# SAFETY DATA SHEET



# SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Trade name or designation

Strep A CONTROL +

of the mixture

Registration number

**Synonyms** None.

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

Issue date 31-May-2012

Version number 01 **Revision date** Supersedes date

1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified uses For external quality control testing.

Uses advised against Use in accordance with supplier's recommendations.

1.3. Details of the supplier of the safety data sheet

**Corporate Headquarters** Sekisui Diagnostics, LLC

31 New York Avenue, Framingham, MA 01701 USA

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

Distributor Sekisui Diagnostics (UK) Limited

50 Gibson Drive, Kings Hill, West Malling

Kent ME19 4AF UK

www.sekisuidiagnostics.com Phone: 44 (0) 1732 220022 Info@sekisuidiagnostics.com

1.4. Emergency telephone

number

Americas 1-760-476-3962

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

Asia Pacific +1-760-476-3960

Access code

# **SECTION 2: Hazards identification**

## 2.1. Classification of the substance or mixture

The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

### Classification according to Directive 67/548/EEC or 1999/45/EC as amended

Classification Xn:R22

# Classification according to Regulation (EC) No 1272/2008 as amended

This mixture does not meet the criteria for classification according to Regulation (EC) 1272/2008 as amended.

**Hazard summary** 

Physical hazards Not classified for physical hazards.

**Health hazards** Harmful if swallowed.

**Environmental hazards** Not classified for hazards to the environment.

Specific hazards Avoid contact with eyes and skin. Do not ingest or inhale.

Main symptoms Ingestion may cause irritation and malaise.

2.2. Label elements

### Label according to Regulation (EC) No. 1272/2008 as amended

None **Hazard pictograms** Signal word None.

The mixture does not meet the criteria for classification. **Hazard statements** 

**Precautionary statements** 

Strep A CONTROL +

Prevention None. Response None

Storage None. None. Disposal

Supplemental label information Not applicable.

2.3. Other hazards Not a PBT or vPvB substance or mixture.

# **SECTION 3: Composition/information on ingredients**

#### 3.2. Mixtures

**General information** 

**Chemical name** % CAS-No. / EC No. REACH Registration No. INDEX No. **Notes** 

Non-viable Group A Streptococci 1 - 5 N/A

Classification: DSD: -

CLP: -

Sodium azide < 0.2 26628-22-8 011-004-00-7 #

247-852-1

Classification: DSD: T+;R28, R32, N;R50/53

CLP: Acute Tox. 2;H300, Aquatic Acute 1;H400, Aquatic Chronic 1;H410

DSD: Directive 67/548/EEC CLP: Regulation No. 1272/2008

#: This substance has been assigned Community workplace exposure limit(s).

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

percent by volume. The full text for all R-phrases is displayed in Section 16.

# **SECTION 4: First aid measures**

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

protect themselves.

4.1. Description of 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 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.

4.2. Most important symptoms and effects, both acute and

delayed

Ingestion may cause irritation and malaise.

4.3. Indication of any immediate medical attention and special treatment needed

Provide general supportive measures and treat symptomatically.

### **SECTION 5: Firefighting measures**

General fire hazards The product is not flammable.

5.1. Extinguishing media

media

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

surrounding fire.

Unsuitable extinguishing

Suitable extinguishing

media

None known.

5.2. Special hazards arising from the substance or mixture When heated to decomposition, may produce hydrazoic acid fumes.

5.3. Advice for firefighters

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

Special fire fighting

procedures

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

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Strep A CONTROL + SDS UK

### SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless

personnel

wearing appropriate protective clothing.

For emergency responders

Use personal protection as recommended in section 8 of the SDS.

6.2. Environmental precautions

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

potentially explosive metal azides. Follow proper disposal procedures.

6.3. Methods and material for containment and cleaning up Absorb spill with vermiculite or other inert material. Dispose of waste in accordance with all

6.4. Reference to other

sections

applicable federal, state, local and provincial environmental regulations, per Section 13.

For personal protection, see section 8. For waste disposal, see section 13.

# **SECTION 7: Handling and storage**

7.1. 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.

7.2. 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.

7.3. Specific end use(s) For external quality control testing.

# **SECTION 8: Exposure controls/personal protection**

### 8.1. Control parameters

### Occupational exposure limits

## UK. EH40 Workplace Exposure Limits (WELs)

Components	Туре	Value	
Sodium azide (26628-22-8)	STEL	0.3 mg/m3	
	TWA	0.1 mg/m3	

### EU. Indicative Exposure and Directives relating to the protection of risks related to work exposure to chemical, physical, and biological agents.

Components	Туре	Value
Sodium azide (26628-22-8)	STEL	0.3 mg/m3
	TWA	0.1 mg/m3

**Biological limit values** 

Follow standard monitoring procedures.

Recommended monitoring procedures

8.2. Exposure controls Appropriate engineering

controls

Provide adequate ventilation. Observe Occupational Exposure Limits and minimise the risk of

inhalation of vapours.

### Individual protection measures, such as personal protective equipment

**General information** Personal protective equipment should be chosen according to the CEN standards and in

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

discussion with the supplier of the 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 vapours, use suitable respiratory

equipment.

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

Hygiene measures Handle in accordance with good industrial hygiene and safety practices.

**Environmental exposure** 

controls

Inform appropriate managerial or supervisory personnel of all environmental releases.

# **SECTION 9: Physical and chemical properties**

# 9.1. Information on basic physical and chemical properties

**Appearance** Colourless liquid.

Physical state Liquid. **Form** Liquid.

Colour Clear, colorless.

