

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.



Corporate Headquarters
Genzyme Corporation
500 Kendall Street
Cambridge, MA 02142
USA

Phone: 617-252-7500

Manufacturer
Genzyme Diagnostics
6659 Top Gun Street
San Diego, CA 92121
USA

Phone: 858-452-3198

MATERIAL SAFETY DATA SHEETS

Catalog Number:	Kit Name:
755725	ImmunoCard STAT!® Mono Test

Item Number:	Component Name:
2098	ImmunoCard STAT!® Mono Test Diluent
2099	ImmunoCard STAT!® Mono Test Positive Control
2101	ImmunoCard STAT!® Mono Test Negative Control

Note: The page numbers on the 3 individual MSDSs for this kit are specific to each document. There are a total of 22 pages including this cover sheet.

ImmunoCard STAT!® Mono Test Card is an “article” and does not require an MSDS.

1. Product and Company Identification

Material name	ImmunoCard STAT!® Mono Diluent
Version #	01
Issue date	05-24-2013
Revision date	-
Supersedes date	-
CAS #	Mixture
Kit number	755725
Product use	Component of ImmunoCard STAT!® Mono Test kit (Catalog # 755725). For use in the qualitative detection of heterophile antibodies specific to infectious mononucleosis. For In Vitro Diagnostic use only.
Synonym(s)	Mono DILUENT
Manufacturer information	
Corporate Headquarters	Sekisui Diagnostics, LLC 4 Hartwell Place, Lexington, MA 02421, 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	CAUTION
	May be harmful if swallowed. The chemical, physical and toxicological properties of this preparation have not been thoroughly characterized.
OSHA regulatory status	This product is hazardous according to OSHA 29 CFR 1910.1200.
Potential health effects	
Routes of exposure	Inhalation. Ingestion. Skin contact. Eye contact.
Eyes	Splashes may irritate and cause redness.
Skin	Prolonged skin contact may cause redness, irritation and dry skin. Sodium azide may be absorbed through the skin and result in systemic effects.
Inhalation	Vapors and mist may irritate throat and respiratory system and cause coughing.
Ingestion	May be harmful if swallowed. Do not ingest.
Signs and symptoms	Ingestion may cause irritation and malaise.
Potential environmental effects	Not expected to be harmful to aquatic organisms.

3. Composition / Information on Ingredients

Components	CAS #	Percent
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

For skin contact flush with large amounts of water while removing contaminated clothing. Get medical attention if irritation develops and persists.

Inhalation

Move to fresh air. Call a physician if symptoms develop or persist.

Ingestion

If material is ingested, immediately contact a poison control center.

Notes to physician

Provide general supportive measures and treat symptomatically.

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

Fire will generate toxic and irritating gases. Carbon monoxide and carbon dioxide. Nitrogen 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

Clean up in accordance with all applicable regulations. Absorb small leaks or spills with sponge, mop up large spills with plenty of soap and water.

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.

Storage

Store at controlled room temperature at 15–30 °C (59–86°F). Store in a closed container away from incompatible materials.

8. Exposure Controls / Personal Protection

Occupational exposure limits

US. ACGIH Threshold Limit Values

Components	Type	Value
Sodium azide (CAS 26628-22-8)	Ceiling	0.29 mg/m ³
		0.11 ppm

Canada. Alberta OELs (Occupational Health & Safety Code, Schedule 1, Table 2)

Components	Type	Value	Form
Sodium azide (CAS 26628-22-8)	Ceiling	0.3 mg/m3	Vapor.
		0.29 mg/m3	
		0.11 ppm	Vapor.

Canada. British Columbia OELs. (Occupational Exposure Limits for Chemical Substances, Occupational Health and Safety Regulation 296/97, as amended)

Components	Type	Value	Form
Sodium azide (CAS 26628-22-8)	Ceiling	0.29 mg/m3	
		0.11 ppm	Vapor.

