SAFETY DATA SHEET



1. Identification

Product identifier Strep A CONTROL +

Other means of identification

Kit number 141; 141E; 141E-20; 147; 149; 141-10; 148

Recommended use For external quality control testing.

Recommended restrictions Use in accordance with supplier's recommendations.

Manufacturer/Importer/Supplier/Distributor information **Corporate Headquarters**

Sekisui Diagnostics, LLC

4 Hartwell Place, Lexington, MA 02421, USA

www.sekisuidiagnostics.com Phone: 800-332-1042

Americas 1-760-476-3962

Emergency Telephone

Numbers

Europe, Middle East & Africa +1-760-476-3961

Asia Pacific +1-760-476-3960

Access code 333512

2. Hazard(s) identification

Physical hazards Not classified. Not classified. **Health Hazards OSHA** defined hazards Not classified.

Label elements

None. Hazard symbol Signal word None.

Hazard statement The mixture does not meet the criteria for classification.

Precautionary statement

Prevention None. Response None. Storage None. None. **Disposal**

Hazard(s) not otherwise

classified (HNOC)

None known.

3. Composition/information on ingredients

Mixtures

Chemical name	CAS number	%
Sodium azide	26628-22-8	< 0.2

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

percent by volume.

4. First-aid measures

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

Skin contact Wash skin thoroughly with soap and water. Get medical attention if irritation develops and persists. In case of contact, immediately flush eyes with fresh water for at least 15 minutes while holding the

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

Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person. Get Ingestion

medical attention if irritation develops and persists.

Strep A CONTROL + SDS US Most important symptoms/effects, acute and

delayed

Ingestion may cause irritation and malaise.

Indication of immediate medical attention and special treatment needed

Provide general supportive measures and treat symptomatically.

General information

Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire-fighting measures

Suitable extinguishing media

Extinguish with water spray, carbon dioxide, dry chemical or material appropriate for the

surrounding fire.

Unsuitable extinguishing

media

None known.

Specific hazards arising from

the chemical

When heated to decomposition, may produce hydrazoic acid fumes.

Special protective equipment and precautions for firefighters Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Fire fighting equipment/instructions Use standard firefighting procedures and consider the hazards of other involved materials.

General fire hazards The product is not flammable.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

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.

Methods and materials for containment and cleaning up **Environmental precautions**

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.

Do not allow to enter drains, sewers or watercourses. This mixture contains a small amount of sodium azide which can react with copper, lead, brass or solder in plumbing systems and form potentially explosive metal azides. Follow proper disposal procedures.

7. Handling and storage

Precautions for safe 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.

Conditions for safe storage, including any incompatibilities 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

US. ACGIH Threshold Limit Values

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

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Туре	Value
Sodium azide (CAS 26628-22-8)	Ceiling	0.3 mg/m3
,		0.1 ppm

Biological limit values No biological exposure limits noted for the ingredient(s).

Follow standard monitoring procedures. **Exposure guidelines**

US - California OELs: Skin designation

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

US - Tennessee OELs: Skin designation

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

Strep A CONTROL + SDS US 2/6 904918 Version #: 01

US. NIOSH: Pocket Guide to Chemical Hazards

Sodium azide (CAS 26628-22-8)

Can be absorbed through the skin.

Appropriate engineering Provide adequate ventilation. Observe Occupational Exposure Limits and minimize the risk of

controls inhalation of vapors.

Individual protection measures, such as personal protective equipment

Eye/face protection Wear approved safety glasses or goggles.

Skin protection

Hand protection Wear appropriate chemical resistant gloves.Other Remove contaminated clothing promptly.

Respiratory protection In case of inadequate ventilation or risk of inhalation of vapors, use suitable respiratory equipment.

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

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

considerations

9. Physical and chemical properties

Appearance Colorless liquid.

Physical state Liquid.
Form Liquid.

Color Clear, colorless.

Odor Not available.

Odor threshold Not available.

pH 7.2 Approximate

Melting point/freezing point Not available.

Initial boiling point and boiling Not available.

range

Flash point Not available.

Evaporation rate Not available.

Flammability (solid, gas) Not applicable.

Upper/lower flammability or explosive limits

Flammability limit - lower

(%)

Not available.

Flammability limit - upper

(%)

Not available.

Explosive limit - lower (%) Not available.

Explosive limit - upper (%) Not available.

Vapor pressure Not available.

Vapor density Not available.

Relative density Not available.

