SAFETY DATA SHEET

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1 of 4 SDS for CONSULT® Strep A Dipstick Test (MFR # 4999,5003)

PRODUCT NAME: STREP A RAPID, TEST STRIP

MFR #: 4999,5003

DISTRIBUTED BY: McKesson Medical-Surgical Inc.
9954 Mayland Drive, Suite 4000
Richmond, Virginia 23233

INFORMATION LINE: 1-800-777-4908
Monday – Friday 8:00 a.m. – 6:00 p.m. EST

EMERGENCY PHONE: 1-800-451-8346 (3E Company)  Day or Night

PRODUCT DESCRIPTION: N/A

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

2.2 Label elements No measures required.

2.3 Other hazards None anticipated.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixtures
Description: In vitro diagnostic reagent test device. Preparation. Laminated test strip consisting of solid support materials impregnated with dried chemical / biochemical reagents.

Dangerous components:
EC Classification No. 1272/2008 / GHS

<table>
<thead>
<tr>
<th>Hazardous ingredient(s)</th>
<th>%W/W</th>
<th>EC No.</th>
<th>CAS No.</th>
<th>Classification code: Hazard statement(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium carbonate</td>
<td>5 - 10</td>
<td>207-838-8</td>
<td>497-19-8</td>
<td>Eye Irrit. 2; H319</td>
</tr>
</tbody>
</table>

EC Classification No. 67/548/EEC

<table>
<thead>
<tr>
<th>Hazardous ingredient(s)</th>
<th>%W/W</th>
<th>EC No.</th>
<th>CAS No.</th>
<th>EC Classification and Risk Phrases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium carbonate</td>
<td>5 - 10</td>
<td>207-838-8</td>
<td>497-19-8</td>
<td>Xi; R36</td>
</tr>
</tbody>
</table>

3.3 Additional Information
For full text of R/H phrases see section 16.
Each device is packaged in a foil pouch.
SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General information

The following first aid measures are only relevant in the event of serious misuse, whereby the device is disassembled and there is exposure to the chemicals in the test strip.

Inhalation
Supply fresh air; consult doctor in case of complaint.

Skin Contact
Wash skin with soap and water. If exposed or concerned: Get medical advice/attention.

Eye Contact
Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If irritation develops and persists, get medical attention.

Ingestion
Wash out mouth with water. Consult a doctor.

4.2 Most important symptoms and effects, both acute and delayed

None.

4.3 Indication of the immediate medical attention and special treatment needed

None.

SECTION 5: FIRE-FIGHTING MEASURES

5.1 Extinguishing media

Suitable Extinguishing Media

CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

5.2 Special hazards arising from the substance or mixture

In case of fire, the following can be released: Hazardous fumes, Carbon oxides (COx), nitrogen oxides (NOx).

5.3 Advice for fire-fighters

Use fire-extinguishing methods suitable to surrounding conditions.
Wear full protective suit and self-contained breathing apparatus (SCBA) when extinguishing fires.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Refer to Section 8 for protective measures when handling the spillage.

6.2 Environmental precautions

Avoid release to the environment.

6.3 Methods and material for containment and cleaning up

Collect material and dispose of as waste according to Section 13.

6.4 Reference to other sections

8, 13

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Specimens should be handled as potentially infectious materials. Refer to EU directive 2000/54EC or US regulation 29 CFR 1910.1030 for information on handling biohazardous materials.
Avoid contact with the eyes, skin and mucous membranes.
Keep out of reach of children.
Wash hands before breaks and after work.
Clean work areas with hypochlorite or other disinfecting agent.

7.2 Conditions for safe storage, including any incompatibilities

Store in the original container at 2 to 30°C.

7.3 Specific end use(s)

Use as per instructions for use.
SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters
8.1.1 Occupational Exposure Limits
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

8.2 Exposure controls
8.2.1 Appropriate engineering controls
Not relevant for this material.

8.2.2 Personal protection equipment
Eye/face protection
Safety glasses recommended (EN166)

Hand protection
Disposable gloves (EN374)

Material of gloves: Latex / natural rubber, Nitrile rubber
Penetration time of glove material: Gloves resistance is not critical when the product is handled according to the instructions for use.
Body protection
Laboratory coat
Not normally required

8.2.3 Environmental Exposure Controls
No special measures are required.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties
Appearance Laminated test strip
Colour Variable depending on product
Odour No odour
Odour Threshold (ppm) Not applicable
pH (Value) Not determined
Melting Point (°C) / Freezing Point (°C) Not determined
Boiling point/boiling range (°C) Not determined
Flash Point (°C) Not applicable
Evaporation rate (BA = 1) Not applicable
Flammability (solid, gas) Not determined
Explosive limit ranges Not applicable
Vapour Pressure (mm Hg) Not applicable
Vapour Density (Air=1) Not applicable
Density (g/ml) Not applicable
Solubility (Water) Not determined
Solubility (Other) Not determined
Partition Coefficient (n-Octanol/water) Not determined
Auto Ignition Temperature (°C) Not determined
Decomposition Temperature (°C) Not determined
Viscosity (mPa.s) Not applicable
Explosive properties Not explosive
Oxidising properties Not oxidising

