

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

1.1. Product identifier

Trade name or designation of the mixture	Strep A CONTROL +
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
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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.

Storage	None.
Disposal	None.
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	26628-22-8 247-852-1	-	011-004-00-7	#
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

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.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel	Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless 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	Type	Value
Sodium azide (26628-22-8)	STEL	0.3 mg/m ³
	TWA	0.1 mg/m ³

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

Components	Type	Value
Sodium azide (26628-22-8)	STEL	0.3 mg/m ³
	TWA	0.1 mg/m ³

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 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.

Odour	Not available.
Odour threshold	Not available.
pH	7.2 Approximate
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Not applicable.
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.
Relative density	Not available.
Solubility(ies)	Not available.
Partition coefficient (n-octanol/water)	Not applicable.
Decomposition temperature	Not available.
Viscosity	Not applicable.
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 reactions	Contact with acids liberates toxic gas.
10.4. Conditions to avoid	Heat, sparks, flames, elevated temperatures.
10.5. Incompatible materials	Strong oxidising agents.
10.6. Hazardous decomposition products	No data available.

SECTION 11: Toxicological information

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

Information on likely routes of exposure

Ingestion	May cause discomfort if swallowed.
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	Species	Test results
Sodium azide (26628-22-8)		
Acute		
<i>Dermal</i>		
LD50	Rabbit	20 mg/kg
<i>Oral</i>		
LD50	Rat	27 mg/kg
Skin corrosion/irritation	May cause skin irritation.	
Serious eye damage/irritation	May cause eye irritation.	

Respiratory sensitization	Not classified.
Skin sensitization	Not classified.
Germ cell mutagenicity	Not classified.
Carcinogenicity	Not classifiable as to carcinogenicity to humans.
Reproductive toxicity	Not classified.
Specific target organ toxicity - single exposure	Not classified.
Specific target organ toxicity - repeated exposure	Not classified.
Aspiration hazard	Not classified.
Mixture versus substance information	Not available.
Other information	No other specific acute or chronic health impact noted.

SECTION 12: Ecological information

12.1. Toxicity 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.

Components		Species	Test results
Sodium azide (26628-22-8)			
Aquatic			
Crustacea	EC50	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 n-octanol/water (log Kow) Not applicable.

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

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

Not listed.

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)

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

Follow training instructions when handling this material.

Disclaimer

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

1.1. Product identifier

Trade name or designation of the mixture	Strep A CONTROL -
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
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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.

Storage	None.
Disposal	None.
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	26628-22-8 247-852-1	-	011-004-00-7	#
Classification:	DSD: T+;R28, R32, N;R50/53				
	CLP: Acute Tox. 2;H300, Aquatic Acute 1;H400, Aquatic Chronic 1;H410				

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.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel	Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless 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	Type	Value
Sodium azide (26628-22-8)	STEL	0.3 mg/m ³
	TWA	0.1 mg/m ³

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

Components	Type	Value
Sodium azide (26628-22-8)	STEL	0.3 mg/m ³
	TWA	0.1 mg/m ³

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 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 Colourless, clear.

Odour	No data available.
Odour threshold	Not available.
pH	7.2 approx.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Not applicable.
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.
Relative density	Not available.
Solubility(ies)	Not available.
Partition coefficient (n-octanol/water)	Not applicable.
Decomposition temperature	Not available.
Viscosity	Not applicable.
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 reactions	Contact with acids liberates toxic gas.
10.4. Conditions to avoid	Heat, sparks, flames, elevated temperatures.
10.5. Incompatible materials	Strong oxidising agents.
10.6. Hazardous decomposition products	No data available.

SECTION 11: Toxicological information

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

Information on likely routes of exposure

Ingestion	May cause discomfort if swallowed.
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	Species	Test results
Sodium azide (26628-22-8)		
Acute		
<i>Dermal</i>		
LD50	Rabbit	20 mg/kg
<i>Oral</i>		
LD50	Rat	27 mg/kg
Skin corrosion/irritation	May cause skin irritation.	
Serious eye damage/irritation	May cause eye irritation.	

