

**Section 1 – Product and Company Identification****1.1 Manufacturer Information**

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10165 McKellar Court	Fax:	1.800.453.4338	E-mail:	<a href="mailto:gehs@quidel.com">gehs@quidel.com</a>
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**1.2 Product Information**

**Product Name:** QuickVue hCG Urine Test (Catalog #: 20109)

**Intended Use:** The QuickVue hCG Urine test is a one-step immunoassay intended for the qualitative detection of human Chorionic Gonadotropin (hCG) in urine for the early detection of pregnancy. The test is intended for use by healthcare professionals only.

**Components:** Individually pouched test cassettes.

**Section 2 – Hazard Identification****2.1 Classification of the Substance of Mixture**

Not a hazardous substance or mixture.

**2.2 GHS Label Elements, including Precautionary Statements**

Wash hands thoroughly after handling the components within this kit.

**2.3 Hazards Not Otherwise Classified (HNOC) or not covered by GHS**

None

**Section 3 – Composition / Information on Ingredients****3.1 Mixtures**

Contains non-hazardous quantities of proprietary ingredients according to OSHA (29 CFR 1910.1200). Not a hazardous mixture according to Regulation (EC) No. 1272/2008.

**3.2** No chemicals need to be disclosed according to the applicable regulations for the components in this kit.**Section 4 – First Aid Measures****4.1 Description of First Aid Measures**

**If inhaled:** Move the person to fresh air and support breathing as required.

**In case of skin contact:** Wash affected area with soap and water. Seek medical advice if irritation develops.

**In case of 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 attention.

**If swallowed:** Never give anything by mouth to an unconscious person. Rinse mouth with water (do not swallow). Seek medical advice if irritation develops.

**4.2 Most Important Symptoms and Effects (both acute and delayed)**

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

**4.3 Indication of Any Immediate Medical Attention and Special Treatment Needed**

No specific measures identified.

**Section 5 – Fire Fighting Measures**

Only individuals properly trained and issued appropriate personal protective equipment should respond and attempt to extinguish a fire.

**5.1 Suitable Extinguishing Media**

For small fires, use dry chemical, carbon dioxide or alcohol-resistant foam.

**5.2 Special Hazards Arising from the Substance or Mixture**

Nature of decomposition products not known.

**5.3 General Fire Hazards**

The components within this kit will not significantly contribute to the intensity of a fire.

**5.4 Fire Fighting Equipment**

Firefighters should wear full protective gear when responding to fires.

**Section 6 – Accidental Release Measures**

Only individuals properly trained and issued appropriate personal protective equipment should respond and attempt to clean up a spill or release. Spills unlikely as there are no buffers, reagents or solutions included in this kit.

**6.1 Personal Precautions** No data available

**6.2 Environmental Precautions** No data available

**6.3 Methods and Materials for Clean-Up** No data available

**6.4 Recovery and Neutralization** No data available

**Section 7 – Handling and Storage**

**7.1 Specific Use** Refer to product specific package insert.

**7.2 Precautions for Safe Handling**

Wash exposed areas thoroughly after using this kit. Do not eat or drink while using this kit. Universal Precautions should be followed when handling and working with this kit.

**7.3 Universal Precautions**

No known test method can offer complete assurance that product(s) derived from human blood, serum or plasma used in components of this kit will not transmit infectious agents. All blood products should be treated as potentially infectious; use universal precautions. Users should ensure the use of proper personal protective equipment (PPE), covering of any cuts or abrasions on the skin (hands), and follow standard protocols for the decontamination of work surfaces when testing has been completed. Always wash hands thoroughly after handling the components within this kit.

**7.4 Conditions for Safe Storage (including any incompatibilities)**

To maintain efficacy, store according to the package insert instructions.

**7.5 Incompatibilities**

To maintain efficacy, store according to the package insert instructions.

**Section 8 – Exposure Controls and Personal Protection**

**8.1 Exposure Limits** No data available for the components within this kit.

**8.2 Exposure Controls**

Engineering Measures Use with adequate ventilation.

Personal Protective Equipment

*Respiratory Protection* None needed under normal conditions of use.

**Section 8 – Exposure Controls and Personal Protection (cont'd)**

<i>Skin Protection</i>	Handle with appropriately rated chemical resistant gloves. Gloves should be inspected prior to use. Use proper glove technique to remove gloves to avoid contact with skin. Wash hands after handling the components within this kit.
<i>Eye Protection</i>	Wear safety glasses with side shields or goggles to prevent eye contact.
<i>Body Protection</i>	Use body protection appropriate for the task. A laboratory coat is recommended.
<i>Hygiene Measures</i>	Wash hands before use, after use and at the end of the workday.

