

## Section 1 – Product and Company Identification

### Manufacturer Information

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### Product Information

**Product Name:** QuickVue H. pylori Test (Catalog #: OW009 and OW010)

**Recommended Use:** The QuickVue H. pylori test is a lateral-flow immunoassay intended for the rapid, qualitative detection of IgG antibodies specific to *Helicobacter pylori* in human serum, plasma or whole blood as an aid in the diagnosis of *H. pylori* infection in patients with clinical signs and symptoms of gastrointestinal disease. This test is intended for use by health care professionals.


**Components:** Kit is composed of individually pouched Test Cassettes, Disposable Droppers, Capillary Tubes, Positive Control (diluted human plasma containing *H. pylori* specific IgG) and Negative Control (diluted human plasma). The Positive and Negative Controls contain Thimerosal (<0.01%) as a preservative.

## Section 2 – Hazards Identification

### Emergency Overview

Component	OSHA Hazards	Target Organs	GHS Classification
<b>Positive and Negative Controls</b> (Microcide III, 0.1%)	Irritant, Sensitizer	Skin, eyes	Eye Irritation (Category 2A) Skin Irritation (Category 2) Skin Sensitizer (Category 1)

### GHS Label Elements & Precautionary Statements

Component	Pictogram	Hazard Statements	Precautionary Statements
<b>Positive and Negative Controls</b> (Microcide III, 0.1%)	 Warning	H315 Causes skin irritation. H317 May cause an allergic skin reaction. H319 Causes serious eye irritation.	P261 Avoid breathing mist or spray. P280 Wear protective gloves and eye protection. P305+P351+P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
<b>Supplemental Hazard Statements</b>		Avoid release to the environment.	

## Section 3 – Composition / Information on Ingredients

Component	Chemical Name	CAS #	EINECS #	Conc. (%)	Component Volume	Chemical Classification
Positive and Negative Controls	Microcide III	55965-84-9	N/A	0.1	0.6 mL (per control)	Acute Tox. 3, Skin Corr. 1B, Skin Sens. 1, Eye Dam. 1, Aquatic Acute 1, Aquatic Chronic 1; H301, H331, H311, H314, H317, H400, H410

\*\*For the full text of the H-Statements and R-Phrases mention in this Section, see Section 16.

## Section 4 – First Aid Measures

### General Advice

Move out of exposure area. Consult a physician. Show this safety data sheet to the doctor in attendance, as necessary.

<i>If inhaled:</i>	Move the person to fresh air and support breathing as required.
<i>In case of skin contact:</i>	Wash affected area with soap and water. Seek medical advice if irritation develops.
<i>In case of eye contact:</i>	Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists get medical attention.
<i>If swallowed:</i>	Never give anything by mouth to an unconscious person. Rinse mouth with water. Seek medical advice if irritation develops.

Note to Physicians: Treat symptomatically.

## Section 5 – Fire Fighting Measures

### General Advice

Only individuals properly trained and issued appropriate personal protective equipment should respond and attempt to extinguish a fire.

<i>Extinguishing Media:</i>	For small fires, use dry chemical, water spray, carbon dioxide or alcohol-resistant foam.
<i>General Fire Hazards:</i>	The components within this kit will not significantly contribute to the intensity of a fire.
<i>Hazardous Combustion Products:</i>	No data available.
<i>Fire Fighting Equipment:</i>	Firefighters should wear full protective gear when responding to fires.

## Section 6 – Accidental Release Measures

### General Advice

Only individuals properly trained and issued appropriate personal protective equipment should respond and attempt to clean up a spill or release. Large spills of the solutions, controls, or reagents contained within this kit are unlikely.

<i>Personal Precautions:</i>	Use personal protective equipment, including protective gloves and safety glasses when cleaning up spills of the solutions, controls or reagents within this kit. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Keep all unnecessary personnel away from the spill area.
<i>Materials / Methods for Clean-Up:</i>	Soak up with inert absorbent material (e.g., paper towel, etc.). Thoroughly wash the area with soap and water after a spill or release clean-up.
<i>Recovery and Neutralization:</i>	Collect spilled material and clean-up supplies and place in a sealed container for disposal. Refer to Section 13 for disposal guidance.
<i>Environmental Precautions:</i>	Contain spill to prevent migration to drains, sewers or open water sources. Discharge into the environment must be avoided.

