

Catalog No.: 20110

Revision Date: November 7, 2011

1. Product and Company Identification

- 1.1 **QuickVue One-Step hCG Combo Test** *(For In Vitro Diagnostic Use Only)*
- 1.2 The QuickVue One-Step hCG Combo Test is a one-step immunoassay intended for the qualitative detection of human Chorionic Gonadotropin (hCG) in serum or urine for early detection of pregnancy.
- 1.3 **Manufacturer:** Quidel Corporation 10165 McKellar Court, San Diego, CA 92121
Telephone No.: 1-858-552-1100 **Toll Free No.:** 1-800-874-1517 **Fax No.:** 1-858-453-4338
- 1.4 **Emergency No.:** Poison Control @ 1-800-222-1222 (USA only)

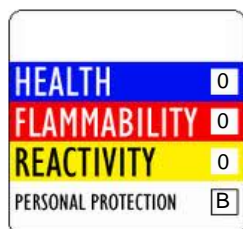
2. Hazards Identification

2.1 Emergency Overview

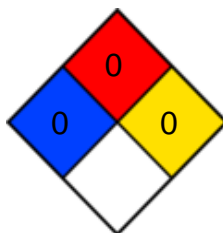
OSHA Hazards: No known OSHA hazards

GHS Classification: Not a dangerous substance or mixture

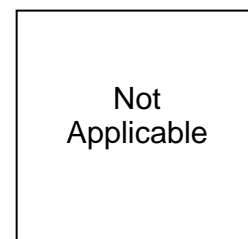
HMIS Classification:



NFPA Classification:



EU Classification:



2.2 Potential Health Effects

Inhalation: None anticipated with normal use

Skin: None anticipated with normal use

Eyes: None anticipated with normal use

Ingestion: May be harmful if swallowed

2.3 Potential Effects of Chronic Exposure:

 None anticipated with normal use

2.4 **Universal Precautions:** All patient samples and contaminated components should be handled as potentially infectious. Wear personal protective equipment and wash hands after handling test.

2.5 **Warning Properties:** None related to the components within this kit.

3. Composition / Information on Components

- 3.1 **Description of Components:** Test cassette with test strip and disposable pipette
- 3.2 **Hazardous Ingredients:** No hazardous substances or mixtures are contained within this kit

4. First Aid Measures

- 4.1 **If inhaled:** Inhalation of any component within this kit is unlikely.
- 4.2 **In case of skin contact:** Wash off with soap and plenty of water.
- 4.3 **In case of eye contact:** Flush eyes with water as a precaution.
- 4.4 **If swallowed:** Never give anything by mouth to an unconscious person. Rinse mouth with water.

***Contact with the test strip contained within the test cassette is unlikely when handling the test per the supplied package insert. Do not remove the test strip from the test cassette.*

5. Fire-Fighting Measures

- 5.1 **Suitable Extinguishing Media:** For small fires, use dry chemical, carbon dioxide, or alcohol-resistant foam.
- 5.2 **Special Fire Fighting Procedures:** This material will not significantly contribute to the intensity of a fire. Trained emergency responders should wear self-contained breathing apparatus and appropriate personal protective gear to prevent contact with skin, eyes and respiratory system.
- 5.3 **Unusual Fire and Explosion Hazards:** When involved in a fire, this material may decompose and produce irritating fumes and toxic gases (e.g., Carbon monoxide, Carbon dioxide).
- 5.4 **Additional Considerations:** Not Applicable

6. Accidental Release Measures

- 6.1 **Personal Precautions:** Follow Universal Precautions when cleaning-up patient samples.
- 6.2 **Environmental Precautions:** Not applicable
- 6.3 **Spill and Leak Procedures:** Not applicable (no reagents or solutions are included with this kit).

7. Handling and Storage

- 7.1 **Precautions for Safe Handling:**

As with all chemicals and biological substances, avoid getting components within this kit ON YOU or IN YOU. Wash exposed areas thoroughly after using this kit. Do not eat or drink while using this kit. This kit should be handled only by qualified clinical or laboratory employees trained on the use of this kit and who are familiar with the potential hazards. Universal Precautions should be followed when using this kit.
- 7.2 **Conditions for Safe Storage:** To maintain efficacy, store according to the package insert instructions.
- 7.3 **Specific Use:** For *in vitro* diagnostic use only – Not for use by general public!

