

SECTION 1: Identification

1.1. Identification

Product form : Mixture
 Product name : Ultra Strep A REAG A
 Product code : 149

1.2. Recommended use and restrictions on use

Use of the substance/mixture : For the qualitative detection of Group A Streptococcal antigen from throat swabs or confirmation of presumptive Group A Streptococcal colonies recovered from culture in vitro diagnostics
 Restrictions on use : Restricted to professional users

1.3. Supplier

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

1.4. Emergency telephone number

Emergency 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: Hazard(s) identification

2.1. Classification of the substance or mixture

GHS US classification

Acute toxicity (oral) Category 4 H302 Harmful if swallowed
 Full text of H statements : see section 16

2.2. GHS Label elements, including precautionary statements

GHS US labeling

Hazard pictograms (GHS US) :



Signal word (GHS US) : Warning
 Hazard statements (GHS US) : H302 - Harmful if swallowed
 Precautionary statements (GHS US) : P264 - Wash hands, forearms and face thoroughly after handling.
 P270 - Do not eat, drink or smoke when using this product.
 P301+P312 - If swallowed: Call a poison center or doctor if you feel unwell.
 P330 - Rinse mouth.
 P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

2.3. Other hazards which do not result in classification

No additional information available

2.4. Unknown acute toxicity (GHS US)

Not applicable

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SECTION 3: Composition/Information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	GHS US classification
sodium nitrite	(CAS No) 7632-00-0	10-20	Ox. Sol. 3, H272 Acute Tox. 3 (Oral), H301 Aquatic Acute 1, H400
2-amino-2-(hydroxymethyl)-1,3-propanediol, hydrochloride	(CAS No) 1185-53-1	1-5	Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335

Full text of hazard classes and H-statements : see section 16

SECTION 4: First-aid measures

4.1. Description of first aid measures

- First-aid measures general : Call a poison center or a doctor if you feel unwell.
First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing.
First-aid measures after skin contact : Wash skin with plenty of water.
First-aid measures after eye contact : Rinse eyes with water as a precaution.
First-aid measures after ingestion : Rinse mouth. Call a poison center or a doctor if you feel unwell.

4.2. Most important symptoms and effects (acute and delayed)

- Symptoms/effects after eye contact : May cause slight irritation.
Symptoms/effects after ingestion : Harmful if swallowed.

4.3. Immediate medical attention and special treatment, if necessary

Treat symptomatically.

SECTION 5: Fire-fighting measures

5.1. Suitable (and unsuitable) extinguishing media

- Suitable extinguishing media : Water spray. Dry powder. Foam. Carbon dioxide.

5.2. Specific hazards arising from the chemical

- Hazardous decomposition products in case of fire : Toxic fumes may be released.

5.3. Special protective equipment and precautions for fire-fighters

- Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

- Emergency procedures : Exercise caution. Spill area may be slippery.

6.1.2. For emergency responders

- Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

- Methods for cleaning up : Take up liquid spill into absorbent material.
Other information : Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

- Precautions for safe handling : Ensure good ventilation of the work station. Wear personal protective equipment.

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Hygiene measures : Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a well-ventilated place. Keep cool.
Storage temperature : 15 – 30 °C

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Ultra Strep A REAG A
No additional information available
2-amino-2-(hydroxymethyl)-1,3-propanediol, hydrochloride (1185-53-1)
No additional information available
sodium nitrite (7632-00-0)
No additional information available

8.2. Appropriate engineering controls

Appropriate engineering controls : Ensure good ventilation of the work station.
Environmental exposure controls : Avoid release to the environment.

8.3. Individual protection measures/Personal protective equipment

Hand protection:

Protective gloves

Type	Material	Permeation	Thickness (mm)	Penetration
Disposable gloves	Nitrile rubber (NBR)	6 (> 480 minutes)	0.11	

Eye protection:

Safety glasses

Skin and body protection:

Wear suitable protective clothing

Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment.

Personal protective equipment symbol(s):



SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Liquid
Appearance : Clear.
Color : pink
Odor : Odorless
Odor threshold : No data available
pH : ≈ 9
Melting point : Not applicable
Freezing point : No data available
Boiling point : No data available
Flash point : No data available
Relative evaporation rate (butyl acetate=1) : No data available

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Flammability (solid, gas)	: Not applicable.
Vapor pressure	: No data available
Relative vapor density at 20 °C	: No data available
Relative density	: ≈ 1.08
Solubility	: Soluble.
Partition coefficient n-octanol/water (Log Pow)	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosion limits	: No data available
Explosive properties	: Product is not explosive.
Oxidizing properties	: Not oxidising.

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

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

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity (oral)	: Harmful if swallowed.
Acute toxicity (dermal)	: Not classified
Acute toxicity (inhalation)	: Not classified

2-amino-2-(hydroxymethyl)-1,3-propanediol, hydrochloride (1185-53-1)

LD50 oral rat	> 5000 mg/kg
LD50 dermal rat	> 5000 mg/kg

sodium nitrite (7632-00-0)

LD50 oral rat	180 mg/kg body weight
ATE US (oral)	180 mg/kg body weight

Skin corrosion/irritation	: Not classified pH: ≈ 9
Serious eye damage/irritation	: Not classified pH: ≈ 9
Respiratory or skin sensitization	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
STOT-single exposure	: Not classified

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2-amino-2-(hydroxymethyl)-1,3-propanediol, hydrochloride (1185-53-1)

STOT-single exposure	May cause respiratory irritation.
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STOT-repeated exposure : Not classified

sodium nitrite (7632-00-0)

NOAEL (subchronic,oral,animal/male,90 days)	220 mg/kg body weight
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NOAEL (subchronic,oral,animal/female,90 days)	165 mg/kg body weight
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Aspiration hazard : Not classified

Viscosity, kinematic : No data available

Symptoms/effects after eye contact : May cause slight irritation.

