

### SECTION 1: Identification

#### 1.1. Identification

Product form : Mixture  
 Product name : QuickVue Dipstick Strep A  
 Product code : 20108, 20108IN, 20125, 20152, 20318

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

Recommended use : For medical diagnostic use.  
 Restrictions on use : Professional Use of Medical Devices

#### 1.3. Supplier

##### Manufacturer

Quidel Corporation  
 10165 McKellar Court  
 San Diego, 92121 - USA  
 T 1.800.874.1517 - F 1.858.453.4338  
[qehs@quidel.com](mailto:qehs@quidel.com) - [quidel.com](http://quidel.com)

#### 1.4. Emergency telephone number

Emergency number : 1.866.519.4752

### SECTION 2: Hazard(s) identification

#### 2.1. Classification of the substance or mixture


##### GHS US classification



Components	GHS US classification
Negative Control, QuickVue Strep A	Skin Sens. 1, H317
Reagent B, QuickVue Strep A	Skin Irrit. 2, H315 Eye Irrit. 2A, H319
Reagent A, QuickVue Strep A	Acute Tox. 4 (Oral), H302 Eye Irrit. 2A, H319

Full text of H statements : see section 16

#### 2.2. GHS Label elements, including precautionary statements

##### GHS US labeling

Components	Pictograms	Signal word	Hazard statements	Precautionary statements
Reagent A, QuickVue Strep A		Warning	H302 - Harmful if swallowed H319 - Causes serious eye irritation	P264 - Wash hands thoroughly after handling P270 - Do not eat, drink or smoke when using this product. P280 - Wear protective gloves/protective clothing/eye protection/face protection. P301+P312 - If swallowed: Call a poison center or doctor if you feel unwell. P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337+P313 - If eye irritation persists: Get medical advice/attention. P501 - Dispose of contents/container: Dispose in a safe manner in accordance with local/national regulations.

Components	Pictograms	Signal word	Hazard statements	Precautionary statements
Reagent B, QuickVue Strep A		Warning	H315 - Causes skin irritation H319 - Causes serious eye irritation	P264 - Wash hands thoroughly after handling P280 - Wear protective gloves/protective clothing/eye protection/face protection. P302+P352 - If on skin: Wash skin thoroughly with mild soap and water P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P321 - Specific treatment: Seek medical attention if ill effect develops P332+P313 - If skin irritation occurs: Get medical advice/attention. P337+P313 - If eye irritation persists: Get medical advice/attention.
Negative Control, QuickVue Strep A		Warning	H317 - May cause an allergic skin reaction	P280 - Wear protective gloves/protective clothing/eye protection/face protection. P302+P352 - If on skin: Wash skin thoroughly with mild soap and water P321 - Specific treatment: Seek medical attention if ill effect develops

### 2.3. Other hazards which do not result in classification

No additional information available

### 2.4. Unknown acute toxicity (GHS US)

Not applicable

## SECTION 3: Composition/Information on ingredients

### 3.1. Substances

Not applicable

### 3.2. Mixtures

Name	Chemical name	CAS #	%	GHS US classification
Reagent A, QuickVue Strep A	Sodium nitrite	7632-00-0	25 – 30	Ox. Sol. 3, H272 Acute Tox. 3 (Oral), H301 Eye Irrit. 2A, H319
Reagent B, QuickVue Strep A	Acetic acid	64-19-7	1 – 5	Flam. Liq. 3, H226 Skin Corr. 1A, H314
Negative Control, QuickVue Strep A	Microcide III	--	0.3	Skin Sens. 1, H317

Full text of hazard classes and H-statements : see section 16

## SECTION 4: First-aid measures

### 4.1. Description of first aid measures

First-aid measures general	: Call a poison center/doctor/physician if you feel unwell.
First-aid measures after inhalation	: Remove person to fresh air and keep comfortable for breathing.
First-aid measures after skin contact	: Wash skin with plenty of water. Take off contaminated clothing. If skin irritation or rash occurs: Get medical advice/attention.
First-aid measures after 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.
First-aid measures after ingestion	: Rinse mouth. Call a poison center/doctor/physician if you feel unwell.

### 4.2. Most important symptoms and effects (acute and delayed)

Symptoms/effects after skin contact	: Irritation. May cause an allergic skin reaction.
Symptoms/effects after eye contact	: Eye irritation.

### 4.3. Immediate medical attention and special treatment, if necessary

Treat symptomatically.

## SECTION 5: Fire-fighting measures

### 5.1. Suitable (and unsuitable) extinguishing media

Suitable extinguishing media : Water spray. Dry powder. Foam. Carbon dioxide.

### 5.2. Specific hazards arising from the chemical

No additional information available

### 5.3. Special protective equipment and precautions for fire-fighters

Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

#### 6.1.1. For non-emergency personnel

Emergency procedures : Ventilate spillage area. Avoid contact with skin and eyes. Avoid breathing dust/fume/gas/mist/vapours/spray.

#### 6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

### 6.2. Environmental precautions

Avoid release to the environment.