9.2 Other information
Not available

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity
None known

10.2 Chemical stability
The product is stable in accordance with the recommended storage conditions.

10.3 Possibility of hazardous reactions
None known. Hazardous polymerisation will not occur

10.4 Conditions to avoid
None

10.5 Incompatible materials
None known

10.6 Hazardous Decomposition Product(s)
None known
SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

11.1.2 Mixtures

- Acute toxicity: Based upon the available data, the classification criteria are not met.
- Irritation: Based upon the available data, the classification criteria are not met.
- Corrosivity: Based upon the available data, the classification criteria are not met.
- Sensitisation: Based upon the available data, the classification criteria are not met.
- Repeated dose toxicity: Based upon the available data, the classification criteria are not met.
- Carcinogenicity: Based upon the available data, the classification criteria are not met.
- Mutagenicity: Based upon the available data, the classification criteria are not met.
- Toxicity for reproduction: Based upon the available data, the classification criteria are not met.
- STOT-single exposure: Based upon the available data, the classification criteria are not met.
- STOT-repeated exposure: Based upon the available data, the classification criteria are not met.
- Aspiration hazard: Based upon the available data, the classification criteria are not met.

11.2 Other information

Not applicable

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

The product does not contain significant quantities of ingredients that are environmentally toxic.

12.2 Persistence and degradability

The device contains plastic and other components that are not readily degradable.

12.3 Bioaccumulative potential

None anticipated.

12.4 Mobility in soil

The product is predicted to have low mobility in soil.

12.5 Results of PBT and vPvB assessment

Not applicable.

12.6 Other adverse effects

Not applicable.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product:

Used devices and other contaminated materials should be disposed of as potentially biohazardous waste. Disposal should be in accordance with local, state or national legislation. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

European waste catalogue:

18 01 03.

Packaging:

Disposal should be in accordance with local, state or national legislation. Contaminated packaging must be disposed of in the same manner as the product. Non-contaminated packaging materials may be recycled. Contact your local service providers for further information.
SECTION 14: TRANSPORT INFORMATION

14.1 UN number
Not applicable

14.2 UN Proper Shipping Name
Not applicable

14.3 Transport hazard class(es)
Not classified as dangerous for transport.

14.4 Packing Group
Not applicable

14.5 Environmental hazards
Not applicable

14.6 Special precautions for user
Not applicable

14.7 Transport in bulk according to Annex Ilof MARPOL73/78 and the IBC Code
Not applicable

SECTION 15: REGULATORY INFORMATION

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

<table>
<thead>
<tr>
<th>Carcinogen listings</th>
</tr>
</thead>
<tbody>
<tr>
<td>IARC: None of the ingredients is listed.</td>
</tr>
<tr>
<td>NTP: None of the ingredients is listed.</td>
</tr>
<tr>
<td>ACGIH: None of the ingredients is listed.</td>
</tr>
<tr>
<td>OSHA: None of the ingredients is listed.</td>
</tr>
<tr>
<td>EPA: None of the ingredients is listed.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Californian Proposition 65</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemicals known to cause cancer: None of the ingredients is listed.</td>
</tr>
<tr>
<td>Chemicals known to cause reproductive toxicity: None of the ingredients is listed.</td>
</tr>
</tbody>
</table>

15.2 Chemical Safety Assessment
Not applicable.

SECTION 16: OTHER INFORMATION

LEGEND
STOT Specific Target Organ Toxicity

Classification code:

| Eye Irrit. 2 | Eye irritation; Category 2 |
| Xi | Irritant |

Hazard statement(s)

H319: Causes serious eye irritation.

Risk Phrases
R36: Irritating to eyes.

References: Raw material safety data sheets.

Additional Information


Supersedes: Version: 2

Prepared by: Dr. J. J. Tobin, ChemHaz Solutions, Email: info@chemhazsolutions.com
To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.
SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

2 of 4 SDS for CONSULT® Strep A Dipstick Test (MFR # 4999, 5003)

PRODUCT NAME: STREP A RAPID, POSITIVE CONTROL/NEGATIVE CONTROL

MFR #: 4999, 5003

DISTRIBUTED BY: McKesson Medical-Surgical Inc.
9954 Mayland Drive, Suite 4000
Richmond, Virginia 23233

INFORMATION LINE: 1-800-777-4908
Monday – Friday 8:00 a.m. – 6:00 p.m. EST

EMERGENCY PHONE: 1-800-424-9300 (CHEMTREC)
Day or night

PRODUCT DESCRIPTION: N/A

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture
Regulation (EC) No. 1272/2008 (CLP)
Not classified as hazardous.

Risk Phrases
R22: Harmful if swallowed.
OSHA Hazard Communication Standard29
CVR 1910.1200 (HazCom 2012) / GHS
Not classified as hazardous.

2.2 Label elements
No measures required.

2.3 Other hazards
None anticipated.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixtures
Description: In vitro diagnostic reagent. Aqueous solution.

