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

Regulation (EC) No. 1272/2008 (CLP) Not classified as hazardous.

Directive 67/548/EEC & Directive 1999/45/EC Not classified as dangerous for supply/use.

OSHA Hazard Communication Standard 29 CFR 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 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

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

EC Classification No. 67/548/EEC

Hazardous ingredient(s)	%W/W	EC No.	CAS No.	EC Classification and Risk Phrases
Sodium carbonate	5 - 10	207-838-8	497-19-8	Xi; R36

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 — CO_2, 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.
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	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 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.
OSHA Hazard Communication Standard 29 CFR 1910.1200
Consumer Product Safety Regulations 16 CFR 1600
IVD Product Labelling 21 CFR 809

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):	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

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

Reason for update: Update in accordance with Regulation (EU) No 453/2010.
Regulation (EC) No. 1272/2008 (CLP) & GHS.
Changes to all sections.

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 OFTHE 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.

Directive 67/548/EEC & Directive 1999/45/EC Harmful
Risk Phrases
R22: Harmful if swallowed.

OSHA Hazard Communication Standard 29 CFR 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

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

EC Classification No. 67/548/EEC

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

* 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 — CO_2, 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

SUBSTANCE.	CAS No.	LTEL (8 hr TWA ppm)	LTEL (8 hr TWA mg/m³)	STEL (ppm)	STEL (mg/m³)	Note:
Sodium Azide	26628-22-8		0.1		0.3	Sk

	0.11 (HN_3)	0.29 (NaN_3)	ACGIH TLV

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

Acute toxicity	Based upon the available data, the classification criteria are not met. ATE = 27,000 mg/kg
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	No significant harmful effects anticipated.
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. OSHA Hazard Communication Standard 29 CFR 1910.1200 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

Reason for update:	Update in accordance with Regulation (EU) No 453/2010. 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

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.
	Directive 67/548/EEC & Directive 1999/45/EC	Toxic
	Risk Phrases:	R25: Toxic if swallowed.
	OSHA Hazard Communication Standard 29 CFR 1910.1200 (HazCom 2012) / GHS	Acute Tox. 4, Eye Irrit. 2
	Hazard statement(s)	Harmful if swallowed. Causes serious eye irritation.
2.2	**Label elements**	According to Regulation (EC) No. 1272/2008 (CLP)/GHS
	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

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

EC Classification No. 67/548/EEC

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

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: CO_2, 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 adsorbent material. Collect material and dispose of 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**	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 LD_{50} (oral, rat): 85 – 180 mg/kg LD_{50} (Inhalation, rat): 5.5 mg/l/4hr LD_{0} (oral, Human): 1 – 2 g

11.1.2 Mixtures

Acute toxicity	Harmful if swallowed. ATE calculated: LD_{50} (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
LC_{50} (96h, Fish): 0.19 mg/l
EC_{50} (48h, Daphnia magna): 66 mg/l
Based upon the available data, the classification criteria are not met.
Mixture: LC_{50} (96h, Fish) calculated: 1.38 mg/l

12.2	**Persistence and degradability**	No data.
12.3	**Bioaccumulative potential**	None anticipated.
12.4	**Mobility in soil**	No data.
12.5	**Results of PBT and vPvB assessment**	Not relevant for this material.
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 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

In Vitro diagnostics medical devices directive 98/79/EC.
OSHA Hazard Communication Standard 29 CFR 1910.1200
Consumer Product Safety Regulations 16 CFR 1600
IVD Product Labelling 21 CFR 809
Water hazard class: (Germany): 2.

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):	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

STOT	Specific Target Organ Toxicity
ATE	Acute toxicity estimate

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
T	TOXIC
O	OXIDIZING
N	DANGEROUS FOR THE ENVIRONMENT

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:	Update in accordance with Regulation (EU) No 453/2010. 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

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

Regulation (EC) No. 1272/2008 (CLP) Not classified as hazardous.

Directive 67/548/EEC & Directive 1999/45/EC Not classified as dangerous for supply/use.

OSHA Hazard Communication Standard 29 CFR 1910.1200 (HazCom 2012) / GHS Not classified as hazardous.

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

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

EC Classification No. 67/548/EEC

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

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 — CO_2, 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

SUBSTANCE.	CAS No.	LTEL (8 hr TWA ppm)	LTEL (8 hr TWA mg/m³)	STEL (ppm)	STEL (mg/m³)	Note:

Acetic Acid	64-19-7	10	25			US PEL
Acetic Acid	64-19-7	10	25	15	37	IRL OELV ACGIH TLV

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/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)	~ 1.0
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.
OSHA Hazard Communication Standard 29 CFR 1910.1200
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.

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):	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
LTEL	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

Reason for update:	Update in accordance with Regulation (EU) No 453/2010. 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

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