

Document Name	Material Safety Data Sheet Strep A Test Dipstick	Document No. CAR- MS- 0010
Effective Date:	2009年7月02日	Version: A Revision: 00
		Page 1 of 23



## Cardinal Health MATERIAL SAFETY DATA SHEET Strep A Dipstick

According to REACH Regulation (EC) No. 1907/2006, Annex II

This document contains MSDS for the following kit components

Test Device

Positive Control & Negative Control

Reagent A

Reagent B

### 1. Identification of the substance/preparation and of the company/undertaking

#### Identification of the substance or preparation

Trade name:	Reference No.	Part No.
Cardinal Strep A Dipstick SP™ Brand Rapid Test	IST-511 (50T)	B1077-30

**Use of the substance/preparation:** In vitro diagnostic medical device. For professional use only.

#### Company/undertaking identification:

Alere North America, LLC

30 South Keller Road, Suite 100

Orlando, FL 32810 USA

Tel: + 1-877-441-7440, Option 2

Fax: + 1-877-441-7441

Email: us.productsupport@alere.com

**Further information obtainable from:** For further information, contact your local distributor/supplier.

**Emergency telephone:** ChemTel Inc. International access: + (0)1-813-248-0585

ChemTel Inc. Free phone (North America only): 1-(800)-255-3924

### 2. Hazards identification

#### Hazard description:

Xi, Irritant.

#### Information concerning particular hazards for human and environment:

R36 Irritating to eyes.

#### Classification system:

The classification is according to the latest editions of the EU-lists, and extended by company and literature data.

#### Classification according to OSHA Hazard Communication Standard 29 CFR 1910.1200:

As an article, the device is exempt from OSHA's Hazard Communication Standard 29 CFR 1910.1200.

### 3. Composition/information on ingredients

#### Chemical characterisation

**Description:** In vitro diagnostic medical device. Test strip impregnated with dried chemical / biochemical reagents.

#### Dangerous components:

Component	CAS No.	EINECS No.	Classification	Concentration
Tris (hydroxymethyl) aminomethane	77-86-1	201-064-4	Xi, R 36/37/38	10 – 20 %
Sodium Carbonate	497-19-8	207-838-8	Xi, R 36	5 – 10 %

#### Additional information:

Each device is packaged in a foil pouch.

For the wording of the listed risk phrases refer to section 16.

Document Name	Material Safety Data Sheet Strep A Test Dipstick	Document No. CAR- MS- 0010
Version: A	Revision: 00	
Effective Date:	2009年7月02日	Page 2 of 23
 <b>CardinalHealth</b> <b>MATERIAL SAFETY DATA SHEET</b> <b>Strep A Dipstick</b> According to REACH Regulation (EC) No. 1907/2006, Annex II		
<p>This document contains MSDS for the following kit components</p> <p>Test Device            Positive Control &amp; Negative Control            Reagent A            Reagent B</p>		
<b>4. First-aid measures</b> <p><b>General Information:</b>            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.</p> <p><b>After skin contact:</b>            Wash with soap and water and rinse thoroughly. Consult a doctor if irritation persists.</p> <p><b>After eye contact:</b>            Immediately rinse opened eye for several minutes under running water. Seek medical advice.</p> <p><b>After ingestion:</b>            If desiccant or other components are swallowed seek medical attention.</p>		
<b>5. Fire-fighting measures</b> <p><b>Suitable extinguishing agents:</b>            CO<sub>2</sub>, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.            Use fire-extinguishing methods suitable to surrounding conditions.</p> <p><b>Special hazards caused by the substance, its products of combustion or resulting gases:</b>            In case of fire, the following can be released: Hazardous fumes and vapours, Carbon oxides (CO<sub>x</sub>), Nitrogen oxides (NO<sub>x</sub>),</p> <p><b>Protective equipment:</b>            Wear full protective suit and self-contained respiratory protective device when extinguishing fires.</p> <p><b>Additional information:</b>            The device contains combustible materials.</p>		
<b>6. Accidental release measures</b> <p><b>Person-related safety precautions:</b>            Refer to Section 8 for protective measures when handling the spillage.</p> <p><b>Measures for environmental protection:</b>            Avoid release to the environment.</p> <p><b>Measures for cleaning/collecting:</b>            Collect material and dispose of as waste according to Section 13.</p>		
<b>7. Handling and storage</b> <p><b>Information for safe handling:</b>            Keep out of reach of children.</p> <p><b>Storage:</b>            Store in the original container at 2 - 30°C</p> <p><b>Requirements to be met by storerooms and receptacles:</b>            No special requirements.</p>		

Document Name	Material Safety Data Sheet Strep A Test Dipstick	Document No. CAR- MS- 0010
Effective Date:	2009年7月02日	Version: A Revision: 00
		Page 3 of 23

  
**CardinalHealth**  
**MATERIAL SAFETY DATA SHEET**  
**Strep A Dipstick**

According to REACH Regulation (EC) No. 1907/2006, Annex II

This document contains MSDS for the following kit components  
 Test Device

Positive Control & Negative Control  
 Reagent A  
 Reagent B

## 8. Exposure controls/personal protection

### Ingredients with limit values that require monitoring in the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored in the workplace.

