

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

Product form : Mixture
 Product name : QuickVue H. pylori Test
 Product code : OW009, OW010

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, CA - 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: Hazards identification
2.1. Classification of the substance or mixture

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

Components	CLP classification
Negative Control, H. pylori GII	Skin Sens. 1, H317
Positive Control, H. pylori GII	Skin Sens. 1, H317



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

Adverse physicochemical, human health and environmental effects

May cause an allergic skin reaction.

2.2. Label elements

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

Components	Pictograms	Signal word	Hazard statements	Precautionary statements
Negative Control, H. pylori GII		Warning	H317 - May cause an allergic skin reaction.	P280 – Wear labcoat, safety glasses, and gloves. P302+P352 - IF ON SKIN: Wash with plenty of water. P321 - Specific treatment (see supplemental first aid instruction on this label).
Positive Control, H. pylori GII		Warning	H317 - May cause an allergic skin reaction.	P280 – Wear labcoat, safety glasses, and gloves. P302+P352 - IF ON SKIN: Wash with plenty of water. P321 - Specific treatment (see supplemental first aid instruction on this label).

2.3. Other hazards

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
Positive Control, H. pylori GII	Microcide III	- -	0.1	Skin Sens. 1, H317
Negative Control, H. pylori GII	Microcide III	- -	0.1	Skin Sens. 1, H317

Specific concentration limits:

Name	Product identifier	Specific concentration limits
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- 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 eyes with water as a precaution.
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	: May cause an allergic skin reaction.
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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.
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5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire	: Toxic fumes may be released.
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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.
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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.
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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".
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6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up	: Take up liquid spill into absorbent material.
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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. Avoid breathing dust/fume/gas/mist/vapours/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.

7.3. Specific end use(s)

No additional information available.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Thimerosal (54-64-8)		
Belgium	OEL TWA	0.1 mg/m ³
France	VME (OEL TWA)	0.1 mg/m ³
USA - ACGIH	ACGIH OEL TWA	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.

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 : Liquid

Appearance : In vitro diagnostic medical test kit

Colour : No data available

Odour : No data available

Odour threshold : No data available

pH	: Neutral
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: Not applicable
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability	: 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	: 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

11.1. Information on toxicological effects

Acute toxicity (oral)	: Not classified
Acute toxicity (dermal)	: Not classified
Acute toxicity (inhalation)	: Not classified
Skin corrosion/irritation	: Not classified
	pH: Neutral
Serious eye damage/irritation	: Not classified
	pH: Neutral
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 : 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

Thimerosal (54-64-8)

LC50 - Fish [1]	0.16 mg/l (96 h, Cyprinus carpio, Literature study, Mercury ion)
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12.2. Persistence and degradability

Thimerosal (54-64-8)

Persistence and degradability	Not readily biodegradable in water.
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12.3. Bioaccumulative potential

Thimerosal (54-64-8)

Partition coefficient n-octanol/water (Log Pow)	-1.88 (Estimated value, KOWWIN)
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Bioaccumulative potential	Not bioaccumulative.
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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)
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Ecology - soil	Low potential for adsorption in soil.
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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.
 Product/Packaging disposal recommendations : Dispose of contents/container: Dispose in a safe manner in accordance with local/national regulations.
 Ecology - waste materials : Avoid release to the environment.

SECTION 14: Transport information

In accordance with ADR / IATA

14.1. UN number

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

14.2. UN proper shipping name

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

14.3. Transport hazard class(es)

ADR

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

IATA

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

14.4. Packing group

Packing group (ADR) : Not regulated

Packing group (IATA) : Not regulated

14.5. Environmental hazards

Dangerous for the environment : No

Other information : No supplementary information available

14.6. Special precautions for user

Overland transport

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

Listed on REACH Annex XVII (Restriction Conditions). The following restrictions are applicable:

18. Mercury compounds	Thimerosal
3(b) Substances or mixtures fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008: Hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10	QuickVue H. pylori Test

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

Not listed on the Canadian DSL (Domestic Substances List)/NDSL (Non-Domestic Substances List)

Germany

Regulatory reference : WGK 3, Highly hazardous to water (Classification according to AwSV, Annex 1)

Employment restrictions : Observe restrictions according Act on the Protection of Working Mothers (MuSchG)
Observe restrictions according Act on the Protection of Young People in Employment (JArbSchG)

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
Pregnant/breastfeeding women working with the product must not be in direct contact with the product

15.2. Chemical safety assessment

No chemical safety assessment has been carried out.

SECTION 16: Other information
Indication of changes:

Regulatory Review.

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

Training advice : Normal use of this product shall imply use in accordance with the instructions on the packaging.

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. 2 (Oral)	Acute toxicity (oral), Category 2
Aquatic Acute 1	Hazardous to the aquatic environment – Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment – Chronic Hazard, Category 1
H300	Fatal if swallowed

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830
Issue date: 3/2/2015 Revision date: 12/6/2022 Supersedes version of: 1/31/2020 Version: 1.2

H310	Fatal in contact with skin
H317	May cause an allergic skin reaction
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
Skin Sens. 1	Skin sensitisation, Category 1
STOT RE 2	Specific target organ toxicity – Repeated exposure, Category 2

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.