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Revision Number 1

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING**Product identifier****Product Name** ImmunoCard STAT!® Strep A Reagent 1**Other means of identification****Product Code(s)** 755250 R1**Recommended use of the chemical and restrictions on use****Recommended use** In vitro diagnostic**Uses advised against** No information available**Details of the supplier of the safety data sheet****Supplier Address**

Sekisui Diagnostics, LLC
6659 Top Gun Street, San Diego, CA
92121, USA
Tel. +1-858-777-2600
Sekisui Diagnostics P.E.I. Inc.
70 Watts Avenue, Charlottetown Prince
Edward Island, C1E 2B9 Canada
Tel. +1-800-565-0265
Sekisui Diagnostics (UK) Limited
Liphook Way, Allington, Maidstone, Kent
ME16 0LQ
Tel. +44 (0) 1622 607800
www.sekisuidiagnostics.com

Manufacturer Address

Meridian Bioscience, Inc.
3471 River Hills Drive
Cincinnati, Ohio 45244
(800) 343-3858

E-mail Address www.meridianbioscience.com**Emergency telephone number**

Emergency Telephone Emergency telephone CHEMTREC:
US: 1-800-424-9300
International: 1-703-527-3887
Philippines: 1800 1 322 0553
Taiwan: 00801-49-1821
Thailand: 1800014808
South Korea: 080-880-0454
Asia-Pacific: +65 3163 8374

2. HAZARDS IDENTIFICATION**Classification**

This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Acute toxicity - Oral

Category 4

Hazards not otherwise classified (HNOC)

Not applicable

Label elements**Signal word**

Warning

Hazard statements

Harmful if swallowed

**Appearance** aqueous solution**Physical state** Liquid**Odor** Odorless**Precautionary Statements - Prevention**

Wash face, hands and any exposed skin thoroughly after handling
Do not eat, drink or smoke when using this product

Precautionary Statements - Response

Specific treatment (see Section 4 on this label)

Precautionary Statements - Response Specific treatment (see supplemental instructions on the administration of antidotes on this label)

IF SWALLOWED: Immediately call a POISON CENTER or doctor

Rinse mouth

Precautionary Statements - Storage

Store locked up

Precautionary Statements - Disposal

Dispose of contents/container in accordance with local, regional, national, and international regulations as applicable

Other information

Not applicable

Unknown acute toxicity

90 % of the mixture consists of ingredient(s) of unknown toxicity

90 % of the mixture consists of ingredient(s) of unknown acute oral toxicity

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance

Not applicable.

Mixture

Chemical name	CAS No.	Weight-%	Trade secret
Sodium nitrite	7632-00-0	10-20	*
1,3-Propanediol, 2-amino-2-(hydroxymethyl)-, hydrochloride	1185-53-1	1-5	*

*The exact percentage (concentration) of composition has been withheld as a trade secret.

4. FIRST AID MEASURES

Description of first aid measures

General advice	Show this safety data sheet to the doctor in attendance.
Inhalation	Remove to fresh air.
Eye contact	Rinse thoroughly with plenty of water, also under the eyelids.
Skin contact	Wash skin with soap and water.
Ingestion	Do NOT induce vomiting. Rinse mouth. Never give anything by mouth to an unconscious person. Get medical attention.

Most important symptoms and effects, both acute and delayed

Symptoms	No information available.
Effects of Exposure	No information available.

Indication of any immediate medical attention and special treatment needed

Note to physicians	Treat symptomatically.
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5. FIRE-FIGHTING MEASURES

Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Large Fire	CAUTION: Use of water spray when fighting fire may be inefficient.
Unsuitable extinguishing media	Do not scatter spilled material with high pressure water streams.
Specific hazards arising from the chemical	No information available.
Explosion data	
Sensitivity to mechanical impact	None.
Sensitivity to static discharge	None.
Special protective equipment and precautions for fire-fighters	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal precautions	Ensure adequate ventilation.
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Environmental precautions

Environmental precautions See Section 12 for additional Ecological Information.

Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust).

Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

7. HANDLING AND STORAGE

Precautions for safe handling

Advice on safe handling Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities

Storage Conditions Keep containers tightly closed in a dry, cool and well-ventilated place. Keep out of the reach of children.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure Limits This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

Appropriate engineering controls

Engineering controls Showers
Eyewash stations
Ventilation systems.

Individual protection measures, such as personal protective equipment

Eye/face protection Wear safety glasses with side shields (or goggles).

Hand protection Wear suitable gloves.

Skin and body protection Wear suitable protective clothing.

Respiratory protection No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.

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

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical state	Liquid
Appearance	aqueous solution
Color	Clear pink
Odor	Odorless
Odor threshold	No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
pH	9	None known
Melting point / freezing point	No data available	None known
Initial boiling point and boiling range	No data available	None known
Flash point	No data available	Open cup
Evaporation rate	No data available	None known
Flammability	No data available	None known
Flammability Limit in Air		None known
Upper flammability or explosive limits	No data available	
Lower flammability or explosive limits	No data available	
Vapor pressure	No data available	None known
Relative vapor density	No data available	None known
Relative density	No data available	None known
Water solubility	No data available	Soluble in water
Solubility in other solvents	No data available	None known
Partition coefficient	No data available	None known
Autoignition temperature	No data available	None known
Hyphen	No data available	None known
Kinematic viscosity	No data available	None known
Dynamic viscosity	No data available	None known
Explosive properties	No information available	
Oxidizing properties	No information available	
<u>Other information</u>		
Softening point	No information available	
Molecular weight	No information available	
VOC content	No information available	
Liquid Density	No information available	
Bulk density	No information available	

10. STABILITY AND REACTIVITY

Reactivity	No information available.
Chemical stability	Stable under normal conditions.
Possibility of hazardous reactions	None under normal processing.
Conditions to avoid	None known based on information supplied.
Incompatible materials	None known based on information supplied.
Hazardous decomposition products	None known based on information supplied.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Product Information

Inhalation	Specific test data for the substance or mixture is not available.
Eye contact	Specific test data for the substance or mixture is not available.
Skin contact	Specific test data for the substance or mixture is not available.
Ingestion	Specific test data for the substance or mixture is not available. Toxic if swallowed. (based on components).