Canada. Ontario OELs. (Control of Exposure to Biological or Chemical Agents)

Components	Type	Value
Sodium azide (CAS 26628-22-8)	Ceiling	0.29 mg/m3

Canada. Quebec OELs. (Ministry of Labor - Regulation Respecting the Quality of the Work Environment)

Components	Type	Value
Sodium azide (CAS 26628-22-8)	Ceiling	0.3 mg/m3
		0.11 ppm

Exposure guidelines Follow standard monitoring procedures.

US - California OELs: Skin designation

Sodium azide (CAS 26628-22-8) Can be absorbed through the skin.

US - Tennessee OELs: Skin designation

Sodium azide (CAS 26628-22-8) Can be absorbed through the skin.

US. NIOSH: Pocket Guide to Chemical Hazards

Sodium azide (CAS 26628-22-8) Can be absorbed through the skin.

US. OSHA Table Z-1-A (29 CFR 1910.1000)

Sodium azide (CAS 26628-22-8) Can be absorbed through the skin.

Engineering controls Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.

Personal protective equipment

Eye / face protection Wear approved safety glasses or goggles.

Skin protection Wear lab coat or other protective garments. Remove contaminated clothing promptly.

Respiratory protection Under normal conditions, respirator is not normally required.

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 Colorless, clear.

Odor Not available.

Odor threshold Not available.

pH 7 Approximately

Vapor pressure Not available.

Vapor density Not available.

Boiling point Not available.

Melting point/Freezing point Not available.

Solubility (water) Soluble

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.

10. Chemical Stability & Reactivity Information

Chemical stability	Material is stable under normal conditions.
Conditions to avoid	Protect against direct sunlight.
Incompatible materials	Strong oxidizing agents. Acids. Heavy metals.
Hazardous decomposition products	None.
Possibility of hazardous reactions	Contact with acids liberates toxic gas.

11. Toxicological Information

Toxicological data

Components	Species	Test Results
Sodium azide (CAS 26628-22-8)		
Acute		
Dermal		
LD50	Rabbit	20 mg/kg
Oral		
LD50	Rat	27 mg/kg
Sensitization	Not classified.	
Acute effects	May be harmful if swallowed.	
Local effects	May cause eye irritation on direct contact.	
Chronic effects	No data available.	
Carcinogenicity	Not classified.	
ACGIH Carcinogens		
Sodium azide (CAS 26628-22-8)	A4 Not classifiable as a human carcinogen.	
Epidemiology	No epidemiological data is available for this product.	
Mutagenicity	Not classified.	
Reproductive effects	Not classified.	
Symptoms and target organs	May cause eye irritation on direct contact.	

12. Ecological Information

Ecotoxicological data

Components	Species		Test Results
Sodium azide (CAS 26628-22-8)			
Aquatic			
Crustacea	EC50	Water flea (Daphnia pulex)	2.8 - 6.2 mg/l, 48 hours
Fish	LC50	Bluegill (Lepomis macrochirus)	0.68 mg/l, 96 hours
Ecotoxicity	Not expected to be harmful to aquatic organisms.		
Environmental effects	An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.		
Aquatic toxicity	Not classified.		
Persistence and degradability	No data is available on the degradability of this product.		
Bioaccumulation / Accumulation	Not available.		

Mobility in environmental media The product is soluble in water.

13. Disposal Considerations

Waste codes

US RCRA Hazardous Waste P List: Reference

Sodium azide (CAS 26628-22-8) P105

Disposal instructions Dispose in accordance with all applicable regulations. 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. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

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 hazardous according to OSHA 29 CFR 1910.1200.
All components are on the U.S. EPA TSCA Inventory List.
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.