Dangerous components:
EC Classification No. 1272/2008

<table>
<thead>
<tr>
<th>Hazardous ingredient(s)</th>
<th>CAS No.</th>
<th>EC No.</th>
<th>REACH Registration No.</th>
<th>Classification code: Hazard statement(s)</th>
<th>%W/W</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium azide*</td>
<td>26628-22-8</td>
<td>247-852-1</td>
<td>Not available</td>
<td>Acute Tox. 2; H300 Aquatic Acute 1; H400 Aquatic Chronic 1; H410 EUH032</td>
<td>0.1 – 0.2</td>
</tr>
</tbody>
</table>

EC Classification No. 67/548/EEC

<table>
<thead>
<tr>
<th>Hazardous ingredient(s)</th>
<th>CAS No.</th>
<th>EC No.</th>
<th>REACH Registration No.</th>
<th>EC Classification and Risk Phrases</th>
<th>%W/W</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium azide*</td>
<td>26628-22-8</td>
<td>247-852-1</td>
<td>Not available</td>
<td>T+, N; R28-32-50/53</td>
<td>0.1 – 0.2</td>
</tr>
</tbody>
</table>

* Substance with a community exposure limit.

3.3 Additional Information
For full text of R/H phrases see section 16.
Also contains non-viable Strep A or Strep C organisms.
SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures
Inhalation Supply fresh air; consult doctor in case of complaint.
Skin Contact Wash skin with soap and water. Remove contaminated clothing and wash clothing before reuse.
Eye Contact Rinse cautiously with water for several minutes. Consult a doctor in case of complaint.
Ingestion Wash out mouth with water. Consult a doctor.

4.2 Most important symptoms and effects, both acute and delayed
None.

4.3 Indication of the immediate medical attention and special treatment needed
None.

SECTION 5: FIRE-FIGHTING MEASURES

5.1 Extinguishing media
Suitable Extinguishing Media CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

5.2 Special hazards arising from the substance or mixture
In case of fire, the following can be released: Carbon oxides (COx), nitrogen oxides (NOx), phosphorous oxides (PxOy).

5.3 Advice for fire-fighters
Use fire-extinguishing methods suitable to surrounding conditions.
Wear full protective suit and self-contained breathing apparatus (SCBA) when extinguishing fires.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures
Refer to Section 8 for protective measures when handling the spillage.

6.2 Environmental precautions
Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up
Absorb with liquid-binding material (paper towelling, sand, diatomite, acid binders, universal binders, sawdust). Dispose of contaminated material as waste according to Section 13. Rinse off area with water.

6.4 Reference to other sections
8, 13

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling
Avoid contact with the eyes, skin and mucous membranes. Keep out of reach of children. Wash hands before breaks and after work.

7.2 Conditions for safe storage, including any incompatibilities
Store in the original container at 2 to 30°C.

7.3 Specific end use(s)
Use as per instructions for use.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

8.1.1 Occupational Exposure Limits
EU IOELV / UK EH40 / ACGIH TLV

<table>
<thead>
<tr>
<th>SUBSTANCE.</th>
<th>CAS No.</th>
<th>LTEL (8 hr TWA ppm)</th>
<th>LTEL (8 hr TWA mg/m³)</th>
<th>STEL (ppm)</th>
<th>STEL (mg/m³)</th>
<th>Note:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium Azide</td>
<td>26628-22-8</td>
<td>0.1</td>
<td>0.3</td>
<td>Sk</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Sk - Can be absorbed through skin.

8.2 Exposure controls

8.2.1 Appropriate engineering controls
Not relevant for this material.

8.2.2 Personal protection equipment

Eye/face protection
Safety glasses recommended. (EN166)

Hand protection
Disposable gloves. (EN374).

Material of gloves:
Latex / natural rubber, Nitrile rubber.

Penetration time of glove material:
Gloves resistance is not critical when the product is handled according to the instructions for use.

Body protection
Laboratory coat.

Respiratory protection
Not normally required.

8.2.3 Environmental Exposure Controls
No special measures are required.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance
Clear liquid.

Colour
Colourless.

Odour
Odourless

Odour Threshold (ppm)
Not determined.

pH (Value)
Not determined.

Melting Point (°C) / Freezing Point (°C)
Similar to water, approximately 0°C.

Boiling point/boiling range (°C):
Similar to water, approximately 100°C.

Flash Point (°C)
Not applicable.

Evaporation rate (BA = 1)
Not determined.

Flammability (solid, gas)
Not applicable.

Explosive limit ranges
Not applicable.

Vapour Pressure (Pascal)
Similar to water, approximately 23 hPa.

Vapour Density (Air=1)
Not determined.

Density (g/ml)
1.05

Solubility (Water)
Soluble.

Solubility (Other)
Not determined.

Partition Coefficient (n-Octanol/water)
Not determined.

Auto Ignition Temperature (°C)
Not determined.

Decomposition Temperature (°C)
Not determined.

Viscosity (mPa.s)
Not determined.

Explosive properties
Not explosive.