8. Exposure Control and Personal Protection

- 8.1 **Exposure Limits:** Not available
- 8.2 **Occupational Exposure Controls:**
 - 8.2.1 **Engineering Controls:** No special engineering controls are required when working with this kit.
 - 8.2.2 **Personal Protective Equipment (PPE):** Safety glasses and disposable gloves are recommended.
 - 8.2.3 **Hygiene Measures:** Wash hands and work surfaces after handling the components of this kit.
 - 8.2.4 **Environmental Controls:** No special environmental controls are required.

9. Physical and Chemical Properties

Characteristic	Test Cassette
Boiling Point, Melting Point, Flash Point, Ignition Temperature (°C)	Not available
Specific Gravity / Evaporation Rate (Ether = 1)	Not available
Vapor Pressure (mm Hg) / Vapor Density (AIR = 1) / pH	Not available
Lower Explosion Limit (LEL) / Upper Explosion Limit (UEL)	Not available
Solubility in Water:	Not applicable
Appearance and Odor:	Oblong white plastic test cassette with vents; no odor

10. Stability and Reactivity

Characteristic	Test Cassette
Stability	Stable
Conditions to Avoid	None known
Materials to avoid (Incompatibilities)	None known
Hazardous Decomposition or Byproducts	None known
Hazardous Polymerization	None known

11. Toxicological Information

11.1 Toxicity Data for Hazardous Ingredients: No toxicity data available

11.2 Primary Routes of Exposure: Overexposures to the components within this kit are unlikely.

11.3 Potential Health Effects (Chronic / Acute):

General irritation to skin, eyes and GI tract with repeated contact from the improper use of the test components.

11.4 Symptoms of Overexposure:

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

11.5 Medical Exposure Aggravated by Exposure: None known

11.6 Carcinogenicity:

To the best of our knowledge, this kit does not contain any substances that are listed by ACGIH, IARC, NTP or California Prop 65.

11.7 Specific target organ toxicity – single or repeated exposure (GHS): No data available

12. Ecological Information

12.1 Ecotoxicity, Mobility, Persistence and Degradability, Bioaccumulative Potential and Other Adverse Effects:

No data available

13. Disposal Considerations

Dispose of waste materials, unused components and contaminated packaging in compliance with country (i.e., Canada, EU, Japan, etc.), federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

14. Transport Information

14.1 U.S. Department of Transportation (DOT), International Air Transportation (IATA) and International Maritime Organization (IMDG)

This kit is not regulated for transport.

15. Regulatory Information

- 15.1 U.S. Federal and State Regulations: Not applicable
- 15.2 Label Information – ANSI Z129.1: Not applicable
- 15.3 Canadian Regulations: Not applicable
- 15.4 EU Labeling Classification: Not applicable
- 15.5 Japan – Existing and New Chemical Substances (ENCS): Not applicable

16. Other Information

This MSDS has been prepared in accordance with ANSI Z400.1 format and the guidance provided under the Globally Harmonized System (GHS). Every effort has been made to adhere to the hazard criteria and content requirements of the US 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.

The hazard ratings on this MSDS are for appropriately trained workers using the Hazardous Materials Identification System (HMIS®) or a National Fire Protection Association (NFPA) 704 Program. The ratings are estimates and should be treated as such. The hazard rating scales range from (0) minimal hazards to (4) significant hazards or risks (Refer to Definitions of Terms at the end of this MSDS). Chronic (long-term) health effects are indicated in the HMIS by an asterisk (*). HMIS is a registered trade and service mark of the NPCA. For details on HMIS ratings visit www.paint.org/hmis. For details on NFPA 704 visit www.nfpa.org.

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SUPERCEDES: July 18, 2007

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The information above is provided in good faith. It is believed to be accurate and represents the best information currently available to us. However, we make no warranty of merchantability, fitness for a particular purpose or of any other type, expressed or implied, with respect to products described or data or information provided, and we assume no liability resulting from the use of such products, data or information. Users should make their own investigations to determine the suitability of the information for their particular purposes, and the user assumes all risk arising from their use of the material. The user is required to comply with all laws and regulations relating to the purchase, use, storage and disposal of the material, and must be familiar with and follow generally accepted safe handling procedures. In no event shall Quidel be liable for any claims, losses, or damages of any individual or for lost profits or any special, indirect, incidental, consequential or exemplary damages of any kind, howsoever arising, even if Quidel has been advised of the possibility of such damages.

