

SECTION 1: Identification

1.1. Identification

Product form : Mixture
 Product name : QuickVue Chlamydia Test
 Product code : 0B006

1.2. Recommended use and restrictions on use

Recommended use : For medical diagnostic use.
 Restrictions on use : Restricted to professional users, 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 - 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
Chlamydia Negative Control (1.1 mL)	Skin Sens. 1, H317
Chlamydia Positive Control (1.1 mL)	Skin Sens. 1, H317
Extraction Reagent A, Chlamydia (11 mL)	Skin Corr. 1, H314 Eye Irrit. 2A, H319
Extraction Reagent B, Chlamydia (19 mL)	Aquatic Acute 2, H401

2.2. GHS Label elements, including precautionary statements

GHS US labeling

Components	Pictograms	Signal word	Hazard statements	Precautionary statements
Chlamydia Negative Control (1.1 mL)		Warning	H317 - May cause an allergic skin reaction	P280 - Wear lab coat, 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.
Chlamydia Positive Control (1.1 mL)		Warning	H317 - May cause an allergic skin reaction	P280 - Wear lab coat, 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.
Extraction Reagent A, Chlamydia (11 mL)		Danger	H314 - Causes severe skin burns and eye damage H319 - Causes serious eye irritation	P260 - Do not breathe vapors/spray. P264 - Wash hands thoroughly after handling P280 - Wear lab coat, safety glasses, and gloves. P301+P330+P331 - If swallowed: rinse mouth. Do NOT induce vomiting. P303+P361+P353 - If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. P304+P340 - If inhaled: Remove person to fresh air and keep comfortable for breathing. 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: Seek medical attention if ill effect develops.
Extraction Reagent B, Chlamydia (19 mL)	None	None	H401 - Toxic to aquatic life	P273 - Avoid release to the environment. P501 - Dispose of contents/container: Dispose in a safe manner in accordance with local/national regulations

SECTION 3: Composition/Information on ingredients

Name	Chemical name	CAS #	%	GHS US classification
Chlamydia Negative Control (1.1 mL)	Microcide III	-	0.33	Skin Sens. 1, H317
Chlamydia Positive Control (1.1 mL)	Microcide III	-	0.33	Skin Sens. 1, H317
Extraction Reagent A, Chlamydia (11 mL)	sodium hydroxide, conc=33%, aqueous solution	1310-73-2	0.25	Met. Corr. 1, H290 Skin Corr. 1A, H314 Eye Dam. 1, H318 Aquatic Acute 3, H402
Extraction Reagent B, Chlamydia (19 mL)	Thimerosal	54-64-8	0.05	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

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 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 : 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 : Irritation. May cause an allergic skin reaction.
- Symptoms/effects after eye contact : Eye irritation.
- 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 : Carbon dioxide. Water spray. Dry powder. Foam.

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 : Mechanically recover the product. 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

Sodium Hydroxide (1310-73-2)		
OSHA	OSHA PEL TWA [1]	2 mg/m ³
OSHA	Regulatory reference (US-OSHA)	OSHA Annotated Table Z-1
Thimerosal (54-64-8)		
ACGIH	ACGIH OEL TWA	0.1 mg/m ³

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

Skin and body protection:

Wear suitable protective clothing

Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment

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	: Solid
Appearance	: In vitro diagnostic medical test kit.
Color	: No data available
Odor	: No data available
Odor threshold	: No data available
pH	: Extraction Reagent A: pH 12.9
Melting point	: Not applicable
Freezing point	: Not applicable
Boiling point	: No data available
Flash point	: Not applicable
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	: Not applicable
Decomposition temperature	: No data available
No data available	Viscosity, kinematic : Not applicable
Viscosity, dynamic	: No data available
Explosion limits	: Not applicable
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

Thimerosal (54-64-8)	
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 : Causes serious eye irritation.
 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

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

Aspiration hazard : Not classified
 Viscosity, kinematic : Not applicable
 Symptoms/effects after skin contact : Irritation. May cause an allergic skin reaction.
 Symptoms/effects after eye contact : Eye irritation.

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : Toxic to aquatic life.

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

12.2. Persistence and degradability

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

12.3. Bioaccumulative potential

Thimerosal (54-64-8)	
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.
- Additional information : Thimerosal contains ethylmercury. Wastes containing mercury salts are regulated as toxic hazardous waste when the mercury is present in concentrations greater than 0.2 mg/L. Under no circumstances should any waste containing mercury be disposed of in the trash, put down the drain, or placed in biohazard bags or sharps containers.
- 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 Chlamydia

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:

Sodium Hydroxide	CAS No 1310-73-2	< 1%
Microcide III	CAS No	< 1%
Thimerosal	CAS No 54-64-8	≤ 0.05%

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.

Sodium Hydroxide (1310-73-2)

CERCLA RQ	1000 lb
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15.2. International regulations

CANADA

Sodium Hydroxide (1310-73-2)

Listed on the Canadian DSL (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

Indication of changes:

Regulatory Review. Updated SDS template.

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.