

### SECTION 1: Identification

#### 1.1. Identification

|              |                                       |
|--------------|---------------------------------------|
| Product form | : Mixture                             |
| Product name | : Strep A Extraction Reagent (Bottle) |
| Product code | : 147                                 |
| Synonyms     | : Extraction Reagent                  |

#### 1.2. Recommended use and restrictions on use

|                              |                                    |
|------------------------------|------------------------------------|
| Use of the substance/mixture | : 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. +1-800-565-0265  
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<br>Europe, Middle East & Africa +1-760-476-3961<br>Asia Pacific +1-760-476-3960<br>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.<br>P270 - Do not eat, drink or smoke when using this product.<br>P301+P312 - If swallowed: Call a poison center or doctor if you feel unwell.<br>P330 - Rinse mouth.<br>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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according to 29 CFR § 1910.1200, Hazard Communication Standard (HCS)

### 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<br>Acute Tox. 3 (Oral), H301<br>Aquatic Acute 1, H400 |
| 2-amino-2-(hydroxymethyl)-1,3-propanediol, hydrochloride | (CAS-No.) 1185-53-1 | 1-5   | Skin Irrit. 2, H315<br>Eye Irrit. 2, H319<br>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)

No additional information available

#### 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

|   |
|---|
| <b>Strep A Extraction Reagent (Bottle)</b>                                  |
| No additional information available   |
| <b>2-amino-2-(hydroxymethyl)-1,3-propanediol, hydrochloride (1185-53-1)</b> |
| No additional information available   |
| <b>sodium nitrite (7632-00-0)</b>   |
| 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 : Liquid.  
Color : No data available  
Odor : No data available  
Odor threshold : No data available  
pH : No data available  
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                                    | : Not applicable.           |
| Vapor pressure                                  | : No data available         |
| Relative vapor density at 20°C                  | : No data available         |
| Relative density                                | : No data available         |
| Solubility                                      | : Soluble.                  |
| Partition coefficient n-octanol/water (Log Pow) | : No data available         |
| Auto-ignition temperature                       | : No data available         |
| Decomposition temperature                       | : No data available         |
| No data available                               | : 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        |

| <b>2-amino-2-(hydroxymethyl)-1,3-propanediol, hydrochloride (1185-53-1)</b> |                                   |
|---|-----------------------------------|
| LD50 oral rat   | > 5000 mg/kg body weight OECD 425 |
| LD50 dermal rat   | > 5000 mg/kg body weight OECD 402 |
| <b>sodium nitrite (7632-00-0)</b>   |                                   |
| LD50 oral rat   | 180 mg/kg body weight             |
| LC50 Inhalation - Rat   | > 0.095 mg/l (4 h, 14 d)          |
| ATE US (oral)   | 180 mg/kg body weight             |

|                                   |                  |
|-----------------------------------|------------------|
| Skin corrosion/irritation         | : Not classified |
| Serious eye damage/irritation     | : Not classified |
| 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. |
|----------------------|-----------------------------------|

STOT-repeated exposure : Not classified

### sodium nitrite (7632-00-0)

|   |                       |
|---|-----------------------|
| NOAEL (subchronic,oral,animal/male,90 days) | 220 mg/kg body weight |
|---|-----------------------|

|   |                       |
|---|-----------------------|
| NOAEL (subchronic,oral,animal/female,90 days) | 165 mg/kg body weight |
|---|-----------------------|

Aspiration hazard : Not classified

Viscosity, kinematic : No data available

## 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 melanotus</i> |
|-----------------|--|

|                      |                                 |
|----------------------|---------------------------------|
| EC50 - Crustacea [1] | > 117 mg/l <i>Daphnia magna</i> |
|----------------------|---------------------------------|

