

### SECTION 1: Identification

#### 1.1. Identification

Product form : Mixture  
 Product name : QuickVue hCG Control Set - Serum  
 Product code : 00281

#### 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](mailto:qehs@quidel.com) - [quidel.com](http://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
hCG Serum Control, Negative	Skin Sens. 1, H317
hCG Serum Control, Low and High Positive	Skin Sens. 1, H317

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
hCG Serum Control, Low and High Positive		Warning	H317 - May cause an allergic skin reaction	P280 - Wear protective gloves/protective clothing/eye protection/face protection. P302+P352 - If on skin: Wash skin thoroughly with mild soap and water P321 - Specific treatment: Seek medical attention if ill effect develops
hCG Serum Control, Negative		Warning	H317 - May cause an allergic skin reaction	P280 - Wear protective gloves/protective clothing/eye protection/face protection. P302+P352 - If on skin: Wash skin thoroughly with mild soap and water P321 - Specific treatment: Seek medical attention if ill effect develops

#### 2.3. Other hazards which do not result in classification

No additional information available

#### 2.4. Unknown acute toxicity (GHS US)

Not applicable

### SECTION 3: Composition/Information on ingredients

#### 3.1. Substances

Not applicable

#### 3.2. Mixtures

Name	Chemical name	CAS #	%	GHS US classification
hCG Serum Control, Low and High Positive	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
hCG Serum Control, Negative	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

Full text of hazard classes and H-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/doctor/physician if you feel unwell.

#### 4.2. Most important symptoms and effects (acute and delayed)

- Symptoms/effects after skin contact : May cause an allergic skin reaction.

#### 4.3. Immediate medical attention and special treatment, if necessary

Treat symptomatically.

### SECTION 5: Fire-fighting measures

#### 5.1. Suitable (and unsuitable) extinguishing media

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

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

No additional information available

#### 5.3. 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.

### 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.
- 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.

### SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

hCG Serum Control, Low and High Positive
Not applicable

hCG Serum Control, Negative
Not applicable

#### 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

**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):**



**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 : White pellet.
- Color : No data available
- Odor : Odorless
- Odor threshold : No data available
- pH : No data available

Melting point	: No data available
Freezing point	: Not applicable
Boiling point	: No data available
Flash point	: Not applicable
Relative evaporation rate (butyl acetate=1)	: No data available
Flammability (solid, gas)	: Non flammable.
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
Explosive properties	: No data available
Oxidizing properties	: 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
Serious eye damage/irritation	: Not classified
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
Aspiration hazard	: Not classified
Viscosity, kinematic	: No data available
Symptoms/effects after skin contact	: May cause an allergic skin reaction.

## SECTION 12: Ecological information

### 12.1. Toxicity

Ecology - general : The product is not considered harmful to aquatic organisms or to cause long-term adverse effects in the environment.

### 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. Other adverse effects

No additional information available

## SECTION 13: Disposal considerations

### 13.1. Disposal methods

Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions.

## SECTION 14: Transport information

### Department of Transportation (DOT)

In accordance with DOT

Not regulated

### Transport by sea

Not regulated

### Air transport

Not regulated

## SECTION 15: Regulatory information

### 15.1. US Federal regulations

No additional information available

### 15.2. International regulations

#### CANADA

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

#### EU-Regulations

No additional information available

#### National regulations

No additional information available



# QuickVue hCG Control Set - Serum

## Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations  
Date of issue: 01/31/2020 Supersedes: 12/10/2013 Version: 1.0

### 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

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Full text of H-phrases:

H317	May cause an allergic skin reaction
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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.*