

Section 1 - Product and Company Identification

Manufacturer Information

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Product Information

Product Name: QuickVue® Chlamydia Test (Catalog #: OB006, OB008, OB009)

Intended Use: The QuickVue Chlamydia test is a lateral flow immunoassay intended for the rapid, qualitative detection of chlamydia directly from endocervical swab and cytology brush specimens. For professional use only.

Components: Kit is composed of individually pouched test cassettes, Reagent A (0.2N Sodium Hydroxide), Reagent B (0.1N Hydrochloric Acid, <0.05% Thimerosal), Positive Control (formalin-inactivated chlamydia, 0.3% Microcide III), Negative Control (heat-inactivated group B Streptococcus, 0.3% Microcide III) and Tubes, Tips, Disposable Droppers and Transport Tubes with 2 Sterile Swabs.



Section 2 – Hazards Identification

Emergency Overview

Significant health effects are not anticipated from routine use of this kit when following the precautions listed within this SDS and the kit specific Package Insert. **Reagent A and the Positive and Negative Controls** contained within this kit are considered hazardous as defined by the U.S. Occupational Safety and Health Administration (OSHA), the Canadian Workplace Materials Information System (WHMIS), or the European Union (EU) Directives 1999/45/EC, 67/548/EEC and/or 1272/2008.

Component	OSHA Hazards	Target Organs	GHS Classification
Reagent A (0.2N NaOH)	Irritant	Eyes and Skin	Skin Irritation (Category 2) Eye Irritation (Category 2A)
Positive and Negative Controls (0.3% Microcide III)	Irritant	Eyes and Skin	Eye Irritation (Category 2B) Skin Sensitizer (Category 3) Aquatic Chronic (Category 4)

GHS Classification and Label Elements

Component	Pictogram	Hazard Statements	Precautionary Statements
Reagent A (0.2N NaOH)	 Warning	H315 Causes skin irritation. H319 Causes serious eye irritation.	P264 Wash hands thoroughly after handling. P272 Contaminated work clothing should not be allowed out of the workplace. P280 Wear protective gloves and safety glasses.
Positive and Negative Controls (0.3% Microcide III)	 Warning	H316 Causes mild skin irritation. H319 Causes serious eye irritation. H317 May cause an allergic skin reaction. H413 May cause long lasting harmful effects to aquatic life.	P264 Wash hands thoroughly after handling. P272 Contaminated work clothing should not be allowed out of the workplace. P273 Avoid release to the environment. P280 Wear protective gloves and safety glasses.
Supplemental Hazard Statements		Avoid release to the environment.	

Section 3 – Composition / Information on Ingredients

Component	Chemical Name	CAS #	EINECS #	Concentration (%)	Volume
Reagent A	Sodium Hydroxide	1310-73-2	215-185-5	<1.0	11 mL
Reagent B	Thimerosal	54-64-8	200-210-4	0.05	19 mL
Positive and Negative Controls	Microcide III	N/A	N/A	0.3	1.1 mL

***All of the above components are considered as mixtures / preparations.*

Section 4 – First Aid Measures

General Advice

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

- If inhaled:* Move the person to fresh air and support breathing as required.
- In case of skin contact:* Wash affected area with soap and water. Seek medical advice if irritation develops.
- In case of 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 attention.
- If swallowed:* Never give anything by mouth to an unconscious person. Rinse mouth with water. Seek medical advice if irritation develops.

Most important symptoms and effects, both acute and delayed

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated for the components with in this kit.

Indication of any immediate medical attention and special treatment needed

Note to doctors – 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.

- Suitable Extinguishing Media:* For small fires, use dry chemical, carbon dioxide or alcohol-resistant foam.
- General Fire Hazards:* The components within this kit will not significantly contribute to the intensity of a fire.
- Hazardous Combustion Products:* No data available
- Fire Fighting Equipment:* 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 components contained within this kit are unlikely.

- Personal Precautions:* Use personal protective equipment, including protective gloves and safety glasses when cleaning up small spills. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Keep all unnecessary personnel away from spill area.
- Materials and Methods for Clean-Up:* Wipe up with appropriate absorbent (e.g., paper towel, etc.).

Section 6 – Accidental Release Measures (cont'd)

- Recovery and Neutralization:* Collect spilled material and clean-up supplies and place in sealed container for disposal. Refer to Section 13 for disposal guidance. Thoroughly wash the area with soap and water.
- Environmental Precautions:* Contain spill to prevent migration to public industrial / sanitary sewers or open water sources.

Section 7 – Handling and Storage

Specific Use: For *in vitro* diagnostic use only. For professional use only.

