

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1. Product identifier

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

#### 1.2. Relevant identified uses of the substance or mixture and uses advised against

##### 1.2.1. Relevant identified uses

Industrial/Professional use spec : For in vitro diagnostic use

##### 1.2.2. Uses advised against

Restrictions on use : Restricted to professional users, Professional Use of Medical Devices

#### 1.3. Details of the supplier of the safety data sheet

##### Manufacturer

Quidel Corporation  
10165 McKellar Court  
92121 San Diego, CA - 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: Hazards identification

#### 2.1. Classification of the substance or mixture

##### Classification according to Regulation (EC) No. 1272/2008 [CLP]

Components	CLP 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. 1A, H314 Eye Dam. 1, H318



Full text of H- and EUH-statements: see section 16


##### Adverse physicochemical, human health and environmental effects

Causes skin irritation. May cause an allergic skin reaction. Causes serious eye irritation.

#### 2.2. Label elements

##### Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Components	Pictograms	Signal word	Hazard statements	Precautionary statements	Extra phrases
<b>Chlamydia Negative Control (1.1 mL)</b>		Warning	H317 - May cause an allergic skin reaction.	P280 - Wear lab coat, safety glasses, and gloves. P302+P352 - IF ON SKIN: Wash with plenty of water. P321 - Specific treatment: Seek medical attention if ill effect develops. P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.	No additional information available
<b>Chlamydia Positive Control (1.1 mL)</b>		Warning	H317 - May cause an allergic skin reaction.	P280 - Wear protective gloves and safety glasses. P302+P352 - IF ON SKIN: Wash with plenty of water. P321 - Specific treatment: Seek medical attention if ill effect develops. P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.	No additional information available

<p><b>Extraction Reagent A, Chlamydia (11 mL)</b></p>		<p>Danger</p>	<p>H314 - Causes severe skin burns and eye damage.</p>	<p>P260 - Do not breathe vapours/spray.                  P264 - Wash hands thoroughly after handling.                  P280 - Wear protective gloves and safety glasses.                  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 .                  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.                  P501 - Dispose of contents to in accordance with local, regional, national regulations.</p>	<p>No additional information available</p>
---	---	---------------	--	--	--

**2.3. Other hazards**

Other hazards which do not result in classification : 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.

Contains no PBT/vPvB substances ≥ 0.1% assessed in accordance with REACH Annex XIII

**SECTION 3: Composition/information on ingredients**

**3.1. Substances**

Not applicable

**3.2. Mixtures**

Name	Chemical name	CAS No EC-No.	%	CLP classification
Chlamydia Positive Control (1.1 mL)	Microcide III	- -	0.33	Skin Sens. 1, H317
	disodium hydrogenorthophosphate	7558-79-4 -	< 1	Acute Tox. 3 (Inhalation:dust,mist), H331
Chlamydia Negative Control (1.1 mL)	Microcide III	- -	0.33	Skin Sens. 1, H317

**Specific concentration limits:**

Name	Product identifier	Specific concentration limits
Microcide III	-	( 0.1 ≤ C < 100) Skin Sens. 1, H317
Sodium Hydroxide	(CAS No) 1310-73-2 (EC-No.) 215-185-5 (EC Index-No.) 011-002-00-6	( 0.5 ≤ C < 2) Skin Irrit. 2, H315 ( 0.5 ≤ C < 2) Eye Irrit. 2, H319 ( 2 ≤ C < 5) Skin Corr. 1B, H314 ( 5 ≤ C ≤ 100) Skin Corr. 1A, H314

Full text of H- and EUH-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 or a doctor if you feel unwell.

### 4.2. Most important symptoms and effects, both acute and delayed

Symptoms/effects after skin contact : Irritation. May cause an allergic skin reaction.  
 Symptoms/effects after eye contact : Eye irritation.

### 4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

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

### 5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : Toxic fumes may be released.

### 5.3. Advice for firefighters

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/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

Avoid release to the environment.

