

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

Product form : Mixture
 Product name : QuickVue+ Strep A Test
 Product code : 20122, 20122IN

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 - USA
 T 1.800.874.1517 - F 1.858.453.4338
gehs@quidel.com - 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
Negative Control, QuickVue Strep A	Skin Sens. 1, H317
Reagent B, QuickVue Strep A	Skin Irrit. 2, H315 Eye Irrit. 2, H319
Reagent A, QuickVue Strep A	Acute Tox. 4 (Oral), H302 Eye Irrit. 2, H319 Aquatic Acute 1, H400


Full text of H statements : see section 16

Adverse physicochemical, human health and environmental effects



Harmful if swallowed. Causes skin irritation. May cause an allergic skin reaction. Causes serious eye irritation.

2.2. Label elements

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

Components	Pictograms	Signal word	Hazard statements	Precautionary statements
Reagent A, QuickVue Strep A		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 protective gloves/protective clothing/eye protection. 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. P501 - Dispose of contents/container in accordance with local/national regulations.

2.2. Label elements (cont'd)
Labeling according to Regulation (EC) No. 1272/2008 [CLP]

Components	Pictograms	Signal word	Hazard statements	Precautionary statements
Reagent B, QuickVue Strep A		Warning	H315 - Causes skin irritation. H319 - Causes serious eye irritation.	P280 - Wear protective gloves/protective clothing/eye protection. P302+P352 - IF ON SKIN: Wash with plenty of 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 (see ... on this label). 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/hearing protection. P302+P352 - IF ON SKIN: Wash with plenty of water. P321 - Specific treatment: Seek medical attention if ill effects develop.

2.3. Other hazards

No additional information available

SECTION 3: Composition/Information on ingredients
3.1. Substances

Not applicable

3.2. Mixtures

Name	Chemical name	CAS-No. EC-No.	%	CLP classification
Negative Control, QuickVue Strep A	Microcide III	-- --	0.3	Skin Sens. 1, H317
Reagent B, QuickVue Strep A	Acetic acid	64-19-7 --	1.2	Flam. Liq. 3, H226 Skin Corr. 1A, H314
Reagent A, QuickVue Strep A	Sodium nitrite	7632-00-0 --	27.6	Ox. Sol. 3, H272 Acute Tox. 3 (Oral), H301 Eye Irrit. 2, H319 Aquatic Acute 1, H400

Full text of H-phrases: 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, both acute and delayed

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

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection**8.1. Control parameters**

No additional information available

8.2. Exposure controls**Appropriate engineering controls:**

Ensure good ventilation of the work station.

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):

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.
Color	: No data available
Odor	: No data available
Odor threshold	: No data available
pH	: Reagent B, Acetic Acid (1.2%), pH 2.0
Relative evaporation rate (butyl acetate=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 (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
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidizing properties	: No data available
Explosion 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 body weight
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Skin corrosion/irritation : Causes skin irritation.
 pH: Reagent B, Acetic Acid (1.2%), pH 204
 Serious eye damage/irritation : Causes serious eye irritation.
 pH: Reagent B, Acetic Acid (1.2%), pH 204
 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

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.
 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 regulated
UN-No. (IATA)	: Not regulated

14.2. UN proper shipping name

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

14.3. Transport hazard class(es)
ADR

Transport hazard class(es) (ADR)	: Not regulated
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IATA

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

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

14.5. Environmental hazards

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

14.6. Special precautions for user
Overland transport

Not regulated

Air transport

Not regulated

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 REACH substances with Annex XVII restrictions
 Contains no REACH candidate substance
 Contains no REACH Annex XIV substances.

15.1.2. National regulations

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

Germany

Regulatory reference	: WGK 2, significant 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
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SZW-lijst van mutagene stoffen	: None of the components are listed
NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Borstvoeding	: None of the components are listed
NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Vruchtbaarheid	: None of the components are listed
NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Ontwikkeling	: None of the components are listed

Denmark

Danish National Regulations : Young people below the age of 18 years are not allowed to use the product

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

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.

Classification according to Regulation (EC) No. 1272/2008 [CLP]:	
Acute Tox. 4 (Oral)	H302
Skin Irrit. 2	H315
Eye Irrit. 2	H319
Skin Sens. 1	H317
Aquatic Acute 1	H400
Full text of H- and EUH-phrases:	
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
Skin Irrit. 2	Skin corrosion/irritation Category 2
Skin Sens. 1	Skin sensitization, Category 1
H302	Harmful if swallowed.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
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.