

## **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](http://www.sekisuidiagnostics.com)  
Phone: 800-332-1042

**Manufacturer:**

Sekisui Diagnostics, LLC  
6659 Top Gun Street  
San Diego, CA 92121 USA  
[www.sekisuidiagnostics.com](http://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:
<b>755525</b>	<b>ImmunoCard STAT!<sup>®</sup> hCG Serum Control Set</b>

Item Number:	Component Name:
<b>2239</b>	<b>ImmunoCard STAT!<sup>®</sup> hCG Serum Control – Positive</b>
<b>2240</b>	<b>ImmunoCard STAT!<sup>®</sup> hCG Serum Control – Negative</b>

Note: The page numbers on the 2 individual MSDSs for this kit are specific to each document. There are a total of 15 pages including this cover sheet.



## MATERIAL SAFETY DATA SHEET

### ImmunoCard STAT!<sup>®</sup> hCG Serum Control - Positive

#### 1. PRODUCT AND COMPANY IDENTIFICATION

**Product Name:** ImmunoCard STAT!<sup>®</sup> hCG Serum Control - Positive

**Synonym(s):** hCG Serum Positive Control

**Product Use:** Component of ImmunoCard STAT!<sup>®</sup> hCG Serum Control Set (Catalog # 755525). For use in quality control testing with the ImmunoCard STAT!<sup>®</sup> hCG Combo Test. For In Vitro Diagnostic Use Only.

**Description:** Aqueous solution containing purified hCG (glycoprotein hormone), horse serum, and preservative.

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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. Contains animal source material of U.S. origin. Harmful by ingestion. The human hCG in this preparation was tested by FDA-approved methods and found to be negative for the presence of hepatitis B virus surface antigen (HBsAg), human immunodeficiency virus (HIV) 1 & 2 and hepatitis C virus (HCV). However, because no test method can provide complete assurance that infectious agents are absent, this product should be handled as a potentially biohazardous material in accordance with universal/standard precautions. Preparation appearance: clear, yellowish liquid.

**Routes of Exposure:**

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

**Potential Health Effects:**

<b>Inhalation</b>	Aerosol inhalation may cause coughing and sore throat.
<b>Eye</b>	Eye exposure may cause irritation, redness and watering.
<b>Skin</b>	Skin contact may cause irritation, dryness and redness. Sodium azide may be absorbed through the skin and result in systemic effects.
<b>Ingestion</b>	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.
<b>Chronic Effects</b>	No data available.
<b>Target Organs</b>	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.



## MATERIAL SAFETY DATA SHEET

### ImmunoCard STAT!<sup>®</sup> hCG Serum Control - Positive

#### 3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient Name	CAS #	EC #	% (wt/wt)
Horse Serum EC R-Phrases: None	Not Assigned EC Hazard Class: None	Not Assigned	> 98.8
Human Chorionic Gonadotropin (hCG) EC R-Phrases: None	Not Assigned EC Hazard Class: None	Not Assigned	< 1
Sodium azide EC R-Phrases: R28, R32, R50, R53	26628-22-8 EC Hazard Class: T+, N	247-852-1	0.2

#### 4. FIRST AID MEASURES

**General Advice:**

In the event of occupational exposure, follow company-specific bloodborne pathogen post-exposure requirements.

**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:**

Carbon dioxide, chemical foam, dry chemical or water spray.

**Unsuitable Extinguishing Media:**

Unknown.

**Specific Hazards Arising from the Chemical:**

None expected.

**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!<sup>®</sup> hCG Serum Control - Positive

#### 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 for biohazardous spills. 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. Follow universal/standard precautions when preparing or handling this material. See Section 8, Engineering Controls. Minimize contact and contamination of personal clothing and skin. Wash hands thoroughly after handling. Avoid physical contact.