## Section 7 – Handling and Storage

**Specific Use:** For *In Vitro* Diagnostic use. Not for use by the general public.

### Precautions for Safe Handling

As with all chemical and biological substances, avoid getting the components within this kit ON YOU or IN YOU. Wash exposed areas thoroughly after using this kit. Do not eat or drink while handling this kit. This kit should be handled only by qualified clinical or laboratory employees trained on the use of this kit and who are familiar with the potential hazards. Universal Precautions should be followed when handling and working with this kit. Keep out of reach of the general public.

**Conditions for Safe Storage:** To maintain efficacy, store according to the kit specific Package Insert instructions.

**Incompatibilities:** To maintain efficacy, store according to the kit specific Package Insert instructions.

## Section 8 – Exposure Controls and Personal Protection

**Exposure Limits:** No data available for the specific components within this kit.

### Exposure Controls:

**Engineering Measures** Use with adequate ventilation.

#### Personal Protective Equipment

*Respiratory Protection:* None needed under normal conditions of use.

*Hand Protection:* Handle with appropriately rated chemical resistant gloves (nitrile or equivalent). Gloves should be inspected prior to use. Use proper glove technique to remove gloves to avoid contact with skin. Wash hands after handling the components within this kit.

*Eye Protection:* Wear safety glasses with side shields or goggles to prevent eye contact.

*Skin and Body Protection:* Use body protection appropriate for the task. A laboratory coat is recommended.

*Hygiene Measures:* Wash hands before and after use and at the end of the workday.

#### Environmental Exposure Controls

No special environmental controls are required.

## Section 9 – Physical and Chemical Properties

Characteristic	Positive and Negative Controls
Boiling Point (°C)	No data available
Melting Point (°C)	No data available
Specific Gravity (H <sub>2</sub> O = 1)	No data available
Vapor Pressure (mm Hg)	No data available
Vapor Density (Air = 1)	No data available
Evaporation Rate (Ether = 1)	No data available
pH	6.3
Solubility in Water	Soluble
Appearance and Odor	Clear to pale yellow liquid, with no odor

## Section 10 – Stability and Reactivity

Characteristic	Positive and Negative Controls
Component Stability	Stable
Hazard Reaction Potential	No data available
Conditions to Avoid	No data available
Materials to Avoid	No data available
Hazardous Decomposition Products	No data available

## Section 11 – Toxicological Information

### Acute Toxicity

**Component Analysis – LD50 / LC50 / Irritation** (No data available for specific kit components)

Chemical Name	CAS #	RTECS #	Information
Microcide III	55965-84-9	--	Oral LD <sub>50</sub> Rat >5000 mg/kg Inhalation LC <sub>50</sub> Rat (4-hr) 0.33 mg/L (dust/mist) Dermal LD <sub>50</sub> Rabbit >5000 mg/kg

#### Potential Health Effects:

<i>Skin Corrosion/ Irritation:</i>	May cause transient irritation.	<i>Inhalation:</i>	May be harmful if inhaled. Causes respiratory tract irritation.
<i>Serious Eye Damage / Irritation:</i>	No data available	<i>Skin:</i>	May be harmful if absorbed through skin. Causes skin irritation.
<i>Respiratory or Skin Sensitization:</i>	May cause sensitization by skin contact.	<i>Eyes:</i>	Causes eye irritation.
<i>Generative Cell Mutagenicity:</i>	No data available	<i>Ingestion:</i>	May cause irritation if swallowed.

### Carcinogenicity

ACGIH, IARC, NTP, OSHA: No component of this material present at levels greater than or equal to 0.1% is identified as a carcinogen, anticipated carcinogen or potential carcinogen.

### Reproductive Toxicity

No data available

### Teratogenicity

No data available

### Specified Target Organ General Toxicity (GHS)

*Single Exposure (GHS):* No data available

*Repeated Exposure (GHS):* No data available

### Aspiration Respiratory Organs Hazard

No data available

### Signs and Symptoms of Exposure

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated for the controls contained within this kit.

