

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

www.genzyme.com Phone: 617-252-7500 Manufacturer
Genzyme Diagnostics
6659 Top Gun Street
San Diego, CA 92121
USA

www.genzymediagnostics.com Phone: 858-452-3198

MATERIAL SAFETY DATA SHEETS

Catalog Number:	Kit Name:
755250	Immuno Card STAT!® Strep A Test

MSDS Number:	Component Name:
2102	Immuno Card STAT!® Strep A REAG 1
2103	Immuno Card STAT!® Strep A REAG 2
2105	Immuno Card STAT!® Strep A CONTROL +
2104	Immuno Card STAT!® Strep A CONTROL -

Note: The page numbers on the 4 individual MSDSs for this kit are specific to each document. There are a total of 21 pages including this cover sheet.

Immuno Card STAT!® Strep A Test Stick is an "article" and does not require a MSDS.

Effective Date: April 21, 2010

MATERIAL SAFETY DATA SHEET



1. Product and Company Identification

Material name ImmunoCard STAT!® Strep A REAG 2

Version # 01

Issue date 05-24-2013

Revision date Supersedes date

CAS# Mixture 755250 Kit number

Product use For the qualitative detection of Group A Streptococcal antigen from throat swabs or confirmation of

presumptive Group A Streptococcal colonies recovered from culture.

Manufacturer information

Sekisui Diagnostics, LLC **Corporate Headquarters**

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

Liquid. Physical state

Appearance Colorless liquid. WARNING **Emergency overview**

Causes skin and eye irritation. Physical and health hazard information on reagent mixtures have

not been determined.

OSHA regulatory status This product is hazardous according to OSHA 29 CFR 1910.1200.

Potential health effects

Routes of exposure Skin contact. Eve contact.

Eyes Causes eye irritation. Exposed individuals may experience eye tearing, redness, and discomfort.

Skin Causes skin irritation.

Inhalation In high concentrations, vapors may irritate throat and respiratory system and cause coughing.

Ingestion May cause discomfort if swallowed.

Target organs Skin. 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
Acetic acid	64-19-7	1 - < 3

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

CPH MSDS NA ImmunoCard STAT!® Strep A REAG 2

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.

None known.

Protection of firefighters

Specific hazards arising

from the chemical

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

Hazardous combustion

products

Use standard firefighting procedures and consider the hazards of other involved materials.

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

Methods for containment

Methods for cleaning up

Do not allow to enter drains, sewers or watercourses.

Absorb spillage with non-combustible, absorbent material.

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.

Store between 15°C - 30°C (60°F - 86°F). Store in a closed container away from incompatible Storage

materials.

8. Exposure Controls / Personal Protection

Occupational exposure limits

US. ACGIH Threshold Limit Values

Components	Туре	Value	
Acetic acid (CAS 64-19-7)	STEL	15 ppm	_
	TWA	10 ppm	

ImmunoCard STAT!® Strep A REAG 2 CPH MSDS NA

Components	Туре	Value	
Acetic acid (CAS 64-19-7)	PEL	25 mg/m3	
		10 ppm	

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

Components	Туре	Value	
Acetic acid (CAS 64-19-7)	STEL	37 mg/m3	
		15 ppm	
	TWA	25 mg/m3	
		10 ppm	

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

Components	Туре	Value	
Acetic acid (CAS 64-19-7)	STEL	15 ppm	
	TWA	10 ppm	

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

Components	Туре	Value	
Acetic acid (CAS 64-19-7)	STEL	15 ppm	
	TWA	10 ppm	

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

Components	Туре	Value	
Acetic acid (CAS 64-19-7)	STEL	37 mg/m3	
		15 ppm	
	TWA	25 mg/m3	
		10 ppm	

Mexico. Occupational Exposure Limit Values

Components	Туре	Value	
Acetic acid (CAS 64-19-7)	STEL	37 mg/m3	
		15 ppm	
	TWA	25 mg/m3	
		10 ppm	

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 stateLiquid.FormLiquid.

ColorColorless, clear.OdorNo data available.Odor thresholdNot available.

pH 2.6

Vapor pressure Not available.

905980 Version #: 01 Revision date: - Issue date: 05-24-2013

3/7

Not available. Vapor density Not available. **Boiling point** Melting point/Freezing point Not available. Soluble. Solubility (water) Not available. Specific gravity Not available. Flash point Flammability limits in air, Not available.

upper, % by volume

Flammability limits in air, lower, % by volume

Not available.