Oxidising properties
Not oxidising

9.2 Other information
Not available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity
None known.

10.2 Chemical stability
The product is stable in accordance with the recommended storage conditions.

10.3 Possibility of hazardous reactions
Preparation contains sodium azide, which may react with lead to form explosive compounds. Contact with acids may liberate trace amounts of toxic gas (hydrazoic acid). Hazardous polymerisation will not occur.

10.4 Conditions to avoid
None known.

10.5 Incompatible materials
Concentrated acids, heavy metals, metallic salts.

10.6 Hazardous Decomposition Product(s)
None known.
SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

11.1.2 Mixtures

Based upon the available data, the classification criteria are not met.

Acute toxicity

Irritation

Corrosivity

Sensitisation

Repeated dose toxicity

Carcinogenicity

Mutagenicity

Toxicity for reproduction

STOT-single exposure

STOT-repeated exposure

Aspiration hazard

Health Effects and Symptoms

Skin Contact

Eye Contact

Ingestion

No significant harmful effects anticipated.

No significant harmful effects anticipated.

No significant harmful effects anticipated.

Not applicable.

11.2 Other information

Not applicable.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

The product does not contain significant quantities of ingredients that are environmentally toxic.

12.2 Persistence and degradability

The product is biodegradable.

12.3 Bioaccumulative potential

None anticipated.

12.4 Mobility in soil

The product is predicted to have high mobility in soil.

12.5 Results of PBT and vPvB assessment

Not applicable.

12.6 Other adverse effects

Not applicable.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product:

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

European waste catalogue:

18 01 07.

Packaging:

Disposal should be in accordance with local, state or national legislation.
Packaging materials may be recycled. Contact your local service providers for further information.

SECTION 14: TRANSPORT INFORMATION

14.1 UN number  
Not applicable
14.2 UN Proper Shipping Name  
Not applicable
14.3 Transport hazard class(es)  
Not classified as dangerous for transport.
14.4 Packing Group  
Not applicable
14.5 Environmental hazards  
Not applicable
14.6 Special precautions for user  
Not applicable
14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code  
Not applicable

SECTION 15: REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
In Vitro diagnostics medical devices directive 98/79/EC.  
Consumer Product Safety Regulations 16 CFR 1600  
IVD Product Labelling 21 CFR 809  
Water hazard class: (Germany): 1

Carcinogen listings
IARC:  
None of the ingredients is listed.
NTP:  
None of the ingredients is listed.
ACGIH:  
None of the ingredients is listed.
OSHA:  
None of the ingredients is listed.
EPA:  
None of the ingredients is listed.

Californian Proposition 65
Chemicals known to cause cancer:  
None of the ingredients is listed.
Chemicals known to cause reproductive toxicity:  
None of the ingredients is listed.

SARA
Section 355 (extremely hazardous substances):  
Sodium azide.
Section 313 (specific toxic chemical listings):  
Sodium azide.

15.2 Chemical Safety Assessment  
Not applicable.

SECTION 16: OTHER INFORMATION

LEGEND
STOT  Specific Target Organ Toxicity
STEL  Short Term Exposure Limit
LTEL  Long Term Exposure limit
TWA  Time Weighted Average
TLV  Threshold Limit Value
ATE  Acute toxicity estimate

Classification code:
Acute Tox. 2  Acute toxicity: Category 2
Aquatic Acute 1  Acute Aquatic toxicity: Category 1
Aquatic Chronic 1  Chronic Aquatic toxicity: Category 1
T+  Very toxic.
N  Dangerous for the environment.

Hazard statement(s)
H300: Fatal if swallowed.
H400: Very toxic to aquatic life.
H410: Very toxic to aquatic life with long lasting effects.
EUH032: Contact with acids liberates very toxic gas.
Risk Phrases
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.

References:
Raw material safety data sheets.

Additional Information
Regulation (EC) No. 1272/2008 (CLP) & GHS.
Changes to all sections.

Supersedes: Version: 3

Prepared by: Dr. J. J. Tobin, ChemHaz Solutions, Email: info@chemhazsolutions.com

To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.
SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

3 of 4 SDS for CONSULT® Strep A Dipstick Test (MFR # 4999,5003)

PRODUCT NAME: STREP A RAPID, REAGENT A

MFR #: 4999, 5003

DISTRIBUTED BY: McKesson Medical-Surgical Inc.
9954 Mayland Drive, Suite 4000
Richmond, Virginia 23233

INFORMATION LINE: 1-800-777-4908
Monday – Friday 8:00 a.m. – 6:00 p.m. EST

EMERGENCY PHONE: 1-800-424-9300 (CHEMTREC)
Day or night

PRODUCT DESCRIPTION: N/A

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Regulation (EC) No. 1272/2008 (CLP)
Acute Tox. 4, Eye Irrit. 2
Hazard statement(s)
H302: Harmful if swallowed.
H319: Causes serious eye irritation.

Toxic
Risk Phrases:
R25: Toxic if swallowed.

OSHA Hazard Communication Standard 29
Acute Tox. 4, Eye Irrit. 2
CFR 1910.1200 (HazCom 2012) /GHS
Hazard statement(s)
Harmful if swallowed.
Causes serious eye irritation.