### Additional information:

The lists valid during the creation of this MSDS were used as a basis for this assessment.

### Personal protective equipment:

#### General protective and hygienic measures:

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 bio hazardous materials.

Wash hands before breaks and at the end of work. Clean work areas with hypochlorite or other disinfecting agent.

#### Respiratory protection:

Not required

#### Protection of hands:

Disposable gloves (for sample handling)

#### Material of gloves:

Latex/natural rubber

#### Penetration time of glove material:

Glove resistance is not critical as the gloves are intended to provide protection against the sample material.

#### Eye protection:

Not required

#### Body protection:

Lab coat

## 9. Physical and chemical properties

### General Information

**Form:** The device is an article containing solid components

**Appearance:** Laminated test strip.

**Odour:** Odourless

**Flash point:** Not applicable.

**Self-igniting:** Product is not self-igniting.

**Danger of explosion:** Product does not present an explosion hazard.

## 10. Stability and reactivity

**Stability:** The product is stable in accordance with the recommended storage conditions.

**Materials to be avoided:** None

**Hazardous reactions:** No dangerous reactions known.

**Hazardous decomposition products:** No dangerous decomposition products known.

Document Name	Material Safety Data Sheet Strep A Test Dipstick	Document No. CAR- MS- 0010
Effective Date:	2009年7月02日	Version: A Revision: 00
		Page 4 of 23

  
**CardinalHealth**  
**MATERIAL SAFETY DATA SHEET**  
**Strep A Dipstick**

According to REACH Regulation (EC) No. 1907/2006, Annex II

This document contains MSDS for the following kit components

Test Device

Positive Control & Negative Control

Reagent A

Reagent B

## 11. Toxicological information

### Acute toxicity:

Quantitative data on the toxic effects of this product is not available.

### Primary effects:

**After skin contact:** Contact with the chemicals impregnated in the test strip may cause mild irritation.

**After eye contact:** Irritating effect following contact with the chemicals impregnated in the test strip.

**Sensitisation:** No sensitising effects known.

## 12. Ecological information

### Environmental Toxicity:

Quantitative data on the toxic effects of this product is not available.

### Persistence and Degradability:

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

## 13. Disposal considerations

### Product:

Used devices and other contaminated materials should be disposed of as potentially bio hazardous waste.

To ensure compliance with anti-pollution and other laws of the country concerned, we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

### European waste catalogue:

18 01 03 wastes whose collection and disposal is subject to special requirements in order to prevent infection.

### Packaging:

Disposal must be made in accordance with local waste management regulations.

Non-contaminated packaging materials may be recycled. Contact your local service providers for further information.

## 14. Transport information

### Land transport ADR/RID (cross-border)

Not regulated for transport.

### US DOT Transport Regulations:

Not regulated for transport.

### Maritime transport IMDG:

Not regulated for transport.

**Marine pollutant:** No

### Air transport ICAO-TI and IATA-DGR:

Not regulated for transport.

Document Name	Material Safety Data Sheet Strep A Test Dipstick	Document No. CAR- MS- 0010
Effective Date:	2009年7月02日	Version: A Revision: 00
		Page 5 of 23

  
**CardinalHealth**  
**MATERIAL SAFETY DATA SHEET**  
**Strep A Dipstick**

According to REACH Regulation (EC) No. 1907/2006, Annex II

This document contains MSDS for the following kit components

Test Device

Positive Control & Negative Control

Reagent A

Reagent B

## 15. Regulatory information

### Labelling according to EU guidelines:

#### Code letter and hazard designation of product:



Xi Irritant

#### Risk phrases:

36 Irritating to eyes.

#### Safety phrases:

S2 Keep out of reach of children

26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

46 If swallowed, seek medical advice immediately and show this container or label.

60 This material and its container must be disposed of as hazardous waste

#### Note:

The preparation is exempt from the above labelling requirements in accordance to Article 12.2 of Directive 99/45/EC as the form in which it is placed on the market does not present any significant risk to man or the environment when used according to the instructions for use.

### US Hazard warnings according to 16 CFR 1600 and ANSI Standard Z129.1:

Not required.

### Chemical inventory listings relevant to US regulations:

#### 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.

Document Name	Material Safety Data Sheet Strep A Test Dipstick	Document No. CAR- MS- 0010
Effective Date:	2009年7月02日	Version: A Revision: 00
		Page 6 of 23



## CardinalHealth

### MATERIAL SAFETY DATA SHEET

#### Strep A Dipstick

According to REACH Regulation (EC) No. 1907/2006, Annex II

This document contains MSDS for the following kit components

Test Device

Positive Control & Negative Control

Reagent A

Reagent B

#### 16. Other information

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.

#### Relevant R-phrases

- 36 Irritating to eyes.
- 36/37/38 Irritating to eyes, respiratory system and skin.