US EPCRA (SARA Title III) Section 302 - Extremely Hazardous Spill: Reportable quantity

Sodium azide (CAS 26628-22-8) 1000 lbs

US EPCRA (SARA Title III) Section 302 - Extremely Hazardous Substance: Threshold Planning Quantity

Sodium azide (CAS 26628-22-8) 500 lbs

US EPCRA (SARA Title III) Section 313 - Toxic Chemical: De minimis concentration

Sodium azide (CAS 26628-22-8) 1.0 %

US EPCRA (SARA Title III) Section 313 - Toxic Chemical: Listed substance

Sodium azide (CAS 26628-22-8) Listed.

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

Sodium azide: 1000

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - Yes
Delayed Hazard - No
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

Section 302 extremely hazardous substance (40 CFR 355, Appendix A) No

SARA 311/312 Hazardous chemical 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)*
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).

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory 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 Hazardous Substances (Director's): Listed substance

Sodium azide (CAS 26628-22-8) Listed.

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

Not listed.

US - New Jersey RTK - Substances: Listed substance

Sodium azide (CAS 26628-22-8) Listed.

US. Massachusetts RTK - Substance List

Sodium azide (CAS 26628-22-8) Listed.

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

Sodium azide (CAS 26628-22-8) 500 lbs

US. Pennsylvania RTK - Hazardous Substances

Sodium azide (CAS 26628-22-8) Listed.

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: 1 Flammability: 0 Physical hazard: 1
----------------------	--

NFPA ratings	Health: 1 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

ImmunoCard STAT!® Mono Positive Control

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: ImmunoCard STAT!® Mono Positive Control

Synonym(s): Mono CONTROL +

Product Use: Component of ImmunoCard STAT!® Mono Test kit (Catalog # 755725). For external quality control testing. For In Vitro Diagnostic Use Only.

Description: Aqueous solution containing salt, antibodies (protein) and preservatives.

Corporate Headquarters

Genzyme Corporation

500 Kendall Street
Cambridge, MA 02142
USA

Phone: 617-252-7500

Manufacturer

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:

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. Harmful by ingestion. Allergic skin reaction may result in certain sensitive individuals upon exposure to the aminoglycoside antibiotic in this preparation. Preparation appearance: clear, colorless liquid.

Routes of Exposure:

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

Potential Health Effects:

Inhalation	Aerosol inhalation may cause coughing and sore throat.
Eye	Eye exposure may cause irritation, redness and watering.
Skin	Skin contact may cause irritation and possible allergic reaction with itching and rash. 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.

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.

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:

Unknown.

3. COMPOSITION / INFORMATION ON INGREDIENTS



MATERIAL SAFETY DATA SHEET
ImmunoCard STAT!® Mono Positive Control

Ingredient Name	CAS #	EC #	% (wt/wt)
Water	7732-18-5	231-791-2	97 - 99
EC R-Phrases: None	EC Hazard Class: None		
Rabbit anti-beef stroma antiserum	Not Assigned	Not Assigned	0.1 - 2
EC R-Phrases: None	EC Hazard Class: None		
Sodium azide	26628-22-8	247-852-1	0.2
EC R-Phrases: R28, R32, R50, R53	EC Hazard Class: T+, N		
Tris(hydroxymethyl)methylamine	77-86-1	201-064-4	0.2
EC R-Phrases: None	EC Hazard Class: None		
Gentamicin sulfate	1405-41-0	215-778-9	0.05
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 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

Flammable Properties:

Dilute aqueous solution not considered 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 hydrazoic acid fumes.

Standard Protective Equipment and Precautions for Firefighters:

Firefighters should wear NIOSH-approved or equivalent Self-Contained Breathing Apparatus and full protective gear.



