

**SECTION 1: Identification of the substance/mixture and of the company/undertaking**
**1.1. Product identifier**

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

**1.2. Relevant identified uses of the substance or mixture and uses advised against**
**1.2.1. Relevant identified uses**

Industrial/Professional use spec : For in vitro diagnostic use

**1.2.2. Uses advised against**

Restrictions on use : Professional Use of Medical Devices

**1.3. Details of the supplier of the safety data sheet**
**Manufacturer**

Quidel Corporation  
 10165 McKellar Court  
 92121 San Diego, CA - 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: Hazards identification**
**2.1. Classification of the substance or mixture**

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Components	CLP classification
Extraction Solution (ERDs)	Acute Tox. 4 (Oral), H302 Eye Irrit. 2, H319 Aquatic Acute 1, H400



Full text of H- and EUH-statements: see section 16

**Adverse physicochemical, human health and environmental effects**

Harmful if swallowed. Causes serious eye irritation. Very toxic to aquatic life.

**2.2. Label elements**

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Components	Pictograms	Signal word	Hazard statements	Precautionary statements
Extraction Solution (ERDs)	 	Warning	H302 - Harmful if swallowed. H319 - Causes serious eye irritation. H400 - Very toxic to aquatic life.	P264 - Wash hands thoroughly after handling. P273 - Avoid release to the environment. P280 - Wear labcoat, safety glasses, and gloves. P301+P312 - IF SWALLOWED: Call a 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. P330 - Rinse mouth. P337+P313 - If eye irritation persists: Get medical advice/attention. P391 - Collect spillage. P501 - Dispose of in accordance with local/national regulations. to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

**2.3. Other hazards**

 Contains no PBT/vPvB substances  $\geq$  0.1% assessed in accordance with REACH Annex XIII.

**SECTION 3: Composition/information on ingredients**
**3.1. Substances**

Not applicable.

**3.2. Mixtures**

Name	Chemical name	CAS No EC-No.	%	CLP classification
Extraction Solution (ERDs)	sodium nitrite	7632-00-0 -	25 – 30	Ox. Sol. 3, H272 Acute Tox. 3 (Oral), H301 Eye Irrit. 2, H319 Aquatic Acute 1, H400
	acetic acid	64-19-7 -	1 – 5	Flam. Liq. 3, H226 Skin Corr. 1A, H314

Full text of H- and EUH-statements: see section 16

**SECTION 4: First aid measures**
**4.1. Description of first aid measures**

First-aid measures general	: Call a poison center or a doctor 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.
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 or a doctor if you feel unwell.

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

Symptoms/effects after eye contact : Eye irritation.

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

Treat symptomatically.

**SECTION 5: Firefighting measures**
**5.1. Extinguishing media**

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

**5.2. Special hazards arising from the substance or mixture**

Hazardous decomposition products in case of fire : Toxic fumes may be released.

**5.3. Advice for firefighters**

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**

Avoid release to the environment.

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

For containment	: Collect spillage.
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.  
Hygiene measures : 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.

### 7.3. Specific end use(s)

No additional information available.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

Extraction Solution (ERDs)		
USA - OSHA	Local name	Acetic acid
USA - OSHA	OSHA PEL TWA [1]	25 mg/m <sup>3</sup>
USA - OSHA	OSHA PEL TWA [2]	10 ppm

### 8.2. Exposure controls

#### Appropriate engineering controls:

Ensure good ventilation of the work station.

#### Materials for protective clothing:

Lab coat.

#### Hand protection:

Protective gloves.

#### 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):



#### Environmental exposure controls:

Avoid release to the environment.