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Odour Not available. **Odour threshold** Not available. 7.2 Approximate Not available. Melting point/freezing point Initial boiling point and boiling Not available.

range

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

Flammability limit - lower

Not available.

Flammability limit - upper

(%)

Not available.

Vapour pressure Not applicable. Vapour density Not applicable. Not available. Relative density Not available. Solubility(ies) **Partition coefficient** Not applicable. (n-octanol/water)

**Decomposition temperature** Not available. Not applicable. **Viscosity Explosive properties** Not available. Oxidizing properties Not available.

9.2. Other information No relevant additional information available.

# **SECTION 10: Stability and reactivity**

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

10.2. Chemical stability Material is stable under normal conditions. 10.3. Possibility of hazardous Contact with acids liberates toxic gas. reactions

10.4. Conditions to avoid

Heat, sparks, flames, elevated temperatures.

10.5. Incompatible materials Strong oxidising agents. 10.6. Hazardous No data available.

decomposition products

## **SECTION 11: Toxicological information**

**General information** Occupational exposure to the substance or mixture may cause adverse effects.

Information on likely routes of exposure

May cause discomfort if swallowed. Ingestion

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

Skin contact May cause skin irritation. Eye contact May cause eye irritation.

**Symptoms** Ingestion may cause irritation and malaise.

## 11.1. Information on toxicological effects

**Acute toxicity** May cause discomfort if swallowed.

Components **Test results Species** 

Sodium azide (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/irritation May cause eye irritation.

Strep A CONTROL + SDS UK 4/7

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

Not classifiable as to carcinogenicity to humans. Carcinogenicity

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

Specific target organ toxicity -

repeated exposure

single exposure

Not classified.

Not classified. **Aspiration hazard** Mixture versus substance

information

Not available.

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

# **SECTION 12: Ecological information**

The product is not classified as environmentally hazardous. However, this does not exclude the 12.1. Toxicity

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

Components Species **Test results** 

Sodium azide (26628-22-8)

**Aquatic** 

EC50 Crustacea Water flea (Daphnia pulex) 2.8 - 6.2 mg/l, 48 hours Fish LC50 Bluegill (Lepomis macrochirus) 0.68 mg/l, 96 hours

12.2. Persistence and

degradability

No data is available on the degradability of this product.

12.3. Bioaccumulative potential Not available.

Partition coefficient

Not applicable.

n-octanol/water (log Kow)

**Bioconcentration factor (BCF)** Not available. 12.4. Mobility in soil Not available

Mobility in general The product is soluble in water.

12.5. Results of PBT

and vPvB assessment Not a PBT or vPvB substance or mixture.

12.6. 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.

# **SECTION 13: Disposal considerations**

13.1. Waste treatment methods

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

agency.

Contaminated packaging

EU waste code

Empty containers should be taken to an approved waste handling site for recycling or disposal. The Waste code should be assigned in discussion between the user, the producer and the waste

disposal company.

Disposal methods/information

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.

# **SECTION 14: Transport information**

**ADR** 

The product is not covered by international regulation on the transport of dangerous goods.

RID

The product is not covered by international regulation on the transport of dangerous goods.

**ADN** 

The product is not covered by international regulation on the transport of dangerous goods.

**IATA** 

The product is not covered by international regulation on the transport of dangerous goods.

Strep A CONTROL + SDS UK

### **IMDG**

The product is not covered by international regulation on the transport of dangerous goods.

# **SECTION 15: Regulatory information**

### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

### **EU** regulations

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex I

Not listed.

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex II

Not listed.

Regulation (EC) No. 850/2004 on persistent organic pollutants, Annex I as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 1 as amended

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 2 as amended Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 3 as amended

Not listed

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex V as amended

Not listed

Regulation (EC) No. 166/2006 Annex II Pollutant Release and Transfer Registry

Not listed

Regulation (EC) No. 1907/2006, REACH Article 59(1) Candidate List as currently published by ECHA

Not listed.

## **Authorisations**

Regulation (EC) No. 143/2011 Annex XIV Substances Subject to Authorisation

Not listed.

#### Restrictions on use

Regulation (EC) No. 1907/2006, REACH Annex XVII Substances subject to restriction on marketing and use as amended Not listed.

Directive 2004/37/EC: on the protection of workers from the risks related to exposure to carcinogens and mutagens at work

Not regulated.

Directive 92/85/EEC: on the safety and health of pregnant workers and workers who have recently given birth or are breastfeeding

Not regulated.

### Other EU regulations

Directive 96/82/EC (Seveso II) on the control of major-accident hazards involving dangerous substances

Not regulated

Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work Sodium azide (CAS 26628-22-8)

Directive 94/33/EC on the protection of young people at work

Sodium azide (CAS 26628-22-8)

Other regulations The product is classified and labelled in accordance with EC directives or respective national

laws. This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006. In the European Union this product is regulated under the In Vitro Diagnostic Medical Devices

Directive (98/79/EC).

**National regulations**The product has not been classified as dangerous according to the legislation in force.

15.2. Chemical safety

assessment

No Chemical Safety Assessment has been carried out.

### **SECTION 16: Other information**

**List of abbreviations**DNEL: Derived No-Effect Level.

PNEC: Predicted No-Effect Concentration.

LD50: Lethal Dose, 50%.

References IARC Monographs. Overall Evaluation of Carcinogenicity

HSDB (2005)

Strep A CONTROL + SDS UK

Information on evaluation method leading to the classification of mixture

Full text of any statements or R-phrases and H-statements under Sections 2 to 15 The classification for health and environmental hazards is derived by a combination of calculation methods and test data, if available.