### 6.3. Methods and material for containment and cleaning up

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.

### 6.4. 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.

### 7.3. Specific end use(s)

No additional information available

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

QuickVue Chlamydia Kit		
USA - OSHA	Local name	Sodium hydroxide

Sodium Hydroxide (1310-73-2)		
USA - OSHA	Local name	Sodium hydroxide
USA - OSHA	OSHA PEL TWA [1]	2 mg/m <sup>3</sup>

**8.2. Exposure controls**

**Appropriate engineering controls:**

Ensure good ventilation of the work station.

**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):**



**Environmental exposure controls:**

Avoid release to the environment.

**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.
Colour	: No data available
Odour	: No data available
Odour threshold	: No data available
pH	: Extraction Reagent A: pH 12.9
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: No data available
Freezing point	: Not applicable
Boiling point	: No data available
Flash point	: Not applicable
Auto-ignition temperature	: Not applicable
Decomposition temperature	: No data available
Flammability	: Non flammable.
Vapour pressure	: No data available
Relative vapour density at 20°C	: No data available
Relative density	: Not applicable
Solubility	: No data available
Partition coefficient n-octanol/water (Log Pow)	: No data available
Viscosity, kinematic	: Not applicable

Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: Not applicable

### 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

### 11.1. Information on toxicological effects

Acute toxicity (oral)	: Not classified
Acute toxicity (dermal)	: Not classified
Acute toxicity (inhalation)	: Not classified

<b>disodium hydrogenorthophosphate (7558-79-4)</b>	
LD50 oral rat	> 2000 mg/kg bodyweight (OECD 420: Acute Oral toxicity – Acute Toxic Class Method, Rat, Female, Experimental value, Oral, 14 day(s))
LD50 dermal rat	> 2000 mg/kg bodyweight (OECD 402: Acute Dermal Toxicity, 24 h, Rat, Male / female, Experimental value, Dermal, 14 day(s))
LC50 Inhalation - Rat	> 0.83 mg/l (EPA OPP 81-3: Acute Inhalation Toxicity, 4 h, Rat, Male / female, Experimental value, Inhalation (dust), 14 day(s))

Skin corrosion/irritation	: Causes skin irritation. pH: Extraction Reagent A: pH 12.9
Serious eye damage/irritation	: Causes serious eye irritation. pH: Extraction Reagent A: pH 12.9
Respiratory or skin sensitisation	: 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
Aspiration hazard	: Not classified

<b>QuickVue Chlamydia Kit</b>	
Viscosity, kinematic	Not applicable

### SECTION 12: Ecological information

#### 12.1. Toxicity

Ecology - general	: The product is not considered harmful to aquatic organisms nor to cause long-term adverse effects in the environment.
Hazardous to the aquatic environment, short-term (acute)	: Not classified
Hazardous to the aquatic environment, long-term (chronic)	: Not classified

disodium hydrogenorthophosphate (7558-79-4)	
LC50 - Fish [1]	> 100 mg/l (OECD 203: Fish, Acute Toxicity Test, 96 h, Oncorhynchus mykiss, Semi-static system, Fresh water, Experimental value, GLP)
EC50 - Crustacea [1]	> 100 mg/l (OECD 202: Daphnia sp. Acute Immobilisation Test, 48 h, Daphnia magna, Static system, Fresh water, Experimental value, GLP)
ErC50 algae	> 100 mg/l (OECD 201: Alga, Growth Inhibition Test, 72 h, Desmodesmus subspicatus, Static system, Fresh water, Experimental value, GLP)

#### 12.2. Persistence and degradability

disodium hydrogenorthophosphate (7558-79-4)	
Persistence and degradability	Biodegradability: not applicable.
Chemical oxygen demand (COD)	Not applicable
ThOD	Not applicable
BOD (% of ThOD)	Not applicable

#### 12.3. Bioaccumulative potential

disodium hydrogenorthophosphate (7558-79-4)	
Bioaccumulative potential	Not bioaccumulative.