Not available. **Auto-ignition temperature**

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 No data available.

products

Possibility of hazardous

Polymerization will not occur.

reactions

11. Toxicological Information

Toxicological data

Components	Species	Test Results	
Acetic acid (CAS 64-19-7)			
Acute			
Dermal			
LD50	Rabbit	1060 mg/kg	
Inhalation			
LC50	Rat	11.4 mg/l, 4 Hours	
Oral			
LD50	Rat	3.31 g/kg	
Sensitization	ization Not classified.		
Acute effects	May cause discomfort if swallowed.		
Local effects	Causes skin and eye irritation.		
Chronic effects	No data available.		
Carcinogenicity	Not classified.		
Epidemiology	No epidemiological data is available for this product.		

Not classified. Mutagenicity

Reproductive effects Not classified.

Symptoms and target organs Ingestion may cause irritation and malaise.

No other specific acute or chronic health impact noted. **Further information**

12. Ecological Information

Ecotoxicological data

Components		Species	Test Results
Acetic acid (CAS 64-19-7)			
Aquatic			
Crustacea	EC50	Water flea (Daphnia magna)	65 mg/l, 48 hours
Fish	LC50	Bluegill (Lepomis macrochirus)	75 mg/l, 96 hours
		Fathead minnow (Pimephales promelas)	79 mg/l, 96 Hours

ImmunoCard STAT!® Strep A REAG 2 905980 Version #: 01 Revision date: -Issue date: 05-24-2013

The product is not classified as environmentally hazardous. However, this does not exclude the **Ecotoxicity**

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 /

Not available.

Accumulation

Not applicable. Partition coefficient

Acetic acid (CAS 64-19-7) -0.17

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.

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 a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 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)

Acetic acid: 5000

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

Yes

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 Controlled

WHMIS labeling



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
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

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

Toxic Substances Control Act (TSCA) Inventory

State regulations

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

Yes

6/7

US - California Hazardous Substances (Director's): Listed substance

Acetic acid (CAS 64-19-7)

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

United States & Puerto Rico

US - New Jersey RTK - Substances: Listed substance

Acetic acid (CAS 64-19-7) Listed.

US. Massachusetts RTK - Substance List

Acetic acid (CAS 64-19-7) Listed.

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

Not regulated.

US. Pennsylvania RTK - Hazardous Substances

Acetic acid (CAS 64-19-7) 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: 2

> Flammability: 0 Physical hazard: 0

NFPA ratings Health: 2

Flammability: 0 Instability: 0

CPH MSDS NA 905980 Version #: 01 Revision date: -Issue date: 05-24-2013

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).

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.

MATERIAL SAFETY DATA SHEET



1. Product and Company Identification

Material name ImmunoCard STAT!® Strep A CONTROL +

Version # 01

Issue date 09-04-2012

Revision date Supersedes date

CAS# Mixture Kit number 755250

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

Liquid. **Physical state**

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	< 1	

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

In case of contact, immediately flush eyes with fresh water for at least 15 minutes while holding Eye contact

the eyelids open. Remove contact lenses if worn. Get medical attention if irritation persists.

1/5

CPH MSDS NA ImmunoCard STAT!® Strep A CONTROL + 905860 Version #: 01 Revision date: -Issue date: 09-04-2012

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

Protective equipment and precautions for firefighters

When heated to decomposition, may produce hydrazoic acid fumes.

Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Fire fighting

equipment/instructions

Hazardous combustion

products

Use standard firefighting procedures and consider the hazards of other involved materials.

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

Methods for containment

Absorb spillage with non-combustible, absorbent material.

Do not allow to enter drains, sewers or watercourses.

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

Absorb sirial leaks of spills with sporige, mobile the large spills with pierty of soap and with the large spills and sold spills with spills and sold spills and spil

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. Remove contaminated clothing promptly.

Respiratory protection

In case of inadequate ventilation or risk of inhalation of vapors, use suitable respiratory

equipment.

General hygiene considerations

Skin protection

Handle in accordance with good industrial hygiene and safety practice.

ImmunoCard STAT!® Strep A CONTROL +

9. Physical & Chemical Properties

Appearance Colorless liquid.

Physical state Liquid. **Form** Liquid.

Color Clear, colorless. Odor Not available. **Odor threshold** Not available.

рΗ 7.2 Approximate Not available. Vapor pressure Vapor density Not available. Not available. **Boiling point** Melting point/Freezing point Not available. Not available. Solubility (water) Specific gravity Not available. Not available. Flash point

Flammability limits in air,

upper, % by volume

Flammability limits in air, lower, % by volume

Not available.

Not available.

Not available. **Auto-ignition temperature** Partition coefficient Not applicable.

(n-octanol/water)

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.

May cause discomfort if swallowed. **Acute effects** Local effects May cause skin and eye irritation.