R22 Harmful if swallowed. R28 Very toxic if swallowed.

R32 Contact with acids liberates very toxic gas.

R50/53 Very toxic to aquatic organisms, May cause long-term adverse effects in the aquatic

environment.

H300 - Fatal if swallowed. H400 - Very toxic to aquatic life.

H410 - Very toxic to aquatic life with long lasting effects.

Training information Disclaimer

Follow training instructions when handling this material.

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 CONTROL + SDS UK

904918 Version No.: 01 Revision date: - Issue date: 31-May-2012

# SAFETY DATA SHEET



# SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Trade name or designation

Strep A CONTROL -

of the mixture

Registration number -

Synonyms None.

**Kit number** 141; 141E; 141E-20; 147; 149

Issue date 31-May-2012

Version number 01
Revision date Supersedes date -

1.2. Relevant identified uses of the substance or mixture and uses advised against

**Identified uses** For external quality control testing.

**Uses advised against** Use in accordance with supplier's recommendations.

1.3. Details of the supplier of the safety data sheet

Corporate Headquarters Sekisui Diagnostics, LLC

31 New York Avenue, Framingham, MA 01701 USA

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

**Distributor** Sekisui Diagnostics (UK) Limited

50 Gibson Drive, Kings Hill, West Malling

Kent ME19 4AF UK

www.sekisuidiagnostics.com Phone: 44 (0) 1732 220022 Info@sekisuidiagnostics.com Americas 1-760-476-3962

1.4. Emergency telephone

number

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

Asia Pacific +1-760-476-3960

Access code 333512

# **SECTION 2: Hazards identification**

## 2.1. Classification of the substance or mixture

The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

### Classification according to Directive 67/548/EEC or 1999/45/EC as amended

Classification Xn;R22

# Classification according to Regulation (EC) No 1272/2008 as amended

This mixture does not meet the criteria for classification according to Regulation (EC) 1272/2008 as amended.

**Hazard summary** 

Physical hazards Not classified for physical hazards.

**Health hazards** Harmful if swallowed.

**Environmental hazards** Not classified for hazards to the environment.

**Specific hazards** Avoid contact with eyes and skin. Do not ingest or inhale.

Main symptoms Ingestion may cause irritation and malaise.

2.2. Label elements

### Label according to Regulation (EC) No. 1272/2008 as amended

Hazard pictograms None.
Signal word None.

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

**Precautionary statements** 

Prevention None.
Response None.

Strep A CONTROL - SDS UK

904906 Version No.: 01 Revision date: - Issue date: 31-May-2012

Storage None. None. Disposal

Supplemental label information Not applicable.

2.3. Other hazards Not a PBT or vPvB substance or mixture.

# **SECTION 3: Composition/information on ingredients**

#### 3.2. Mixtures

**General information** 

**Chemical name** % CAS-No. / EC No. REACH Registration No. INDEX No. **Notes** 

Non-viable Group C Streptococci 1 - 5 N/A

Classification: DSD: -

CLP: -

Sodium azide < 0.2 26628-22-8 011-004-00-7 #

247-852-1

Classification: DSD: T+;R28, R32, N;R50/53

> Acute Tox. 2;H300, Aquatic Acute 1;H400, Aquatic Chronic 1;H410 CLP:

CLP: Regulation No. 1272/2008. DSD: Directive 67/548/EEC.

#: This substance has been assigned Community workplace exposure limit(s).

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

percent by volume. The full text for all R-phrases is displayed in Section 16.

# **SECTION 4: First aid measures**

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

protect themselves.

4.1. Description of 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 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.

4.2. Most important symptoms and effects, both acute and

delayed

Ingestion may cause irritation and malaise.

4.3. Indication of any immediate medical attention and special treatment needed

Provide general supportive measures and treat symptomatically.

### **SECTION 5: Firefighting measures**

General fire hazards The product is not flammable.

5.1. 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.

5.2. Special hazards arising from the substance or mixture When heated to decomposition, may produce hydrazoic acid fumes.

5.3. Advice for firefighters

Special protective equipment for firefighters

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

Special fire fighting procedures

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

Strep A CONTROL -SDS UK 2/7

### SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless

personnel

wearing appropriate protective clothing.

For emergency responders Use personal protection as recommended in section 8 of the SDS.

6.2. Environmental precautions Do not allow to enter drains, sewers or watercourses. This mixture contains a small amount of

sodium azide which can react with copper, lead, brass or solder in plumbing systems and form

potentially explosive metal azides. Follow proper disposal procedures.

6.3. Methods and material for containment and 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.

6.4. Reference to other

sections

For personal protection, see section 8. For waste disposal, see section 13.

# **SECTION 7: Handling and storage**

7.1. 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.

7.2. 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.

7.3. Specific end use(s) For external quality control testing

# **SECTION 8: Exposure controls/personal protection**

### 8.1. Control parameters

### Occupational exposure limits

## UK. EH40 Workplace Exposure Limits (WELs)

Components	Туре	Value
Sodium azide (26628-22-8)	STEL	0.3 mg/m3
	TWA	0.1 mg/m3

### EU. Indicative Exposure and Directives relating to the protection of risks related to work exposure to chemical, physical, and biological agents.

Components	Туре	Value
Sodium azide (26628-22-8)	STEL	0.3 mg/m3
	TWA	0.1 mg/m3

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

Recommended monitoring

procedures

Follow standard monitoring procedures.

8.2. Exposure controls

Appropriate engineering

controls

Provide adequate ventilation. Observe Occupational Exposure Limits and minimise the risk of

inhalation of vapours.