MATERIAL SAFETY DATA SHEET

ImmunoCard STAT!® Mono Positive Control

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions:

Wear Personal Protective Equipment (PPE) as indicated in Section 8. Avoid physical contact with material. 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 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. 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

Exposure Guidelines:

ACGIH - Threshold Limits Values - Ceilings (TLV-C)

Sodium azide 26628-22-8 0.29 mg/m³ Ceiling (as NaN₃); 0.11 ppm Ceiling (vapor, as hydrazoic acid)

Canada - Quebec - Occupational Exposure Limits - Ceilings

Sodium azide 26628-22-8 0.11 ppm Ceiling; 0.3 mg/m³ Ceiling

EU - Occupational Exposure Directive (2006/15/EC) Indicative Occupational Exposure Limit Values (IOELV) - Skin Notations

Sodium azide 26628-22-8 possibility of significant uptake through the skin

EU - Occupational Exposure Directive (2006/15/EC) Indicative Occupational Exposure Limit Values (IOELV) - STELs

Sodium azide 26628-22-8 0.3 mg/m³ STEL

EU - Occupational Exposure Directive (2006/15/EC) Indicative Occupational Exposure Limit Values (IOELV) - TWAs

Sodium azide 26628-22-8 0.1 mg/m³ TWA

Germany - DFG - Recommended Exposure Limits - Ceilings (Peak Limitations)

Sodium azide 26628-22-8 0.4 mg/m³ Peak (inhalable fraction)

Germany - DFG - Recommended Exposure Limits - MAK Values

Sodium azide 26628-22-8 0.2 mg/m³ MAK (inhalable fraction)

Germany - TRGS 900 - Occupational Exposure Limits - TWAs

Sodium azide 26628-22-8 0.2 mg/m³ TWA (exposure factor 2)

Israel - Occupational Exposure Limits - Ceilings

Sodium azide 26628-22-8 0.29 mg/m³ Ceiling (as NaN₃); 0.11 ppm Ceiling (vapor, as Hydrazoic acid)

Korea - Occupational Exposure Limits - Ceilings

Sodium azide 26628-22-8 0.1 ppm Ceiling; 0.3 mg/m³ Ceiling

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.

Personal Protective Equipment (PPE):

Respiratory A respirator is not required under normal conditions of use.

Eye/Face Wear appropriate protective chemical safety glasses.



MATERIAL SAFETY DATA SHEET

ImmunoCard STAT!® Mono Positive Control

Personal Protective Equipment (PPE):

Skin	Wear lab coat or other protective garments. Remove contaminated clothing promptly.
Gloves	Wear chemical resistant protective gloves.
General	Follow company-specific safety procedures.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Clear, colorless liquid	pH:	7.0 (approximate)
Odor:	Not available	Solubility:	Water-soluble
Boiling Point:	Not available	Vapor Pressure:	Not available
Melting Point:	Not applicable	Partition Coefficient (n-octanol/water):	Not available
Freezing Point:	Not available	Vapor Density:	Not available
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:

Avoid prolonged exposure to direct sunlight.

Incompatible Materials:

Avoid strong oxidizing agents, acids, heavy metals and their salts.

Hazardous Decomposition Products:

None expected under normal conditions of use.

Possibility of Hazardous Reactions:

Hazardous polymerization will not occur.

11. TOXICOLOGICAL INFORMATION

Acute Effects:

Toxicology Data - Selected LD50s and LC50s

Sodium azide 26628-22-8 Oral LD50 Rat: 27 mg/kg; Dermal LD50 Rabbit: 20 mg/kg

Local Effects:

No data available.

Chronic Effects:

No data available.



MATERIAL SAFETY DATA SHEET

ImmunoCard STAT!® Mono Positive Control

Carcinogenicity:

ACGIH - Threshold Limits Values - Carcinogens

Sodium azide 26628-22-8 A4 - Not Classifiable as a Human Carcinogen

Canada - Manitoba - Occupational Exposure Limits - Carcinogens

Sodium azide 26628-22-8 A4 - Not Classifiable as a Human Carcinogen

Mutagenicity:

No data available.

Teratogenicity:

No data available.

Reproductive Effects:

No data available.

Sensitization:

Sensitization to aminoglycoside antibiotics may occur with dermal exposure.

12. ECOLOGICAL INFORMATION

Ecotoxicity:

Ecotoxicity - Freshwater Fish Species Data

Sodium azide 26628-22-8 96 Hr LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 Hr LC50 Lepomis macrochirus: 0.7 mg/L; 96 Hr LC50 Pimephales promelas: 5.46 mg/L [flow-through]

Persistence and Degradability:

No data available.

