QUIDEL®

hCG Control Set

Material Safety Data Sheet

Catalog No.: 00272 / 00255
Reference No.: 931761

Revision Date: July 20, 2007

SECTION 1 – Product / Preparation and Company Identification

1.1 **hCG Control Set** (For *In Vitro* Diagnostic Use Only)

1.2 The hCG Control Set is intended for use with QuickVue+® One-Step hCG Combo, QuickVue® One-Step hCG Urine or Combo, RapidVue® hCG and QuickVue Semi-Q® hCG Combo Test. These controls provide an aid in the interpretation of positive and negative test results and verify proper test performance.

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 @ 1-800-876-4766 (USA only)

SECTION 2 – Composition / Ingredients Information

2.1 **Description of Components:** hCG Negative Control and hCG High Positive Control

2.2 **Hazardous Ingredients:** Dangerous solid or liquid substances present in >1% (or as required by applicable U.S., Canadian and E.U. regulations): The classifications listed below are based on the 0.1% sodium azide concentration.

CAS#	EINECS	Chemical Name	Kit Component	% Weight	Classification:			
					US OSHA	WHMIS	EU	Risk Phrases
26628-22-8	247-852-1	**Sodium Azide**	All Controls	0.1%	Irritant	N/A	Xi	R32

** See Section 15 and Section 16 – Regulatory Information for additional information on hazard classifications.

SECTION 3 – Hazard Identification

Emergency Overview: As part of good industrial and personal hygiene and safety procedure, avoid all unnecessary exposure to the chemical components of this kit and ensure prompt removal from skin, eyes, and clothing.

3.1 Significant health effects are ***NOT*** anticipated from routine use of this kit when adhering to the instructions listed in the Package Insert provided with the kit and when following the precautions listed within this document.

3.2 Contact with these hCG Controls to the eyes and/or skin may cause irritation upon a single exposure. Avoid prolonged contact.

3.3 This kit contains material of human origin and should be considered as potentially capable of transmitting infectious diseases.

3.4 All patient samples and hCG Controls should be handled as potentially infectious. Follow ***Universal Precautions*** as necessary.

3.5 **Warning Properties:** None

SECTION 4 – First Aid Measures

Special Instructions:

4.1 ***Inhalation*** Inhalation of the hCG Controls contained within this kit is unlikely.

4.2 ***Eye Contact*** If any component of this kit enters the eyes, wash eyes gently under potable running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occurs, obtain medical attention.

4.3 ***Skin Contact*** If any component of this kit contacts the skin and causes discomfort, remove any contaminated clothing. Wash affected area with plenty of soap and water. If pain or irritation occurs, obtain medical attention.

4.4 ***Ingestion*** If any component of this kit is ingested, wash mouth out with water. If irritation or discomfort occurs, obtain medical attention.

SECTION 5 – Fire Fighting Measures

5.1 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. Use extinguishing material suitable to the surrounding fire. Utilize proper personal protective equipment when responding to <u>any</u> fire. Incipient fire responders should wear eye protection. Structural firefighters must wear Self-Contained Breathing Apparatus and full protective equipment. Move containers from fire area if it can be done without risk to personnel. If possible, prevent runoff water from entering storm drains, bodies of water, or other environmentally sensitive areas.

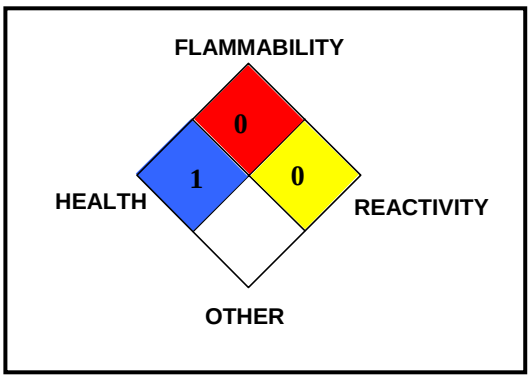
5.3 Unusual Fire and Explosion Hazards: When involved in a fire, this material can decompose and produce irritating fumes and toxic gases (e.g., Carbon monoxide, Carbon dioxide).

5.4 Additional Considerations (hCG Controls):

5.4.1	Flash Point	Non Combustible
5.4.2	Auto-ignition Temperature	Not Applicable
5.4.3	Upper / Lower Explosion Limit	Not Applicable

5.5 NFPA Ratings (see 'Definition of Terms' for explanation of numerical ratings)**:**

hCG Controls
Sodium Azide 0.1%



*** Only trained and competent personnel shall attempt to extinguish a fire. Contact emergency response personnel as required. Be cautious of surrounding materials that may react with the extinguishing media.*

SECTION 6 – Accidental Release Measures

6.1 Personal Precautions: This kit contains materials of biological origin. Avoid personal contact. Use Universal Precautions during clean-up and handling procedures.

6.2 Environmental Precautions: No environmental hazard is anticipated provided that the material is handled and disposed of with due care. Contain spill to prevent migration.