### Individual protection measures, such as personal protective equipment

**General information** Personal protective equipment should be chosen according to the CEN standards and in

discussion with the supplier of the personal protective equipment.

Eye/face protection

Skin protection

Wear approved safety glasses or goggles.

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

Respiratory protection In case of inadequate ventilation or risk of inhalation of vapours, use suitable respiratory

equipment.

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

Hygiene measures Handle in accordance with good industrial hygiene and safety practices.

**Environmental exposure** 

controls

Inform appropriate managerial or supervisory personnel of all environmental releases.

## **SECTION 9: Physical and chemical properties**

# 9.1. Information on basic physical and chemical properties

**Appearance** Colourless liquid.

Physical state Liquid. **Form** Liquid.

Colour Colourless, clear.

Strep A CONTROL -SDS UK Odour No data available. **Odour threshold** Not available. 7.2 approx. Not available. Melting point/freezing point Initial boiling point and boiling Not available.

range

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

Flammability limit - lower

Not available.

Flammability limit - upper

(%)

Not available.

Vapour pressure Not applicable. Vapour density Not applicable. Not available. Relative density Not available. Solubility(ies) **Partition coefficient** Not applicable.

(n-octanol/water) **Decomposition temperature Viscosity** 

**Explosive properties** 

Oxidizing properties

Not available. Not applicable. Not available. Not available.

9.2. Other information No relevant additional information available.

# **SECTION 10: Stability and reactivity**

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

10.2. Chemical stability Material is stable under normal conditions. 10.3. Possibility of hazardous Contact with acids liberates toxic gas.

reactions

10.5. Incompatible materials Strong oxidising agents. 10.6. Hazardous No data available.

decomposition products

10.4. Conditions to avoid

## **SECTION 11: Toxicological information**

**General information** Occupational exposure to the substance or mixture may cause adverse effects.

Heat, sparks, flames, elevated temperatures.

Information on likely routes of exposure

May cause discomfort if swallowed. Ingestion

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

Skin contact May cause skin irritation. Eye contact May cause eye irritation.

**Symptoms** Ingestion may cause irritation and malaise.

## 11.1. Information on toxicological effects

**Acute toxicity** May cause discomfort if swallowed.

Components **Test results Species** Sodium azide (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/irritation May cause eye irritation.

Strep A CONTROL -SDS UK

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

Not classifiable as to carcinogenicity to humans. Carcinogenicity

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

single exposure

Specific target organ toxicity -

repeated exposure

Not classified.

Not classified. **Aspiration hazard** Mixture versus substance Not available.

information Other information

No other specific acute or chronic health impact noted.

# **SECTION 12: Ecological information**

The product is not classified as environmentally hazardous. However, this does not exclude the 12.1. Toxicity

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

Components Species **Test results** 

Sodium azide (26628-22-8)

**Aquatic** 

EC50 Crustacea Water flea (Daphnia pulex) 2.8 - 6.2 mg/l, 48 hours Fish LC50 Bluegill (Lepomis macrochirus) 0.68 mg/l, 96 hours

12.2. Persistence and

degradability

No data is available on the degradability of this product.

12.3. Bioaccumulative potential Not available. Not applicable.

Partition coefficient

n-octanol/water (log Kow)

**Bioconcentration factor (BCF)** Not available. 12.4. Mobility in soil Not available

Mobility in general The product is soluble in water.

12.5. Results of PBT

and vPvB assessment Not a PBT or vPvB substance or mixture.

12.6. 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.

# **SECTION 13: Disposal considerations**

13.1. Waste treatment methods

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

agency.

Contaminated packaging

EU waste code

Empty containers should be taken to an approved waste handling site for recycling or disposal. The Waste code should be assigned in discussion between the user, the producer and the waste

disposal company.

Disposal methods/information

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.

# **SECTION 14: Transport information**

**ADR** 

The product is not covered by international regulation on the transport of dangerous goods.

RID

The product is not covered by international regulation on the transport of dangerous goods.

**ADN** 

The product is not covered by international regulation on the transport of dangerous goods.

**IATA** 

The product is not covered by international regulation on the transport of dangerous goods.

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### **IMDG**

The product is not covered by international regulation on the transport of dangerous goods.

# **SECTION 15: Regulatory information**

### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

### **EU** regulations

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex I

Not listed.

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex II

Not listed.

Regulation (EC) No. 850/2004 on persistent organic pollutants, Annex I as amended

Not listed

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 1 as amended

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 2 as amended Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 3 as amended

Not listed

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex V as amended

Not listed

Regulation (EC) No. 166/2006 Annex II Pollutant Release and Transfer Registry

Not listed

Regulation (EC) No. 1907/2006, REACH Article 59(1) Candidate List as currently published by ECHA

Not listed.

## **Authorisations**

Regulation (EC) No. 143/2011 Annex XIV Substances Subject to Authorisation

Not listed.

#### Restrictions on use

Regulation (EC) No. 1907/2006, REACH Annex XVII Substances subject to restriction on marketing and use as amended Not listed.

Directive 2004/37/EC: on the protection of workers from the risks related to exposure to carcinogens and mutagens at work

Not regulated.

Directive 92/85/EEC: on the safety and health of pregnant workers and workers who have recently given birth or are breastfeeding

Not regulated.

### Other EU regulations

Directive 96/82/EC (Seveso II) on the control of major-accident hazards involving dangerous substances

Not regulated.

Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work Sodium azide (CAS 26628-22-8)

Directive 94/33/EC on the protection of young people at work

Sodium azide (CAS 26628-22-8)

Other regulations This product does not meet the criteria for classification according to Regulation (EC) 1272/2008

(CLP Regulation) and Directive 67/548/EEC and their amendments respectively. This Safety Data

Sheet complies with the requirements of Regulation (EC) No 1907/2006.

In the European Union this product is regulated under the In Vitro Diagnostic Medical Devices

Directive (98/79/EC).

National regulations The product has not been classified as dangerous according to the legislation in force.

15.2. Chemical safety

No Chemical Safety Assessment has been carried out.

assessment

### **SECTION 16: Other information**

**List of abbreviations** DNEL: Derived No-Effect Level.

PNEC: Predicted No-Effect Concentration.

LD50: Lethal Dose, 50%.

References IARC Monographs. Overall Evaluation of Carcinogenicity

HSDB (2005)

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Information on evaluation method leading to the classification of mixture

Full text of any statements or R-phrases and H-statements under Sections 2 to 15 The classification for health and environmental hazards is derived by a combination of calculation methods and test data, if available.

R22 Harmful if swallowed. R28 Very toxic if swallowed.

R32 Contact with acids liberates very toxic gas.

R50/53 Very toxic to aquatic organisms, May cause long-term adverse effects in the aquatic

environment.

H300 - Fatal if swallowed. H400 - Very toxic to aquatic life.

H410 - Very toxic to aquatic life with long lasting effects.

Training information Disclaimer

Follow training instructions when handling this material.

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# MATERIAL SAFETY DATA SHEET

### 1. Product and Company Identification

Ultra Strep A REAG A Product name

Synonym(s) OSOM® Ultra Strep A Extraction Reagent A

CAS# Mixture Kit Number: 149

Product description Aqueous, alkaline solution containing trace color indicator.

Component of OSOM® Ultra Strep A Test kit. For the qualitative detection of Group A Product use

Streptococcal antigen directly from throat swab specimens. For In Vitro Diagnostic Use Only.

Corporate Headquarters Manufacturer/Distributor **Emergency Telephone Numbers** 

617-562-4555 Genzyme Diagnostics Genzyme (U.S.): Genzyme Corporation CHEMTREC (U.S.): 6659 Top Gun Street 800-424-9300 500 Kendall Street San Diego, CA 92121 USA CHEMTREC (Outside U.S.): +1 703-527-3887 Cambridge, MA 02142 USA

www.genzymediagnostics.com www.genzyme.com Phone: 858-452-3198 Phone: 617-252-7500

#### 2. Hazards Identification

Regulatory status This preparation is classified as hazardous under U.S. OSHA 29 CFR 1910.1200.

> This medical diagnostic kit is controlled under the Canadian Food and Drugs Act and is exempt from classification, labeling and MSDS requirements under the Canadian Hazardous Products Act

and Controlled Products Regulations.

Precautionary statements WARNING! The chemical, physical and toxicological properties of this preparation have not been

thoroughly characterized. Toxic by ingestion. Avoid contact with eyes and skin. Do not ingest or

inhale. Preparation appearance: clear, pink liquid.

Potential health effects

No data available. Substantial aerosol inhalation may result in symptoms similar to those Inhalation

specified for ingestion.

No data available. Eye exposure may cause severe irritation, redness, watering, swelling and Eves

No data available. Skin contact with sufficient chemical absorption may result in symptoms similar Skin

to those specified for ingestion.

Ingestion of sodium nitrite may cause gastric irritation, nausea, vomiting and abdominal pain. Ingestion

Significant exposure may result in a drop in blood pressure, headache, dizziness, rapid pulse and visual problems. Skin may be flushed and sweaty and then become cold. Skin and lips may turn

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

pressure.

Sodium nitrite: Cardiovascular and central nervous systems. Target organs

Potential environmental effects See Section 12.

## 3. Composition / Information on Ingredients

Components	CAS#	Percent
Sodium nitrite	7632-00-0	12 - 14
Non-hazardous and other components below reportable levels		8n - an

#### 4. First Aid Measures

First aid procedures

Skin contact

Inhalation If inhaled, move from exposure area to fresh air. Seek medical attention if breathing becomes

difficult or if cough or other symptoms develop.

Eye contact Immediately flush eyes with plenty of tepid water for 15 minutes while separating eyelids with

fingers. Remove contact lenses if worn. Obtain immediate medical attention.

In case of contact, immediately flush skin with cool water and remove contaminated clothing. Obtain medical attention if needed or if irritation or other symptoms develop.

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Ingestion In case of ingestion, contact a poison control center or physician for instructions.

### 5. Fire Fighting Measures

Extinguishing media

Suitable extinguishing

Use extinguishing media suitable for surrounding fire, such as carbon dioxide, chemical foam, dry

Unsuitable extinguishing

media

media

Unknown.

Specific hazards 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

Hazardous combustion

products

When heated to decomposition, may produce carbon monoxide (CO), carbon dioxide (CO2),

nitrogen oxides (NOx) and sulphur oxides (SOx).

Protection of firefighters

Protective equipment and precautions for firefighters

Firefighters should wear NIOSH-approved or equivalent Self-Contained Breathing Apparatus and

full protective gear.

#### 6. Accidental Release Measures

Personal precautions Wear Personal Protective Equipment (PPE) as indicated in Section 8. Ensure adequate

ventilation. Avoid physical contact with material and avoid aerosol inhalation. Wash hands

thoroughly after handling.

Environmental precautions Do not let product enter drains.

