

SECTION 1: Identification of the substance/mixture and of the company/undertaking
1.1. Product identifier

Product form	: Mixture
Product name	: QuickVue Chlamydia Kit
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 : 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 - USA
 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: 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 Irrit, 2, H319

Full text of H statements : see section 16

Adverse physicochemical, human health and environmental effects

Causes skin irritation. May cause an allergic skin reaction. Toxic to aquatic life.

2.2. Label elements
Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Components	Pictograms	Signal word	Hazard statements	Precautionary statements	Extra phrases
Chlamydia Negative Control (1.1 mL)		Warning	H317 - May cause an allergic skin reaction.	P280 - Wear protective gloves/protective clothing/eye protection/face protection/hearing protection. P302+P352 - IF ON SKIN: Wash with plenty of water P321 - Specific treatment: Seek medical attention if ill effect develops	No additional information available
Chlamydia Positive Control (1.1 mL)		Warning	H317 - May cause an allergic skin reaction.	P280 - Wear protective gloves/protective clothing/eye protection/face protection/hearing protection P302+P352 - IF ON SKIN: Wash with plenty of water P321 - Specific treatment: Seek medical attention if ill effect develops	No additional information available

Extraction Reagent A, Chlamydia (11 mL)		Danger	H314 - Causes severe skin burns and eye damage. H319 - Causes serious eye irritation	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	No additional information available
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2.3. Other hazards

Other hazards not contributing to the 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.

SECTION 3: Composition/information on ingredients
3.1. Substances

Not applicable

3.2. Mixtures

Name	Chemical name	CAS No EC-No.	%	CLP classification
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
Chlamydia Positive Control (1.1 mL)	Microcide III	- -	0.33	Skin Sens. 1, H317
Chlamydia Negative Control (1.1 mL)	Microcide III	- -	0.33	Skin Sens. 1, H317

Specific concentration limits:

Name	Product identifier	Specific concentration limits
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
Microcide III	--	(0.1 ≤ C < 100) Skin Sens. 1, H317
Thimerosal	(CAS No) 54-64-8 (EC-No.) 200-210-4 (EC Index-No.) 080-004-00-7	(0.1 ≤ C < 100) STOT RE 2, H373

Full text of H-statements: see section 16SECTION 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. Carbon dioxide.

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

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.

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

Sodium Hydroxide (1310-73-2)		
USA - OSHA	Local name	Sodium hydroxide
USA - OSHA	OSHA PEL (TWA) (mg/m ³)	2 mg/m ³
Thimerosal (54-64-8)		
Belgium	Limit value (mg/m ³)	0.1 mg/m ³
France	VME (mg/m ³)	0.1 mg/m ³
USA - ACGIH	ACGIH TWA (mg/m ³)	0.1 mg/m ³

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	: Not applicable
Freezing point	: Not applicable
Boiling point	: No data available
Flash point	: Not applicable
Auto-ignition temperature	: Not applicable
Decomposition temperature	: No data available

Flammability (solid, gas)	: Not applicable
Vapour pressure	: No data available
Relative vapour 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
Viscosity, kinematic	: No data available
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

Thimerosal (54-64-8)

LD50 oral rat	75 mg/kg (Rat)
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Skin corrosion/irritation	: Causes skin irritation.
Serious eye damage/irritation	: Causes serious eye irritation.
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

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general	: Toxic to aquatic life.
Hazardous to the aquatic environment, short-term (acute)	: Not classified

Hazardous to the aquatic environment, long-term (chronic) : Not classified

Sodium Hydroxide (1310-73-2)	
LC50 fish 1	45.4 mg/l (96 h, Salmo gairdneri, Literature study, Solution >=50%)
EC50 Daphnia 1	40.38 mg/l (48 h, Ceriodaphnia dubia, Fresh water, Literature study, Pure substance)
TLM fish 1	99 mg/l (48 h, Lepomis macrochirus, Pure substance)
TLM fish 2	125 ppm (96 h, Gambusia affinis, Pure substance)

Thimerosal (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

Sodium Hydroxide (1310-73-2)	
Persistence and degradability	Biodegradability: not applicable.
Chemical oxygen demand (COD)	Not applicable
ThOD	Not applicable
BOD (% of ThOD)	Not applicable

12.3. Bioaccumulative potential

Sodium Hydroxide (1310-73-2)	
Partition coefficient n-octanol/water (Log Pow)	-3.88 (Estimated value)
Bioaccumulative potential	Not bioaccumulative.

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

12.4. Mobility in soil

Sodium Hydroxide (1310-73-2)	
Ecology - soil	No (test) data on mobility of the components available.

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

12.5. Results of PBT and vPvB assessment

No additional information available

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 / IATA / IMDG

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 REACH substances with Annex XVII restrictions
 Contains no substance on the REACH candidate list
 Contains no REACH Annex XIV substances

15.1.2. National regulations

Germany

Regulatory reference : WGK 3, Highly 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

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Borstvoeding : None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Vruchtbaarheid : None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige 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

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

Full text of H- and EUH-statements:	
Acute Tox. 1 (Dermal)	Acute toxicity (dermal), Category 1
Acute Tox. 2 (Inhalation)	Acute toxicity (inhal.), Category 2
Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
Aquatic Acute 1	Hazardous to the aquatic environment — Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment — Chronic Hazard, Category 1
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Met. Corr. 1	Corrosive to metals, Category 1
Skin Corr. 1A	Skin corrosion/irritation, Category 1A
Skin Corr. 1B	Skin corrosion/irritation, Category 1B
Skin Irrit. 2	Skin corrosion/irritation, Category 2
Skin Sens. 1	Skin sensitisation, Category 1
STOT RE 2	Specific target organ toxicity — Repeated exposure, Category 2
H290	May be corrosive to metals.
H301	Toxic if swallowed.
H310	Fatal in contact with skin.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H330	Fatal if inhaled.
H373	May cause damage to organs through prolonged or repeated exposure.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

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.