2.2 Label elements

Hazard pictogram(s)

Signal word(s)
WARNING
Hazard statement(s)
Harmful if swallowed.
Causes serious eye irritation.

Precautionary statement(s)
Keep out of the reach of children.
Wear protective gloves/protective clothing/eye protection/face protection.
If SWALLOWED: Call a POISON CENTRE or doctor/physician if you feel unwell.
If IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
If eye irritation persists, get medical advice/attention.

Hazardous component(s) for labelling
Sodium nitrite

2.3 Other hazards

None anticipated.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixtures
Description: *In vitro diagnostic reagent.* Aqueous preparation containing the hazardous components listed below.

### Dangerous components:

**EC Classification No. 1272/2008**

<table>
<thead>
<tr>
<th>Hazardous ingredient(s)</th>
<th>CAS No.</th>
<th>EC No.</th>
<th>REACH Registration No.</th>
<th>Classification code: Hazard statement(s)</th>
<th>%W/W</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium Nitrite</td>
<td>7632-00-0</td>
<td>231-555-9</td>
<td>Not available</td>
<td>Ox. Sol. 3; H272 Acute Tox. 3; H301 Eye Irrit. 2; H319 Aquatic Acute 1; H400</td>
<td>10 – 20</td>
</tr>
</tbody>
</table>

**EC Classification No. 67/548/EEC**

<table>
<thead>
<tr>
<th>Hazardous ingredient(s)</th>
<th>CAS No.</th>
<th>EC No.</th>
<th>REACH Registration No.</th>
<th>EC Classification and Risk Phrases</th>
<th>%W/W</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium Nitrite</td>
<td>7632-00-0</td>
<td>231-555-9</td>
<td>Not available</td>
<td>O, T, N; R 8-25-50</td>
<td>10 - 20</td>
</tr>
</tbody>
</table>

### 3.3 Additional Information

For full text of R/H phrases see section 16.

#### SECTION 4: FIRST AID MEASURES

4.1 **Description of first aid measures**

- **Inhalation**
  - Supply fresh air; consult doctor in case of complaint.

- **Skin Contact**
  - Wash affected skin with plenty of water. Remove contaminated clothing and wash clothing before reuse.

- **Eye Contact**
  - Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical advice/attention.

- **Ingestion**
  - Wash out mouth with water and give 200-300 ml (half a pint) of water to drink. Call a POISON CENTRE or doctor if you feel unwell.

4.2 **Most important symptoms and effects, both acute and delayed**

- Cyanosis, Narcosis, Nausea, Unconsciousness.

4.3 **Indication of the immediate medical attention and special treatment needed**

- Treat symptomatically – sodium nitrite poisoning. Activated charcoal (10%Slurry).

#### SECTION 5: FIRE-FIGHTING MEASURES

5.1 **Extinguishing media**

- Suitable Extinguishing Media: CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

5.2 **Special hazards arising from the substance or mixture**

- In case of fire, the following can be released: nitrogen oxides (NOx).

5.3 **Advice for fire-fighters**

- Use fire-extinguishing methods suitable to surrounding conditions.

- Wear full protective suit and self-contained breathing apparatus (SCBA) when extinguishing fires.

5.4 **Additional Information**

- Non-combustible.

#### SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 **Personal precautions, protective equipment and emergency procedures**

- Isolate spillage and clean up immediately. Refer to Section 8 for protective measures when handling the spillage.

6.2 **Environmental precautions**

- Do not allow to enter drains, sewers or watercourses.

6.3 **Methods and material for containment and cleaning up**

- Adsorb spillages onto sand, earth or any suitable absorbent material. Collect material and dispose of as waste according to Section 13. Rinse off area with water.
SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling
Avoid contact with the eyes, skin and mucous membranes.
Keep out of reach of children.
Wash hands before breaks and after work.

7.2 Conditions for safe storage, including any incompatibilities
Store in the original container at 2 to 30°C.

7.3 Specific end use(s)
Use as per instructions for use.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters
8.1.1 Occupational Exposure Limits
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

8.2 Exposure controls
8.2.1 Appropriate engineering controls
Not relevant for this material.

8.2.2 Personal protection equipment
Eye/face protection
Safety glasses (EN166)

Hand protection
Disposable gloves (EN374).

Material of gloves:
Latex / natural rubber, Nitrile rubber.
Penetration time of glove material:
Gloves resistance is not critical when the product is handled according to the instructions for use.

Body protection
Laboratory coat.
Respiratory protection
Not normally required.

8.2.3 Environmental Exposure Controls
No special measures are required.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties
Appearance
Liquid.
Colour
Red.
Odour
No odour.
Odour Threshold (ppm)
Not applicable.
pH (Value)
6.9
Melting Point (°C) / Freezing Point (°C):
Similar to water, approximately 0°C.
Boiling point/boiling range (°C):
Similar to water, approximately 100°C.
Flash Point (°C)
Not applicable.
Evaporation rate (BA = 1)
Not determined.
Flammability (solid, gas)
Not applicable.
 Explosive limit ranges
Not applicable.
Vapour Pressure (Pascal)
Similar to water, approximately 23 hPa.
Vapour Density (Air=1)
Not determined.
Density (g/ml)
1.08
Solubility (Water)
Miscible.
Solubility (Other)
Not determined.
Partition Coefficient (n-Octanol/water)
Not determined.
Auto Ignition Temperature (°C)
Not determined.
Decomposition Temperature (°C)
Not determined.
Viscosity (mPa.s)
Not determined.
Explosive properties
Not explosive.
Oxidising properties
Not oxidising.