### sodium nitrite (7632-00-0)

|                 |   |
|-----------------|---|
| LC50 - Fish [1] | 0.54 – 26.3 mg/l <i>Oncorhynchus mykiss</i> |
|-----------------|---|

|                      |                                |
|----------------------|--------------------------------|
| EC50 - Crustacea [1] | 15.4 mg/l <i>Daphnia magna</i> |
|----------------------|--------------------------------|

|             |  |
|-------------|--|
| ErC50 algae | > 100 mg/l (OECD 201: Alga, Growth Inhibition Test, 72 h, <i>Desmodesmus subspicatus</i> , Static system, Fresh water, Experimental value, Measured concentration) |
|-------------|--|

### 12.2. Persistence and degradability

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

|                               |   |
|-------------------------------|---|
| Persistence and degradability | Biodegradability in water: no data available. |
|-------------------------------|---|

### sodium nitrite (7632-00-0)

|                               |                         |
|-------------------------------|-------------------------|
| Persistence and degradability | Biodegradable in water. |
|-------------------------------|-------------------------|

|                              |                |
|------------------------------|----------------|
| Chemical oxygen demand (COD) | Not applicable |
|------------------------------|----------------|

|      |                |
|------|----------------|
| ThOD | Not applicable |
|------|----------------|

### 12.3. Bioaccumulative potential

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

|   |      |
|---|------|
| Partition coefficient n-octanol/water (Log Pow) | -3.6 |
|---|------|

|                           |                                    |
|---------------------------|------------------------------------|
| Bioaccumulative potential | No bioaccumulation data available. |
|---------------------------|------------------------------------|

### sodium nitrite (7632-00-0)

|   |                        |
|---|------------------------|
| Partition coefficient n-octanol/water (Log Pow) | -3.7 (OECD 107, 25 °C) |
|---|------------------------|

|                           |                      |
|---------------------------|----------------------|
| Bioaccumulative potential | Not bioaccumulative. |
|---------------------------|----------------------|

### 12.4. Mobility in soil

### sodium nitrite (7632-00-0)

|                |   |
|----------------|---|
| Ecology - soil | No (test)data on mobility of the substance available. |
|----------------|---|

### 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.

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according to 29 CFR § 1910.1200, Hazard Communication Standard (HCS)

### SECTION 14: Transport information

#### Department of Transportation (DOT)

In accordance with DOT

Not applicable

#### 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 present and listed as Active on the United States Environmental Protection Agency Toxic Substances Control Act (TSCA) inventory

|  |                   |        |
|--|-------------------|--------|
| 2-amino-2-(hydroxymethyl)-1,3-propanediol, hydrochloride | CAS-No. 1185-53-1 | 1-5%   |
| sodium nitrite   | CAS-No. 7632-00-0 | 10-20% |

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)

#### **sodium nitrite (7632-00-0)**

Listed on the Canadian DSL (Domestic Substances List)

##### EU-Regulations

Contains no substance(s) listed on REACH Annex XVII (Restriction Conditions)

Contains no substance(s) listed on the REACH Candidate List

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

##### National regulations

#### **sodium nitrite (7632-00-0)**

Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active

Listed on INSQ (Mexican National Inventory of Chemical Substances)

| 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

# Strep A Extraction Reagent (Bottle)

## Safety Data Sheet

according to 29 CFR § 1910.1200, Hazard Communication Standard (HCS)

according to 29 CFR § 1910.1200, Hazard Communication Standard (HCS)

Revision date : 04/02/2025

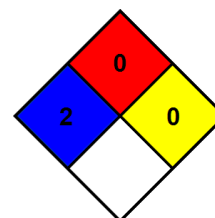
Full text of hazard classes and H-statements:

|      |                                  |
|------|----------------------------------|
| 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:

according to 29 CFR § 1910.1200, Hazard Communication Standard (HCS).

| Section | Changed item          | Change | Comments |
|---------|-----------------------|--------|----------|
| 16      | Indication of changes | Added  |          |

SDS US (GHS HazCom 2012)

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