

**SECTION 1: Identification**
**1.1. Identification**

Product form : Mixture  
 Product name : QuickVue In-Line Strep A Test  
 Product code : 00343, 00343IN, 00346

**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, CA 92121 - U.S.A  
 T 1.800.874.1517 - F 1.858.453.4338  
[gehs@quidel.com](mailto:gehs@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   |
|----------------------------|---|
| Extraction Solution (ERDs) | Acute Tox. 4 (Oral), H302<br>Skin Irrit. 2, H315<br>Eye Irrit. 2A, H319 |

**2.2. GHS Label elements, including precautionary statements**
**GHS US labeling**

| Components                 | Pictograms  | Signal word | Hazard statements  | Precautionary statements  |
|----------------------------|---|-------------|--|---|
| Extraction Solution (ERDs) |  | Warning     | H302 - Harmful if swallowed<br>H315 - Causes skin irritation<br>H319 - Causes serious eye irritation | P264 - Wash hands thoroughly after handling<br>P270 - Do not eat, drink or smoke when using this product.<br>P280 - Wear labcoat, safety glasses, and gloves.<br>P301+P312 - If swallowed: Call a poison center or doctor if you feel unwell.<br>P302+P352 - If on skin: Wash skin thoroughly with mild soap and water<br>P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.<br>P321 - Specific treatment: Seek medical attention if ill effect develops<br>P501 - Dispose of contents/container: Dispose in a safe manner in accordance with local/national regulations |

**SECTION 3: Composition/Information on ingredients**

| Name                       | Chemical name  | CAS #     | %       | GHS US classification  |
|----------------------------|----------------|-----------|---------|--|
| Extraction Solution (ERDs) | acetic acid    | 64-19-7   | 1 – 5   | Flam. Liq. 3, H226<br>Skin Corr. 1A, H314                            |
|                            | sodium nitrite | 7632-00-0 | 25 – 30 | Ox. Sol. 3, H272<br>Acute Tox. 3 (Oral), H301<br>Eye Irrit. 2A, H319 |

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 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.
- Symptoms/effects after eye contact : Eye irritation.
- 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.

**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**

- 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.
- 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.
- Hygiene measures : Wash contaminated clothing before reuse. 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**

| Extraction Solution (ERDs) |                  |                      |
|----------------------------|------------------|----------------------|
| OSHA                       | OSHA PEL TWA [1] | 25 mg/m <sup>3</sup> |

| Extraction Solution (ERDs) |                                |                          |
|----------------------------|--------------------------------|--------------------------|
| OSHA                       | OSHA PEL TWA [2]               | 10 ppm                   |
| OSHA                       | Regulatory reference (US-OSHA) | OSHA Annotated Table Z-1 |

**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.

**Hand protection:**

protective gloves.

**Eye protection:**

Safety glasses.

**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 : No data available  
 pH : ≤ 2.4 Extraction Solution (ERDs), Acetic Acid  
 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 : 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  
 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**

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

| QuickVue In-Line Strep A   |                           |
|----------------------------|---------------------------|
| ATE US (oral)              | 652.174 mg/kg body weight |
| Extraction Solution (ERDs) |                           |
| ATE US (oral)              | 652.174 mg/kg body weight |

|                                     |                                 |
|-------------------------------------|---------------------------------|
| Skin corrosion/irritation           | : Causes skin irritation        |
| Serious eye damage/irritation       | : Causes serious eye irritation |
| Respiratory or skin sensitization   | : Not classified                |
| 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                    |
| 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.
- Ecology – waste materials : Avoid release to the environment.

**SECTION 14 : Transport information**
**Department of Transportation (DOT)**

Not applicable.

**Transport by sea**

Not applicable.

**Air transport**

Not applicable.

**SECTION 15: Regulatory information**
**15.1. US Federal regulations**
**QuickVue In-Line Strep A**

All components of this product are present and listed as Active on the United States Environmental Protection Agency Toxic Substances Control Act (TSCA) inventory, except for:

| Extraction Solution (ERDs)  | CAS No | 100% |
|---|--------|------|
| This product or mixture is not known to contain a toxic chemical or chemicals in excess of the applicable de minimis concentration as specified in 40 CFR §372.38(a) subject to the reporting requirements of section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 and 40 CFR Part 372. |        |      |

**15.2. International regulations**
**CANADA**
**QuickVue In-Line 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.

**SECTION 16: Other information**

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

**Indication of changes:**

Regulatory Review.

*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.*