Chronic effects No data available.

Carcinogenicity Not classifiable as to carcinogenicity to humans. No epidemiological data is available for this product. **Epidemiology**

Not classified. Mutagenicity Reproductive effects Not classified.

Ingestion may cause irritation and malaise. Symptoms and target organs

Further information No other specific acute or chronic health impact noted.

12. Ecological Information

The product is not classified as environmentally hazardous. However, this does not exclude the **Ecotoxicity**

possibility that large or frequent spills can have a harmful or damaging effect on the environment.

An environmental hazard cannot be excluded in the event of unprofessional handling or disposal. **Environmental effects**

Persistence and degradability No data is available on the degradability of this product.

Bioaccumulation / Not available.

Accumulation

Partition coefficient Not applicable.

ImmunoCard STAT!® Strep A CONTROL + 905860 Version #: 01 Revision date: -Issue date: 09-04-2012 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

No

Not controlled

370)

Drug Enforcement

Canadian regulations

CFR

Administration (DEA) (21 CFR

1308.11-15)

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 regionInventory nameOn inventory (yes/no)*AustraliaAustralian Inventory of Chemical Substances (AICS)YesCanadaDomestic Substances List (DSL)YesCanadaNon-Domestic Substances List (NDSL)No

ImmunoCard STAT!® Strep A CONTROL + CPH MSDS NA

Country(s) or region Inventory name On inventory (yes/no)* China Inventory of Existing Chemical Substances in China (IECSC) Europe European Inventory of Existing Commercial Chemical Yes

Substances (EINECS)

Europe European List of Notified Chemical Substances (ELINCS) No Inventory of Existing and New Chemical Substances (ENCS) Japan Yes Korea Existing Chemicals List (ECL) Yes

New Zealand New Zealand Inventory Yes Yes

Philippines Philippine Inventory of Chemicals and Chemical Substances

(PICCS)

United States & Puerto Rico Toxic Substances Control Act (TSCA) Inventory Yes

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

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.

ImmunoCard STAT!® Strep A CONTROL +

CPH MSDS NA

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

MATERIAL SAFETY DATA SHEET



1. Product and Company Identification

Material name ImmunoCard STAT!® Strep A REAG 1

Version # 01

Issue date 05-24-2013

Revision date Supersedes date

CAS# Mixture 755250 Kit number

Product use For the qualitative detection of Group A Streptococcal antigen from throat swabs or confirmation of

presumptive Group A Streptococcal colonies recovered from culture.

Manufacturer information

Sekisui Diagnostics, LLC **Corporate Headquarters**

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

Liquid. Physical state

Appearance Clear pink liquid. WARNING **Emergency overview**

Harmful if swallowed. May cause skin and eye irritation. 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. Eve contact.

Eyes May cause eye irritation. Exposed individuals may experience eye tearing, redness, and

discomfort.

Skin Contact may cause skin irritation.

Inhalation Vapors and mist may irritate throat and respiratory system and cause coughing. Ingestion Harmful if swallowed. Ingestion may cause dizziness, nausea and vomiting.

Target organs Eye Skin Cardiovascular system. Nervous system

Chronic effects Chronic exposure to nitrites may cause headaches, visual problems and decreased blood

pressure.

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	
Sodium nitrite	7632-00-0	10 - 15	

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

percent by volume.

ImmunoCard STAT!® Strep A REAG 1 CPH MSDS NA 1/6

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.

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

materials more flammable if it is absorbed and dries.

Protective equipment and precautions for firefighters

Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Sodium nitrite is an oxidizing agent. It is not flammable itself, but it can make combustible

Fire fighting equipment/instructions

Hazardous combustion

products

Use standard firefighting procedures and consider the hazards of other involved materials.

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

Methods for containment

Absorb spillage with non-combustible, absorbent material.

Do not allow to enter drains, sewers or watercourses.

Methods for cleaning up

Other information

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.

up in accordance with all applicable regulations.

Absorb small leaks or spills with sponge, mop up large spills with plenty of soap and water. Clean

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.

Store between 15°C - 30°C (60°F - 86°F). Store in a closed container away from incompatible Storage

materials.

8. Exposure Controls / Personal Protection

Occupational exposure limits No exposure limits noted for ingredient(s). **Exposure guidelines** Follow standard monitoring procedures.

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.

ImmunoCard STAT!® Strep A REAG 1 905861 Version #: 01 Revision date: -Issue date: 05-24-2013 General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice.

9. Physical & Chemical Properties

Appearance Clear pink liquid.