Symptoms/effects after ingestion : Harmful if swallowed.

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : The product is not considered harmful to aquatic organisms or to cause long-term adverse effects in the environment.

2-amino-2-(hydroxymethyl)-1,3-propanediol, hydrochloride (1185-53-1)

LC50 fish 1	460 mg/l <i>Leuciscus idus</i> (golden orfe)
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sodium nitrite (7632-00-0)

LC50 fish 1	0.54 – 26.3 mg/l <i>Oncorhynchus mykiss</i> (<i>Salmo gairdneri</i>)
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EC50 <i>Daphnia</i> 1	15.4 mg/l <i>Daphnia magna</i>
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12.2. Persistence and degradability

2-amino-2-(hydroxymethyl)-1,3-propanediol, hydrochloride (1185-53-1)

Persistence and degradability	Readily biodegradable in water.
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sodium nitrite (7632-00-0)

Persistence and degradability	Biodegradable in water.
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12.3. Bioaccumulative potential

2-amino-2-(hydroxymethyl)-1,3-propanediol, hydrochloride (1185-53-1)

Bioaccumulative potential	No bioaccumulation data available.
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sodium nitrite (7632-00-0)

Partition coefficient n-octanol/water (Log Pow)	-3.7 (OECD 107: 25 °C)
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Bioaccumulative potential	Not bioaccumulative.
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12.4. Mobility in soil

sodium nitrite (7632-00-0)

Ecology - soil	No (test)data on mobility of the substance available.
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12.5. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Disposal methods

Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions.

SECTION 14: Transport information

Department of Transportation (DOT)

In accordance with DOT

Not applicable

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Transportation of Dangerous Goods

Not applicable

Transport by sea

Not applicable

Air transport

Not applicable

SECTION 15: Regulatory information

15.1. US Federal regulations

All components of this product are listed, or excluded from listing, on the United States Environmental Protection Agency Toxic Substances Control Act (TSCA) inventory

Contains chemical(s) subject to TSCA 12b export notification if product is shipped outside the U.S

sodium nitrite	CAS No 7632-00-0	10-20%
Chemical(s) subject to the reporting requirements of Section 313 or Title III of the Superfund Amendments and Reauthorization Act (SARA) of 1986 and 40 CFR Part 372.		
sodium nitrite	CAS No 7632-00-0	10-20%
sodium nitrite (7632-00-0)		
EPA TSCA Regulatory Flag	S - S - indicates a substance that is identified in a final Significant New Use Rule.	
CERCLA RQ	100 lb	

15.2. International regulations

CANADA

2-amino-2-(hydroxymethyl)-1,3-propanediol, hydrochloride (1185-53-1)
Listed on the Canadian DSL (Domestic Substances List) inventory.
sodium nitrite (7632-00-0)
Listed on the Canadian DSL (Domestic Substances List) inventory.

EU-Regulations

The following restrictions are applicable according to Annex XVII of the REACH Regulation (EC) No 1907/2006:

Reference code	Applicable	Entry title or description
3(b)	Ultra Strep A REAG A	Substances or mixtures fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008: Hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10

Contains no REACH candidate substance

Contains no REACH Annex XIV substances.

Contains no substance subject to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals.

Contains no substance(s) subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants

National regulations

No additional information available

15.3. US State regulations

Component	State or local regulations
sodium nitrite(7632-00-0)	U.S. - Delaware - Pollutant Discharge Requirements - Reportable Quantities; U.S. - New York City - Right to Know Hazardous Substances List

SECTION 16: Other information

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Revision date : 05/28/2020

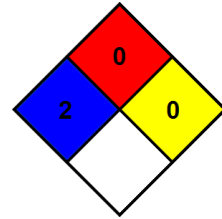
Full text of H-phrases:

H272	May intensify fire; oxidizer
H301	Toxic if swallowed
H302	Harmful if swallowed
H315	Causes skin irritation
H319	Causes serious eye irritation
H335	May cause respiratory irritation
H400	Very toxic to aquatic life

NFPA health hazard : 2 - Materials that, under emergency conditions, can cause temporary incapacitation or residual injury.

NFPA fire hazard : 0 - Materials that will not burn under typical fire conditions, including intrinsically noncombustible materials such as concrete, stone, and sand.

NFPA reactivity : 0 - Material that in themselves are normally stable, even under fire conditions.



Hazard Rating

Health : 2 Moderate Hazard - Temporary or minor injury may occur

Flammability : 0 Minimal Hazard - Materials that will not burn

Physical : 0 Minimal Hazard - Materials that are normally stable, even under fire conditions, and will NOT react with water, polymerize, decompose, condense, or self-react. Non-Explosives.

Personal protection : B
B - Safety glasses, Gloves

Indication of changes:

Section	Changed item	Change	Comments
2	GHS-US classification	Modified	
3	Composition/Information on ingredients	Modified	

SDS US (GHS HazCom 2012)

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