##### Storage:

Store at 2 to 8°C (36 to 46°F). 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/m<sup>3</sup> Ceiling (as NaN<sub>3</sub>); 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/m<sup>3</sup> 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/m<sup>3</sup> STEL

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

Sodium azide 26628-22-8 0.1 mg/m<sup>3</sup> TWA

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

Sodium azide 26628-22-8 0.4 mg/m<sup>3</sup> Peak (inhalable fraction)

###### Germany - DFG - Recommended Exposure Limits - MAK Values

Sodium azide 26628-22-8 0.2 mg/m<sup>3</sup> MAK (inhalable fraction)

###### Germany - TRGS 900 - Occupational Exposure Limits - TWAs

Sodium azide 26628-22-8 0.2 mg/m<sup>3</sup> TWA (exposure factor 2)

###### Israel - Occupational Exposure Limits - Ceilings

Sodium azide 26628-22-8 0.29 mg/m<sup>3</sup> Ceiling (as NaN<sub>3</sub>); 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/m<sup>3</sup> 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!<sup>®</sup> hCG Serum Control - Positive

#### Personal Protective Equipment (PPE):

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

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Appearance:</b>	Clear, yellowish liquid	<b>pH:</b>	8.1 (approx.)
<b>Odor:</b>	Not available	<b>Solubility:</b>	Water-soluble
<b>Boiling Point:</b>	Not available	<b>Vapor Pressure:</b>	Not available
<b>Melting Point:</b>	Not applicable	<b>Partition Coefficient (n-octanol/water):</b>	Not available
<b>Freezing Point:</b>	Not available	<b>Vapor Density:</b>	Not available
<b>Flammability/Explosivity Limits in Air, Lower:</b>	Not available		
<b>Flammability/Explosivity Limits in Air, Upper:</b>	Not available		
<b>Auto-Ignition Temperature:</b>	Not available		
<b>Flash Point:</b>	Not available		

### 10. STABILITY AND REACTIVITY

#### Chemical Stability:

Stable under ordinary conditions of use and storage. See Section 7.

#### Conditions to Avoid:

There are no physical conditions known to result in a hazardous situation.

#### Incompatible Materials:

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

#### Hazardous Decomposition Products:

Thermal decomposition may lead to release of irritating gases and vapors.

#### Possibility of Hazardous Reactions:

Hazardous polymerization will not occur.

### 11. TOXICOLOGICAL INFORMATION

#### Acute Effects:

The human source material in this preparation presents a risk for exposure to infectious agents.

#### 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!<sup>®</sup> hCG Serum Control - Positive

**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:**

No data available.

## 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. Remaining unused material and product waste should be treated as biohazardous/infectious waste and contaminated instruments and surfaces should be disinfected in accordance with your employer's universal/standard precautions.

**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!<sup>®</sup> hCG Serum Control - Positive

#### 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!<sup>®</sup> hCG Serum Control - Positive

#### 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!<sup>®</sup> 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:** August 21, 2007

**Version #:** 2

**Revision Date:** November 07, 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.



## MATERIAL SAFETY DATA SHEET

### ImmunoCard STAT!® hCG Serum Control - Negative

#### 1. PRODUCT AND COMPANY IDENTIFICATION

**Product Name:** ImmunoCard STAT!® hCG Serum Control - Negative

**Synonym(s):** hCG Serum Negative Control

**Product Use:** Component of ImmunoCard STAT!® hCG Serum Control Set (Catalog # 755525). For use in quality control testing with the ImmunoCard STAT!® hCG Combo Test. For In Vitro Diagnostic Use Only.

**Description:** Aqueous solution containing horse serum and preservative.

**Corporate Headquarters**

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**Phone:** 617-252-7500

**Manufacturer**

**Genzyme Diagnostics**

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San Diego, CA 92121  
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**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. Contains animal source material of U.S. origin. Harmful by ingestion. Preparation appearance: clear, yellowish liquid.