Bioaccumulative Potential:

No data available.

Mobility in Environmental Media:

No data available.

13. DISPOSAL CONSIDERATIONS

Methods of Disposal:

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.

Waste Classification:

U.S. - California - 22 CCR - Presumed Hazardous Wastes

Sodium azide 26628-22-8 Ignitable; Reactive

U.S. - RCRA (Resource Conservation & Recovery Act) - P Series Wastes - Acutely Toxic Wastes

Sodium azide 26628-22-8 waste number P105

14. TRANSPORT INFORMATION

Basic Shipping Description:

Not classified as dangerous goods. Not regulated per IATA and DOT regulations.



MATERIAL SAFETY DATA SHEET

ImmunoCard STAT!® Mono Positive Control

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 azide	26628-22-8	Present
--------------	------------	---------

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

Sodium azide	26628-22-8	1000 lb final RQ; 454 kg final RQ
--------------	------------	-----------------------------------

U.S. - CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs

Sodium azide	26628-22-8	1000 lb EPCRA RQ
--------------	------------	------------------

U.S. - CERCLA/SARA - Section 302 Extremely Hazardous Substances TPQs

Sodium azide	26628-22-8	500 lb TPQ (This material is a reactive solid. The TPQ does not default to 10000 pounds for non-powder, non-molten, non-solvent form)
--------------	------------	---

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

Sodium azide	26628-22-8	1.0 % de minimis concentration
--------------	------------	--------------------------------

US State Regulations:

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

Sodium azide	26628-22-8	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 - Classifications of Substances

Sodium azide	26628-22-8	D1A
--------------	------------	-----

Canada - WHMIS - Ingredient Disclosure List

Sodium azide	26628-22-8	1 %
--------------	------------	-----

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

Sodium azide	26628-22-8	T+;R28 R32 N;R50-53
--------------	------------	---------------------

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

Sodium azide	26628-22-8	S:1/2-28-45-60-61
--------------	------------	-------------------

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

Sodium azide	26628-22-8	ID Number 636, hazard class 2 - hazard to waters
--------------	------------	--

Inventory - Australia - Inventory of Chemical Substances (AICS)

Sodium azide	26628-22-8	Present
--------------	------------	---------

Inventory - Canada - Domestic Substances List (DSL)

Sodium azide	26628-22-8	Present
--------------	------------	---------

Inventory - China

Sodium azide	26628-22-8	Present
--------------	------------	---------

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

Sodium azide	26628-22-8	247-852-1
--------------	------------	-----------

Inventory - Japan Existing and New Chemical Substances (ENCS)

Sodium azide	26628-22-8	1-482
--------------	------------	-------

Inventory - Korea - Existing and Evaluated Chemical Substances

Sodium azide	26628-22-8	KE-31357
--------------	------------	----------

Canadian Hazardous Products:

WHMIS Status	Exempt
--------------	--------



MATERIAL SAFETY DATA SHEET

ImmunoCard STAT!® Mono Positive Control

European Communities Dangerous Substances/Preparations:

EC Hazard Class Xn - Harmful

Symbols



Risk Phrases

R22 Harmful if swallowed.
R32 Contact with acids liberates very toxic gas.

Safety Phrases

S35 This material and its container must be disposed of in a safe way.
S45 In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

16. OTHER INFORMATION

Further Information:

ImmunoCard STAT!® is a registered trademark of Meridian Bioscience, Inc.

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).