#### 12.4. Mobility in soil

disodium hydrogenorthophosphate (7558-79-4)	
Ecology - soil	No (test) data on mobility of the substance available.

#### 12.5. Results of PBT and vPvB assessment

Component	
disodium hydrogenorthophosphate (7558-79-4)	This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

#### 12.6. Other adverse effects

No additional information available

### SECTION 13: Disposal considerations

#### 13.1. Waste treatment 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

In accordance with ADR / IMDG / IATA

#### 14.1. UN number

UN-No. (ADR) : Not regulated  
 UN-No. (IMDG) : Not regulated  
 UN-No. (IATA) : Not regulated

#### 14.2. UN proper shipping name

Proper Shipping Name (ADR) : Not regulated  
 Proper Shipping Name (IMDG) : Not regulated  
 Proper Shipping Name (IATA) : Not regulated

#### 14.3. Transport hazard class(es)

##### ADR

Transport hazard class(es) (ADR) : Not regulated

##### IMDG

Transport hazard class(es) (IMDG) : Not regulated

##### IATA

Transport hazard class(es) (IATA) : Not regulated

#### 14.4. Packing group

Packing group (ADR) : Not regulated  
 Packing group (IMDG) : Not regulated  
 Packing group (IATA) : Not regulated

#### 14.5. Environmental hazards

Dangerous for the environment : No  
 Marine pollutant : No  
 Other information : No supplementary information available

#### 14.6. Special precautions for user

##### Overland transport

Not regulated

##### Transport by sea

Not regulated

##### Air transport

Not regulated

#### 14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable

### SECTION 15: Regulatory information

#### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

##### 15.1.1. EU-Regulations

Contains no substance(s) listed on REACH Annex XVII (Restriction Conditions)  
 Contains no substance(s) listed on the REACH Candidate List  
 Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

##### 15.1.2. National regulations

###### Germany

Regulatory reference : WGK 2, Significantly hazardous to water (Classification according to AwSV, Annex 1)  
 Hazardous Incident Ordinance (12. BImSchV) : Is not subject of the 12. BImSchV (Hazardous Incident Ordinance)

###### Netherlands

SZW-lijst van kankerverwekkende stoffen : None of the components are listed

SZW-lijst van mutagene stoffen : None of the components are listed  
 SZW-lijst van reprotoxische stoffen – Borstvoeding : None of the components are listed  
 SZW-lijst van reprotoxische stoffen – Vruchtbaarheid : None of the components are listed  
 SZW-lijst van reprotoxische stoffen – Ontwikkeling : None of the components are listed

### Denmark

Danish National Regulations : Young people below the age of 18 years are not allowed to use the product

## 15.2. Chemical safety assessment

No chemical safety assessment has been carried out

## SECTION 16: Other information

Indication of changes:	
Regulatory Review. New EU SDS template.	
Abbreviations and acronyms:	
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ATE	Acute Toxicity Estimate
BLV	Biological limit value
CAS No	Chemical Abstract Service number
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
EC50	Median effective concentration
EC-No.	European Community number
EN	European Standard
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
OEL	Occupational Exposure Limit
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet
vPvB	Very Persistent and Very Bioaccumulative
WGK	Water Hazard Class

Other information : Please review product insert prior to using this product.



### Full text of H- and EUH-statements:

Acute Tox. 3 (Inhalation:dust,mist)	Acute toxicity (inhalation:dust,mist) Category 3
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H331	Toxic if inhaled.
Skin Corr. 1A	Skin corrosion/irritation, Category 1, Sub-Category 1A
Skin Corr. 1B	Skin corrosion/irritation, Category 1, Sub-Category 1B
Skin Irrit. 2	Skin corrosion/irritation, Category 2
Skin Sens. 1	Skin sensitisation, Category 1

*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.*