### Synergistic Effects

No data available

### Additional Information

No data available

## Section 12 – Ecological Information

### Ecotoxicity

No data available

### Mobility in Soil

No data available

### Persistence / Degradability

No data available

### PBT and vPvB Assessment

No data available

### Bioaccumulation

No data available

### Other Adverse Effects

An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

## Section 13 – Disposal Considerations

### Waste Disposal Instructions

Utilize appropriate personal protective equipment and spill control when handling wastes generated from using this kit. Do not discharge the solutions, reagents or controls into drains, water courses or onto the ground.

### Disposal of Product and Contaminated Packaging

Dispose of waste materials, unused components and contaminated packaging in compliance with country (e.g., Canada, EU, Japan, etc.), Federal, State and Local regulations. If unsure of the applicable regulatory requirements, contact a licensed professional waste disposal service to dispose of this material.

## Section 14 – Transportation Information

### U.S. Department of Transportation (DOT):

This kit is not regulated for transport.

### International Air Transportation (IATA):

This kit is not regulated for transport.

### International Maritime Dangerous Goods (IMDG):

This kit is not regulated for transport.

## Section 15 – Regulatory Information

### Regulatory Information

#### U.S. Federal Regulations

**OSHA Hazards** Positive and Negative Control: Irritant, Sensitizer

**SARA 302** The following chemicals are subject to reporting levels established by SARA Title III, Section 302:  
No chemicals in this kit are subject to the reporting requirements of SARA Title III, Section 302.

**SARA 313** The following chemicals are subject to reporting levels established by SARA Title III, Section 313:  
No chemicals in this kit are subject to the reporting requirements of SARA Title III, Section 313.

**SARA 311/312** No SARA hazards.

#### State Regulations

The following chemicals appear on one or more of the following state hazardous substances lists:

Chemical Name	CAS #	CA	MA	MN	NJ	PA	RI
Microcide III	55965-84-9	No	No	No	No	No	No

**California Prop 65:** This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

#### Canadian - WHMIS IDL

Chemical Name	CAS #	Minimum Concentration
Microcide III	55965-84-9	No data available

## Section 15 – Regulatory Information (cont'd)

### Additional Regulatory Information

**Safety, Health and Environmental regulations/legislation specific for the mixture:**

No data available

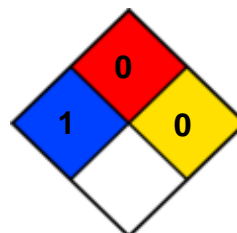
**Chemical Safety Assessment:**

Not completed for the components contained within this kit.

**HMIS Classification:**



**NFPA Classification:**



## Section 16 – Other Information

**Microcide III**     Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1) and 2-methyl-4-isothiazolin-3-one [EC no. 220-239-6] (3:1)

### Text of H-code(s) mentioned in Section 3:

H301	Toxic if swallowed.	Acute Tox.	Acute toxicity
H311	Toxic in contact with skin.		
H331	Toxic if inhaled.		
H314	Causes severe skin burns and eye damage.	Eye Dam.	Eye damage
H317	May cause an allergic skin reaction	Skin Sens.	Skin sensitizer
H400	Very toxic to aquatic life.	Aquatic Acute	Acute aquatic toxicity
H410	Very toxic to aquatic life with long lasting effects	Aquatic Chronic	Chronic aquatic toxicity

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**SUPERCEDES:** December 10, 2013

**REVISIONS:** Addition of Microcide III at 0.1% to Positive and Negative Controls.

The information above is provided in good faith. It is believed to be accurate and represents the best information currently available to us. However, we make no warranty of merchantability, fitness for a particular purpose or of any other type, expressed or implied, with respect to products described or data or information provided, and we assume no liability resulting from the use of such products, data or information. Users should make their own investigations to determine the suitability of the information for their particular purposes, and the user assumes all risk arising from their use of the material. The user is required to comply with all laws and regulations relating to the purchase, use, storage and disposal of the material, and must be familiar with and follow generally accepted safe handling procedures. In no event shall Quidel be liable for any claims, losses, or damages of any individual or for lost profits or any special, indirect, incidental, consequential or exemplary damages of any kind, howsoever arising, even if Quidel has been advised of the possibility of such damages.