Physical state Liquid. **Form** Liquid. Color Clear pink. Odor Odorless. Not available. **Odor threshold** pН 9 Approx. Not available. Vapor pressure Not available. Vapor density **Boiling point** Not available. Melting point/Freezing point Not available. Solubility (water) Soluble. 1.08 Approx. Specific gravity

Flammability limits in air,

upper, % by volume

Flammability limits in air,

lower, % by volume

Flash point

Auto-ignition temperature

Not available.

Not available.

Not available.

Not available.

10. Chemical Stability & Reactivity Information

Chemical stability Material is stable under normal conditions.

Conditions to avoid Avoid high temperatures. Incompatible materials Amines. Reducing agents.

Hazardous decomposition

products

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

Possibility of hazardous

reactions

Hazardous polymerization does not occur.

11. Toxicological Information

Toxicological data

Components	Species	Test Results	
Sodium nitrite (CAS 7632-0	0-0)		
Acute			
Inhalation			
LC50	Rat	5.5 mg/l, 4 Hours	
Oral			
LD50	Rat	158 mg/kg	
Sensitization	Not classified.		
Acute effects		Harmful if swallowed. Sodium nitrite exposure may result in a drop in blood pressure, headache, vertigo, palpitations, visual disturbances, methemoglobinemia, dyspnea and respiratory depression.	
Local effects	May cause skin and eye irritati	May cause skin and eye irritation.	
Chronic effects	Chronic exposure to nitrites mapressure.	Chronic exposure to nitrites may cause headaches, visual problems and decreased blood pressure.	
Carcinogenicity	No data available.		
Epidemiology	No epidemiological data is available for this product.		

ImmunoCard STAT!® Strep A REAG 1

Mutagenicity

CPH MSDS NA

905861 Version #: 01 Revision date: - Issue date: 05-24-2013

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

Ecotoxicological data

 Components
 Species
 Test Results

 Sodium nitrite (CAS 7632-00-0)

 Aquatic
 Crustacea
 EC50
 Greasyback shrimp (Metapenaeus ensis)
 16.14 - 26.61 mg/l, 48 hours ensis)

 Fish
 LC50
 Rainbow trout,donaldson trout (Oncorhynchus mykiss)
 0.15 - 0.25 mg/l, 96 hours

EcotoxicityThe 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.

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

The Waste code should be assigned in discussion between the user, the producer and the waste

disposal company.

Disposal instructions Dispose in accordance with all applicable regulations.

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

Basic shipping requirements:

UN number UN1500
Proper shipping name Sodium nitrite

Hazard class 5.1
Subsidiary hazard class 6.1
Packing group III
Additional information:

Special provisions A1, A29, IB8, IP3, T1, TP33

Packaging exceptions152Packaging non bulk213Packaging bulk240

IATA

UN number UN1500 UN proper shipping name Sodium nitrite

Transport hazard class(es) 5.1
Subsidiary class(es) 6.1
Packing group III
ERG code 5P

IMDG

UN number UN1500

UN proper shipping name SODIUM NITRITE

Transport hazard class(es) 5.1 Subsidiary class(es) 6.1 Packing group III

ImmunoCard STAT!® Strep A REAG 1
905861 Version #: 01 Revision date: - Issue date: 05-24-2013

F-A, S-Q **EmS**

TDG

UN number UN1500

Proper shipping name SODIUM NITRITE

Hazard class 5.1 **Packing group** Ш

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)

Sodium nitrite (CAS 7632-00-0) 1.0 % One-Time Export Notification only.

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

Not regulated.

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

Sodium nitrite (CAS 7632-00-0)

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

Sodium nitrite (CAS 7632-00-0) Listed.

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

Sodium nitrite: 100

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

Not controlled

Section 302 extremely No

hazardous substance (40 CFR 355, Appendix A)

SARA 311/312 Hazardous Yes

chemical

Drug Enforcement

Administration (DEA) (21 CFR

1308.11-15)

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 Controlled WHMIS classification C - Oxidizing

D1B - Immediate/Serious-TOXIC

WHMIS labeling





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
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

ImmunoCard STAT!® Strep A REAG 1

Country(s) or region Inventory name On inventory (yes/no)*

Korea Existing Chemicals List (ECL) New Zealand New Zealand Inventory Yes

Philippine Inventory of Chemicals and Chemical Substances **Philippines** Yes

(PICCS)

United States & Puerto Rico Toxic Substances Control Act (TSCA) Inventory

*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 material is not known to contain any chemicals currently listed as carcinogens or reproductive

toxins

US - California Hazardous Substances (Director's): Listed substance

Sodium nitrite (CAS 7632-00-0)

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

Not listed

US - New Jersey RTK - Substances: Listed substance

Sodium nitrite (CAS 7632-00-0) Listed.