Solubility(ies)

Solubility (water) Not available.

Partition coefficient Not applicable.

(n-octanol/water)

Auto-ignition temperatureNot available.Decomposition temperatureNot available.ViscosityNot available.

10. Stability and reactivity

ReactivityThe product is stable and non-reactive under normal conditions of use, storage and transport.

Chemical stability Material is stable under normal conditions.

Possibility of hazardous Contact with acids liberates toxic gas.

reactions

Conditions to avoid Heat, sparks, flames, elevated temperatures.

Incompatible materials Strong oxidizing agents.

Strep A CONTROL + SDS US

Hazardous decomposition

products

No data available.

11. Toxicological information

Information on likely routes of exposure

Vapors may irritate throat and respiratory system and cause coughing. Inhalation

May cause skin irritation. Skin contact **Eve contact** May cause eye irritation.

Ingestion May cause discomfort if swallowed.

Symptoms related to the physical, chemical and toxicological characteristics Ingestion may cause irritation and malaise.

Information on toxicological effects

Acute toxicity May cause discomfort if swallowed.

Components **Species Test Results**

Sodium azide (CAS 26628-22-8)

Acute

Dermal

LD50 Rabbit 20 mg/kg

Oral

LD50 Rat 27 mg/kg

May cause skin irritation. Skin corrosion/irritation Serious eye damage/eye May cause eye irritation.

irritation

Respiratory or skin sensitization

Respiratory sensitization Not classified. Skin sensitization Not classified. Germ cell mutagenicity Not classified.

Carcinogenicity Not classifiable as to carcinogenicity to humans.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Not classified. Reproductive toxicity Specific target organ toxicity -Not classified. single exposure

Specific target organ toxicity -

Not classified.

repeated exposure

Not classified. **Aspiration hazard Chronic effects** No data available.

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

12. Ecological information

Ecotoxicity

Components **Species Test Results** Sodium azide (CAS 26628-22-8) Aquatic Algae EC50 Pseudokirchnerella subcapitata 0.35 mg/l, 96 hours Fish LC50 5.7 mg/l, 96 hours Fish Persistence and degradability No data is available on the degradability of this product. Bioaccumulative potential Not available. Mobility in soil Not available. The product is soluble in water. Mobility in general

Strep A CONTROL + SDS US

904918 Version #: 01 Issue date: 13-October-2014 Revision date: -

Other adverse 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.

13. Disposal considerations

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.

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

disposal company.

Waste from residues / unused

Contaminated packaging

Dispose in accordance with all applicable regulations. Contract with a licensed chemical disposal agency.

products

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

14. Transport information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

This substance/mixture is not intended to be transported in bulk.

15. Regulatory information

US federal regulationsThis product is not hazardous according to OSHA 29CFR 1910.1200. This mixture is a component

LISTED

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.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

CERCLA Hazardous Substance List (40 CFR 302.4)

Sodium azide (CAS 26628-22-8)

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

SARA 302 Extremely hazardous substance

Chemical name CAS number Reportable Threshold Threshold Threshold quantity planning quantity planning quantity, planning quantity, lower value upper value

Sodium azide 26628-22-8 1000 500 lbs

SARA 311/312 Hazardous

No

chemical

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

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

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act

Not regulated.

(SDWA)

Strep A CONTROL + SDS US

This product does not contain a chemical known to the State of California to cause cancer, birth

defects or other reproductive harm.

US. Massachusetts RTK - Substance List

Sodium azide (CAS 26628-22-8)

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

Sodium azide (CAS 26628-22-8)

US. Pennsylvania Worker and Community Right-to-Know Law

Sodium azide (CAS 26628-22-8)

US. Rhode Island RTK

Sodium azide (CAS 26628-22-8)

US. California Proposition 65

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

Not listed.

International Inventories

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

Toxic Substances Control Act (TSCA) Inventory

16. Other information, including date of preparation or last revision

13-October-2014 Issue date

Revision date Version # 01

United States & Puerto Rico

NFPA ratings



LD50: Lethal Dose, 50%. List of abbreviations

ACGIH References

HSDB® - Hazardous Substances Data Bank

IARC Monographs. Overall Evaluation of Carcinogenicity

The information above is provided in good faith. It is believed to be accurate and represents the **Disclaimer**

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.