#### 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

Colour	: No data available
Odour	: No data available
Odour threshold	: No data available
pH	: ≤ 2.4 Extraction Solution (ERDs), Acetic Acid
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: Not applicable
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability	: Not applicable
Vapour pressure	: No data available
Relative vapour 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
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: 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 CLP (oral)	652.174 mg/kg bodyweight
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Skin corrosion/irritation	: Not classified
	pH: ≤ 2.4 Extraction Solution (ERDs), Acetic Acid
Serious eye damage/irritation	: Causes serious eye irritation.
	pH: ≤ 2.4 Extraction Solution (ERDs), Acetic Acid
Respiratory or skin sensitisation	: 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

## SECTION 12: Ecological information

### 12.1. Toxicity

Ecology - general	: Very toxic to aquatic life
Hazardous to the aquatic environment, short-term (acute)	: Very toxic to aquatic life
Hazardous to the aquatic environment, long-term (chronic)	: Not classified

### 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. Results of PBT and vPvB assessment

No additional information available.

### 12.6. Other adverse effects

No additional information available.

## SECTION 13: Disposal considerations

### 13.1. Waste treatment 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

In accordance with ADR / IATA

### 14.1. UN number

UN-No. (ADR)	: Not applicable
UN-No. (IATA)	: Not applicable

### 14.2. UN proper shipping name

Proper Shipping Name (ADR)	: Not applicable
Proper Shipping Name (IATA)	: Not applicable

### 14.3. Transport hazard class(es)

#### ADR

Transport hazard class(es) (ADR)	: Not applicable
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#### IATA

Transport hazard class(es) (IATA)	: Not applicable
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### 14.4. Packing group

Packing group (ADR)	: Not applicable
Packing group (IATA)	: Not applicable

**14.5. Environmental hazards**

Dangerous for the environment : Yes  
 Other information : No supplementary information available

**14.6. Special precautions for user**
**Overland transport**

Not applicable

**Air transport**

Not applicable

**14.7. Transport in bulk according to Annex II of Marpol and the IBC Code**

Not applicable.

**SECTION 15: Regulatory information**
**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**
**15.1.1. EU-Regulations**

Contains no substance(s) listed on REACH Annex XVII (Restriction Conditions)  
 Contains no substance(s) listed on the REACH Candidate List  
 Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

**15.1.2. National regulations**

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

**Germany**

Regulatory reference : WGK 2, Significantly hazardous to water (Classification according to AwSV, Annex 1)  
 Employment restrictions : Observe restrictions according Act on the Protection of Working Mothers (MuSchG)  
 Observe restrictions according Act on the Protection of Young People in Employment (JArbSchG)  
 Hazardous Incident Ordinance (12. BImSchV) : Is not subject of the 12. BImSchV (Hazardous Incident Ordinance)

**Netherlands**

SZW-lijst van kankerverwekkende stoffen : None of the components are listed  
 SZW-lijst van mutagene stoffen : None of the components are listed  
 SZW-lijst van reprotoxische stoffen – Borstvoeding : None of the components are listed  
 SZW-lijst van reprotoxische stoffen – Vruchtbaarheid : None of the components are listed  
 SZW-lijst van reprotoxische stoffen – Ontwikkeling : None of the components are listed

**15.2. Chemical safety assessment**

No chemical safety assessment has been carried out.

**SECTION 16: Other information**
**Indication of changes:**

Regulatory Review.

**Abbreviations and acronyms:**

ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ATE	Acute Toxicity Estimate
BLV	Biological limit value
CAS No	Chemical Abstract Service number
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
EC50	Median effective concentration
EC-No.	European Community number

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830  
 Issue date: 4/27/2016 Revision date: 12/13/2022 Supersedes version of: 2/3/2020 Version: 1.2

EN	European Standard
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
OEL	Occupational Exposure Limit
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet
vPvB	Very Persistent and Very Bioaccumulative
WGK	Water Hazard Class

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- and EUH-statements:**

Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Aquatic Acute 1	Hazardous to the aquatic environment – Acute Hazard, Category 1
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Flam. Liq. 3	Flammable liquids, Category 3
H226	Flammable liquid and vapour
H302	Harmful if swallowed
H319	Causes serious eye irritation
H400	Very toxic to aquatic life

*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.*