MSDS Origination Date: March 27, 2007

Version #: 3

Revision Date: November 12, 2008

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	ImmunoCard STAT!® Mono Negative Control
Version #	01
Issue date	05-24-2013
Revision date	-
Supersedes date	-
CAS #	Mixture
Product code	755725
Product use	Component of ImmunoCard STAT!® Mono Test kit (Catalog # 755725). For external quality control testing. For In Vitro Diagnostic use only.
Synonym(s)	Mono CONTROL -
Manufacturer information	
Corporate Headquarters	Sekisui Diagnostics, LLC 4 Hartwell Place, Lexington, MA 02421, 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

2. Hazards Identification

Physical state	Liquid.
Appearance	Clear. Colorless liquid.
Emergency overview	CAUTION May be harmful if swallowed. The chemical, physical and toxicological properties of this preparation have not been thoroughly characterized.
OSHA regulatory status	This product is hazardous according to OSHA 29 CFR 1910.1200.
Potential health effects	
Routes of exposure	Inhalation. Ingestion. Skin contact. Eye contact.
Eyes	Splashes may irritate and cause redness.
Skin	Prolonged skin contact may cause redness, irritation and dry skin. Sodium azide may be absorbed through the skin and result in systemic effects.
Inhalation	Vapors and mist may irritate throat and respiratory system and cause coughing.
Ingestion	May be harmful if swallowed. Do not ingest.
Signs and symptoms	Ingestion may cause irritation and malaise.
Potential environmental effects	Not expected to be harmful to aquatic organisms.

3. Composition / Information on Ingredients

Components	CAS #	Percent
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	For skin contact flush with large amounts of water while removing contaminated clothing. Get medical attention if irritation develops and persists.
Inhalation	Move to fresh air. Call a physician if symptoms develop or persist.
Ingestion	If material is ingested, immediately contact a poison control center.
Notes to physician	Provide general supportive measures and treat symptomatically.

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	Fire will generate toxic and irritating gases. Carbon monoxide and carbon dioxide. Nitrogen 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.
Storage	Store at controlled room temperature at 15–30 °C (59-86°F). Store in a closed container away from incompatible materials.

8. Exposure Controls / Personal Protection

Occupational exposure limits

US. ACGIH Threshold Limit Values

Components	Type	Value
Sodium azide (CAS 26628-22-8)	Ceiling	0.29 mg/m3
		0.11 ppm

Canada. Alberta OELs (Occupational Health & Safety Code, Schedule 1, Table 2)

Components	Type	Value	Form
Sodium azide (CAS 26628-22-8)	Ceiling	0.3 mg/m3	Vapor.
		0.29 mg/m3	
		0.11 ppm	Vapor.

Canada. British Columbia OELs. (Occupational Exposure Limits for Chemical Substances, Occupational Health and Safety Regulation 296/97, as amended)

Components	Type	Value	Form
Sodium azide (CAS 26628-22-8)	Ceiling	0.29 mg/m3	
		0.11 ppm	Vapor.

Canada. Ontario OELs. (Control of Exposure to Biological or Chemical Agents)

Components	Type	Value
Sodium azide (CAS 26628-22-8)	Ceiling	0.29 mg/m3

Canada. Quebec OELs. (Ministry of Labor - Regulation Respecting the Quality of the Work Environment)

Components	Type	Value
Sodium azide (CAS 26628-22-8)	Ceiling	0.3 mg/m3
		0.11 ppm

Exposure guidelines Follow standard monitoring procedures.

US - California OELs: Skin designation

Sodium azide (CAS 26628-22-8) Can be absorbed through the skin.

US - Tennessee OELs: Skin designation

Sodium azide (CAS 26628-22-8) Can be absorbed through the skin.

US. NIOSH: Pocket Guide to Chemical Hazards

Sodium azide (CAS 26628-22-8) Can be absorbed through the skin.

US. OSHA Table Z-1-A (29 CFR 1910.1000)

Sodium azide (CAS 26628-22-8) Can be absorbed through the skin.

Engineering controls Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.

Personal protective equipment

Eye / face protection Wear approved safety glasses or goggles.

Skin protection Wear lab coat or other protective garments. Remove contaminated clothing promptly.

Respiratory protection Under normal conditions, respirator is not normally required.