Respiratory sensitization	Not classified.
Skin sensitization	Not classified.
Germ cell mutagenicity	Not classified.
Carcinogenicity	Not classifiable as to carcinogenicity to humans.
Reproductive toxicity	Not classified.
Specific target organ toxicity - single exposure	Not classified.
Specific target organ toxicity - repeated exposure	Not classified.
Aspiration hazard	Not classified.
Mixture versus substance information	Not available.
Other information	No other specific acute or chronic health impact noted.

SECTION 12: Ecological information

12.1. Toxicity 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.

Components		Species	Test results
Sodium azide (26628-22-8)			
Aquatic			
Crustacea	EC50	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 n-octanol/water (log Kow) Not applicable.

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

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

Not listed.

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 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)

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

Follow training instructions when handling this material.

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.

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

1.1. Product identifier

Trade name or designation of the mixture	Strep A REAG 1
Registration number	-
Synonyms	None.
Kit number	141, 141E, 141E-20
Issue date	20-July-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 the qualitative detection of Group A Streptococcal antigen from throat swabs or confirmation of presumptive Group A Streptococcal colonies recovered from culture.
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
Contact person	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	T;R25
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The full text for all R-phrases is displayed in section 16.

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

Health hazards		
Acute toxicity, oral	Category 4	H302 - Harmful if swallowed.

Hazard summary

Physical hazards	Not classified for physical hazards.
Health hazards	Toxic if swallowed.
Environmental hazards	Not classified for hazards to the environment.
Specific hazards	May irritate eyes and skin.
Main symptoms	Ingestion may cause irritation and malaise.

2.2. Label elements

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

Contains:	Sodium nitrite
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Hazard pictograms



Signal word

Warning

Hazard statements

H302 - Harmful if swallowed.

Precautionary statements

Prevention

P264 - Wash thoroughly after handling.
P270 - Do not eat, drink or smoke when using this product.

Response

None.

Storage

None.

Disposal

None.

Supplemental label information

None.

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
Sodium nitrite	10 - 15	7632-00-0 231-555-9	-	007-010-00-4	
Classification:	DSD: O;R8, T;R25, N;R50				
	CLP: Ox. Sol. 3;H272, Acute Tox. 3;H301, Aquatic Acute 1;H400				

DSD: Directive 67/548/EEC.

CLP: Regulation No. 1272/2008.

Composition comments

The full text for all R- and H-phrases is displayed in section 16. All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

SECTION 4: First aid measures

General information

Not available.

4.1. Description of first aid measures

Inhalation

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

Skin contact

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

If material is ingested, immediately contact a physician or poison control centre.

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

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.

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.

SECTION 6: Accidental release measures**6.1. Personal precautions, protective equipment and emergency procedures**

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

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 the qualitative detection of Group A Streptococcal antigen from throat swabs or confirmation of presumptive Group A Streptococcal colonies recovered from culture.

SECTION 8: Exposure controls/personal protection**8.1. Control parameters**

Occupational exposure limits No exposure limits noted for ingredient(s).

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

Recommended monitoring procedures Follow standard monitoring procedures.

Derived No Effect Level (DNEL)

Components	Type	Route	Value	Form
Sodium nitrite (CAS 7632-00-0)	Workers	Inhalation	2 mg/m3	Acute exposure systemic effect
		Inhalation	2 mg/m3	Long term exposure systemic effects

Predicted no effect concentrations (PNECs)

Components	Type	Route	Value	Form
Sodium nitrite (CAS 7632-00-0)	Aqua (freshwater)	Not applicable	0.0054 mg/l	
	Aqua (intermittent releases)	Not applicable	0.0054 mg/l	
	Aqua (marine water)	Not applicable	0.0062 mg/l	
	Sediment (freshwater)	Not applicable	0.0195 mg/kg	
	Sediment (marine water)	Not applicable	0.0223 mg/kg	
	Sewage Treatment Plant	Not applicable	21 mg/l	
	Soil	Not applicable	0.0007 mg/kg	

8.2. Exposure controls

Appropriate engineering controls Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.