Absorb spill with inert material/sorbent. Decontaminate the spill site following standard Methods for cleaning up

procedures. Dispose of materials in accordance with all applicable federal, state, local and

provincial environmental regulations, per Section 13.

### 7. Handling and Storage

Handling Follow good laboratory hygiene practices. See Section 8, Engineering Controls. Mixing Strep A

Reagents A and B yields nitrous acid, which may immediately decompose into toxic nitrous gas, a short-term reaction by-product. Minimize contact and contamination of personal clothing and skin.

Avoid vapor or aerosol inhalation. Wash hands thoroughly after handling.

Storage Store at 15 to 30°C (59 to 86°F). Keep container tightly closed in a dry and well-ventilated place.

Do not store with incompatible substances; see Section 10.

#### 8. Exposure Controls / Personal Protection

There are no ACGIH, NIOSH or OSHA occupational exposure limits currently established for this Exposure guidelines

mixture or its components at concentrations equal to or greater than 1% (0.1% if carcinogen).

Engineering controls Minimize potential for aerosolization. Handle within a containment system or with local exhaust

ventilation. Facilities storing or using this material should be equipped with an eyewash fountain

and a safety shower.

Personal protective equipment

Respiratory protection A respirator is not expected to be required under normal conditions of use.

Eye / face protection Wear appropriate protective chemical safety goggles.

Wear appropriate protective clothing, such as a lab coat or other long-sleeved garment over Skin protection

clothing to minimize contact and contamination of clothing.

Hand protection Wear chemical resistant protective gloves. Follow company-specific safety procedures. General

#### 9. Physical & Chemical Properties

Liquid. Physical state Clear, pink Color Odor Not available Chemical family Alkaline solution pН 9.0 (approximate) Melting point Not applicable Not available Freezing point Not available Boiling point Flash point Not available Evaporation rate Not available

Ultra Strep A REAG A MSDS US Flammability Not available.
Flammability limits in air, Not available

upper, % by volume

Flammability limits in air,

lower, % by volume

Not available

Vapor pressure Not available
Vapor density Not available

Specific gravity

Relative density

Solubility (water)

Partition coefficient
(n-octanol/water)

Not available
Not available

Auto-ignition temperature Not applicable
Decomposition temperature Not available
Viscosity Not available

# 10. Chemical Stability & Reactivity Information

Reactivity Mixing Strep A Reagents A and B yields nitrous acid, which may immediately decompose into

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

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

Possibility of hazardous

Hazardous polymerization will not occur.

reactions

Conditions to avoid Solution is oxidized by air. Avoid high temperatures.

Incompatible materials Avoid amines, ammonium salts, cyanides and reducing agents. Heat and acids will result in

release of nitrous gas. Under certain conditions, nitrite compounds may react with secondary and

tertiary amines to form nitrosamines, which are known carcinogens in animals.

Hazardous decomposition

products

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

### 11. Toxicological Information

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

Acute effects Sodium nitrite exposure may result in a drop in blood pressure, headache, vertigo, palpitations,

visual disturbances, methemoglobinemia, dyspnea and respiratory depression.

Toxicological data

Components Test Results

Sodium nitrite (7632-00-0) Acute Inhalation LC50 Rat: 5.5 mg/l 4 Hours

Acute Oral LD50 Rat: 85 mg/kg

Skin corrosion/irritation No data available.
Chronic effects No data available.
Carcinogenicity No data available.
Mutagenicity No data available.
Reproductive effects No data available.
Teratogenicity No data available.
Sensitization No data available.

### 12. Ecological Information

Ecotoxicological data

Components Test Results

Sodium nitrite (7832-00-0) EC50 Greasyback shrimp (Metapenaeus ensis): 18.14 - 28.81

mg/I 48 hours

LC50 Channel catfish (Ictalurus punctatus): 0.048 mg/l 96

hours

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Components Test Results

Sodium nitrite (7632-00-0)

LC50 Rainbow trout, donaldson trout (Oncorhynchus mykiss): 0.19 - 0.24 mg/l 96 hours

Mobility in environmental

No data available.

media

Persistence / degradability No data available. Bioaccumulation No data available

#### 13. Disposal Considerations

Disposal instructions Dispose of unused product, spilled material and waste in accordance with all applicable federal,

state, local and provincial environmental and hazardous waste regulations.

#### 14. Transport Information

DOT

Basic shipping requirements:

**UN** number UN1500

SODIUM NITRITE SOLUTION Proper shipping name

Hazard class 5.1 (6.1)



DOT

#### 15. Regulatory Information

US federal regulations This preparation is a component of an FDA-regulated in vitro diagnostic device.

US CERCLA Hazardous Substances: Listed substance Sodium nitrite (7632-00-0) US CERCLA Hazardous Substances: Reportable quantity

100 LBS Sodium nitrite (7632-00-0) US CWA Section 311 Hazardous Substances: Listed substance Sodium nitrite (7632-00-0)

US CWA Section 311 Reporting Quantities of Hazardous Substances: Listed substance

Sodium nitrite (7632-00-0) Listed

US CWA Section 311 Reporting Quantities of Hazardous Substances: Reportable quantity

Sodium nitrite (7632-00-0) 100 LBS

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

Sodium nitrite (7632-00-0) 1.0 %

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

Sodium nitrite (7632-00-0) Listed.

US TSCA Inventory: Registration Status

Sodium nitrite (7632-00-0) Listed.

US TSCA Section 12(b) Export Notification: Export Notification requirement/De minimis concentration Sodium nitrite (7632-00-0) 1.0 % TSCA Section: 5 One-Time Export Notification only.