Document Name	Material Safety Data Sheet Strep A Test Dipstick	Document No. CAR- MS- 0010
Effective Date:	2009年7月02日	Version: A Revision: 00
		Page 7 of 23



**CardinalHealth**  
**MATERIAL SAFETY DATA SHEET**  
**Strep A Dipstick**

According to REACH Regulation (EC) No. 1907/2006, Annex II

This document contains MSDS for the following kit components

Test Device

Positive Control & Negative Control

Reagent A

Reagent B

## 1. Identification of the substance/preparation and of the company/undertaking

### Identification of the substance or preparation

#### Trade name: Strep A Dipstick, Positive Control / Negative Control

Trade name:	Reference No.	Part No.
Cardinal Strep A Dipstick SP™ Brand Rapid Test	IST-511 (50T)	B1077-30

**Use of the substance/preparation:** In vitro diagnostic medical device. For professional use only.

#### Company/undertaking identification:

Alere North America, LLC  
 30 South Keller Road, Suite 100  
 Orlando, FL 32810 USA  
 Tel: + 1-877-441-7440, Option 2  
 Fax: + 1-877-441-7441  
 Email: us.productsupport@alere.com

**Further information obtainable from:** For further information, contact your local distributor/supplier.

**Emergency telephone:** ChemTel Inc. International access: + (0)1-813-248-0585  
 ChemTel Inc. Free phone (North America only): 1-(800)-255-3924

## 2. Hazards identification

### Hazard description:

Xn, Harmful

### Information concerning particular hazards for human and environment:

R 22 Harmful if swallowed.

### Classification system:

The classification is according to the latest editions of the EU-lists, and extended by company and literature data.

### Classification according to OSHA Hazard Communication Standard 29 CFR 1910.1200:

Not classified as hazardous.

## 3. Composition/information on ingredients

### Chemical characterisation

#### Description:

Aqueous preparation containing the hazardous components listed below.

#### Dangerous components:

Component	CAS No.	EINECS No.	Classification	Concentration
Sodium Azide	26628-22-8	247-852-1	T+, N, R 28-32-50/53	0. 09%

#### Additional information:

Also contains non-viable Strep A or Strep C organisms.

For the wording of the listed risk phrases refer to section 16.

Document Name	Material Safety Data Sheet Strep A Test Dipstick	Document No. CAR- MS- 0010
Version: A	Revision: 00	
Effective Date:	2009年7月02日	Page 8 of 23
 <b>CardinalHealth</b> <b>MATERIAL SAFETY DATA SHEET</b> <b>Strep A Dipstick</b> According to REACH Regulation (EC) No. 1907/2006, Annex II		
<p>This document contains MSDS for the following kit components</p> <p>Test Device</p> <p>Positive Control &amp; Negative Control</p> <p>Reagent A</p> <p>Reagent B</p>		
<b>4. First-aid measures</b> <p><b>After inhalation:</b> Supply fresh air; consult doctor in case of complaints.</p> <p><b>After skin contact:</b> Wash with soap and water and rinse thoroughly. Remove soiled clothing.</p> <p><b>After eye contact:</b> Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.</p> <p><b>After ingestion:</b> Wash out mouth with water. Consult a doctor.</p>		
<b>5. Fire-fighting measures</b> <p><b>Suitable extinguishing agents:</b> CO<sub>2</sub>, powder or water spray. Fight larger fires with water spray or alcohol resistant foam. Use fire-extinguishing methods suitable to surrounding conditions.</p> <p><b>Special hazards caused by the substance, its products of combustion or resulting gases:</b> In case of fire, the following can be released: Carbon oxides (CO<sub>x</sub>), Nitrogen oxides (NO<sub>x</sub>), Phosphorous oxides (P<sub>x</sub>O<sub>y</sub>)</p> <p><b>Protective equipment:</b> Wear full protective suit and self-contained respiratory protective device when extinguishing fires.</p>		
<b>6. Accidental release measures</b> <p><b>Person-related safety precautions:</b> Isolate spillage and clean up immediately. Refer to Section 8 for protective measures when handling the spillage.</p> <p><b>Measures for environmental protection:</b> Do not allow to enter sewers/surface or ground water.</p> <p><b>Measures for cleaning/collecting:</b> Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust) Dispose of contaminated material as waste according to Section 13. Rinse off area with water.</p>		
<b>7. Handling and storage</b> <p><b>Information for safe handling:</b> Observe the general safety regulations when handling chemicals. Avoid contact with the eyes, skin and mucous membranes. Keep out of reach of children.</p> <p><b>Storage:</b> Store in the original container at 2 - 30°C</p> <p><b>Requirements to be met by storerooms and receptacles:</b> No special requirements.</p>		

Document Name	Material Safety Data Sheet Strep A Test Dipstick	Document No. CAR- MS- 0010
Effective Date:	2009年7月02日	Version: A Revision: 00
		Page 9 of 23


  
**CardinalHealth**  
**MATERIAL SAFETY DATA SHEET**  
**Strep A Dipstick**

According to REACH Regulation (EC) No. 1907/2006, Annex II

This document contains MSDS for the following kit components

Test Device

Positive Control & Negative Control

Reagent A

Reagent B

## 8. Exposure controls/personal protection

### Ingredients with limit values that require monitoring in the workplace:

Sodium azide CAS No.: 26628-22-8  
 UK WEL / IRL OELV 8-hour TWA: 0.1 mg/m<sup>3</sup> Short-term value: 0.3 mg/m<sup>3</sup> as NaN<sub>3</sub>  
 TLV (ACGIH) Short-term value: 0.29 mg/m<sup>3</sup> as NaN<sub>3</sub>, 0.11 ppm as HN<sub>3</sub>

### Additional information:

The lists valid during the creation of this MSDS were used as a basis for this assessment.