### 6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Take up liquid spill into absorbent material.  
Other information : Dispose of materials or solid residues at an authorized site.

### 6.4. Reference to other sections

For further information refer to section 13.

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station. Avoid contact with skin and eyes. Wear personal protective equipment. Avoid breathing dust/fume/gas/mist/vapours/spray.  
Hygiene measures : Wash contaminated clothing before reuse. Contaminated work clothing should not be allowed out of the workplace. Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

### 7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a well-ventilated place. Keep cool.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

#### Reagent A, QuickVue Strep A

Not applicable

#### Reagent B, QuickVue Strep A

Not applicable

#### Negative Control, QuickVue Strep A

Not applicable

### 8.2. Appropriate engineering controls

Appropriate engineering controls : Ensure good ventilation of the work station.  
Environmental exposure controls : Avoid release to the environment.

### 8.3. Individual protection measures/Personal protective equipment

#### Materials for protective clothing:

Lab coat

#### Eye protection:

Safety glasses

#### Skin and body protection:

Wear suitable protective clothing

#### Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment

#### Personal protective equipment symbol(s):



#### Other information:

Do not eat, drink or smoke when using this product.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Appearance	: In vitro diagnostic medical test kit.
Color	: No data available
Odor	: No data available
Odor threshold	: ≤ ppm
pH	: Reagent B, Acetic Acid (1.2%), pH 2.4
Melting point	: Not applicable
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Relative evaporation rate (butyl acetate=1)	: No data available
Flammability (solid, gas)	: Not applicable.
Vapor pressure	: No data available
Relative vapor density at 20 °C	: No data available
Relative density	: No data available
Solubility	: No data available
Partition coefficient n-octanol/water (Log Pow)	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosion limits	: No data available
Explosive properties	: No data available
Oxidizing properties	: No data available

### 9.2. Other information

No additional information available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

### 10.2. Chemical stability

Stable under normal conditions.

### 10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

### 10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

### 10.5. Incompatible materials

No additional information available

### 10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

Acute toxicity (oral) : Harmful if swallowed.  
 Acute toxicity (dermal) : Not classified  
 Acute toxicity (inhalation) : Not classified

ATE US (oral)	652.174 mg/kg body weight
<b>Reagent A, QuickVue Strep A</b>	
ATE US (oral)	652.174 mg/kg body weight

Skin corrosion/irritation : Causes skin irritation.  
 pH: Reagent B, Acetic Acid (1.2%), pH 2.4  
 Serious eye damage/irritation : Causes serious eye irritation.  
 pH: Reagent B, Acetic Acid (1.2%), pH 2.4  
 Respiratory or skin sensitization : May cause an allergic skin reaction.  
 Germ cell mutagenicity : Not classified  
 Carcinogenicity : Not classified  
 Reproductive toxicity : Not classified  
 STOT-single exposure : Not classified  
 STOT-repeated exposure : Not classified  
 Aspiration hazard : Not classified  
 Viscosity, kinematic : No data available  
 Symptoms/effects after skin contact : Irritation. May cause an allergic skin reaction.  
 Symptoms/effects after eye contact : Eye irritation.

## SECTION 12: Ecological information

### 12.1. Toxicity

Ecology - general : The product is not considered harmful to aquatic organisms or to cause long-term adverse effects in the environment.

**12.2. Persistence and degradability**

No additional information available

**12.3. Bioaccumulative potential**

No additional information available

**12.4. Mobility in soil**

No additional information available

**12.5. Other adverse effects**

No additional information available

**SECTION 13: Disposal considerations****13.1. Disposal methods**

Regional legislation (waste)	: Disposal must be done according to official regulations.
Waste treatment methods	: Dispose of contents/container in accordance with licensed collector's sorting instructions.
Sewage disposal recommendations	: Disposal must be done according to official regulations.
Product/Packaging disposal recommendations	: Dispose of contents/container: Dispose in a safe manner in accordance with local/national regulations.
Ecology - waste materials	: Avoid release to the environment.

**SECTION 14: Transport information**

Department of Transportation (DOT)	Not regulated
Transport by sea	Not regulated
Air transport	Not regulated

**SECTION 15: Regulatory information****15.1. US Federal regulations**

No additional information available

**15.2. International regulations****CANADA****Reagent A, QuickVue Strep A**

Not listed on the Canadian DSL (Domestic Substances List)/NDSL (Non-Domestic Substances List)

**EU-Regulations**

No additional information available

**National regulations**

No additional information available

**15.3. US State regulations**

California Proposition 65 - This product does not contain any substances known to the state of California to cause cancer, developmental and/or reproductive harm



# QuickVue Dipstick Strep A

## Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Date of issue: 01/31/2020

Supersedes: 09/10/2018 Version: 1.0

### SECTION 16: Other information

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

- Training advice : Normal use of this product shall imply use in accordance with the instructions on the packaging.  
Other information : Please review product insert prior to using this product.

Full text of H-phrases:

H302	Harmful if swallowed
H315	Causes skin irritation
H317	May cause an allergic skin reaction
H319	Causes serious eye irritation

*This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.*