Strep A CONTROL + 904918 Version #: 01 Issue date: 13-October-2014 Revision date: -

Yes

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

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

SAFETY DATA SHEET



1. Identification

Product identifier Strep A CONTROL -

Other means of identification

Kit number 141; 141E; 141E-20; 147; 149; 141-10; 148

Recommended use For external quality control testing.

Recommended restrictionsUse in accordance with supplier's recommendations.

Manufacturer/Importer/Supplier/Distributor information

Corporate Headquarters Sekisui Diagnostics, LLC

4 Hartwell Place, Lexington, MA 02421, USA

www.sekisuidiagnostics.com Phone: 800-332-1042 Americas 1-760-476-3962

Emergency Telephone

Numbers

Europe, Middle East & Africa +1-760-476-3961

Asia Pacific +1-760-476-3960

Access code 333512

2. Hazard(s) identification

Physical hazards Not classified.

Health Hazards Not classified.

OSHA defined hazards Not classified.

Label elements

Hazard symbol None.
Signal word None.

Hazard statement The mixture does not meet the criteria for classification.

Precautionary statement

Prevention None.

Response None.

Storage None.

Disposal None.

Hazard(s) not otherwise

classified (HNOC)

None known.

3. Composition/information on ingredients

Mixtures

Chemical name	CAS number	%
Sodium azide	26628-22-8	< 0.2

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

percent by volume.

4. First-aid measures

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

Skin contact Wash skin thoroughly with soap and water. Get medical attention if irritation develops and persists.

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

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

Ingestion Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person. Get

medical attention if irritation develops and persists.

Strep A CONTROL - SDS US

Most important symptoms/effects, acute and

delayed

Indication of immediate medical attention and special Provide general supportive measures and treat symptomatically.

Ingestion may cause irritation and malaise.

treatment needed

General information

Ensure that medical personnel are aware of the material(s) involved, and take precautions to

protect themselves.

5. Fire-fighting measures

Suitable extinguishing media

Extinguish with water spray, carbon dioxide, dry chemical or material appropriate for the

surrounding fire.

Unsuitable extinguishing

media

None known.

Specific hazards arising from

the chemical

When heated to decomposition, may produce hydrazoic acid fumes.

Special protective equipment and precautions for firefighters Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Fire fighting General fire hazards

equipment/instructions

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

The product is not flammable.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

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.

Methods and materials for containment and cleaning up **Environmental precautions**

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.

Do not allow to enter drains, sewers or watercourses. This mixture contains a small amount of sodium azide which can react with copper, lead, brass or solder in plumbing systems and form potentially explosive metal azides. Follow proper disposal procedures.

7. Handling and storage

Precautions for safe 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.

Conditions for safe storage, including any incompatibilities 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

US. ACGIH Threshold Limit Values

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

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Туре	Value
Sodium azide (CAS 26628-22-8)	Ceiling	0.3 mg/m3
,		0.1 ppm

Biological limit values No biological exposure limits noted for the ingredient(s).

Follow standard monitoring procedures. **Exposure guidelines**

US - California OELs: Skin designation

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

US - Tennessee OELs: Skin designation

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

Strep A CONTROL -SDS US 2/7 904906 Version #: 01 Revision date: -Issue date: 13-October-2014

US. NIOSH: Pocket Guide to Chemical Hazards

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

Provide adequate ventilation. Observe Occupational Exposure Limits and minimize the risk of Appropriate engineering

inhalation of vapors. controls

Individual protection measures, such as personal protective equipment Eye/face protection Wear approved safety glasses or goggles.

Skin protection

Hand protection Wear appropriate chemical resistant gloves. Remove contaminated clothing promptly. Other

Colorless, clear.

In case of inadequate ventilation or risk of inhalation of vapors, use suitable respiratory equipment. Respiratory protection

Wear appropriate thermal protective clothing, when necessary. Thermal hazards

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

considerations

Color

9. Physical and chemical properties

Colorless liquid. **Appearance**

Physical state Liquid. **Form** Liquid.

No data available. Odor **Odor threshold** Not available. 7.2 Approx. Melting point/freezing point Not available.

Initial boiling point and boiling range

Not available. Flash point Not available. **Evaporation rate** Flammability (solid, gas) Not applicable.

Upper/lower flammability or explosive limits

Flammability limit - lower

(%)

Not available.

Not available.

Flammability limit - upper

(%)

Not available.

Not available. Explosive limit - lower (%) Explosive limit - upper (%) Not available. Vapor pressure Not available. Not available. Vapor density Relative density Not available.

Solubility(ies)

Solubility (water) Not available. Partition coefficient Not applicable.

