SAFETY DATA SHEET

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

1.1. Product identifier

Trade name or designation of the mixture	Ultra Strep A REAG A
Registration number	-
Synonyms	None.
Product code	147, 148, 149
Issue date	14-December-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
Contact person	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	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	O;R7, T;R25

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	May cause fire.
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

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 P301 + P312 - IF SWALLOWED: Call a POISON CENTRE or doctor/physician if you feel unwell.
P330 - Rinse mouth.

Storage None.

Disposal P501 - Dispose of contents/container in accordance with local/regional/national/international regulations.

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 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 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.
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	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.

Components	Species	Test results
Sodium nitrite (CAS 7632-00-0)		
Acute		
Inhalation		
LC50	Rat	5.5 mg/l, 4 Hours
Oral		
LD50	Rat	158 mg/kg

Skin corrosion/irritation May cause skin irritation.

Serious eye damage/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.

Components		Species	Test results
Sodium nitrite (CAS 7632-00-0)			
Aquatic			
Crustacea	EC50	Greasyback shrimp (Metapenaeus ensis)	16.14 - 26.61 mg/l, 48 hours
Fish	LC50	Channel catfish (Ictalurus punctatus)	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	Not available.
Labels required	5.1 +6.1
14.6. Special precautions for user	Not available.

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	Not available.

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	Not available.

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	Not available.
Labels required	Not available.
ERG Code	5P
14.6. Special precautions for user	Not available.

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	Not available.
EmS	F-A, S-Q
14.6. Special precautions for user	Not available.
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.

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.
National regulations	The product has been classified 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. 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	R7 May cause fire. 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.
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