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms No information available.

Numerical measures of toxicity**Acute toxicity**

The following values are calculated based on chapter 3.1 of the GHS document

ATEmix (oral)	85.00 mg/kg
ATEmix (dermal)	99,999.00 mg/kg
ATEmix (inhalation-gas)	99,999.00 ppm
ATEmix (inhalation-dust/mist)	1,949.20 mg/l
ATEmix (inhalation-vapor)	99,999.00 mg/l

Unknown acute toxicity 90 % of the mixture consists of ingredient(s) of unknown toxicity
90 % of the mixture consists of ingredient(s) of unknown acute oral toxicity

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Sodium nitrite 7632-00-0	85 mg/kg (Rat)	-	5.5 mg/L (Rat) 4 h

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Skin corrosion/irritation	No information available.
Serious eye damage/eye irritation	No information available.
Respiratory or skin sensitization	No information available.
Germ cell mutagenicity	No information available.
Carcinogenicity	No information available.

The table below indicates whether each agency has listed any ingredient as a carcinogen.

Chemical name	ACGIH	IARC	NTP	OSHA
Sodium nitrite 7632-00-0	-	Group 2A	-	X

Legend

IARC (International Agency for Research on Cancer)

Group 2A - Probably Carcinogenic to Humans

OSHA (Occupational Safety and Health Administration of the US Department of Labor)

X - Present

Reproductive toxicity	No information available.
STOT - single exposure	No information available.
STOT - repeated exposure	No information available.

Aspiration hazard

No information available.

12. ECOLOGICAL INFORMATION**Ecotoxicity**

Not considered to be harmful to aquatic life.

Chemical name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Sodium nitrite 7632-00-0	-	0.65 - 1: 96 h Oncorhynchus mykiss mg/L LC50 static 0.19: 96 h Oncorhynchus mykiss mg/L LC50 flow-through 2.3: 96 h Pimephales promelas mg/L LC50 flow-through 20: 96 h Pimephales promelas mg/L LC50 static 0.4 - 0.6: 96 h Oncorhynchus mykiss mg/L LC50 semi-static 0.092 - 0.13: 96 h Oncorhynchus mykiss mg/L LC50 flow-through	-	-

Persistence and degradability

No information available.

Component Information

Chemical name	Partition coefficient
Sodium nitrite 7632-00-0	-3.7

Other adverse effects

No information available.

13. DISPOSAL CONSIDERATIONS**Disposal methods****Waste from residues/unused products**

Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

Contaminated packaging

Do not reuse empty containers.

California Hazardous Waste Status

This product contains one or more substances that are listed with the State of California as a hazardous waste.

Chemical name	California Hazardous Waste Status
Sodium nitrite 7632-00-0	Toxic Ignitable Reactive

14. TRANSPORT INFORMATION

DOT

Not regulated

15. REGULATORY INFORMATION**International Inventories**

TSCA	Complies
DSL/NDSL	Complies
EINECS/ELINCS	Complies
ENCS	Complies
IECSC	Complies
KECL	Complies
PICCS	Complies
AIIC	Complies

Legend:**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory**DSL/NDSL** - Canadian Domestic Substances List/Non-Domestic Substances List**EINECS/ELINCS** - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances**ENCS** - Japan Existing and New Chemical Substances**IECSC** - China Inventory of Existing Chemical Substances**KECL** - Korean Existing and Evaluated Chemical Substances**PICCS** - Philippines Inventory of Chemicals and Chemical Substances**AICS** - Australian Inventory of Chemical Substances**US Federal Regulations****SARA 313**

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product contains a chemical or chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

Chemical name	SARA 313 - Threshold Values %
Sodium nitrite - 7632-00-0	1.0

SARA 311/312 Hazard Categories

Acute health hazard	Yes
Chronic Health Hazard	No
Fire hazard	No
Sudden release of pressure hazard	No
Reactive Hazard	No

CWA (Clean Water Act)

This product contains the following substances which are regulated pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

Chemical name	CWA - Reportable Quantities	CWA - Toxic Pollutants	CWA - Priority Pollutants	CWA - Hazardous Substances
Sodium nitrite 7632-00-0	100 lb	-	-	X

CERCLA

This material, as supplied, contains one or more substances regulated as a hazardous substance under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302).

Chemical name	Hazardous Substances RQs	Extremely Hazardous Substances RQs
Sodium nitrite 7632-00-0	100 lb	-

US State Regulations**California Proposition 65**

This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

US State Regulations This product may contain substances regulated by state right-to-know regulations

Chemical name	New Jersey	Massachusetts	Pennsylvania
Sodium nitrite 7632-00-0	X	X	X

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

16. OTHER INFORMATION, INCLUDING DATE OF PREPARATION OF THE LAST REVISION

NFPA	Health hazards 2	Flammability 0	Instability 0	Special hazards -
HMIS	Health hazards 2	Flammability 0	Physical hazards 0	Personal protection X

Prepared By Meridian Bioscience, Inc.

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Revision Note No information available.

Disclaimer

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. Meridian Bioscience, Inc. shall not be held liable for any damages resulting from handling or from contact with the above product.

End of Safety Data Sheet