(n-octanol/water)

Not available. **Auto-ignition temperature Decomposition temperature** Not available. **Viscosity** Not available.

10. Stability and reactivity

Reactivity The product is stable and non-reactive under normal conditions of use, storage and transport.

Chemical stability Material is stable under normal conditions. Possibility of hazardous Contact with acids liberates toxic gas.

reactions

Heat, sparks, flames, elevated temperatures. Conditions to avoid

Incompatible materials Strong oxidizing agents.

Strep A CONTROL -SDS US Hazardous decomposition

products

No data available.

11. Toxicological information

Information on likely routes of exposure

Inhalation Vapors may irritate throat and respiratory system and cause coughing.

Skin contactMay cause skin irritation.Eye contactMay cause eye irritation.

Ingestion May cause discomfort if swallowed.

Symptoms related to the physical, chemical and toxicological characteristics

Ingestion may cause irritation and malaise.

Information on toxicological effects

Acute toxicity May cause discomfort if swallowed.

Components Species Test Results

Sodium azide (CAS 26628-22-8)

Acute

Dermal

LD50 Rabbit 20 mg/kg

Oral

LD50 Rat 27 mg/kg

Skin corrosion/irritation May cause skin irritation.
Serious eye damage/eye May cause eye irritation.

irritation

Respiratory or skin sensitization

Respiratory sensitization Not classified.
Skin sensitization Not classified.
Germ cell mutagenicity Not classified.

Carcinogenicity Not classifiable as to carcinogenicity to humans.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Reproductive toxicity Not classified.

Specific target organ toxicity - Not classified.

single exposure

Not classified.

Specific target organ toxicity - repeated exposure

Aspiration hazard Not classified.

Chronic effects No data available.

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

12. Ecological information

Ecotoxicity

Components **Species Test Results** Sodium azide (CAS 26628-22-8) Aquatic Algae EC50 Pseudokirchnerella subcapitata 0.35 mg/l, 96 hours Fish LC50 5.7 mg/l, 96 hours Fish Persistence and degradability No data is available on the degradability of this product. Bioaccumulative potential Not available. Mobility in soil Not available. The product is soluble in water. Mobility in general

Strep A CONTROL - SDS US

904906 Version #: 01 Revision date: - Issue date: 13-October-2014

Other adverse 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.

13. Disposal considerations

Disposal instructionsCollect 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.

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

disposal company.

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 dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code This substance/mixture is not intended to be transported in bulk.

15. Regulatory information

US federal regulationsThis 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.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

CERCLA Hazardous Substance List (40 CFR 302.4)

Sodium azide (CAS 26628-22-8) LISTED

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

SARA 302 Extremely hazardous substance

Chemical name CAS number Reportable Threshold Threshold Threshold quantity planning quantity planning quantity, planning quantity, lower value upper value

Sodium azide 26628-22-8 1000 500 lbs

SARA 311/312 Hazardous

chemical

No

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

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

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act

Not regulated.

(SDWA)

Strep A CONTROL - SDS US

904906 Version #: 01 Revision date: - Issue date: 13-October-2014

This product does not contain a chemical known to the State of California to cause cancer, birth

defects or other reproductive harm.

US. Massachusetts RTK - Substance List

Sodium azide (CAS 26628-22-8)

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

Sodium azide (CAS 26628-22-8)

US. Pennsylvania Worker and Community Right-to-Know Law

Sodium azide (CAS 26628-22-8)

US. Rhode Island RTK

Sodium azide (CAS 26628-22-8)

US. California Proposition 65

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

International Inventories

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

Toxic Substances Control Act (TSCA) Inventory

16. Other information, including date of preparation or last revision

13-October-2014 Issue date

Revision date Version # 01

United States & Puerto Rico

NFPA ratings



LD50: Lethal Dose, 50%. List of abbreviations

ACGIH References

HSDB® - Hazardous Substances Data Bank

IARC Monographs. Overall Evaluation of Carcinogenicity

The information above is provided in good faith. It is believed to be accurate and represents the **Disclaimer**

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.

Strep A CONTROL -

Yes

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

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

This SDS contains revisions in 1, 3, 8, 12, 15, 16. the following section(s):

Strep A CONTROL - SDS US

904906 Version #: 01 Revision date: - Issue date: 13-October-2014

SAFETY DATA SHEET



1. Identification

Product identifier Strep A REAG 1

Other means of identification

Kit number 141, 141E, 141E-20, 141-10

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

presumptive Group A Streptococcal colonies recovered from culture.