### Personal protective equipment:

#### General protective and hygienic measures:

Adhere to good laboratory practices (GLP).

Wash hands before breaks and at the end of work.

#### Respiratory protection:

Not required

#### Protection of hands:

Disposable gloves

#### Material of gloves:

Latex/natural rubber

#### Penetration time of glove material:

Gloves resistance is not critical when the product is handled according to the instructions for use.

#### Eye protection:

Not required

#### Body protection:

Lab coat

## 9. Physical and chemical properties

### General Information

**Form:** Liquid

**Colour:** Colourless

**Odour:** Odourless

### Change in condition

**Melting point/Melting range:** Similar to water, approximately 0°C.

**Boiling point/Boiling range:** Similar to water, approximately 100°C.

**Flash point:** Not applicable.

**Self-igniting:** Product is not self-igniting.

**Danger of explosion:** Product does not present an explosion hazard.

**Vapour pressure:** Similar to water, approximately 23 hPa.

**Density at 20°C:** 1.05 g/cm<sup>3</sup>

### Solubility in/Miscibility with:

**Water:** Fully miscible.

**pH-value at 20°C:**

Document Name	Material Safety Data Sheet Strep A Test Dipstick	Document No. CAR- MS- 0010
Effective Date:	2009年7月02日	Version: A Revision: 00
		Page 10 of 23

  
**CardinalHealth**  
**MATERIAL SAFETY DATA SHEET**  
**Strep A Dipstick**

According to REACH Regulation (EC) No. 1907/2006, Annex II

This document contains MSDS for the following kit components

Test Device

Positive Control & Negative Control

Reagent A

Reagent B

## 10. Stability and reactivity

**Stability:** The product is stable in accordance with the recommended storage conditions.

**Materials to be avoided:** concentrated acids, heavy metals, metallic salts

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

**Hazardous decomposition products:** No dangerous decomposition products known.

## 11. Toxicological information

### Acute toxicity:

Quantitative data on the toxic effects of this product is not available.

### LD<sub>50</sub>/LC<sub>50</sub> values relevant for classification:

Sodium azide CAS No.: 26628-22-8

LD<sub>50</sub> (Oral, rat): 27 mg/kg

TDL<sub>0</sub>(Human): 0.71 mg/kg

LD<sub>50</sub> (Dermal, rabbit): 20 mg/kg

### Primary effects:

**After skin contact:** No irritating effects anticipated.

**After eye contact:** No irritating effects anticipated.

**After ingestion:** Possible systemic effects following ingestion of substantial quantities: headache, dizziness, nausea, vomiting, CNS disorders, drop in blood pressure, cardiovascular failure, collapse.

**Sensitization:** No sensitizing effects known.

## 12. Ecological information

### Ecotoxic Effects:

Quantitative data on the toxic effects of this product are not available.

No ecological problems are to be expected when the product is handled and used with due care and attention.

### Aquatic toxicity:

Sodium azide CAS No.: 26628-22-8

LC<sub>50</sub> (96 h, Fish): 0.7 mg/l

EC<sub>50</sub> (96 h, Daphnia): 4.2 mg/l

### Persistence and Degradability:

The product is biodegradable.

### Mobility and bioaccumulation potential:

Does not accumulate in organisms

Document Name	Material Safety Data Sheet Strep A Test Dipstick	Document No. CAR- MS- 0010
Effective Date:	2009年7月02日	Version: A Revision: 00
		Page 11 of 23

  
**CardinalHealth**  
**MATERIAL SAFETY DATA SHEET**  
**Strep A Dipstick**

According to REACH Regulation (EC) No. 1907/2006, Annex II

This document contains MSDS for the following kit components

Test Device

Positive Control & Negative Control

Reagent A

Reagent B

### 13. Disposal considerations

**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.

To avoid the possible build-up of azide compounds, flush plumbing with water after the disposal of undiluted reagent.

**European waste catalogue:**

18 01 06 chemicals consisting of or containing dangerous substances

**Packaging:**

Disposal must be made in accordance with local waste management regulations.

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.

### 14. Transport information

**Land transport ADR/RID (cross-border)**

Not regulated for transport.

**US DOT Transport Regulations:**

Not regulated for transport.

**Maritime transport IMDG:**

Not regulated for transport.

**Marine pollutant:** No

**Air transport ICAO-TI and IATA-DGR:**

Not regulated for transport.

Document Name	Material Safety Data Sheet Strep A Test Dipstick	Document No. CAR- MS- 0010
Effective Date:	2009年7月02日	Version: A Revision: 00
		Page 12 of 23

  
**CardinalHealth**  
**MATERIAL SAFETY DATA SHEET**  
**Strep A Dipstick**

According to REACH Regulation (EC) No. 1907/2006, Annex II

This document contains MSDS for the following kit components

Test Device

Positive Control & Negative Control

Reagent A

Reagent B

## 15. Regulatory information

**Labelling according to EU guidelines:**

**Code letter and hazard designation of product:**



Xn Harmful

**Hazard-determining components of labelling:**

Sodium Azide

**Risk phrases:**

22 Harmful if swallowed.

**Safety phrases:**

S2 Keep out of reach of children

35 This material and its container must be disposed of in a safe way.

46 If swallowed, seek medical advice immediately and show this container or label.

**Water Hazard Class (Germany):** WGK 1, slightly hazardous for water.

**US Hazard warnings according to 16 CFR 1600 and ANSI Standard Z129.1:**

Not required.