DEFINITIONS OF TERMS

A large number of abbreviations and acronyms appear on a MSDS. Some of these, which are commonly used, include the following:

CAS #: This is the Chemical Abstract Service Number that uniquely identifies each compound.

ACGIH - American Conference of Governmental Industrial Hygienists, a professional association that establishes exposure limits.

TLV - Threshold Limit Value - an airborne concentration of a substance that represents conditions under which it is generally believed that nearly all workers can be repeatedly exposed without adverse effect. The duration must be considered, including the 8-hour Time Weighted Average (**TWA**), the 15-minute Short Term Exposure Limit, and the instantaneous Ceiling Level (**C**). Skin absorption effects must also be considered.

OSHA - U.S. Occupational Safety and Health Administration

ANSI - American National Standards Institute

GHS - Globally Harmonized System

PEL - Permissible Exposure Limit - This exposure value means exactly the same as a TLV, except that it is enforceable by OSHA. The OSHA Permissible Exposure Limits are based in the 1989 PELs and the June, 1993 Air Contaminants Rule (Federal Register: 58: 35338-35351 and 58: 40191). Both the current PELs and the vacated PELs are indicated. The phrase, "Vacated 1989 PEL," is placed next to the PEL that was vacated by Court Order.

IDLH - Immediately Dangerous to Life and Health - This level represents a concentration from which one can escape within 30-minutes without suffering escape-preventing or permanent injury. **The DFG - MAK** is the Republic of Germany's Maximum Exposure Level, similar to the U.S. PEL. **NIOSH** is the National Institute of Occupational Safety and Health, which is the research arm of the U.S. Occupational Safety and Health Administration (**OSHA**). NIOSH issues exposure guidelines called Recommended Exposure Levels (**RELs**). When no exposure guidelines are established, an entry of **NE** is made for reference. **Protective Equipment** - **A:** Safety Glasses. **B:** Safety glasses and gloves. **C:** Safety glasses, gloves and body protection. **D:** Splash goggles with face shield, gloves and body protection. **E:** Eye protection, gloves and dust mask respiratory protection. **F:** Eye protection, gloves, body protection and dust mask respiratory protection. **G:** Eye protection, gloves and air purifying respiratory protection.

HAZARD RATINGS:

HAZARDOUS MATERIALS IDENTIFICATION SYSTEM: Health Hazard: **0** (minimal acute or chronic exposure hazard); **1** (slight acute or chronic exposure hazard); **2** (moderate acute or significant chronic exposure hazard); **3** (severe acute exposure hazard; onetime overexposure can cause permanent injury and can be fatal); **4** (extreme acute exposure hazard; single overexposure can be fatal). * Indicates chronic hazard. Flammability Hazard: **0** (minimal hazard); **1** (materials that require substantial pre-heating before burning); **2** (combustible liquid or solids; liquids with a flash point of 38-93°C [100-200°F]); **3** (Class IB and IC flammable liquids with flash points below 38°C [100°F]); **4** (Class IA flammable liquids with flash points below 23°C [73°F] and boiling points below 38°C [100°F]). Reactivity Hazard: **0** (normally stable); **1** (material that can become unstable at elevated temperatures or which can react slightly with water); **2** (materials that are unstable but do not detonate or which can react violently with water); **3** (materials that can detonate when initiated or which can react explosively with water); **4** (materials that can detonate at normal temperatures or pressures).

NATIONAL FIRE PROTECTION ASSOCIATION: Health Hazard: **0** (material that on exposure under fire conditions would offer no hazard beyond that of ordinary combustible materials); **1** (materials that on exposure under fire conditions could cause irritation or minor residual injury); **2** (materials that on intense or continued exposure under fire conditions could cause temporary incapacitation or possible residual injury); **3** (materials that can on short exposure could cause serious temporary or residual injury); **4** (materials that under very short exposure could cause death or major residual injury). Flammability Hazard and Reactivity Hazard: Refer to definitions for "Hazardous Materials Identification System".