9.2 Other information
Not available.
**SECTION 10: STABILITY AND REACTIVITY**

10.1 Reactivity
None known.

10.2 Chemical stability
The product is stable in accordance with the recommended storage conditions.

10.3 Possibility of hazardous reactions
None known. Hazardous polymerisation will not occur.

10.4 Conditions to avoid
None.

10.5 Incompatible materials
None known.

10.6 Hazardous Decomposition Product(s)
None known.

**SECTION 11: TOXICOLOGICAL INFORMATION**

11.1 Information on toxicological effects

11.1.1 Substances

Acute toxicity
Sodium nitrite
LD₅₀ (oral, rat): 85 – 180 mg/kg
LD₅₀ (Inhalation, rat): 5.5 mg/l/4hr
LD₅₀ (oral, Human): 1 – 2 g

11.1.2 Mixtures

Acute toxicity
Harmful if swallowed. ATE calculated: LD₅₀ (oral, rat): 616 – 1,324 mg/kg
Irritation
Causes serious eye irritation.
Corrosivity
Based upon the available data, the classification criteria are not met.
Sensitisation
Based upon the available data, the classification criteria are not met.
Repeated dose toxicity
Based upon the available data, the classification criteria are not met.
Carcinogenicity
Based upon the available data, the classification criteria are not met.
Mutagenicity
Based upon the available data, the classification criteria are not met.
Toxicity for reproduction
Based upon the available data, the classification criteria are not met.
STOT-single exposure
Based upon the available data, the classification criteria are not met.
STOT-repeated exposure
Based upon the available data, the classification criteria are not met.
Aspiration hazard
Based upon the available data, the classification criteria are not met.

Health Effects and Symptoms
Skin Contact
Can be absorbed through skin causing systemic toxic effects.
Eye Contact
Causes serious eye irritation.
Ingestion
Cyanosis, Nausea, Narcosis, Unconsciousness, spasms of abdominal pain, rapid heart beat, irregular breathing, coma, and convulsions, which can ultimately lead to death due to circulatory collapse.

11.2 Other information
Not applicable

**SECTION 12: ECOLOGICAL INFORMATION**

12.1 Toxicity
Sodium nitrite
LC₅₀ (96h, Fish): 0.19 mg/l
EC₅₀ (48h, Daphnia magna): 66 mg/l
Based upon the available data, the classification criteria are not met.
Mixture: LC₅₀ (96h, Fish) calculated: 1.38 mg/l
### SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods
- **Product:** Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.
- **European waste catalogue:** 18 01 06.
- **Packaging:** Disposal should be in accordance with local, state or national legislation. Contaminated packaging must be disposed of in the same manner as the product. Non-contaminated packaging materials may be recycled. Contact your local service providers for further information.

### SECTION 14: TRANSPORT INFORMATION

14.1 UN number Not applicable
14.2 UN Proper Shipping Name Not applicable
14.3 Transport hazard class(es) Not classified as dangerous for transport.
14.4 Packing Group Not applicable
14.5 Environmental hazards Not applicable
14.6 Special precautions for user Not applicable
14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code Not applicable

### SECTION 15: REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- **Carcinogen listings**
  - **IARC:** None of the ingredients is listed.
  - **NTP:** None of the ingredients is listed.
  - **ACGIH:** None of the ingredients is listed.
  - **OSHA:** None of the ingredients is listed.
  - **EPA:** None of the ingredients is listed.
- **California Proposition 65**
  - Chemicals known to cause cancer: None of the ingredients is listed.
  - Chemicals known to cause reproductive toxicity: None of the ingredients is listed.
- **SARA**
  - Section 355 (extremely hazardous substances): None of the ingredients is listed.
  - Section 313 (specific toxic chemical listings): Sodium nitrite.
15.2 Chemical Safety Assessment Not applicable.
**SECTION 16: OTHER INFORMATION**

**Legend**

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>STOT</td>
<td>Specific Target Organ Toxicity</td>
</tr>
<tr>
<td>ATE</td>
<td>Acute toxicity estimate</td>
</tr>
</tbody>
</table>

**Classification code:**

| Ox. Sol. 3 | Oxidising solid, Category 3 |
| Acute Tox. 3 | Acute toxicity; Category 3 |
| Acute Tox. 4 | Acute toxicity; Category 4 |
| Aquatic Acute 1 | Hazardous to the aquatic environment Acute: Category 1 |

**Hazard statement(s):**

- H272: May intensify fire; oxidizer.
- H301: Toxic if swallowed.
- H302: Harmful if swallowed.
- H319: Causes serious eye irritation.
- H400: Very toxic to aquatic life.