**Routes of Exposure:**

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

**Potential Health Effects:**

<b>Inhalation</b>	Aerosol inhalation may cause coughing and sore throat.
<b>Eye</b>	Eye exposure may cause irritation, redness and watering.
<b>Skin</b>	Skin contact may cause irritation, dryness and redness. Sodium azide may be absorbed through the skin and result in systemic effects.
<b>Ingestion</b>	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.
<b>Chronic Effects</b>	No data available.
<b>Target Organs</b>	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!<sup>®</sup> hCG Serum Control - Negative

Ingredient Name	CAS #	EC #	% (wt/wt)
Horse Serum EC R-Phrases: None	Not Assigned EC Hazard Class: None	Not Assigned	99.8
Sodium azide EC R-Phrases: R28, R32, R50, R53	26628-22-8 EC Hazard Class: T+, N	247-852-1	0.2

#### 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:**

Carbon dioxide, chemical foam, dry chemical or water spray.

**Unsuitable Extinguishing Media:**

Unknown.

**Specific Hazards Arising from the Chemical:**

None expected.

**Standard 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. 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.



## MATERIAL SAFETY DATA SHEET

### ImmunoCard STAT!® hCG Serum Control - Negative

#### 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 2 to 8°C (36 to 46°F). 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/m<sup>3</sup> Ceiling (as NaN<sub>3</sub>); 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/m<sup>3</sup> 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/m<sup>3</sup> STEL

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

Sodium azide 26628-22-8 0.1 mg/m<sup>3</sup> TWA

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

Sodium azide 26628-22-8 0.4 mg/m<sup>3</sup> Peak (inhalable fraction)

**Germany - DFG - Recommended Exposure Limits - MAK Values**

Sodium azide 26628-22-8 0.2 mg/m<sup>3</sup> MAK (inhalable fraction)

**Germany - TRGS 900 - Occupational Exposure Limits - TWAs**

Sodium azide 26628-22-8 0.2 mg/m<sup>3</sup> TWA (exposure factor 2)

**Israel - Occupational Exposure Limits - Ceilings**

Sodium azide 26628-22-8 0.29 mg/m<sup>3</sup> Ceiling (as NaN<sub>3</sub>); 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/m<sup>3</sup> 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):**

<b>Respiratory</b>	A respirator is not required under normal conditions of use.
<b>Eye/Face</b>	Wear appropriate protective chemical safety glasses.
<b>Skin</b>	Wear lab coat or other protective garments. Remove contaminated clothing promptly.
<b>Gloves</b>	Wear chemical resistant protective gloves.
<b>General</b>	Follow company-specific safety procedures.

#### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Appearance:</b>	Clear, yellowish liquid	<b>pH:</b>	8.1 (approx.)
<b>Odor:</b>	Not available	<b>Solubility:</b>	Water-soluble
<b>Boiling Point:</b>	Not available	<b>Vapor Pressure:</b>	Not available
<b>Melting Point:</b>	Not applicable	<b>Partition Coefficient (n-octanol/water):</b>	Not available
<b>Freezing Point:</b>	Not available	<b>Vapor Density:</b>	Not available



## MATERIAL SAFETY DATA SHEET

### ImmunoCard STAT!® hCG Serum Control - Negative

**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:

There are no physical conditions known to result in a hazardous situation.

### Incompatible Materials:

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

### Hazardous Decomposition Products:

Thermal decomposition may lead to release of irritating gases and vapors.

### 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.

### 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:

No data available.

## 12. ECOLOGICAL INFORMATION



## MATERIAL SAFETY DATA SHEET

### ImmunoCard STAT!® hCG Serum Control - Negative

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

Sodium azide	26628-22-8	waste number P105
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### 14. TRANSPORT INFORMATION

**Basic Shipping Description:**

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

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

Sodium azide	26628-22-8	1000 lb final RQ; 454 kg final RQ
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**U.S. - CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs**

Sodium azide	26628-22-8	1000 lb EPCRA RQ
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**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)
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**U.S. - CERCLA/SARA - Section 313 - Emission Reporting**

Sodium azide	26628-22-8	1.0 % de minimis concentration
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**US State Regulations:****U.S. - California - 8 CCR Section 339 - Director's List of Hazardous Substances**

Sodium azide	26628-22-8	Present
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## MATERIAL SAFETY DATA SHEET

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#### 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

#### **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).



## MATERIAL SAFETY DATA SHEET

### ImmunoCard STAT!<sup>®</sup> hCG Serum Control - Negative

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