**Chemical inventory listings relevant to US regulations:**

**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): Yes, Sodium azide CAS No. 26628-22-8.

Section 313 (specific toxic chemical listings): Yes, Sodium azide CAS No. 26628-22-8

## 16. Other information

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.

*Relevant R-phrases*

28 Very toxic if swallowed.

32 Contact with acids liberates very toxic gas.

50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Document Name	Material Safety Data Sheet Strep A Test Dipstick	Document No. CAR- MS- 0010
Effective Date:	2009年7月02日	Version: A Revision: 00
		Page 13 of 23

  
**CardinalHealth**  
**MATERIAL SAFETY DATA SHEET**  
**Strep A Dipstick**

According to REACH Regulation (EC) No. 1907/2006, Annex II

This document contains MSDS for the following kit components

Test Device

Positive Control & Negative Control

Reagent A

Reagent B

## 1. Identification of the substance/preparation and of the company/undertaking

### Identification of the substance or preparation

#### Trade name: Strep A Dipstick, Reagent A

Trade name:	Reference No.	Part No.
Cardinal Strep A Dipstick SP™ Brand Rapid Test	IST-511 (50T)	B1077-30

**Use of the substance/preparation:** In vitro diagnostic medical device. For professional use only.

#### Company/undertaking identification:

Alere North America, LLC  
 30 South Keller Road, Suite 100  
 Orlando, FL 32810 USA  
 Tel: + 1-877-441-7440, Option 2  
 Fax: + 1-877-441-7441  
 Email: us.productsupport@alere.com

**Further information obtainable from:** For further information, contact your local distributor/supplier.

**Emergency telephone:** ChemTel Inc. International access: + (0)1-813-248-0585  
 ChemTel Inc. Free phone (North America only): 1-(800)-255-3924

## 2. Hazards identification

### Hazard description:

T, Toxic

### Information concerning particular hazards for human and environment:

R 25 Toxic if swallowed.

### Classification system:

The classification is according to the latest editions of the EU-lists, and extended by company and literature data.

### Classification according to OSHA Hazard Communication Standard 29 CFR 1910.1200:

Toxic, Irritant

## 3. Composition/information on Ingredients

### Chemical characterisation

#### Description:

Aqueous preparation containing the hazardous components listed below.

#### Dangerous components:

Component	CAS No.	EINECS No.	Classification	Concentration
Sodium Nitrite	7632-00-0	231-555-9	O, T, N, R 8-25-50	10 – 20 %

#### Additional information:

For the wording of the listed risk phrases refer to section 16.

Document Name	Material Safety Data Sheet Strep A Test Dipstick	Document No. CAR- MS- 0010
Effective Date:	2009年7月02日	Version: A Revision: 00
		Page 14 of 23


  
**CardinalHealth**  
**MATERIAL SAFETY DATA SHEET**  
**Strep A Dipstick**

According to REACH Regulation (EC) No. 1907/2006, Annex II

This document contains MSDS for the following kit components

Test Device

Positive Control & Negative Control

Reagent A

Reagent B

#### 4. First-aid measures

**After inhalation:** Supply fresh air; consult doctor in case of complaints.

**After skin contact:**

Wash with soap and water and rinse thoroughly. Remove soiled clothing.

**After eye contact:**

Rinse opened eye for several minutes under running water. Consult a doctor in case of complaints.

**After ingestion:**

Wash out mouth with water provided person is conscious. Seek immediate medical advice.

**The following symptoms may occur:** Cyanosis, nausea, narcosis.

#### 5. Fire-fighting measures

**Suitable extinguishing agents:**

CO<sub>2</sub>, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

Use fire-extinguishing methods suitable to surrounding conditions.

**Special hazards caused by the substance, its products of combustion or resulting gases:**

In case of fire, the following can be released: Nitrogen oxides (NO<sub>x</sub>).

**Protective equipment:**

Wear full protective suit and self-contained respiratory protective device when extinguishing fires.

#### 6. Accidental release measures

**Person-related safety precautions:**

Isolate spillage and clean up immediately.

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

**Measures for environmental protection:**

Do not allow to enter sewers/surface or ground water.

**Measures for cleaning/collecting:**

Absorb with liquid-binding material (sand, diatomite, acid binders, and universal binders)

Dispose of contaminated material as waste according to Section 13.

Rinse off area with water.

#### 7. Handling and storage

**Information for safe handling:**

Observe the general safety regulations when handling chemicals.

Avoid contact with the eyes, skin and mucous membranes.

Keep out of reach of children.

**Storage:**

Store in the original container at 2 - 30°C

**Requirements to be met by storerooms and receptacles:**

No special requirements.