**Risk Phrases:**

- R8: Contact with combustible material may cause fire.
- R25: Toxic if swallowed.
- R50: Very toxic to aquatic organisms.

**References:**

Raw material safety data sheets.

**Additional Information**

Reason for update:


Supersedes:

Version: 3

Prepared by: Dr. J. J. Tobin, ChemHaz Solutions, Email: info@chemhazsolutions.com

To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.
SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

4 of 4 SDS for CONSULT® Strep A Dipstick Test (MFR # 4999,5003)

PRODUCT NAME: STREP A RAPID, REAGENT B

MFR #: 4999, 5003

DISTRIBUTED BY: McKesson Medical-Surgical Inc.
9954 Mayland Drive, Suite 4000
Richmond, Virginia 23233

INFORMATION LINE: 1-800-777-4908
Monday – Friday 8:00 a.m. – 6:00 p.m. EST

EMERGENCY PHONE: 1-800-424-9300 (CHEMTREC)
Day or night

PRODUCT DESCRIPTION: N/A

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

2.2 Label elements Safety data sheet available on request

2.3 Other hazards None anticipated.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixtures
Description: In vitro diagnostic reagent. Aqueous solution.

Dangerous components:

EC Classification No. 1272/2008

<table>
<thead>
<tr>
<th>Hazardous ingredient(s)</th>
<th>CAS No.</th>
<th>EC No.</th>
<th>REACH Registration No.</th>
<th>Classification code: Hazard statement(s)</th>
<th>%W/W</th>
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</thead>
<tbody>
<tr>
<td>Acetic acid</td>
<td>64-19-7</td>
<td>200-580-7</td>
<td>Not available</td>
<td>Flam. Liq. 3; H226 Skin Corr. 1A, H314</td>
<td>1 - 2</td>
</tr>
</tbody>
</table>

EC Classification No. 67/548/EEC

<table>
<thead>
<tr>
<th>Hazardous ingredient(s)</th>
<th>CAS No.</th>
<th>EC No.</th>
<th>REACH Registration No.</th>
<th>EC Classification and Risk Phrases</th>
<th>%W/W</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetic acid</td>
<td>64-19-7</td>
<td>200-580-7</td>
<td>Not available</td>
<td>C; R10-35</td>
<td>1 - 2</td>
</tr>
</tbody>
</table>

3.3 Additional Information For full text of R/H phrases see section 16.
SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures
Inhalation Supply fresh air; consult doctor in case of complaint.
Skin Contact Wash skin with soap and water. Remove contaminated clothing and wash clothing before reuse.
Eye Contact Rinse cautiously with water for several minutes. Consult a doctor in case of complaint.
Ingestion Wash out mouth with water. Consult a doctor in case of complaint.

4.2 Most important symptoms and effects, both acute and delayed
May cause transient irritation - Eyes.

4.3 Indication of the immediate medical attention and special treatment needed
None.

SECTION 5: FIRE-FIGHTING MEASURES

5.1 Extinguishing media
Suitable Extinguishing Media CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

5.2 Special hazards arising from the substance or mixture
In case of fire, the following can be released: Carbon oxides (COx), acetic acid vapours.

5.3 Advice for fire-fighters
Use fire-extinguishing methods suitable to surrounding conditions.
Wear full protective suit and self-contained breathing apparatus (SCBA) when extinguishing fires.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures
Refer to Section 8 for protective measures when handling the spillage.

6.2 Environmental precautions
Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up
Absorb with liquid-binding material (paper towelling, sand, diatomite, acid binders, universal binders, sawdust). Dispose of contaminated material as waste according to Section 13. Rinse off area with water.

6.4 Reference to other sections
8, 13

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling
Avoid contact with the eyes, skin and mucous membranes. Keep out of reach of children. Wash hands before breaks and after work.

7.2 Conditions for safe storage, including any incompatibilities
Store in the original container at 2 to 30°C.

7.3 Specific end use(s)
Use as per instructions for use.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

8.1.1 Occupational Exposure Limits

<table>
<thead>
<tr>
<th>SUBSTANCE</th>
<th>CAS No.</th>
<th>LTEL (8 hr TWA ppm)</th>
<th>LTEL (8 hr TWA mg/m³)</th>
<th>STEL (ppm)</th>
<th>STEL (mg/m³)</th>
<th>Note</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetic Acid</td>
<td>64-19-7</td>
<td>10</td>
<td>25</td>
<td>15</td>
<td>37</td>
<td>US PEL (IRL OELV ACGIH TLV)</td>
</tr>
<tr>
<td>------------</td>
<td>---------</td>
<td>-----</td>
<td>----</td>
<td>----</td>
<td>----</td>
<td>-----------------------------</td>
</tr>
</tbody>
</table>

8.2 Exposure controls
8.2.1 Appropriate engineering controls
Not relevant for this material.

8.2.2 Personal protection equipment

- Eye/face protection: Safety glasses recommended. (EN166)
- Hand protection: Disposable gloves. (EN374).

Material of gloves: Latex / natural rubber, Nitrile rubber.
Penetration time of glove material: Gloves resistance is not critical when the product is handled according to the instructions for use.
Body protection: Laboratory coat.
Respiratory protection: Not normally required.