**8.3 Environmental Exposure Controls** No special environmental controls are required.

**8.4 Special Notes** No data available.

**Section 9 – Physical and Chemical Properties**

Characteristic	Test Cassette
Boiling Point (°C)	No data available
Melting Point (°C)	No data available
Specific Gravity (H <sub>2</sub> O = 1)	No data available
Vapor Pressure (mm Hg)	No data available
Vapor Density (Air = 1)	No data available
Evaporation Rate (Ether = 1)	No data available
pH	No data available
Solubility in Water	No data available
Appearance and Odor	White plastic cassette, odorless

**Section 10 – Stability and Reactivity**

Characteristic	Test Cassette
Component Stability	Stable
Hazard Reaction Potential	No data available
Conditions to Avoid	No data available
Materials to Avoid	No data available
Hazardous Decomposition Products	No data available

**Section 11 – Toxicological Properties**
**11.1 Information on Toxicological Effects**

Acute Toxicity	No data available
Skin Corrosion / Irritation	No data available
Respiratory or Skin Sensitization	No data available
Generative Cell Mutagenicity	No data available
Carcinogenicity	No component of this kit present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by the ACGIH, IARC, NTP or OSHA.
Reproductive Toxicity	No data available
Teratogenicity	No data available

### Section 11 – Toxicological Properties (cont'd)

**Specified Target Organ Toxicity**

Single Exposure: No data available      Repeated Exposure: No data available

Aspiration Hazard      No data available

**Potential Health Effects**

*Inhalation:*      No data available.      *Skin:*      May cause skin irritation upon contact.  
*Ingestion:*      May be harmful if swallowed.      *Eyes:*      May cause eye irritation.

**11.2 Signs and Symptoms of Exposure**

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated for the components within this kit.

**11.3 Additional Information**      None

### Section 12 – Ecological Information

**12.1 Toxicity**      No data available  
**12.2 Persistence and Degradability**      No data available  
**12.3 Bioaccumulative Potential**      No data available  
**12.4 Mobility in Soil**      No data available  
**12.5 PBT and vPvB Assessment**      No data available  
**12.6 Other Adverse Effects**      An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

### Section 13 – Disposal Considerations

**13.1 Waste Disposal Instructions**

Utilize appropriate personal protective equipment and spill control when handling wastes generated from using this kit. Do not discharge any of the solutions, reagents or controls into drains, water courses or onto the ground.

**13.2 Disposal of Product and Contaminated Packaging**

Dispose of waste materials, unused components and contaminated packaging in compliance with country, federal, state and local regulations. If unsure of the applicable regulatory requirements, contact a licensed professional waste disposal service to dispose of this material.

### Section 14 – Transportation Information

**14.1 U.S Department of Transportation (DOT)**      This kit is not regulated for transport.  
**14.2 International Air Transportation Association (IATA)**      This kit is not regulated for transport.  
**14.3 International Maritime Dangerous Goods (IMDG)**      This kit is not regulated for transport.

### Section 15 – Regulatory Information

**15.1 U.S. Federal Regulations**

OSHA Hazards      None  
SARA 302      The following chemicals are subject to reporting levels established by Sara Title III, Section 302:  
   No chemicals in this kit are subject to the reporting requirements of SARA Title III, Section 302

**Section 15 – Regulatory Information (cont'd)**

SARA 313                      The following chemicals are subject to reporting levels established by SARA Title III, Section 313:  
    This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313

SARA311/312 Hazards      No SARA Hazards.

**15.2 State Regulations**

The following chemicals appear on one or more of the following state hazardous substance lists:

Chemical Name	CAS #	CA	MA	MN	NJ	PA	RI
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California Prop 65:        This kit does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.

**15.3 Canadian – WHMIS Classification**

Chemical Name	CAS #	Minimum Concentration
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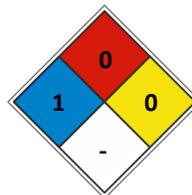
**15.4 Additional Regulatory Information**

**Safety, Health and Environmental Regulations/Legislation Specific for the Mixture**    No data available

**Chemical Safety Assessment**                      Not completed for the components contained within this kit.

**NFPA Kit Classification:**

Health Hazard (blue):    1  
 Fire Hazard (red):        0  
 Reactivity (yellow):      0  
 Special Hazards (white): None


**Section 16 – Other Information**

Every effort has been made to adhere to the hazard criteria and content requirements of the U.S. OSHA Hazard Communication Standard, European Communities Safety Data Sheets Directive, Canadian Controlled Products Regulations, UK Chemical Hazard information and Packaging Regulations, and UN Globally Harmonized System of Classification and Labeling of Chemicals.

**PREPARED BY:**    Quidel Corporation

**SUPERSEDES:**    December 10, 2013

**REVISIONS:**        Change to 16-section SDS format.

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