Document Name	Material Safety Data Sheet Strep A Test Dipstick	Document No. CAR- MS- 0010
Effective Date:	2009年7月02日	Version: A Revision: 00
		Page 15 of 23


  
**CardinalHealth**  
**MATERIAL SAFETY DATA SHEET**  
**Strep A Dipstick**

According to REACH Regulation (EC) No. 1907/2006, Annex II

This document contains MSDS for the following kit components

Test Device

Positive Control & Negative Control

Reagent A

Reagent B

## 8. Exposure controls/personal protection

### Ingredients with limit values that require monitoring in the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored in the workplace.

### Additional information:

The lists valid during the creation of this MSDS were used as a basis for this assessment.

### Personal protective equipment:

#### General protective and hygienic measures:

Adhere to good laboratory practices (GLP).

Wash hands before breaks and at the end of work.

### Respiratory protection:

Not required

### Protection of hands:

Disposable gloves

### Material of gloves:

Latex/natural rubber

### Penetration time of glove material:

Gloves resistance is not critical when the product is handled according to the instructions for use.

### Eye protection:

Safety glasses

### Body protection:

Lab coat

## 9. Physical and chemical properties

### General Information

**Form:** Liquid

**Colour:** Red

**Odour:** Odourless

### Change in condition

**Melting point/Melting range:** Similar to water, approximately 0°C.

**Boiling point/Boiling range:** Similar to water, approximately 100°C.

**Flash point:** Not applicable.

**Self-igniting:** Product is not self-igniting.

**Danger of explosion:** Product does not present an explosion hazard.

**Vapour pressure:** Similar to water, approximately 23 hPa.

**Density at 20°C:** 1.08 g/cm<sup>3</sup>

### Solubility in/Miscibility with:

**Water:** Fully miscible.

**pH-value at 20°C:** 6.9

## 10. Stability and reactivity

**Stability:** The product is stable in accordance with the recommended storage conditions.

**Materials to be avoided:** None

**Hazardous reactions:** No dangerous reactions known. Hazardous polymerisation will not occur.

**Hazardous decomposition products:** No dangerous decomposition products known.

Document Name	Material Safety Data Sheet Strep A Test Dipstick	Document No. CAR- MS- 0010
Effective Date:	2009年7月02日	Version: A Revision: 00
		Page 16 of 23

  
**CardinalHealth**  
**MATERIAL SAFETY DATA SHEET**  
**Strep A Dipstick**

According to REACH Regulation (EC) No. 1907/2006, Annex II

This document contains MSDS for the following kit components

Test Device

Positive Control & Negative Control

Reagent A

Reagent B

## 11. Toxicological information

### Acute toxicity:

Quantitative data on the toxic effects of this product is not available.

### LD50/LC50 values relevant for classification:

Sodium Nitrite CAS No.: 7632-00-0

LD<sub>50</sub> (Oral, rat): 85 mg/kg

LD<sub>L0</sub> (Oral, Human): 1 – 2 g

### Primary effects:

**After skin contact:** No irritating effects anticipated. May be absorbed through skin.

**After eye contact:** May cause mild irritation

**After ingestion:** Cyanosis, nausea, dizziness, vomiting, collapse, spasms of abdominal pain, rapid heart beat, irregular breathing, coma, and convulsions, which can ultimately lead to death due to circulatory collapse.

**Sensitization:** No sensitizing effects known.

## 12. Ecological information

### Ecotoxic Effects:

Quantitative data on the toxic effects of this product are not available.

No ecological problems are to be expected when the product is handled and used with due care and attention.

### Aquatic toxicity:

Sodium Nitrite CAS No.: 7632-00-0

LC<sub>50</sub> (96 h, Fish): 0.19 mg/l

EC<sub>50</sub> (48 h, Daphnia): 66 mg/l

### Mobility and bioaccumulation potential:

Does not accumulate in organisms

## 13. Disposal considerations

### 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 chemicals consisting of or containing dangerous substances

### Packaging:

Disposal must be made in accordance with local waste management regulations.

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.

## 14. Transport information

### Land transport ADR/RID (cross-border)

Not regulated for transport.

### US DOT Transport Regulations:

Not regulated for transport.

### Maritime transport IMDG:

Not regulated for transport.

**Marine pollutant:** No

### Air transport ICAO-TI and IATA-DGR:

Not regulated for transport.

Document Name	Material Safety Data Sheet Strep A Test Dipstick	Document No. CAR- MS- 0010
Effective Date:	2009年7月02日	Version: A Revision: 00
		Page 17 of 23

  
**CardinalHealth**  
**MATERIAL SAFETY DATA SHEET**  
**Strep A Dipstick**

According to REACH Regulation (EC) No. 1907/2006, Annex II

This document contains MSDS for the following kit components

Test Device

Positive Control & Negative Control

Reagent A

Reagent B

## 15. Regulatory information

### Labelling according to EU guidelines:

#### Code letter and hazard designation of product:



T Toxic

#### Hazard-determining components of labelling:

Sodium Nitrite

#### Risk phrases:

25 Toxic if swallowed.

#### Safety phrases:

1/2 Keep locked up and out of the reach of children.

