

## Section 1 – Product and Company Identification

### Manufacturer Information

Quidel Corporation	Phone:	1.800.874.1517	Web:	<a href="http://quidel.com">quidel.com</a>
10165 McKellar Court	Fax:	1.858.453.4338	E-mail:	<a href="mailto:gehs@quidel.com">gehs@quidel.com</a>
San Diego, CA 92121	Emergency # (24-Hour):	1.866.519.4752		

### Product Information

Product Name: QuickVue® Dipstick Strep A Test (Catalog #: 20108, 20125, 20152, and 20318)

Intended Use: The QuickVue Dipstick Strep A test is intended for the rapid, qualitative detection of Group A Streptococcal antigen from throat swabs or confirmation of presumptive Group A Streptococcal colonies recovered from culture. The test is intended for professional and laboratory use as an aid in the diagnosis of Group A Streptococcal infection. This kit is for *in vitro* diagnostic use only.



Components: Kit is composed of individually pouched Dipsticks, Extraction Reagent A (Sodium Nitrite), Extraction Reagent B (Acetic Acid), Sterile Rayon-tipped Throat Swabs, Positive Control (heat inactivated Group A Streptococcus) and Negative Control (heat inactivated Group C Streptococcus).

## Section 2 – Hazards Identification

### Emergency Overview

Component	OSHA Hazards	Target Organs	GHS Classification
Extraction Reagent A (Sodium Nitrite, 27.6%)	Toxic, Irritant	Eyes, Liver	Acute Toxicity, Oral (Category 4) Eye Irritation (Category 2A) Acute Aquatic Toxicity (Category 1)
<b>Negative Control</b> (Microcide III, 0.3%)	Irritant, Sensitizer	Skin, eyes	Eye Irritation (Category 2A) Skin Irritation (Category 2) Skin Sensitizer (Category 1)

### GHS Label Elements and Precautionary Statements

Component	Pictogram	Hazard Statements	Precautionary Statements
Extraction Reagent A (Sodium Nitrite, 27.6%)	 <p style="text-align: center;"><b>WARNING</b></p>	H302 Harmful if swallowed. H319 Causes serious eye irritation. H400 Very toxic to aquatic life.	P280 Wear protective gloves and eye clothing. P305+P351+P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Negative Control (Microcide III, 0.3%)	 <p style="text-align: center;"><b>Warning</b></p>	H315 Causes skin irritation. H317 May cause an allergic skin reaction. H319 Causes serious eye irritation.	P261 Avoid breathing mist or spray. P280 Wear protective gloves and eye protection. P305+P351+P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

## Section 2 – Hazards Identification (cont'd)

**Supplemental Hazard Statements**

1. Follow Universal Precautions when working with this kit. Refer to additional information in Section 7, Handling and Storage.
2. Wash skin thoroughly after handling. (P264)
3. Do not eat, drink or smoke when using this kit. (P270)
4. Avoid release to the environment. (P273)

## Section 3 – Composition / Information on Ingredients

Component	Chemical Name	CAS #	EINECS #	Conc. (%)	Component Volume
Extraction Reagent A	Sodium Nitrite	7632-00-0	231-555-9	27.6	15 mL
Extraction Reagent B	Acetic Acid	64-19-7	200-580-7	1.2	15 mL
Negative Control	Microcide III	--	--	0.3	2.6 mL

## Section 4 – First Aid Measures

**General Advice**

Move out of exposure area. Consult a physician. Show this safety data sheet to the doctor in attendance.

- If inhaled:* Move the person to fresh air and support breathing as required.
- In case of skin contact:* Wash affected area with soap and water. Seek medical advice if irritation develops.
- In case of 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 attention.
- If swallowed:* Do not induce vomiting. Never give anything by mouth to an unconscious person. Rinse mouth with water (do not swallow). Seek medical advice if irritation develops.

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

Symptoms after ingestion: Harmful if swallowed.

**Indication of any immediate medical attention and special treatment needed**

No specific measures identified.

## Section 5 – Fire Fighting Measures

**General Advice**

Only individuals properly trained and issued appropriate personal protective equipment should respond and attempt to extinguish a fire.

- Suitable Extinguishing Media:* For small fires, use dry chemical, carbon dioxide or alcohol-resistant foam.
- General Fire Hazards:* The components within this kit will not significantly contribute to the intensity of a fire.
- Hazardous Combustion Products:* No data available.
- Fire Fighting Equipment:* Firefighters should wear full protective gear when responding to fires.

## Section 6 – Accidental Release Measures

### General Advice

Only individuals properly trained and issued appropriate personal protective equipment should respond and attempt to clean up a spill or release. Large spills of the solutions, controls or reagents contained within this kit are unlikely.

*Personal Precautions (e.g., PPE):* Use personal protective equipment, including protective gloves and safety glasses when cleaning up small spills of the solutions, controls or reagents within this kit. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Keep all unnecessary personnel away from spill area.

*Materials and Methods for Clean-Up:* Wipe up with inert absorbent material (e.g., paper towel, etc.). Thoroughly wash the area with soap and water after a spill or release clean-up.

