

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

Product form : Mixture  
 Product name : QuickVue H. pylori Test  
 Product code : 0W009, 0W010

**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](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
Positive Control, H. pylori GII	Skin Sens. 1, H317
Negative Control, H. pylori GII	Skin Sens. 1, H317

Full text of H statements : see section 16

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

May cause an allergic skin reaction. Harmful to aquatic life.

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

Components	Pictograms	Signal word	Hazard statements	Precautionary statements
Negative Control, H. pylori GII		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.
Positive Control, H. pylori GII		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
Positive Control, H. pylori GII	Microcide III	-- --	0.1	Skin Sens. 1, H317
	Thimerosal	54-64-8 --	0.006	Acute Tox. 3 (Oral), H301 Acute Tox. 1 (Dermal), H310 Acute Tox. 2 (Inhalation), H330 STOT RE 2, H373 Aquatic Acute 1, H400 (M=100) Aquatic Chronic 1, H410
Negative Control, H. pylori GII	Microcide III	-- --	0.1	Skin Sens. 1, H317

Full text of H-phrases: see section 16

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

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 eyes with water as a precaution.
First-aid measures after ingestion	: 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	: May cause an allergic skin reaction.
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**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.
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**5.2. Special hazards arising from the substance or mixture**

Hazardous decomposition products in case of fire	: Toxic fumes may be released.
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**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.
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**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.
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**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".
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**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. Avoid breathing dust/fume/gas/mist/vapours/spray. Wear personal protective equipment.
Hygiene measures	: Contaminated work clothing should not be allowed out of the workplace. 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.
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### 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	: Neutral
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)	: Not classified
Acute toxicity (dermal)	: Not classified
Acute toxicity (inhalation)	: Not classified
Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Not classified
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 : Harmful to aquatic life.  
 Hazardous to the aquatic environment, short-term (acute) : Not classified  
 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.  
 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

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

#### IATA

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

### 14.4. Packing group

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

### 14.5. Environmental hazards

Dangerous for the environment : No  
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 3, Highly 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  
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]:

Skin Sens. 1	H317
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#### Full text of H- and EUH-phrases:

Skin Sens. 1	Skin sensitization, Category 1
H317	May cause an allergic skin reaction.

*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.*