

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations Issue date: 11/13/2013 Revision date: 07/08/2020 Supersedes: 10/03/2019 Version: 2.0

#### **SECTION 1: Identification**

1.1. Identification

Product form : Mixture

Product name : QuickVue Chlamydia

Product code : 0B006

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, 92121 - USA T 1.800.874.1517 - F 1.858.453.4338 qehs@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

Full text of H statements : see section 16

## 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	P280 - Wear protective gloves and safety glasses
	$\langle ! \rangle$		reaction	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	P280 - Wear protective gloves and safety glasses
	$\langle ! \rangle$		reaction	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	P264 - Wash hands thoroughly after handling
			eye damage	P280 - Wear protective gloves and safety glasses
			H319 - Causes serious eye irritation	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

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				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
				P501 - Dispose of contents/container: Dispose in a safe manner in accordance with local/national regulations
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		<0.5	Skin Sens. 1, H317
Chlamydia Positive Control (1.1 mL)	Microcide III		<0.5	Skin Sens. 1, H317
Extraction Reagent A, Chlamydia (11 mL)	Sodium Hydroxide (solution)	1310-73-2	< 1	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. 3 (Oral), H301 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**

#### **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.

: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. First-aid measures after eye contact

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.

## 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, : Treat symptomatically.

if necessary

## **SECTION 5: Fire-fighting measures**

## Suitable (and unsuitable) extinguishing media

Suitable extinguishing media : Water spray. Dry powder. Foam. Carbon dioxide.

#### Specific hazards arising from the chemical 5.2.

No additional information available

## 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.

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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.

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. Wear personal protective

equipment. Avoid breathing dust/fume/gas/mist/vapours/spray.

Hygiene measures : Wash contaminated clothing before reuse. Contaminated work clothing should not be allowed out of

the workplace. 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) (mg/m³) 2 mg/m³		
OSHA	Regulatory reference (US-OSHA)	e (US-OSHA) OSHA Annotated Table Z-1	
Thimerosal (54-64-8)			
ACGIH	ACGIH TWA (mg/m³) 0.1 mg/m³		

#### 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

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#### 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 Kit – Liquid Controls and Reagents

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 : No data available Relative evaporation rate (butyl acetate=1) 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 Auto-ignition temperature Not applicable Decomposition temperature : No data available Viscosity, kinematic No data available Viscosity, dynamic : No data available **Explosion limits** Not applicable

## 9.2. Other information

**Explosive properties** 

Oxidizing properties

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

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: No data available: No data available



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#### 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)		
LD50 oral rat	75 mg/kg (Rat)	
ATE US (oral)	75 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 : No data available

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.

Thimserosal (54-64-8)		
LC50 fish 1	0.033 ppm (96 h, Salmo gairdneri)	
EC50 Daphnia 1	0.0052 mg/l (48 h, Daphnia magna)	

## 12.2. Persistence and degradability

No additional information available

#### 12.3. Bioaccumulative potential

Thimerosal (54-64-8)	
Partition coefficient n-octanol/water (Log Pow)	-1.88

## 12.4. Mobility in soil

Thimerosal (54-64-8)		
Ecology - soil	Adsorbs into the soil.	

## 12.5. Other adverse effects

No additional information available

## **SECTION 13: Disposal considerations**

13.1. Disposal methods	thods	osal meti	Dis	13.1.
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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.

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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

#### Microcide III

Not listed on the United States TSCA (Toxic Substances Control Act) inventory

#### Thimerosal (54-64-8)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

## 15.2. International regulations

#### **CANADA**

#### 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**

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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.

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