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 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.

Respiratory protection Under normal conditions, respirator is not normally required.

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	Clear pink liquid.
Physical state	Liquid.
Form	Liquid.
Colour	Clear pink.
Odour	Odourless.
Odour threshold	Not available.
pH	9 approx.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Not applicable.
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.
Relative density	1.08 approx.
Solubility(ies)	Soluble.
Partition coefficient (n-octanol/water)	Not available.
Decomposition temperature	Not available.
Viscosity	Not applicable.
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	Mixing Strep A Reagents 1 and 2 yields nitrous acid, which may immediately decompose into toxic nitrous gas, a short-term reaction by-product.
10.2. Chemical stability	Material is stable under normal conditions.
10.3. Possibility of hazardous reactions	Hazardous polymerisation does not occur.
10.4. Conditions to avoid	Solution is oxidized by air. Avoid high temperatures.
10.5. Incompatible materials	Amines. Reducing Agents.
10.6. Hazardous decomposition products	Thermal decomposition may lead to release of irritating gases and vapors.

SECTION 11: Toxicological information

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

Information on likely routes of exposure

Ingestion	Harmful if swallowed.
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	Harmful if swallowed. Sodium nitrite exposure may result in a drop in blood pressure, headache, vertigo, palpitations, visual disturbances, methemoglobinemia, dyspnea and respiratory depression.	
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Components	Species	Test results
Sodium nitrite (CAS 7632-00-0)		
Acute		
<i>Inhalation</i>		
LC50	Rat	5.5 mg/l, 4 Hours
<i>Oral</i>		
LD50	Rat	158 mg/kg
Skin corrosion/irritation	May cause skin irritation.	
Serious eye damage/irritation	May cause eye irritation.	
Respiratory sensitisation	Not classified.	
Skin sensitisation	Not classified.	
Germ cell mutagenicity	Not classified.	
Carcinogenicity	No data available.	
Reproductive toxicity	Not classified.	
Specific target organ toxicity - single exposure	Not classified.	
Specific target organ toxicity - repeated exposure	Not classified.	
Aspiration hazard	Not classified.	
Mixture versus substance information	Not available.	
Other information	No other specific acute or chronic health impact noted.	

SECTION 12: Ecological information

12.1. Toxicity	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.
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Components	Species	Test results
Sodium nitrite (CAS 7632-00-0)		
Aquatic		
Crustacea	EC50	Greasyback shrimp (<i>Metapenaeus ensis</i>)
		16.14 - 26.61 mg/l, 48 hours
Fish	LC50	Channel catfish (<i>Ictalurus punctatus</i>)
		0.048 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 n-octanol/water (log Kow)	Not available.	
Bioconcentration factor (BCF)	Not available.	
12.4. Mobility in soil	The product is soluble in water.	
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. 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.
EU waste code	Waste codes should be assigned by the user based on the application for which the product was used.
Disposal methods/information	Dispose in accordance with all applicable regulations.

SECTION 14: Transport information

ADR

14.1. UN number	UN1500
14.2. UN proper shipping name	Sodium nitrite
14.3. Transport hazard class(es)	5.1
Subsidiary class(es)	-
14.4. Packing group	III
14.5. Environmental hazards	No
Tunnel restriction code	E
Labels required	5.1 +6.1
14.6. Special precautions for user	Read safety instructions, SDS and emergency procedures before handling.

RID

14.1. UN number	UN1500
14.2. UN proper shipping name	Sodium nitrite
14.3. Transport hazard class(es)	5.1
Subsidiary class(es)	-
14.4. Packing group	III
14.5. Environmental hazards	No
Labels required	5.1+6.1
14.6. Special precautions for user	Read safety instructions, SDS and emergency procedures before handling.