Recommended restrictionsUse in accordance with supplier's recommendations.

Manufacturer/Importer/Supplier/Distributor information

Corporate Headquarters Sekisui Diagnostics, LLC

4 Hartwell Place, Lexington, MA 02421, USA

www.sekisuidiagnostics.com Phone: 800-332-1042 Americas 1-760-476-3962

Emergency Telephone

Numbers

Europe, Middle East & Africa +1-760-476-3961

Asia Pacific +1-760-476-3960

Access code 333512

2. Hazard(s) identification

Physical hazardsOxidizing liquidsCategory 3Health HazardsAcute toxicity, oralCategory 4

OSHA defined hazards Not classified.

Label elements



Signal word Warning

Hazard statement May intensify fire; oxidizer. Harmful if swallowed.

Precautionary statement

Prevention Keep away from heat. Keep/Store away from combustible materials. Take any precaution to avoid

mixing with combustibles. Wear protective gloves/eye protection/face protection. Wash thoroughly

after handling. Do not eat, drink or smoke when using this product.

Response In case of fire: Use appropriate media for extinction. If swallowed: Call a poison center/doctor if

you feel unwell. Rinse mouth.

Storage None.

Disposal Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazard(s) not otherwise

classified (HNOC)

None known.

3. Composition/information on ingredients

Mixtures

Chemical name	CAS number	%
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.

4. First-aid measures

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

Strep A REAG 1 SDS US

For skin contact flush with large amounts of water while removing contaminated clothing. Get Skin contact

medical attention if irritation develops and persists.

Ingestion may cause irritation and malaise.

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

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

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

Most important

symptoms/effects, acute and

delayed

Indication of immediate medical attention and special

treatment needed

Provide general supportive measures and treat symptomatically.

General information Ensure that medical personnel are aware of the material(s) involved, and take precautions to

protect themselves.

5. Fire-fighting measures

Suitable extinguishing media Extinguish with water spray, carbon dioxide, dry chemical or material appropriate for the

surrounding fire.

Unsuitable extinguishing

media

None known.

Specific hazards arising from

the chemical

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

materials more flammable if it is absorbed and dries.

Special protective equipment and precautions for firefighters

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

Fire fighting

equipment/instructions

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

General fire hazards The product is not flammable. Will burn if involved in a fire.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Methods and materials for

containment and cleaning up **Environmental 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.

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.

Do not allow to enter drains, sewers or watercourses.

7. Handling and storage

Precautions for safe handling Avoid contact with skin and eyes. Wash thoroughly after handling. In case of insufficient

ventilation, wear suitable respiratory equipment. Keep away from clothing and other combustible materials. Handle and open container with care. Observe good industrial hygiene practices.

Conditions for safe storage, including any incompatibilities 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).

Biological limit values

No biological exposure limits noted for the ingredient(s).

Exposure guidelines

Follow standard monitoring procedures.

Appropriate engineering controls

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

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

2/7

shower.

Individual protection measures, such as personal protective equipment

Eye/face protection

Respiratory protection

Wear approved safety glasses or goggles.

Skin protection

Hand protection Wear appropriate chemical resistant gloves.

Other

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

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

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

considerations

Strep A REAG 1 SDS US

904884 Version #: 01 Revision date: -Issue date: 13-October-2014

9. Physical and chemical properties

Clear pink liquid. **Appearance**

Liquid. Physical state **Form** Liquid. Color Clear pink. Odorless. Odor **Odor threshold** Not available. 9 Approx. рH Melting point/freezing point Not available. Initial boiling point and boiling Not available.

range

Not available. Flash point **Evaporation rate** Not available. Flammability (solid, gas) Not applicable. Upper/lower flammability or explosive limits

Flammability limit - lower

Not available.

(%)

Flammability limit - upper

Not available.

(%)

Explosive limit - lower (%) Not available. Explosive limit - upper (%) Not available. Not available. Vapor pressure Vapor density Not available. Relative density 1.08 Approx.

Solubility(ies)

Solubility (water) Soluble.

Partition coefficient Not available.

(n-octanol/water)

Not available. **Auto-ignition temperature** Not available. **Decomposition temperature** Not available. **Viscosity**

10. Stability and reactivity

Reactivity Mixing Strep A Reagents 1 and 2 yields nitrous acid, which may immediately decompose into toxic

nitrous gas, a short-term reaction by-product.