US. Massachusetts RTK - Substance List

Sodium nitrite (CAS 7632-00-0) Listed.

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

500 lbs Sodium nitrite (CAS 7632-00-0)

US. Pennsylvania RTK - Hazardous Substances

Sodium nitrite (CAS 7632-00-0) 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: 2

> Flammability: 0 Physical hazard: 1

NFPA ratings Health: 2

Flammability: 0 Instability: 0

Special hazards: OX

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

CPH MSDS NA

Issue date: 05-24-2013

905861 Version #: 01 Revision date: -

Yes

MATERIAL SAFETY DATA SHEET



1. Product and Company Identification

Material name ImmunoCard STAT!® Strep A CONTROL -

Version # 01

Issue date 09-04-2012

Revision date Supersedes date

CAS# Mixture Kit number 755250

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

Liquid. **Physical state**

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 May cause irritation to mucous membrane and respiratory system.

Ingestion May cause discomfort if swallowed. **Target organs** Eyes. Skin. Respiratory tract.

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 C Streptococci	N/A	1 - 5	
Sodium azide	26628-22-8	< 1	

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

In case of contact, immediately flush eyes with fresh water for at least 15 minutes while holding Eye contact

the eyelids open. Remove contact lenses if worn. Get medical attention if irritation persists.

CPH MSDS NA 905831 Version #: 01 Revision date: -Issue date: 09-04-2012 1/5 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

Protective equipment and precautions for firefighters When heated to decomposition, may produce hydrazoic acid fumes.

Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Use standard firefighting procedures and consider the hazards of other involved materials.

Fire fighting

equipment/instructions

Hazardous combustion

Carbon oxides.

products

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

Methods for containment

Absorb spillage with non-combustible, absorbent material.

Do not allow to enter drains, sewers or watercourses.

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

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.

905831 Version #: 01 Revision date: -Issue date: 09-04-2012

9. Physical & Chemical Properties

Appearance Colorless liquid.

Physical state Liquid. **Form** Liquid.

Color Colorless, clear. Odor No data available. **Odor threshold** Not available. рΗ 7.2 Approx. Not available. Vapor pressure Vapor density Not available. Not available. **Boiling point** Melting point/Freezing point Not available. Not available. Solubility (water) Specific gravity Not available.

Flash point Flammability limits in air,

upper, % by volume

Not available. Not available.

Flammability limits in air,

lower, % by volume

Not available.

Not available. **Auto-ignition temperature** Partition coefficient Not applicable.

(n-octanol/water)

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.

May cause discomfort if swallowed. **Acute effects** Local effects May cause skin and eye irritation.

Chronic effects No data available.

Carcinogenicity Not classifiable as to carcinogenicity to humans. No epidemiological data is available for this product. **Epidemiology**

Not classified. Mutagenicity Reproductive effects Not classified.

Ingestion may cause irritation and malaise. Symptoms and target organs

Further information No other specific acute or chronic health impact noted.

12. Ecological Information

The product is not classified as environmentally hazardous. However, this does not exclude the **Ecotoxicity**

possibility that large or frequent spills can have a harmful or damaging effect on the environment.

An environmental hazard cannot be excluded in the event of unprofessional handling or disposal. **Environmental effects**

Persistence and degradability No data is available on the degradability of this product.

Bioaccumulation / Not available.

Accumulation

Partition coefficient Not applicable.

CPH MSDS NA ImmunoCard STAT!® Strep A CONTROL -

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)

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 No

CFR 355, Appendix A)

No

Section 311/312 (40 CFR 370)

Drug Enforcement

Not controlled

Administration (DEA) (21 CFR

1308.11-15)

This product has been classified in accordance with the hazard criteria of the CPR and the MSDS Canadian regulations

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

ImmunoCard STAT!® Strep A CONTROL -

CPH MSDS NA

Country(s) or region Inventory name On inventory (yes/no)* China Inventory of Existing Chemical Substances in China (IECSC) Europe European Inventory of Existing Commercial Chemical Yes

Substances (EINECS)

Europe European List of Notified Chemical Substances (ELINCS) No Inventory of Existing and New Chemical Substances (ENCS) Japan Yes Korea Existing Chemicals List (ECL) Yes

New Zealand New Zealand Inventory Yes

Philippines Philippine Inventory of Chemicals and Chemical Substances

(PICCS)

United States & Puerto Rico Toxic Substances Control Act (TSCA) Inventory Yes

Yes

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

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

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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.

ImmunoCard STAT!® Strep A CONTROL -

CPH MSDS NA 905831 Version #: 01 Revision date: -Issue date: 09-04-2012 5/5

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