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 using 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 instructions in the kit specific package insert.

Incompatibilities: None

Section 8 – Exposure Controls and Personal Protection

Exposure Limits:

The product does not contain any relevant quantities of materials with critical values that have to be monitored in the workplace.

Exposure Controls:

Engineering Measures Use with adequate ventilation. Provide emergency eyewash stations as appropriate.

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: Safety glasses are recommended.

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

Hygiene Measures: Handle in accordance with good industrial hygiene and laboratory safety practice. 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	Reagent A	Positive and Negative Controls
Boiling Point (°C)	No data available	No data available
Melting Point (°C)	No data available	No data available
Specific Gravity (H ₂ O = 1)	No data available	No data available
Vapor Pressure (mm Hg)	No data available	No data available
Vapor Density (Air = 1)	No data available	No data available
Evaporation Rate (Ether = 1)	No data available	No data available
pH	12.94	Neutral
Solubility in Water	Soluble	Soluble
Appearance and Odor	Clear to yellow; odorless	Clear to yellow; odorless

Section 10 – Stability and Reactivity

Characteristic	Reagent A	Positive and Negative Controls
Component Stability	Stable	Stable
Hazard Reaction Potential	Will not occur	Will not occur
Conditions to Avoid	None	None
Materials to Avoid	None	None
Hazardous Decomposition Products	No data available	No data available

Additional Information:

Sodium azide (0.02%) is present in the Positive and Negative Controls (as a preservative). Contact with acidic solutions or metal compounds over time may form potentially explosive metal azides. Avoid disposal into the sanitary sewer system.

Section 11 – Toxicological Information

Acute Toxicity

Component Analysis – LD50 / LC50 No data available for the components contained within this kit.

Potential Health Effects

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

Carcinogenicity

No component of this kit present at levels greater than or equal to 0.1% is identified as probable, possible, or confirmed human carcinogen by ACGIH, IARC, NTP or OSHA.

Reproductive Toxicity

No data available

Teratogenicity

No data available

Specified Target Organ General Toxicity

Single Exposure (GHS): No data available

Repeated Exposure (GHS): No data available

Aspiration Respiratory Organs Hazard

None anticipated under product use conditions.

Section 11 – Toxicological Information (cont'd)**Signs and Symptoms of Exposure**

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

Synergistic Effects

No data available

Additional Information

Prolonged or repeated exposure to Reagent B (Thimerosal, 0.05%) may cause allergic reactions in certain sensitive individuals.

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. Reagent A and the Positive and Negative Controls may be harmful to aquatic life with long lasting effects.

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 components of this kit 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 the authorities for information.

Section 14 – Transportation Information**U.S. Department of Transportation (DOT)**

Not regulated for transport.

International Air Transportation (IATA)

Not regulated for transport.

International Maritime Dangerous Goods (IMDG)

Not regulated for transport.

Section 15 – Regulatory Information

Regulatory Information

U.S. Federal Regulations

OSHA Hazards Irritant

SARA 302 No chemicals in this kit are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 This kit does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by 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
Sodium Hydroxide	1310-73-2	Yes	Yes	Yes	Yes	Yes
Thimerosal	54-64-8	No	No	No	No	No
Microcide III	N/A	No	No	No	No	No
Sodium Azide	26628-22-8	Yes	Yes	Yes	Yes	Yes

California Proposition 65

WARNING

Reagent A contains a chemical known to the State of California to cause birth defects or other reproductive harm.

Thimerosal CAS #: 54-64-8

Canadian – WHMIS IDL

Chemical Name	CAS #	Minimum Concentration
Sodium Hydroxide	1310-73-2	Not WHMIS Controlled
Thimerosal	54-64-8	Not WHMIS Controlled
Microcide III	N/A	Not WHMIS Controlled
Sodium Azide	26628-22-8	Not WHMIS Controlled

Additional Regulatory Information


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

No data available

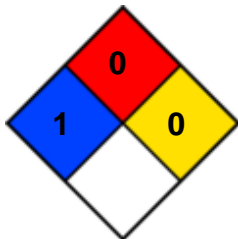
Chemical Safety Assessment

No data available

European Directive 67/548/EEC as amended

Danger Symbol	Risk Phrases	Safety Phrases
 Xi Irritant	R36/R38 Irritating to eyes and skin.	S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. S45 In case of accident or if you feel unwell, seek medical advice immediately.

Section 15 – Regulatory Information

NFPA 704 Rating

HMIS Classification


Section 16 – Other Information

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SUPERCEDES: October 3, 2013

REVISIONS: New brand and brand format.

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.

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