Chemical stability Oxidizer - contact with other material may cause fire.

Possibility of hazardous

reactions

Hazardous polymerization does not occur.

Conditions to avoid Avoid high temperatures. Incompatible materials.

Amines. Reducing agents. Oxidizing agents. Combustible material. Incompatible materials

Hazardous decomposition

products

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

11. Toxicological information

Information on likely routes of exposure

Vapors may irritate throat and respiratory system and cause coughing. Inhalation

May cause skin irritation. Skin contact Eye contact May cause eye irritation. Ingestion Harmful if swallowed.

Symptoms related to the physical, chemical and toxicological characteristics Ingestion may cause irritation and malaise.

Strep A REAG 1 3/7

904884 Version #: 01 Revision date: -Issue date: 13-October-2014

Information on toxicological effects

Acute toxicity Harmful if swallowed. Sodium nitrite exposure may result in a drop in blood pressure, headache,

vertigo, palpitations, visual disturbances, methemoglobinemia, dyspnea and respiratory

depression.

Components Species Test Results

Sodium nitrite (CAS 7632-00-0)

Acute

Inhalation

LC50 Rat 5.5 mg/l, 4 Hours

Oral

LD50 Rat 158 mg/kg

Skin corrosion/irritation May cause skin irritation.

Serious eye damage/eye May cause eye irritation.

irritation

Respiratory or skin sensitization

Respiratory sensitization Not classified.

Skin sensitization Not classified.

Germ cell mutagenicity Not classified.

Carcinogenicity No data available.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Reproductive toxicity Not classified.

Specific target organ toxicity - Not classified.

single exposure

Specific target organ toxicity -

repeated exposure

Not classified.

Aspiration hazard Not classified.

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

pressure.

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

12. Ecological information

Ecotoxicity No ecotoxicity data noted for the ingredient(s).

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

Bioaccumulative potential Not available.

Mobility in soilThe product is soluble in water.Mobility in generalThe product is soluble in water.

Other adverse 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.

13. Disposal considerations

Disposal instructions Dispose in accordance with all applicable regulations.

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

disposal company.

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

UN number UN3219

UN proper shipping name Nitrites, inorganic, aqueous solution, n.o.s. (Sodium nitrite) **Transport hazard class(es)**

Class 5.1

Strep A REAG 1 SDS US

Subsidiary risk 5.1 Label(s) Ш Packing group

Special precautions for user Read safety instructions, SDS and emergency procedures before handling.

IB2, T4, TP1 Special provisions

Packaging exceptions 152 Packaging non bulk 203 Packaging bulk 241

IATA

UN3219 **UN** number

UN proper shipping name Nitrites, inorganic, aqueous solution, n.o.s. (Sodium nitrite)

Transport hazard class(es)

Class 5.1 Subsidiary risk Label(s) 5.1 Packing group Ш **Environmental hazards** No **ERG Code** 5L

Special precautions for user Read safety instructions, SDS and emergency procedures before handling.

IMDG

UN number UN3219

UN proper shipping name NITRITES, INORGANIC, AQUEOUS SOLUTION, N.O.S. (Sodium nitrite)

Transport hazard class(es)

Class 5.1 Subsidiary risk 5.1 Label(s) Packing group Ш **Environmental hazards**

Marine pollutant No F-A, S-Q **EmS**

Special precautions for user Read safety instructions, SDS and emergency procedures before handling.

Transport in bulk according to Annex II of MARPOL 73/78 and

the IBC Code

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 substance/mixture is not intended to be transported in bulk.

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.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

CERCLA Hazardous Substance List (40 CFR 302.4)

LISTED Sodium nitrite (CAS 7632-00-0)

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Immediate Hazard - Yes **Hazard categories**

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

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous Yes

chemical

Strep A REAG 1 SDS US

904884 Version #: 01 Issue date: 13-October-2014 Revision date: -

5/7

SARA 313 (TRI reporting)

Chemical name	CAS number	% by wt.	
Sodium nitrite	7632-00-0	10 - 15	

Other federal regulations

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

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act

Not regulated.

(SDWA)

US state regulations This material is not known to contain any chemicals currently listed as carcinogens or reproductive

toxins.