FLAMMABILITY LIMITS IN AIR: Much of the information related to fire and explosion is derived from the National Fire Protection Association (**NFPA**).

Flash Point - Minimum temperature at which a liquid gives off sufficient vapors to form an ignitable mixture with air.

Auto-ignition Temperature: The minimum temperature required to initiate combustion in air with no other source of ignition. LEL - the lowest percent of vapor in air, by volume, that will explode or ignite in the presence of an ignition source. UEL - the highest percent of vapor in air, by volume, that will explode or ignite in the presence of an ignition source.

TOXICOLOGICAL INFORMATION:

Possible health hazards as derived from human data, animal studies, or from the results of studies with similar compounds are presented. Definitions of some terms used in this section are: **LD₅₀** - Lethal Dose (solids & liquids) which kills 50% of the exposed animals; **LC₅₀** - Lethal Concentration (gases) which kills 50% of the exposed animals; **ppm** concentration expressed in parts of material per million parts of air or water; **mg/m³** concentration expressed in weight of substance per volume of air; **mg/kg** quantity of material, by weight, administered to a test subject, based on their body weight in kg. Other measures of toxicity include **TDLo**, the lowest dose to cause a symptom and **TCLo** the lowest concentration to cause a symptom; **TDo**, **LDLo**, **LDo**, **TC**, **TCo**, **LCLo**, and **LCo**, the lowest dose (or concentration) to cause lethal or toxic effects. **BEI** - Biological Exposure Indices, represent the levels of determinants that are most likely to be observed in specimens collected from a healthy worker who has been exposed to chemicals to the same extent as a worker with inhalation exposure to the TLV. Ecological Information: **EC** is the effect concentration in water.

Data from several sources are used to evaluate the cancer-causing potential of the material. The sources and ratings are: **IARC** - the International Agency for Research on Cancer; 1 = Carcinogenic to humans, 2A, 2B = Probably carcinogenic to humans, 3 = Unclassifiable as to carcinogenicity in humans, and 4 = Probably not carcinogenic to humans. **NTP** - the National Toxicology Program; K = Known to be a human carcinogen, and R = Reasonably anticipated to be a human carcinogen. **RTECS** - the Registry of Toxic Effects of Chemical Substances. **OSHA** - Occupational Safety and Health Administration and **CAL/OSHA** - California's subunit of the Occupational Safety and Health Administration; Ca = Carcinogen defined with no further categorization. **ACGIH** - American Conference of Governmental Industrial Hygienists; A1 = Confirmed human carcinogen, A2 = Suspected human carcinogen, A3 = Confirmed animal carcinogen with unknown relevance to humans, A4 = Not classifiable as a human carcinogen, and A5 = Not suspected as a human carcinogen. **NIOSH** - U.S. National Institute for Occupational Safety and Health; Ca = Potential occupational carcinogen, with no further categorization. **EPA** - U.S. Environmental Protection Agency; A = Human carcinogen, B = Probable human carcinogen, C = Possible human carcinogen, D = Not classifiable as to human carcinogenicity, E = Evidence of Non-carcinogenicity for humans, K = Known human carcinogen, L = Likely to produce cancer in humans, CBD = Cannot be determined, NL = Not likely to be carcinogenic in humans, and I = Data are inadequate for an assessment of human carcinogenic potential.

REGULATORY INFORMATION:

This section explains the impact of various laws and regulations on the material. **EPA** is the U.S. Environmental Protection Agency. **WHMIS** is the Canadian Workplace Hazardous Materials Information System. **DOT** and **TC** are the U.S. Department of Transportation and the Transport Canada, respectively.

Superfund Amendments and Reauthorization Act (SARA); the Canadian Domestic/Non-Domestic Substances List (**DSL/NDL**); the U.S. Toxic Substance Control Act (**TSCA**); Marine Pollutant status according to the **DOT**; the Comprehensive Environmental Response, Compensation, and Liability Act (**CERCLA or Superfund**); and various state regulations. This section also includes information on the precautionary warnings that appear on a material's industrial package label.