US TSCA Section 5(a)(2) Final Significant New Use Rules (SNURs): Listed substance

Sodium nitrite (7632-00-0) Listed.

US TSCA Section 5(a)(2) Final Significant New Use Rules (SNURs): Section number: 40 CFR

Sodium nitrite (7632-00-0) 721,4740 Listed.

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#### CERCLA (Superfund) reportable quantity

Sodium nitrite: 100

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Immediate Hazard - No Hazard categories Delayed Hazard - No

Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No

Section 302 extremely hazardous substance

Section 311 hazardous

No

chemical

State regulations

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

Sodium nitrite (7632-00-0) Listed

#### 16. Other Information

Further information This MSDS has been prepared in accordance with the ANSI Z400.1 format and complies with the

U.S. OSHA Hazard Communication Standard 29 CFR 1910.1200.

The Product name in Section 1 has been revised.

The Transport information in Section 14 has been revised.

1006 MSDS Number Version number

04-22-2010 Issue date Revision date 04-22-2010

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best information currently available to us. HOWEVER, WE MAKE NO WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR OF ANY OTHER TYPE, EXPRESSED OR IMPLIED, WITH RESPECT TO PRODUCTS DESCRIBED OR DATA OR INFORMATION PROVIDED, AND WE ASSUME NO LIABILITY RESULTING FROM THE USE OF SUCH PRODUCTS, DATA OR INFORMATION. Users should make their own investigations to determine the suitability of the information for their particular purposes, and the user assumes all risk arising from their use of the material. The user is required to comply with all laws and regulations relating to the purchase, use, storage and disposal of the material, and must be familiar with and follow generally accepted safe handling procedures. In no event shall Genzyme be liable for any claims, losses, or damages of any individual or for lost profits or any special, indirect, incidental, consequential or exemplary damages, howsoever arising, even if Genzyme

has been advised of the possibility of such damages.

Ultra Strep A REAG A MSDS US 5/5



# MATERIAL SAFETY DATA SHEET

### 1. Product and Company Identification

Product name Ultra Strep A REAG B

Synonym(s) OSOM® Ultra Strep A Extraction Reagent B

CAS # Mixture
Kit Number: 149

Product description Aqueous, acidic solution.

Product use Component of OSOM® Ultra Strep A Test kit. For the qualitative detection of Group A Streptococcal antigen directly from throat swab specimens. For In Vitro Diagnostic Use Only.

Corporate Headquarters <u>Manufacturer/Distributor</u> Emergency Telephone Numbers

 Genzyme Corporation
 Genzyme Diagnostics
 Genzyme (U.S.):
 617-562-4555

 500 Kendall Street
 6659 Top Gun Street
 CHEMTREC (U.S.):
 800-424-9300

 Cambridge, MA 02142 USA
 San Diego, CA 92121 USA
 CHEMTREC (Outside U.S.):
 +1 703-527-3887

www.genzyme.com www.genzymediagnostics.com
Phone: 617-252-7500 Phone: 858-452-3198

2. Hazards Identification

Regulatory status This preparation is classified as hazardous under U.S. OSHA 29 CFR 1910.1200.

This medical diagnostic kit is controlled under the Canadian Food and Drugs Act and is exempt from classification, labeling and MSDS requirements under the Canadian Hazardous Products Act

and Controlled Products Regulations.

Precautionary statements The chemical, physical and toxicological properties of this preparation have not been thoroughly

characterized. May be irritating to eyes, respiratory system and skin. Avoid contact with eyes and

skin. Do not ingest or inhale. Preparation appearance: clear, colorless liquid.

Potential health effects

 Inhalation
 Inhalation may be irritating to the nasal passages and throat.

 Eyes
 Eye exposure may cause irritation, redness, watering and pain.

Skin Prolonged skin contact may cause skin irritation with discomfort and rash.

Ingestion If large amounts are ingested, symptoms may include digestive irritation and discomfort.

Chronic effects Prolonged or repeated skin contact may cause chronic irritation.

Target organs Eyes and skin.

Potential environmental effects None expected.

# 3. Composition / Information on Ingredients

Components	CAS#	Percent	
Acetic acid	64-19-7	2	
Non-hazardous and other components below reportable levels		> 90	

#### 4. First Aid Measures

First aid procedures

Inhalation If inhaled, move from exposure area to fresh air. Seek medical attention if breathing becomes

difficult or if cough or other symptoms develop.

Eye contact Immediately flush eyes with plenty of tepid water for 15 minutes while separating eyelids with

fingers. Remove contact lenses if worn. Obtain immediate medical attention.

Skin contact In case of contact, flush skin with cool water and remove contaminated clothing. Obtain medical

attention if needed or if irritation or other symptoms develop.

Ingestion In case of ingestion, contact a poison control center or physician for instructions.

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#### 5. Fire Fighting Measures

Extinguishing media

Suitable extinguishing

media

Use extinguishing media suitable for surrounding fire, such as carbon dioxide, chemical foam, dry

chemical or water spray.

Unsuitable extinguishing

media

Unknown

Specific hazards Dilute aqueous solution not considered a fire hazard.

Hazardous combustion

products

When heated to decomposition, may produce carbon dioxide (CO2) and carbon monoxide (CO).

Protection of firefighters

Protective equipment and precautions for firefighters Firefighters should wear NIOSH-approved or equivalent Self-Contained Breathing Apparatus and

full protective gear.

#### 6. Accidental Release Measures

Personal precautions Wear Personal Protective Equipment (PPE) as indicated in Section 8. Ensure adequate

ventilation. Avoid physical contact with material and avoid aerosol inhalation. Wash hands

thoroughly after handling.