8.2.3 Environmental Exposure Controls
No special measures are required.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties
- Appearance: Clear liquid.
- Colour: Colourless.
- Odour: Characteristic.
- Odour Threshold (ppm): Not determined.
- pH (Value): ~ 2.5
- Melting Point (°C) / Freezing Point (°C): Similar to water, approximately 0°C.
- Boiling point/burning range (°C): Similar to water, approximately 100°C.
- Flash Point (°C): Not applicable.
- Evaporation rate (BA = 1): Not determined.
- Flammability (solid, gas): Not applicable.
- Explosive limit ranges: Not applicable.
- Vapour Pressure (Pascal): Similar to water, approximately 23 hPa.
- Vapour Density (Air=1): Not determined.
- Density (g/ml): ~ 1.0
- Solubility (Water): Soluble.
- Solubility (Other): Not determined.
- Partition Coefficient (n-Octanol/water): Not determined.
- Auto Ignition Temperature (°C): Not determined.
- Decomposition Temperature (°C): Not determined.
- Viscosity (mPa.s): Not determined.
- Explosive properties: Not explosive.
- Oxidising properties: Not oxidising.

9.2 Other information
Not available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity
None known.

10.2 Chemical stability
The product is stable in accordance with the recommended storage conditions.

10.3 Possibility of hazardous reactions
None known. Hazardous polymerisation will not occur.

10.4 Conditions to avoid
None known.

10.5 Incompatible materials
None known.

10.6 Hazardous Decomposition Product(s)
None known.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects
11.1.2 Mixtures
Acute toxicity Based upon the available data, the classification criteria are not met.
Irritation Based upon the available data, the classification criteria are not met.
Corrosivity Based upon the available data, the classification criteria are not met.
Sensitisation Based upon the available data, the classification criteria are not met.
Repeated dose toxicity Based upon the available data, the classification criteria are not met.
Carcinogenicity Based upon the available data, the classification criteria are not met.
Mutagenicity Based upon the available data, the classification criteria are not met.
Toxicity for reproduction Based upon the available data, the classification criteria are not met.
STOT-single exposure Based upon the available data, the classification criteria are not met.
STOT-repeated exposure Based upon the available data, the classification criteria are not met.
Aspiration hazard Based upon the available data, the classification criteria are not met.

Health Effects and Symptoms
Skin Contact No significant harmful effects anticipated.
Eye Contact May cause transient irritation.
Ingestion No significant harmful effects anticipated.

11.2 Other information
Not applicable.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity The product does not contain significant quantities of ingredients that are environmentally toxic.
12.2 Persistence and degradability The product is biodegradable.
12.3 Bioaccumulative potential None anticipated.
12.4 Mobility in soil The product is predicted to have high mobility in soil.
12.5 Results of PBT and vPvB assessment Not applicable.
12.6 Other adverse effects Not applicable.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods
Product: Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.
European waste catalogue: 18 01 07.
Packaging: Disposal should be in accordance with local, state or national legislation. Packaging materials may be recycled. Contact your local service providers for further information.
SECTION 14: TRANSPORT INFORMATION

14.1 UN number
Not applicable

14.2 UN Proper Shipping Name
Not applicable

14.3 Transport hazard class(es)
Not classified as dangerous for transport.

14.4 Packing Group
Not applicable

14.5 Environmental hazards
Not applicable

14.6 Special precautions for user
Not applicable

14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code
Not applicable

SECTION 15: REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
In Vitro diagnostics medical devices directive 98/79/EC.
Consumer Product Safety Regulations 16 CFR 1600
IVD Product Labelling 21 CFR 809
Water hazard class: (Germany): -

Carcinogen listings
IARC: None of the ingredients is listed.
NTP: None of the ingredients is listed.
ACGIH: None of the ingredients is listed.
OSHA: None of the ingredients is listed.
EPA: None of the ingredients is listed.

California Proposition 65
Chemicals known to cause cancer: None of the ingredients is listed.
Chemicals known to cause reproductive toxicity: None of the ingredients is listed.

SARA
Section 355 (extremely hazardous substances): None of the ingredients is listed.
Section 313 (specific toxic chemical listings): None of the ingredients is listed.

15.2 Chemical Safety Assessment
Not applicable.

SECTION 16: OTHER INFORMATION

LEGEND
STOT Specific Target Organ Toxicity
STEL Short Term Exposure Limit
LTTEL Long Term Exposure limit
TWA Time Weighted Average

Classification code(s):
Flam. Liq. 3 Flammable liquid; Category 3
Skin Corr. 1A Skin Corrosive; Category 1A
C CORROSIVE

Hazard statement(s)
H226: Flammable liquid and vapour.
H314: Causes severe skin burns and eye damage.

Risk Phrases
R10: Flammable.
R35: Causes severe burns.

References:
Raw material safety data sheets.
Additional Information


Supersedes: Version: 3

Prepared by: Dr. J. J. Tobin, ChemHaz Solutions, Email: info@chemhazsolutions.com

To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.