US. Massachusetts RTK - Substance List

Sodium nitrite (CAS 7632-00-0)

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

Sodium nitrite (CAS 7632-00-0)

US. Pennsylvania Worker and Community Right-to-Know Law

Inventory name

Sodium nitrite (CAS 7632-00-0)

US. Rhode Island RTK

Sodium nitrite (CAS 7632-00-0)

US. California Proposition 65

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

Not listed.

International Inventories

Country(s) or region

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

16. Other information, including date of preparation or last revision

Issue date 13-October-2014

Revision date - Version # 01

United States & Puerto Rico

NFPA ratings



References ACGIH

EPA: AQUIRE database

HSDB® - Hazardous Substances Data Bank

IARC Monographs. Overall Evaluation of Carcinogenicity

904884 Version #: 01 Revision date: - Issue date: 13-October-2014 6 / 7

Yes

On inventory (yes/no)*

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.

Strep A REAG 1 SDS US

SAFETY DATA SHEET



1. Identification

Product identifier Strep A REAG 2

Other means of identification

Kit number 141, 141E, 141E-20; 141-10

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

presumptive Group A Streptococcal colonies recovered from culture.

Recommended restrictionsUse in accordance with supplier's recommendations.

Manufacturer/Importer/Supplier/Distributor information

Corporate Headquarters Sekisui Diagnostics, LLC

4 Hartwell Place, Lexington, MA 02421, USA

www.sekisuidiagnostics.com Phone: 800-332-1042 Americas 1-760-476-3962

Emergency Telephone

Numbers

Europe, Middle East & Africa +1-760-476-3961

Asia Pacific +1-760-476-3960

Access code 333512

2. Hazard(s) identification

Physical hazards Not classified.

Health Hazards Skin corrosion/irritation Category 2

Serious eye damage/eye irritation Category 2A

OSHA defined hazards Not classified.

Label elements



Signal word Warning

Hazard statement Causes skin irritation. Causes serious eye irritation.

Precautionary statement

Prevention Wash thoroughly after handling. Wear protective gloves/protective clothing/eye protection/face

protection.

Response If on skin: Wash with plenty of water. If skin irritation occurs: Get medical advice/attention. Take

off contaminated clothing and wash it before reuse. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye

irritation persists: Get medical advice/attention.

Storage None.

Disposal Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazard(s) not otherwise

classified (HNOC)

None known.

3. Composition/information on ingredients

Mixtures

Chemical name	CAS number	%
Acetic acid	64-19-7	1 - < 3

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

Strep A REAG 2 SDS US

4. First-aid measures

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

Skin contact Wash skin thoroughly with soap and water. Get medical attention if irritation develops and persists.

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

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

Ingestion Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person. Get

medical attention if irritation develops and persists.

Ingestion may cause irritation and malaise.

Most important

symptoms/effects, acute and

delaved

Indication of immediate medical attention and special

treatment needed

Provide general supportive measures and treat symptomatically.

General information Ensure that medical personnel are aware of the material(s) involved, and take precautions to

protect themselves.

5. Fire-fighting measures

Suitable extinguishing media Extinguish with water spray, carbon dioxide, dry chemical or material appropriate for the

surrounding fire.

Unsuitable extinguishing

media

None known.

Specific hazards arising from

the chemical

None known.

Special protective equipment

and precautions for firefighters

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

Fire fighting

equipment/instructions

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

General fire hazards The product is not flammable.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

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.

Methods and materials for containment and cleaning up **Environmental precautions**

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.

Do not allow to enter drains, sewers or watercourses.

7. Handling and storage

Precautions for safe 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.

Conditions for safe storage, including any incompatibilities

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

Value

8. Exposure controls/personal protection

Occupational exposure limits

Components

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Type

Components	rype	value	
Acetic acid (CAS 64-19-7)	PEL	25 mg/m3	
		10 ppm	
US. ACGIH Threshold Limit Value	es		
Components	Туре	Value	
Acetic acid (CAS 64-19-7)	STEL	15 ppm	
	TWA	10 ppm	

Strep A REAG 2 SDS US

US. NIOSH: Pocket Guide to Chemical Hazards

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

No biological exposure limits noted for the ingredient(s). **Biological limit values**

Exposure guidelines Follow standard monitoring procedures.

Provide adequate ventilation. Observe Occupational Exposure Limits and minimize the risk of Appropriate engineering

inhalation of vapors. controls

Individual protection measures, such as personal protective equipment

Wear approved safety glasses or goggles. Eye/face protection

Skin protection

Wear appropriate chemical resistant gloves. Hand protection Other Remove contaminated clothing promptly.