ADN

14.1. UN number	UN1500
14.2. UN proper shipping name	Sodium nitrite
14.3. Transport hazard class(es)	5.1
Subsidiary class(es)	-
14.4. Packing group	III
14.5. Environmental hazards	No
Labels required	5.1+6.1
14.6. Special precautions for user	Read safety instructions, SDS and emergency procedures before handling.

IATA

14.1. UN number	UN1500
14.2. UN proper shipping name	Sodium nitrite
14.3. Transport hazard class(es)	5.1
Subsidiary class(es)	6.1
14.4. Packing group	III
14.5. Environmental hazards	No
Labels required	5.1+6.1
ERG Code	5P
14.6. Special precautions for user	Read safety instructions, SDS and emergency procedures before handling.

IMDG

14.1. UN number	UN1500
14.2. UN proper shipping name	Sodium nitrite
14.3. Transport hazard class(es)	5.1
Subsidiary class(es)	6.1
14.4. Packing group	III
14.5. Environmental hazards	
Marine pollutant	No
Labels required	5.1 +6.1
EmS No.	F-A, S-Q

14.6. Special precautions for user	Read safety instructions, SDS and emergency procedures before handling.
14.7. 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.

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	Not listed.
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.
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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 nitrite (CAS 7632-00-0)
Directive 94/33/EC on the protection of young people at work	Sodium nitrite (CAS 7632-00-0)

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.
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National regulations	The product has been classified according to the legislation in force.
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15.2. Chemical safety assessment	No Chemical Safety Assessment has been carried out.
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SECTION 16: Other information

List of abbreviations	DNEL: Derived No-Effect Level. PNEC: Predicted No-Effect Concentration. PBT: Persistent, bioaccumulative and toxic. vPvB: Very Persistent and very Bioaccumulative.
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References	Not available.
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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.

R8 Contact with combustible material may cause fire.
R25 Toxic if swallowed.
R50 Very toxic to aquatic organisms.
H272 - May intensify fire; oxidiser.
H301 - Toxic if swallowed.
H400 - Very toxic to aquatic life.

Training information

Follow training instructions when handling this material.

Disclaimer

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

1.1. Product identifier

Trade name or designation of the mixture	Strep A REAG 2
Registration number	-
Synonyms	None.
Kit number	141, 141E, 141E-20
Issue date	22-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 the qualitative detection of Group A Streptococcal antigen from throat swabs or confirmation of presumptive Group A Streptococcal colonies recovered from culture.
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

This preparation does not meet the criteria for classification according to Directive 1999/45/EC as amended.

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	Not classified for health hazards.
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.
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Response	None.
Storage	None.
Disposal	None.
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
Acetic acid	1 - < 3	64-19-7 200-580-7	-	607-002-00-6	#
Classification:	DSD: R10, C;R35 CLP: Flam. Liq. 3;H226, Skin Corr. 1A;H314				

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

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 None known.

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.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel	Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless 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.
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 the qualitative detection of Group A Streptococcal antigen from throat swabs or confirmation of presumptive Group A Streptococcal colonies recovered from culture.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits

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

Components	Type	Value
Acetic acid (64-19-7)	TWA	25 mg/m ³ 10 ppm

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

Recommended monitoring procedures Follow standard monitoring procedures.