45 In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

60 This material and its container must be disposed of as hazardous waste.

**Water Hazard Class (Germany):** WGK 2, hazardous for water.

#### US Hazard warnings according to 16 CFR 1600 and ANSI Standard Z129.1:

WARNING: Harmful if swallowed or adsorbed through skin. May cause eye irritation.

#### Chemical inventory listings relevant to US regulations:

##### 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): Yes, Sodium Nitrite CAS No.: 7632-00-0

Document Name	Material Safety Data Sheet Strep A Test Dipstick	Document No. CAR- MS- 0010
Effective Date:	2009年7月02日	Version: A Revision: 00
		Page 18 of 23

  
**CardinalHealth**  
**MATERIAL SAFETY DATA SHEET**  
**Strep A Dipstick**

According to REACH Regulation (EC) No. 1907/2006, Annex II

This document contains MSDS for the following kit components

Test Device

Positive Control & Negative Control

Reagent A

Reagent B

#### 16. Other information

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.

##### Relevant R-phrases:

- 8 Contact with combustible material may cause fire.
- 25 Toxic if swallowed.
- 50 Very toxic to aquatic organisms.

Document Name	Material Safety Data Sheet Strep A Test Dipstick	Document No. CAR- MS- 0010
Effective Date:	2009年7月02日	Version: A Revision: 00
		Page 19 of 23

  
**CardinalHealth**  
**MATERIAL SAFETY DATA SHEET**  
**Strep A Dipstick**

According to REACH Regulation (EC) No. 1907/2006, Annex II

This document contains MSDS for the following kit components  
 Test Device

Positive Control & Negative Control  
 Reagent A  
 Reagent B

## 1. Identification of the substance/preparation and of the company/undertaking

### Identification of the substance or preparation

#### Trade name: Strep A Dipstick, Reagent B

Trade name:	Reference No.	Part No.
Cardinal Strep A Dipstick SP™ Brand Rapid Test	IST-511 (50T)	B1077-30

**Use of the substance/preparation:** In vitro diagnostic medical device. For professional use only.

#### Company/undertaking identification:

Alere North America, LLC  
 30 South Keller Road, Suite 100  
 Orlando, FL 32810 USA  
 Tel: + 1-877-441-7440, Option 2  
 Fax: + 1-877-441-7441  
 Email: us.productsupport@alere.com

**Further information obtainable from:** For further information, contact your local distributor/supplier.

**Emergency telephone:** ChemTel Inc. International access: + (0)1-813-248-0585  
 ChemTel Inc. Free phone (North America only): 1-(800)-255-3924

## 2. Hazards identification

### Hazard description:

Preparation not classified as dangerous according to Directive 1999/45/EC.

### Classification system:

The classification is according to the latest editions of the EU-lists, and extended by company and literature data.

### Classification according to OSHA Hazard Communication Standard 29 CFR 1910.1200:

Corrosive

## 3. Composition/information on ingredients

### Chemical characterisation

#### Description:

Aqueous preparation containing the hazardous components listed below.

#### Dangerous components:

Component	CAS No.	EINECS No.	Classification	Concentration
Acetic Acid	64-19-7	200-580-7	C, R 10-35	1 – 2 %

#### Additional information:

For the wording of the listed risk phrases refer to section 16.

Document Name	Material Safety Data Sheet Strep A Test Dipstick	Document No. CAR- MS- 0010
Effective Date:	2009年7月02日	Version: A Revision: 00
		Page 20 of 23

  
**CardinalHealth**  
**MATERIAL SAFETY DATA SHEET**  
**Strep A Dipstick**

According to REACH Regulation (EC) No. 1907/2006, Annex II

This document contains MSDS for the following kit components  
 Test Device  
 Positive Control & Negative Control  
 Reagent A  
 Reagent B

#### 4. First-aid measures

**After inhalation:**

Supply fresh air; consult doctor in case of complaints.

**After skin contact:**

Wash with soap and water and rinse thoroughly. Remove soiled clothing.

**After eye contact:**

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

**After ingestion:**

Wash out mouth and then drink plenty of water. Consult a doctor in case of complaints.

#### 5. Fire-fighting measures

**Suitable extinguishing agents:**

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

Use fire-extinguishing methods suitable to surrounding conditions.

**Special hazards caused by the substance, its products of combustion or resulting gases:**

In case of fire, the following can be released: Acetic acid vapours.

**Protective equipment:**

Wear full protective suit and self-contained respiratory protective device when extinguishing fires.

#### 6. Accidental release measures

**Person-related safety precautions:**

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

**Measures for environmental protection:**

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

**Measures for cleaning/collecting:**

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust)

Dispose of contaminated material as waste according to Section 13.

Rinse off area with water.

#### 7. Handling and storage

**Information for safe handling:**

Observe the general safety regulations when handling chemicals.

Avoid contact with the eyes, skin and mucous membranes.

**Storage:**

Store in the original container at 2 - 30°C

**Requirements to be met by storerooms and receptacles:**

No special requirements.

