

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

1.1. Product identifier

Product form : Mixture
 Product name : QuickVue hCG Control Set - Urine
 Product code : 00272

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
QEHS@quidelortho.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 |
|----------------------|--------------------------------------|
| hCG Negative Control | Skin Sens. 1, H317 Repr. 1B, H360 |
| hCG Positive Control | Skin Sens. 1, H317 Repr. 1B, H360 |

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


Adverse physicochemical, human health and environmental effects

To our knowledge, this product does not present any particular risk, provided it is handled in accordance with good occupational hygiene and safety practice. May damage fertility or the unborn child. 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 | Extra phrases |
|-----------------------------|------------|-------------|---|---|-------------------------------------|
| hCG Negative Control | | Danger | H317 - May cause an allergic skin reaction. H360 - May damage fertility or the unborn child. | P202 - Do not handle until all safety precautions have been read and understood. P261 - Avoid breathing mist/spray. 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 |

| | | | | | |
|-----------------------------|---|--------|---|--|-------------------------------------|
| hCG Positive Control |  | Danger | H317 - May cause an allergic skin reaction. H360 - May damage fertility or the unborn child. | P202 - Do not handle until all safety precautions have been read and understood. P261 - Avoid breathing mist/ spray. 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 |
|-----------------------------|---|--------|---|--|-------------------------------------|

2.3. Other hazards

Other hazards which do not result in classification

: Follow Universal Precautions when handling this component. This product contains material of human and/or animal origin.

Contains no PBT/vPvB substances $\geq 0.1\%$ 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 |
|----------------------|---------------|------------------|------|---|
| hCG Positive Control | Microcide III | - - | 0.68 | Skin Sens. 1, H317 |
| | sodium azide | 26628-22-8 - | 0.1 | Acute Tox. 2 (Oral), H300 Acute Tox. 1 (Dermal), H310 Aquatic Chronic 1, H410 |
| | boric acid | 10043-35-3 - | 0.62 | Repr. 1B, H360FD |
| hCG Negative Control | boric acid | 10043-35-3 - | 0.62 | Repr. 1B, H360FD |
| | Microcide III | - - | 0.3 | Skin Sens. 1, H317 |
| | sodium azide | 26628-22-8 - | 0.1 | Acute Tox. 2 (Oral), H300 Acute Tox. 1 (Dermal), H310 Aquatic Chronic 1, H410 |

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 general | : IF exposed or concerned: Get medical advice/attention. |
| 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.

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. Only qualified personnel equipped with suitable protective equipment may intervene. Avoid breathing mist/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. Notify authorities if product enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Mechanically recover the product. Notify authorities if product enters sewers or public waters.

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. Wear personal protective equipment. Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Avoid contact with skin and eyes. Avoid breathing dust/fume/gas/mist/vapours/spray.

Hygiene measures : Do not eat, drink or smoke when using this product. Always wash hands after handling the product. Separate working clothes from town clothes. Launder separately. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reuse.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a well-ventilated place. Keep cool. Store locked up.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

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. [In case of inadequate ventilation] wear respiratory protection.

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 | : No data available |
| 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 | : Non flammable. |
| 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 | : 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 |
| Skin corrosion/irritation | : Not classified |
| Serious eye damage/irritation | : Not classified |
| Respiratory or skin sensitisation | : May cause an allergic skin reaction. |
| Germ cell mutagenicity | : Not classified |
| Carcinogenicity | : Not classified |
| Reproductive toxicity | : May damage fertility or the unborn child. |
| STOT-single exposure | : Not classified |
| STOT-repeated exposure | : Not classified |
| Aspiration hazard | : Not classified |

QuickVue hCG Control Set - Urine

| | |
|----------------------|----------------|
| 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 |

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

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. |
| 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 applicable |
| UN-No. (IATA) | : Not regulated |

14.2. UN proper shipping name

| | |
|-----------------------------|------------------|
| Proper Shipping Name (ADR) | : Not applicable |
| Proper Shipping Name (IATA) | : Not regulated |

14.3. Transport hazard class(es)

ADR

| | |
|----------------------------------|------------------|
| Transport hazard class(es) (ADR) | : Not applicable |
|----------------------------------|------------------|

IATA

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

14.4. Packing group

| | |
|----------------------|------------------|
| Packing group (ADR) | : Not applicable |
| 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 applicable

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

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

Germany

| | |
|----------------------|---|
| Regulatory reference | : WGK 2, Significantly 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:

New EU SDS template. 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 |

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

| Full text of H- and EUH-statements: | |
|-------------------------------------|---|
| H317 | May cause an allergic skin reaction. |
| H360 | May damage fertility or the unborn child. |
| Repr. 1B | Reproductive toxicity, Category 1B |
| 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.