Environmental precautions

No special environmental precautions required.

Methods for cleaning up

Absorb spill with inert material/sorbent or appropriate neutralizing agent. Decontaminate the spill site following standard procedures. Dispose of materials in accordance with all applicable federal,

state, local and provincial environmental regulations, per Section 13.

#### 7. Handling and Storage

Handling Follow good laboratory hygiene practices. See Section 8, Engineering Controls. Mixing Strep A

Reagents A and B yields nitrous acid, which may immediately decompose into toxic nitrous gas, a

short-term reaction by-product. Avoid vapor or aerosol inhalation. Minimize contact and contamination of personal clothing and skin. Wash hands thoroughly after handling.

Store at 15 to 30°C (59 to 86°F). Keep container tightly closed. Do not store with incompatible Storage

substances; see Section 10.

# 8. Exposure Controls / Personal Protection

#### Occupational exposure limits

ACGIH

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

### U.S. - OSHA

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

Minimize potential for aerosolization. Handle within a containment system or with local exhaust Engineering controls

ventilation. Facilities storing or using this preparation should be equipped with an eyewash

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fountain and a safety shower.

Personal protective equipment

Respiratory protection A respirator is not expected to be required under normal conditions of use.

Eye / face protection Wear appropriate protective chemical safety goggles.

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

Wear chemical resistant protective gloves. Hand protection General Follow company-specific safety procedures.

# 9. Physical & Chemical Properties

Physical state Liquid. Color Clear, colorless

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Odor Sour, pungent odor like vinegar

Chemical family Acidic solution pΗ 2.6 (approximate) Not applicable Melting point Not available Freezing point Not available **Boiling point** Flash point Not available Evaporation rate Not available Not available. Flammability Not available

Flammability limits in air, upper, % by volume

Flammability limits in air,

Not available lower, % by volume

Not available Vapor pressure Vapor density Not available Not available Specific gravity Not available Relative density Solubility (water) Water-soluble Partition coefficient Not available

(n-octanol/water)

Not applicable Auto-ignition temperature Not available Decomposition temperature Viscosity Not available

### 10. Chemical Stability & Reactivity Information

Reactivity Mixing Strep A Reagents A and B yields nitrous acid, which may immediately decompose into

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

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

Possibility of hazardous

Conditions to avoid

reactions

Hazardous polymerization will not occur.

Incompatible materials Avoid strong oxidizing agents, most common metals (except aluminum), strong bases and

None known.

Hazardous decomposition

products

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

### 11. Toxicological Information

Routes of exposure Occupational exposure routes may include inhalation, eye and skin contact.

Toxicological data

Components Test Results

Acetic acid (64-19-7) Acute Dermal LD50 Rabbit: 1060 mg/kg

Acute Inhalation LC50 Guinea pig: 5000 mg/l 1 Hours

Acute Oral LD50 Rat: 3530 mg/kg

Local effects

Eye irritation

Acetic acid (64-19-7) Eye irritation has been noted at a concentration below 10 ppm. Irritating Acetic acid (64-19-7) Irritating

Skin Irritation Acetic acid (64-19-7)

Strongly Irritating

Chronic effects Prolonged or repeated skin contact may cause dermatitis.

Carcinogenicity No data available. Mutagenicity No data available. Reproductive effects No data available.

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No data available. Teratogenicity Sensitization No data available.

### 12. Ecological Information

Ecotoxicological data

Components Test Results

Acetic acid (64-19-7) EC50 Water flea (Daphnia magna): 65 mg/l 48 hours

LC50 Bluegill (Lepomis macrochirus): 75 mg/l 96 hours

Mobility in environmental

No data available.

Persistence / degradability No data available. Bioaccumulation No data available.

13. Disposal Considerations

Disposal instructions Dispose of unused product, spilled material and waste in accordance with all applicable federal,

state, local and provincial environmental and hazardous waste regulations.

### 14. Transport Information

DOT

Not regulated as hazardous goods.

### 15. Regulatory Information

US federal regulations This preparation is a component of an FDA-regulated in vitro diagnostic device.

US CAA Section 111 Volatile Organic Compounds: Listed substance

Acetic acid (64-19-7) Listed US CERCLA Hazardous Substances: Listed substance Acetic acid (64-19-7) US CERCLA Hazardous Substances: Reportable quantity Acetic acid (64-19-7) 5000 LBS

US CWA Section 311 Hazardous Substances: Listed substance Acetic acid (64-19-7) Listed.

US CWA Section 311 Reporting Quantities of Hazardous Substances: Listed substance

Acetic acid (64-19-7) Listed.

US CWA Section 311 Reporting Quantities of Hazardous Substances: Reportable quantity

Acetic acid (64-19-7) 5000 LBS US OSHA Hazard Communication Standard: Listed substance Acetic acid (64-19-7)

US TSCA Inventory: Registration Status

Acetic acid (64-19-7) Listed.

### CERCLA (Superfund) reportable quantity

Acetic acid: 5000

### 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 No hazardous substance

Section 311 hazardous

chemical

### State regulations

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

Acetic acid (64-19-7)

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#### 16. Other Information

Further information This MSDS has been prepared in accordance with the ANSI Z400.1 format and complies with the

U.S. OSHA Hazard Communication Standard 29 CFR 1910.1200.

The Product name in Section 1 has been revised.

The Transport information in Section 14 has been revised.

MSDS Number 1007 Version number 06

Issue date 04-22-2010 Revision date 04-22-2010

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has been advised of the possibility of such damages.

 Ultra Strep A REAG B
 M8DS Us

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