*Recovery and Neutralization:* Collect spilled material and clean-up supplies and place in a sealed container for disposal. Refer to Section 13 for disposal guidance.

*Environmental Precautions:* Contain spill to prevent migration to drains, sewers or open water sources. Discharge into the environment must be avoided.

## Section 7 – Handling and Storage

**Specific Use:** Refer to product specific package insert. Not for use by the general public.

### Precautions for Safe Handling

As with all chemical and biological substances, avoid getting the components within this kit ON YOU or IN YOU. Wash exposed areas thoroughly after using this kit. Do not eat or drink while using this kit. This kit should be handled only by qualified clinical or laboratory employees trained on the use of this kit and who are familiar with the potential hazards. Keep out of reach of the general public.

### Universal Precautions

No known test method can offer complete assurance that product(s) derived from human blood, serum or plasma used in components of this kit will not transmit infectious agents. All blood products should be treated as potentially infectious; use universal precautions. Users should ensure the use of proper personal protective equipment (PPE), covering of any cuts or abrasions on the skin (hands), and follow standard protocols for the decontamination of work surfaces when testing has been completed. Always wash hands thoroughly after handling the components within this kit.

**Conditions for Safe Storage:** To maintain efficacy, store according to the package insert instructions.

**Incompatibilities** To maintain efficacy, store according to the package insert instructions.

## Section 8 – Exposure Controls and Personal Protection

**Exposure Limits:** No data available for the specific components within this kit.

### Exposure Controls:

**Engineering Measures** Use with adequate ventilation. Avoid contact with skin, eyes and clothing.

#### Personal Protective Equipment

*Respiratory Protection:* None needed under normal conditions of use.

*Hand Protection:* Handle with appropriately rated chemical resistant gloves. Gloves should be inspected prior to use. Use proper glove technique to remove gloves to avoid contact with skin. Wash hands after handling the components within this kit.

*Eye Protection:* Wear safety glasses with side shields or goggles to prevent eye contact.

*Skin and Body Protection:* Use body protection appropriate for the task. A laboratory coat is recommended.

*Hygiene Measures:* Wash hands before use, after use and at the end of the workday.

## Section 8 – Exposure Controls and Personal Protection (cont'd)

**Environmental Exposure Controls**

No special environmental controls are required.

**Special Notes**

When mixing Extraction Reagent A with Extraction Reagent B, the initial chemical reaction will create Nitrogen Dioxide and Nitric Oxide as reaction products.

## Section 9 – Physical and Chemical Properties

Characteristic	Extraction Reagent A Sodium Nitrite (27.6%)	Extraction Reagent B Acetic Acid (1.2%)	Negative Control Microcide III (0.3%)
Boiling Point (°C)	No data available	No data available	No data available
Melting Point (°C)	No data available	No data available	No data available
Specific Gravity (H <sub>2</sub> O = 1)	No data available	No data available	No data available
Vapor Pressure (mm Hg)	No data available	No data available	No data available
Vapor Density (Air = 1)	No data available	No data available	No data available
Evaporation Rate (Ether = 1)	No data available	No data available	No data available
pH	8.6	2.4	7.2 to 8.5
Solubility in Water	Soluble	Soluble	Soluble
State, Appearance and Odor	Liquid, yellow with no odor	Liquid, clear with vinegar like odor	Clear, odorless

## Section 10 – Stability and Reactivity

Characteristic	Extraction Reagent A Sodium Nitrite (27.6%)	Extraction Reagent B Acetic Acid (1.2%)	Negative Control Microcide III (0.3%)
Component Stability	Stable	Stable	Stable
Hazard Reaction Potential	No data available	No data available	Will not occur
Conditions to Avoid	No data available	No data available	No data available
Materials to Avoid	No data available	No data available	No data available
Hazardous Decomposition Products	No data available	No data available	No data available

## Section 11 – Toxicological Information

### Acute Toxicity

**Component Analysis – LD50 / LC50 / Irritation** (No data available for the specific kit components)

Chemical Name	CAS #	RTECS #	Information		
Sodium Nitrite	7632-00-0	RA1225000	Inhalation LC50	Rat	5.5 mg/L 4 hr
			Oral LD50	Rat	85 mg/kg
Acetic Acid	64-19-7	AF1225000	Inhalation LC50	Rat	11.4 mg/L 4 hr
			Oral LD50	Rat	3310 mg/kg
			Dermal LD50	Rabbit	1060 mg/kg
Microcide III	--	--	Oral LD <sub>50</sub>	Rat	>5000 mg/kg
			Inhalation LC <sub>50</sub>	Rat (4-hr)	0.33 mg/L (dust/mist)
			Dermal LD <sub>50</sub>	Rabbit	>5000 mg/kg

### Potential Health Effects

<i>Skin Corrosion/ Irritation:</i>	No data available	<i>Inhalation:</i>	May cause respiratory tract irritation.
<i>Serious Eye Damage / Irritation:</i>	No data available	<i>Skin:</i>	May cause skin irritation upon contact.
<i>Respiratory or Skin Sensitization:</i>	No data available	<i>Eyes:</i>	May cause eye irritation.
<i>Generative Cell Mutagenicity:</i>	No data available	<i>Ingestion:</i>	May be harmful if swallowed.