Respiratory protection In case of inadequate ventilation or risk of inhalation of vapors, use suitable respiratory equipment.

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

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

considerations

9. Physical and chemical properties

Colorless liquid. **Appearance**

Physical state Liquid. **Form** Liquid.

Color Colorless, clear. Odor No data available. Odor threshold Not available.

2.6

Not available. Melting point/freezing point Initial boiling point and boiling Not available.

range

Not available. Flash point **Evaporation rate** Not available. Flammability (solid, gas) Not applicable.

Upper/lower flammability or explosive limits

Flammability limit - lower

(%)

Not available.

Flammability limit - upper

Not available.

Explosive limit - lower (%) Not available. Explosive limit - upper (%)

Not available.

Not available. Vapor pressure Vapor density Not available. Not available. Relative density

Solubility(ies)

Solubility (water) Soluble.

Partition coefficient Not applicable.

(n-octanol/water)

Not available. **Auto-ignition temperature** Not available. **Decomposition temperature** Not available. **Viscosity**

Strep A REAG 2 SDS US

10. Stability and reactivity

Reactivity Mixing Strep A Reagents 1 and 2 yields nitrous acid, which may immediately decompose into toxic

nitrous gas, a short-term reaction by-product.

Material is stable under normal conditions. **Chemical stability**

Possibility of hazardous

reactions

Polymerization will not occur.

Conditions to avoid Heat, sparks, flames, elevated temperatures.

Incompatible materials Strong oxidizing agents. No data available. **Hazardous decomposition**

products

11. Toxicological information

Information on likely routes of exposure

Inhalation In high concentrations, vapors may be irritating to the respiratory system.

Skin contact Causes skin irritation.

Eye contact Causes serious eye irritation.

Ingestion May cause discomfort if swallowed.

Symptoms related to the physical, chemical and toxicological characteristics Ingestion may cause irritation and malaise.

Information on toxicological effects

May cause discomfort if swallowed. Acute toxicity

Components **Species Test Results** Acetic acid (CAS 64-19-7) Acute

Dermal

1060 mg/kg LD50 Rabbit

Inhalation

LC50 Rat 11.4 mg/l, 4 Hours

Oral

LD50 Rat 3310 mg/kg

Skin corrosion/irritation Causes skin irritation. Serious eye damage/eye

irritation

Causes serious eye irritation.

Respiratory or skin sensitization

Respiratory sensitization Not classified. Skin sensitization Not classified. Not classified. Germ cell mutagenicity Carcinogenicity Not classified.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Reproductive toxicity Not classified. Specific target organ toxicity -Not classified. single exposure

Specific target organ toxicity -

Not classified.

repeated exposure

Not classified.

Aspiration hazard Chronic effects No data available.

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

Strep A REAG 2 SDS US

904947 Version #: 01 Issue date: 13-October-2014 Revision date: -

12. Ecological information

Ecotoxicity

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

Persistence and degradability

No data is available on the degradability of this product.

Bioaccumulative potential

Not available.

Partition coefficient n-octanol / water (log Kow)

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

Mobility in soil Not available.

Mobility in general The product is soluble in water.

Other adverse 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.

13. Disposal considerations

Disposal instructionsCollect 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.

Hazardous waste code

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

disposal company.

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 dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

This substance/mixture is not intended to be transported in bulk.

15. Regulatory information

US federal regulationsThis 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.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

CERCLA Hazardous Substance List (40 CFR 302.4)

Acetic acid (CAS 64-19-7) LISTED

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

SARA 302 Extremely hazardous substance

Not listed.

Strep A REAG 2 SDS US

SARA 311/312 Hazardous

chemical

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

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

Yes

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA)

Not regulated.

US 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. Massachusetts RTK - Substance List

Acetic acid (CAS 64-19-7)

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

Acetic acid (CAS 64-19-7)

US. Pennsylvania Worker and Community Right-to-Know Law

Acetic acid (CAS 64-19-7)

US. Rhode Island RTK

Acetic acid (CAS 64-19-7)

US. California Proposition 65

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

International Inventories

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

16. Other information, including date of preparation or last revision

Issue date 13-October-2014

Revision date Version # 01

United States & Puerto Rico

NFPA ratings



References **ACGIH**

HSDB® - Hazardous Substances Data Bank

IARC Monographs. Overall Evaluation of Carcinogenicity

Strep A REAG 2 SDS US

Yes

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.

Strep A REAG 2 SDS US