Notes to physician	Provide general supportive measures and treat symptomatically.
General advice	Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire Fighting Measures

Flammable properties	This product is not flammable.
Extinguishing media	
Suitable extinguishing media	Extinguish with water spray, carbon dioxide, dry chemical or material appropriate for the surrounding fire.
Unsuitable extinguishing media	None known.
Protection of firefighters	
Specific hazards arising from the chemical	When heated to decomposition, may produce hydrazoic acid fumes.
Protective equipment and precautions for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire fighting equipment/instructions	Use standard firefighting procedures and consider the hazards of other involved materials.
Hazardous combustion products	Carbon oxides.

6. Accidental Release Measures

Personal precautions	Keep unnecessary personnel away. Wear appropriate protective equipment and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.
Environmental precautions	Do not allow to enter drains, sewers or watercourses. This mixture 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 containment	Absorb spillage with non-combustible, absorbent material.
Methods for cleaning up	Absorb spill with vermiculite or other inert material. Dispose of waste in accordance with all applicable federal, state, local and provincial environmental regulations, per Section 13.
Other information	Absorb small leaks or spills with sponge, mop up large spills with plenty of soap and water. Clean up in accordance with all applicable regulations.

7. Handling and Storage

Handling	Avoid contact with skin and eyes. Wash thoroughly after handling. In case of insufficient ventilation, wear suitable respiratory equipment. Handle and open container with care. Observe good industrial hygiene practices.
Storage	Store between 15°C - 30°C (60°F - 86°F). Store in a closed container away from incompatible materials.

8. Exposure Controls / Personal Protection

Occupational exposure limits	No exposure limits noted for ingredient(s).
Exposure guidelines	Follow standard monitoring procedures.
Engineering controls	Provide adequate ventilation. Observe Occupational Exposure Limits and minimize the risk of inhalation of vapors.
Personal protective equipment	
Eye / face protection	Wear approved safety glasses or goggles.
Skin protection	Remove contaminated clothing promptly.
Respiratory protection	In case of inadequate ventilation or risk of inhalation of vapors, use suitable respiratory equipment.
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice.

9. Physical & Chemical Properties

Appearance	Colorless liquid.
Physical state	Liquid.
Form	Liquid.
Color	Clear, colorless.
Odor	Not available.
Odor threshold	Not available.
pH	7.2 Approximate
Vapor pressure	Not available.
Vapor density	Not available.
Boiling point	Not available.
Melting point/Freezing point	Not available.
Solubility (water)	Not available.
Specific gravity	Not available.
Flash point	Not available.
Flammability limits in air, upper, % by volume	Not available.
Flammability limits in air, lower, % by volume	Not available.
Auto-ignition temperature	Not available.
Partition coefficient (n-octanol/water)	Not applicable.

10. Chemical Stability & Reactivity Information

Chemical stability	Material is stable under normal conditions.
Conditions to avoid	Heat, sparks, flames, elevated temperatures.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	No data available.
Possibility of hazardous reactions	Contact with acids liberates toxic gas.

11. Toxicological Information

Sensitization	Not classified.
Acute effects	May cause discomfort if swallowed.
Local effects	May cause skin and eye irritation.
Chronic effects	No data available.
Carcinogenicity	Not classifiable as to carcinogenicity to humans.
Epidemiology	No epidemiological data is available for this product.
Mutagenicity	Not classified.
Reproductive effects	Not classified.
Symptoms and target organs	Ingestion may cause irritation and malaise.
Further information	No other specific acute or chronic health impact noted.

12. Ecological Information

Ecotoxicity	The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.
Environmental effects	An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.
Persistence and degradability	No data is available on the degradability of this product.
Bioaccumulation / Accumulation	Not available.
Partition coefficient	Not applicable.

Mobility in environmental media The product is soluble in water.

13. Disposal Considerations

Waste codes The Waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Disposal instructions Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Contaminated instruments and surfaces should be disinfected in accordance with your employer's chemical-specific and universal/standard 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. If preparation enters drain, flush with a large volume of water to prevent azide build-up.

Waste from residues / unused products Dispose in accordance with all applicable regulations. Contract with a licensed chemical disposal agency.

Contaminated packaging Empty containers should be taken to an approved waste handling site for recycling or disposal.

14. Transport Information

DOT

Not regulated as a hazardous material by DOT.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

TDG

Not regulated as dangerous goods.

15. Regulatory Information

US federal regulations This product is not hazardous according to OSHA 29CFR 1910.1200. This mixture is a component of an in vitro diagnostic device regulated by the U.S. Food and Drug Administration.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

CERCLA (Superfund) reportable quantity (lbs) (40 CFR 302.4)

None

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 (40 CFR 355, Appendix A) No

Section 311/312 (40 CFR 370) No

Drug Enforcement Administration (DEA) (21 CFR 1308.11-15) Not controlled

Canadian regulations This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all the information required by the CPR.

WHMIS status Non-controlled

Inventory status

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No

Country(s) or region	Inventory name	On inventory (yes/no)*
China	Inventory of Existing Chemical Substances in China (IECSC)	Yes
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	Yes
Korea	Existing Chemicals List (ECL)	Yes
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	Yes
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	Yes

*A "Yes" indicates this product complies with the inventory requirements administered by the governing country(s)

State regulations This product does not contain a chemical known to the State of California to cause cancer, birth defects or other reproductive harm.

US - California Proposition 65 - Carcinogens & Reproductive Toxicity (CRT): Listed substance

Not listed.

US. Massachusetts RTK - Substance List

Not regulated.

US. New Jersey Worker and Community Right-to-Know Act

Not regulated.

US. Pennsylvania RTK - Hazardous Substances

Not regulated.

Mexico regulations This safety data sheet was prepared in accordance with the Official Mexican Standard (NOM-018-STPS-2000).

16. Other Information

Recommended restrictions Use in accordance with supplier's recommendations.

Further information HMIS® is a registered trade and service mark of the NPCA.

HMIS® ratings
Health: 0
Flammability: 0
Physical hazard: 0

NFPA ratings
Health: 0
Flammability: 0
Instability: 0

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 Sekisui Diagnostics 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 Sekisui Diagnostics has been advised of the possibility of such damages.

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 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.

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

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 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/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 Extraction Reagent bottle and ampule 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)
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.

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 (<i>Daphnia magna</i>): 65 mg/l 48 hours LC50 Bluegill (<i>Lepomis macrochirus</i>): 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

1005

Version number

06

Issue date

04-21-2010

Revision date

04-21-2010

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.