Document Name	Material Safety Data Sheet Strep A Test Dipstick	Document No. CAR- MS- 0010
Effective Date:	2009年7月02日	Version: A Revision: 00
		Page 21 of 23


  
**CardinalHealth**  
**MATERIAL SAFETY DATA SHEET**  
**Strep A Dipstick**

According to REACH Regulation (EC) No. 1907/2006, Annex II

This document contains MSDS for the following kit components  
 Test Device  
 Positive Control & Negative Control  
 Reagent A  
 Reagent B

## 8. Exposure controls/personal protection

### Ingredients with limit values that require monitoring in the workplace:

Acetic Acid CAS No.: 64-19-7

OELV (Irl.)	Short-term value: 37 mg/m <sup>3</sup> , 15 ppm	Long-term value: 25 mg/m <sup>3</sup> , 10 ppm
TLV (ACGIH)	Short-term value: 37 mg/m <sup>3</sup> , 15 ppm	Long-term value: 25 mg/m <sup>3</sup> , 10 ppm
PEL (US)		Long-term value: 25 mg/m <sup>3</sup> , 10 ppm

### Additional information:

The lists valid during the creation of this MSDS were used as a basis for this assessment.

### Personal protective equipment:

#### General protective and hygienic measures:

Adhere to good laboratory practices (GLP).

Wash hands before breaks and at the end of work.

#### Respiratory protection:

Not required, except in the unlikely event that occupational exposure limit values may be exceeded.

#### Protection of hands:

Disposable gloves

#### Material of gloves:

Latex/natural rubber

#### Penetration time of glove material:

Gloves resistance is not critical when the product is handled according to the instructions for use.

#### Eye protection:

Safety glasses

#### Body protection:

Lab coat

## 9. Physical and chemical properties

### General Information

**Form:** Liquid

**Colour:** Colourless.

**Odour:** Pungent.

### Change in condition

**Melting point/Melting range:** Similar to water, approximately 0°C.

**Boiling point/Boiling range:** Similar to water, approximately 100°C.

**Flash point:** Not applicable.

**Self-igniting:** Product is not self-igniting.

**Danger of explosion:** Product does not present an explosion hazard.

**Vapour pressure:** Similar to water, approximately 23 hPa.

**Density at 20°C:** 1.00 g/cm<sup>3</sup>

### Solubility in/Miscibility with:

**Water:** Fully miscible.

**pH-value at 20°C:** ~ 2.5

## 10. Stability and reactivity

**Stability:** The product is stable in accordance with the recommended storage conditions.

**Materials to be avoided:** None

**Hazardous reactions:** No dangerous reactions known. Hazardous polymerisation will not occur.

**Hazardous decomposition products:** No dangerous decomposition products known.

Document Name	Material Safety Data Sheet Strep A Test Dipstick	Document No. CAR- MS- 0010
Effective Date:	2009年7月02日	Version: A Revision: 00
		Page 22 of 23

  
**CardinalHealth**  
**MATERIAL SAFETY DATA SHEET**  
**Strep A Dipstick**

According to REACH Regulation (EC) No. 1907/2006, Annex II

This document contains MSDS for the following kit components

Test Device

Positive Control & Negative Control

Reagent A

Reagent B

## 11. Toxicological information

### Acute toxicity:

Quantitative data on the toxic effects of this product is not available.

### Primary effects:

**After inhalation:** May cause mild irritation.

**After skin contact:** May cause mild irritation.

**After eye contact:** May cause mild irritation.

**After ingestion:** May cause mild irritation.

**Sensitization:** No sensitizing effects known.

## 12. Ecological information

### Environmental Toxicity:

Quantitative data on the toxic effects of this product is not available.

No ecological problems are to be expected when the product is handled and used with due care and attention.

### Persistence and Degradability:

The product is biodegradable.

### Mobility and bioaccumulation potential:

Does not accumulate in organisms

## 13. Disposal considerations

### 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 chemicals other than those mentioned in 18 01 06.

### Packaging:

Disposal must be made in accordance with local waste management regulations.

Packaging materials may be recycled. Contact your local service providers for further information.

## 14. Transport information

### Land transport ADR/RID (cross-border)

Not regulated for transport.

### US DOT Transport Regulations:

Not regulated for transport.

### Maritime transport IMDG:

Not regulated for transport.

**Marine pollutant:** No

### Air transport ICAO-TI and IATA-DGR:

Not regulated for transport.

Document Name	Material Safety Data Sheet Strep A Test Dipstick	Document No. CAR- MS- 0010
Effective Date:	2009年7月02日	Version: A Revision: 00
		Page 23 of 23

  
**CardinalHealth**  
**MATERIAL SAFETY DATA SHEET**  
**Strep A Dipstick**

According to REACH Regulation (EC) No. 1907/2006, Annex II

This document contains MSDS for the following kit components

Test Device

Positive Control & Negative Control

Reagent A

Reagent B

## 15. Regulatory information

### Labelling according to EU guidelines:

### Special labelling of certain preparations:

Safety data sheet available for professional user on request.

**Water Hazard Class (Germany):** WGK -, not hazardous for water.

### US Hazard warnings according to 16 CFR 1600 and ANSI Standard Z129.1:

CAUTION: May cause skin, eye and respiratory tract irritation.

### Chemical inventory listings relevant to US regulations:

#### 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.

## 16. Other information

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.

### Relevant R-phrases

10 Flammable.  
35 Causes severe burns