Derived No Effect Level (DNEL)

Components	Type	Route	Value	Form
Acetic acid (64-19-7)	Workers	Inhalation	25 mg/m ³	Acute Local effects
		Inhalation	25 mg/m ³	Long term Local effects

Predicted no effect concentrations (PNECs)

Components	Type	Route	Value	Form
Acetic acid (64-19-7)	Aqua (freshwater)	Water	3.058 mg/l	
	Aqua (intermittent releases)	Water	30.58 mg/l	
	Aqua (marine water)	Water	0.3058 mg/l	
	Sediment (freshwater)	Not applicable	11.36 mg/kg	
	Sediment (marine water)	Not applicable	1.136 mg/kg	
	Sewage Treatment Plant	Not applicable	85 mg/l	
	Soil	Soil	0.47 mg/kg	

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 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	Colourless, clear.
Odour	No data available.
Odour threshold	Not available.
pH	2.6
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Not applicable.
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.
Relative density	Not available.
Solubility(ies)	Soluble.
Partition coefficient (n-octanol/water)	Not applicable.
Decomposition temperature	Not available.
Viscosity	Not applicable.
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	Mixing Strep A Reagents 1 and 2 yields nitrous acid, which may immediately decompose into toxic nitrous gas, a short-term reaction by-product.
10.2. Chemical stability	Material is stable under normal conditions.
10.3. Possibility of hazardous reactions	Polymerization will not occur.
10.4. Conditions to avoid	Heat, sparks, flames, elevated temperatures.
10.5. Incompatible materials	Strong oxidising agents.
10.6. Hazardous decomposition products	No data available.

SECTION 11: Toxicological information

General information	Occupational exposure to the substance or mixture may cause adverse effects.
Information on likely routes of exposure	
Ingestion	May cause discomfort if swallowed.
Inhalation	In high concentrations, vapours may be irritating to the respiratory system.
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	Species	Test results
Acetic acid (64-19-7)		
Acute		
<i>Dermal</i>		
LD50	Rabbit	1060 mg/kg
<i>Inhalation</i>		
LC50	Rat	11.4 mg/l, 4 Hours
<i>Oral</i>		
LD50	Rat	3.31 g/kg
Skin corrosion/irritation	May cause skin irritation.	
Serious eye damage/irritation	May cause eye irritation.	
Respiratory sensitization	Not classified.	
Skin sensitization	Not classified.	
Germ cell mutagenicity	Not classified.	
Carcinogenicity	Not classified.	
Reproductive toxicity	Not classified.	
Specific target organ toxicity - single exposure	Not classified.	
Specific target organ toxicity - repeated exposure	Not classified.	
Aspiration hazard	Not classified.	
Mixture versus substance information	Not available.	
Other information	No other specific acute or chronic health impact noted.	

SECTION 12: Ecological information

12.1. Toxicity 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.

Components	Species	Test results
Acetic acid (64-19-7)		
Aquatic		
Crustacea	EC50	Water flea (Daphnia magna) 65 mg/l, 48 hours
Fish	LC50	Bluegill (Lepomis macrochirus) 75 mg/l, 96 hours
		Fathead minnow (Pimephales promelas) 79 mg/l, 96 Hours
12.2. Persistence and degradability	No data is available on the degradability of this product.	
12.3. Bioaccumulative potential	Not available.	
Partition coefficient n-octanol/water (log Kow)	Not applicable.	
Acetic acid	-0.17	
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	Empty containers should be taken to an approved waste handling site for recycling or disposal.
EU waste code	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.

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.

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

Not listed.

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

Acetic acid (CAS 64-19-7)

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

Acetic acid (CAS 64-19-7)

Other regulations

This product does not meet the criteria for classification according to Regulation (EC) 1272/2008 (CLP Regulation) and Directive 1999/45/EC 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
15.2. Chemical safety assessment

The product has not been classified as dangerous according to the legislation in force.
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.
PBT: Persistent, bioaccumulative and toxic.
vPvB: Very Persistent and very Bioaccumulative.

References

Not available.

Information on evaluation method leading to the classification of mixture

The classification for health and environmental hazards is derived by a combination of calculation methods and test data, if available.

Full text of any statements or R-phrases and H-statements under Sections 2 to 15

R10 Flammable.
R35 Causes severe burns.

H226 - Flammable liquid and vapour.
H314 - Causes severe skin burns and eye damage.

Training information

Follow training instructions when handling this material.

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