

### SECTION 1: Identification

#### 1.1. Identification

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

#### 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
Negative Control, H. pylori GII	Skin Sens. 1, H317 Aquatic Acute 3, H402
Positive Control, H. pylori GII	Skin Sens. 1, H317

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

##### GHS US labeling

Components	Pictograms	Signal word	Hazard statements	Precautionary statements
Negative Control, H. pylori GII		Warning	H317 - May cause an allergic skin reaction H402 - Harmful to aquatic life	P273 - Avoid release to the environment. P280 - Wear labcoat, safety glasses, and gloves. P302+P352 - If on skin: Wash skin thoroughly with mild soap and water P321 - Specific treatment: Seek medical attention if ill effect develops P501 - Dispose of contents/container: Dispose in a safe manner in accordance with local/national regulations
Positive Control, H. pylori GII		Warning	H317 - May cause an allergic skin reaction	P280 - Wear labcoat, safety glasses, and gloves. P302+P352 - If on skin: Wash skin thoroughly with mild soap and water P321 - Specific treatment: Seek medical attention if ill effect develops

### SECTION 3: Composition/Information on ingredients

Name	Chemical name	CAS #	%	GHS US classification
Negative Control, H. pylori GII	Microcide III	--	0.1	Skin Sens. 1, H317
	Thimerosal	54-64-8	<0.01	Acute Tox. 2 (Oral), H300 Acute Tox. 1 (Dermal), H310 Acute Tox. 2 (Inhalation), H330 STOT RE 2, H373 Aquatic Acute 1, H400 Aquatic Chronic 1, H410
Positive Control, H. pylori GII	Microcide III	--	0.1	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 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 (acute and delayed)**

- Symptoms/effects after skin contact : May cause an allergic skin reaction.
- 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/vapors/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**

- 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.
- 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/vapors/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.

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

Thimerosal (54-64-8)		
ACGIH	ACGIH OEL TWA	0.1 mg/m <sup>3</sup>

**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.

**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 : Neutral  
 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) : Not classified  
 Acute toxicity (dermal) : Not classified  
 Acute toxicity (inhalation) : Not classified

<b>Thimerosal (54-64-8)</b>	
ATE US (oral)	5 mg/kg body weight
ATE US (dermal)	5 mg/kg body weight
ATE US (gases)	100 ppmV/4h
ATE US (vapors)	0.5 mg/l/4h
ATE US (dust, mist)	0.05 mg/l/4h

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

<b>Thimerosal (54-64-8)</b>	
STOT-repeated exposure	May cause damage to organs through prolonged or repeated exposure.

Aspiration hazard : Not classified  
 Viscosity, kinematic : No data available  
 Symptoms/effects after skin contact : May cause an allergic skin reaction

**SECTION 12: Ecological information**
**12.1. Toxicity**

Ecology - general : Harmful to aquatic life.

<b>Thimerosal (54-64-8)</b>	
LC50 - Fish [1]	0.16 mg/l (96 h, Cyprinus carpio, Literature study, Mercury ion)

**12.2. Persistence and degradability**

<b>Thimerosal (54-64-8)</b>	
Persistence and degradability	Not readily biodegradable in water.

**12.3. Bioaccumulative potential**

<b>Thimerosal (54-64-8)</b>	
Partition coefficient n-octanol/water (Log Pow)	-1.88 (Estimated value, KOWWIN)
Bioaccumulative potential	Not bioaccumulative.

**12.4. Mobility in soil**

Thimerosal (54-64-8)	
Organic Carbon Normalized Adsorption Coefficient (Log Koc)	2.235 (log Koc, SRC PCKOCWIN v2.0, Calculated value)
Ecology - soil	Low potential for adsorption in soil.

**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**

QuickVue H. pylori Test		
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:		
Microcide III	CAS No	< 1%
Thimerosal	CAS No 54-64-8	< 1%

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 H. pylori Test	
Not listed on the Canadian DSL (Domestic Substances List)/NDSL (Non-Domestic Substances List)	
Microcide III	
Not listed on the Canadian DSL (Domestic Substances List)/NDSL (Non-Domestic Substances List)	
Thimerosal (54-64-8)	
Listed on the Canadian DSL (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.



# QuickVue® H. pylori Test

## Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations  
Issue date: 03/02/2015 Revision date: 12/06/2022 Supersedes: 01/31/2020 Version: 1.2

### 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.*