### Carcinogenicity

IARC: Extraction Reagent A: 2A - Group 2A: Probably carcinogenic to humans (Sodium Nitrite)

These solutions, reagents or controls do not contain chemicals present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by the ACGIH, NTP or OSHA.

**Reproductive Toxicity** No data available

**Teratogenicity** No data available

### Specified Target Organ General Toxicity

Single Exposure (GHS): No data available

Repeated Exposure (GHS): No data available

### Aspiration Respiratory Organs Hazard

None anticipated under product use conditions.

### Signs and Symptoms of Exposure

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated for the components contained within this kit.

**Synergistic Effects** No data available

### Additional Information

Sensitization: The Negative Control contains a small volume of a very dilute, sensitizing preservative (Microcide III). Though the potential for an allergic response is greatly reduced by the dilution, sensitization threshold is unknown; thus, handle accordingly.

Extraction Reagent A (Sodium Nitrite) – Liver – Irregularities – Based on human evidence.

## Section 12 – Ecological Information

<b>Toxicity</b>	No data available
<b>Persistence / Degradability</b>	No data available
<b>Bioaccumulation</b>	No data available
<b>Results of PBT and vPvB Assessment</b>	Not available as chemical safety assessment not required / not conducted.
<b>Mobility in Soil</b>	No data available

## Section 13 – Disposal Considerations

### Waste Disposal Instructions

Utilize appropriate personal protective equipment and spill control when handling wastes generated from using this kit. Do not discharge the solutions, controls, or reagents into drains, water courses or onto the ground.

### Disposal of Product and Contaminated Packaging

Dispose of waste materials, unused components and contaminated packaging in compliance with country, federal, state and local regulations. If unsure of the applicable regulatory requirements, contact a licensed professional waste disposal service to dispose of the components within this kit.

## Section 14 – Transportation Information

<b>U.S. Department of Transportation (DOT)</b>	This kit is not regulated for transport.
<b>International Air Transportation (IATA)</b>	This kit is not regulated for transport.
<b>International Maritime Dangerous Goods (IMDG)</b>	This kit is not regulated for transport.

## Section 15 – Regulatory Information

### Regulatory Information

#### U.S. Federal Regulations

<b>OSHA Hazards</b>	Extraction Reagent A:	Toxic, Irritant
	Negative Control:	Sensitizer, Irritant
<b>SARA 302</b>	The following chemicals are subject to reporting levels established by SARA Title III, Section 302: No chemicals in this kit are subject to the reporting requirements of SARA Title III, Section 302.	
<b>SARA 313</b>	The following chemicals are subject to reporting levels established by SARA Title III, Section 313: Sodium Nitrite    CAS#: 7632-00-0    Revision Date: 2007-07-01	
<b>SARA 311/312</b>	Sodium Nitrite    CAS#: 7632-00-0	Reactivity Hazard, Acute Health Hazard, Chronic Health Hazard
	Acetic Acid    CAS#: 64-19-7	Fire Hazard, Acute Health Hazard, Chronic Health Hazard

#### State Regulations

The following chemicals appear on one or more of the following state hazardous substances lists:

Chemical Name	CAS #	CA	MA	MN	NJ	PA	RI
Sodium Nitrite	7632-00-0	Yes	Yes	No	Yes	Yes	No
Acetic Acid	64-19-7	Yes	Yes	Yes	Yes	Yes	Yes
Microcide III	--	No	No	No	No	No	No

## Section 15 – Regulatory Information (cont'd)

**California Prop 65** This kit does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.

### Canadian - WHMIS Classification

Chemical Name	CAS #	Classification
Sodium Nitrite	7632-00-0	D2B Toxic material causing other toxic effects. - Moderate eye irritant D2A Carcinogen (IARC)
Acetic Acid	64-19-7	E Corrosive Material
<b>Mixture for Microcide III:</b> 2-Methyl-4-isothiazolin-3-one (<1%); Magnesium nitrate (<2%)	--	D2B Toxic material causing other toxic effects. - Sensitizer

### Additional Regulatory Information

#### Safety, Health and Environmental regulations/legislation specific for the mixture

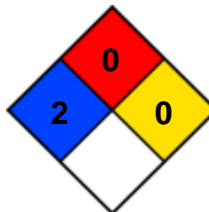
European Union – Regulation (EC) 1907/2006.

#### Chemical Safety Assessment

Not completed for the components contained within this kit.

#### NFPA Kit Classification:

Health Hazard (blue): 2  
 Fire Hazard (red): 0  
 Reactivity (yellow): 0  
 Special Hazards (white): None



## Section 16 – Other Information

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**SUPERCEDES:** February 5, 2018

**REVISIONS:** Section 2, revised Universal Precautions reference; Section 3, removed chemical classification column; Section 7, added Universal Precautions section; Section 15, updated Canadian WHMIS section, removed HMIS Kit Classification, added NFPA symbol; Section 16, removed Text of H-Codes; minor text revisions throughout.

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