

SECTION 1: Identification**1.1. Identification**

Product form : Article
Product name : QuickVue hCG Combo Test
Product code : 20110, 20110IN

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
gehs@quidel.com - 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**

Not classified

2.2. GHS Label elements, including precautionary statements

According to the corresponding national regulations there is no labelling obligation for this product.

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

This mixture does not contain any substances to be mentioned according to the criteria of section 3.2 of HazCom 2012

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.
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)

No additional information available

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

Reactivity : The product is non-reactive under normal conditions of use, storage and transport.

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.

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. Wear personal protective equipment.

Hygiene measures : 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**

No additional information available

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 | : In vitro diagnostic medical test kit. |
| | : No data available |
| | : No data available |
| 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 | : Not classified |
| 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 |

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

| | |
|-------------------------|--|
| QuickVue hCG Combo Test | |
| | |

SECTION 13: Disposal considerations

13.1. Disposal 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. |
| Product/Packaging disposal recommendations | : Dispose in a safe manner in accordance with local/national regulations. |



SECTION 14: Transport information

Department of Transportation (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

QuickVue hCG Combo Test

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

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

Revision date : 01/30/2020

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

SDS US Quidel

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.