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

9. Physical & Chemical Properties

Appearance Clear. Colorless liquid.

Physical state Liquid.

Form Liquid.

Color Colorless, clear.

Odor Not available.

Odor threshold Not available.

pH 7 Approximately

Vapor pressure Not available.

Vapor density Not available.

Boiling point Not available.

Melting point/Freezing point Not available.

Solubility (water) Soluble

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.

10. Chemical Stability & Reactivity Information

Chemical stability Material is stable under normal conditions.
Conditions to avoid Protect against direct sunlight.
Incompatible materials Strong oxidizing agents. Acids. Heavy metals.
Hazardous decomposition products None.

11. Toxicological Information

Toxicological data

Components	Species	Test Results
Sodium azide (CAS 26628-22-8)		
Acute		
Dermal		
LD50	Rabbit	20 mg/kg
Oral		
LD50	Rat	27 mg/kg
Sensitization	Not classified.	
Acute effects	May be harmful if swallowed.	
Local effects	May cause eye irritation on direct contact.	
Chronic effects	No data available.	
Carcinogenicity	Not classified.	
ACGIH Carcinogens		
Sodium azide (CAS 26628-22-8)	A4 Not classifiable as a human carcinogen.	
Epidemiology	No epidemiological data is available for this product.	
Mutagenicity	Not classified.	
Reproductive effects	Not classified.	
Symptoms and target organs	May cause eye irritation on direct contact.	

12. Ecological Information

Ecotoxicological data

Components		Species	Test Results
Sodium azide (CAS 26628-22-8)			
Aquatic			
Crustacea	EC50	Water flea (Daphnia pulex)	2.8 - 6.2 mg/l, 48 hours
Fish	LC50	Bluegill (Lepomis macrochirus)	0.68 mg/l, 96 hours
Ecotoxicity	No data available.		
Environmental effects	An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.		
Aquatic toxicity	Not classified.		
Persistence and degradability	No data is available on the degradability of this product.		
Bioaccumulation / Accumulation	Not available.		
Mobility in environmental media	The product is soluble in water.		

13. Disposal Considerations

Waste codes

US RCRA Hazardous Waste P List: Reference

Sodium azide (CAS 26628-22-8) P105

Disposal instructions	Dispose in accordance with all applicable regulations. 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. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
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 hazardous according to OSHA 29 CFR 1910.1200.
All components are on the U.S. EPA TSCA Inventory List.
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.

US EPCRA (SARA Title III) Section 302 - Extremely Hazardous Spill: Reportable quantity

Sodium azide (CAS 26628-22-8) 1000 lbs

US EPCRA (SARA Title III) Section 302 - Extremely Hazardous Substance: Threshold Planning Quantity

Sodium azide (CAS 26628-22-8) 500 lbs

US EPCRA (SARA Title III) Section 313 - Toxic Chemical: De minimis concentration

Sodium azide (CAS 26628-22-8) 1.0 %

US EPCRA (SARA Title III) Section 313 - Toxic Chemical: Listed substance

Sodium azide (CAS 26628-22-8) Listed.

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

Sodium azide: 1000

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories

Immediate Hazard - Yes
Delayed Hazard - No
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

Section 302 extremely hazardous substance (40 CFR 355, Appendix A)

No

SARA 311/312 Hazardous chemical

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)*
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).

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory 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 Hazardous Substances (Director's): Listed substance

Sodium azide (CAS 26628-22-8) Listed.

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

Not listed.

US - New Jersey RTK - Substances: Listed substance

Sodium azide (CAS 26628-22-8) Listed.

US. Massachusetts RTK - Substance List

Sodium azide (CAS 26628-22-8) Listed.

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

Sodium azide (CAS 26628-22-8) 500 lbs

US. Pennsylvania RTK - Hazardous Substances

Sodium azide (CAS 26628-22-8) Listed.

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: 1
Flammability: 0
Physical hazard: 0

NFPA ratings Health: 1
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.