6.3 Spill and Leak Procedures: Large spills of this kit are unlikely. Personnel who have received basic chemical safety training can generally handle small-scale releases, such as (1) container in this kit. Utilize safety glasses, nitrile gloves, and lab coat/apron when responding to spills involving the components of this kit. Absorb liquid and place in container suitable for disposal. Dispose of in accordance with applicable U.S. Federal, State, or local procedures or appropriate standards of Canada or the EU (see Section 13, Disposal Considerations).

SECTION 7 – Handling and Storage

7.1 Handling: As with all chemicals, avoid getting the preparations of 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.

This kit should be handled as though capable of transmitting infectious diseases. Universal Precautions should be followed when using this kit.

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

7.3 Specific Use: For *in vitro* diagnostic use – ***Not for use by general public!***

SECTION 8 – Exposure Controls and Personal Protection

8.1 Exposure Limits:

There are no ACGIH, NIOSH, OSHA or country specific occupational exposure limits currently established for components present in this preparation at concentrations equal to or greater than 1% (0.1% if carcinogen).

8.2 Occupational Exposure Controls:

8.2.1 Engineering Controls:

No special engineering controls are required when working with this kit. Use with adequate ventilation to ensure exposure levels are maintained below the limits provided above.

8.2.2 Personal Protective Equipment (PPE):

Respiratory Protection:	None needed under normal conditions of use.
Eye Contact:	Safety glasses are recommended to prevent eye contact.
Hand Contact:	Impervious gloves (nitrile or equivalent) should be worn to prevent hand contact.
Skin Contact:	Lab Coat or similar garment should be worn.

8.2.3 Environmental Controls: No special environmental controls are required.

SECTION 9 – Physical and Chemical Properties

Characteristic	hCG Controls: Sodium Azide 0.1%
Boiling Point (°C)	N/A
Melting Point (°C)	N/A
Specific Gravity (H_2O = 1)	N/A
Vapor Pressure (mm Hg)	N/A
Vapor Density (AIR = 1)	N/A
Evaporation Rate (Ether = 1)	N/A
pH:	Neutral
Solubility in Water:	Soluble
Appearance and Odor:	Clear to slightly yellow; Odorless

SECTION 10 – Stability and Reactivity

Characteristic	hCG Controls: Sodium Azide 0.1%
Stability	Stable
Conditions to Avoid	Incompatible materials
Materials to avoid (Incompatibilities)	None Known
Hazardous Decomposition or Byproducts	Nature of decomposition of products not known
Hazardous Polymerization	Will not occur

SECTION 11 – Toxicological Information

11.1 Toxicity Data for Hazardous Ingredients: There are currently no toxicity data available for the components of this kit; the following toxicology information is available for raw materials present in greater than 1% concentration.

hCG Controls:

When used and handled according to specifications, this product does not have any harmful effects according to our experience. The substance is not subject to classification.

11.2 Primary Routes of Exposure:

Overexposures to components within this kit are not expected. Common routes of exposure may include ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with eyes, contact with mucous membranes and inhalation of aerosolized material.

11.3 Potential Effects of Acute Overexposure, By Route Of Exposure:

This kit contains materials of human origin and should be considered as potentially capable of transmitting infectious diseases.

INHALATION:	No irritating effect known
CONTACT WITH SKIN or EYES:	Slight irritation upon contact may occur.
SKIN ABSORPTION:	No irritating effect known
INGESTION:	Slight irritation upon contact may occur.
INJECTION:	No irritating effect known

11.4 Potential Effects of Chronic Exposure:

Long-term skin or eye contact can result in dermatitis or eye irritation.

11.5 Symptoms of Overexposure:

Symptoms of overexposure may include: eye, skin, nose, and throat irritation, headache, nausea and vomiting, and burns to contacted areas. Symptoms may be delayed for several hours after exposure.

11.6 Medical Exposure Aggravated by Exposure:

Persons with pre-existing skin disorders; eye problems or impaired respiratory system function can be more susceptible to health effects associated with overexposures to this product.

11.7 Carcinogenicity:

The ingredients in this kit are not listed as carcinogens by any of the following: ACGIH, IARC, NTP, or OSHA.

SECTION 12 – Ecological Information

12.1 Ecotoxicity – Not Available

No adverse effects on the environment are expected from the components of this kit.

12.2 Mobility, Persistence and Degradability

Mobility, persistence and degradation data are not available for the components of this kit.

12.3 Bioaccumulative Potential

There is limited potential for the components within this kit to accumulate in plant or animal systems. The ecological effects have not been thoroughly investigated, but currently none have been identified.

SECTION 13 – Disposal Considerations

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

SECTION 14 – Transport Information

14.1 U.S., Canadian and International Air Transportation

Proper Shipping Name: None
Non-Hazardous for Transport: This substance is considered to be non-hazardous for transport

SECTION 15 – Regulatory Information

15.1 U.S. Federal and State Regulations

Regulatory Reference	hCG Controls: 0.1% Sodium Azide
40 CFR 355.30/355.40 - SECTION 302	Not Listed
40 CFR 302.4 - SECTION 304	Not Listed
40 CFR 372.65 - SECTION 313	Not Listed

U.S. SARA SECTION 311/312 FOR PRODUCT: Acute health effects; chronic health effects

U.S. TSCA INVENTORY STATUS: The components of this kit are listed on the TSCA Inventory

OTHER U.S. FEDERAL REGULATIONS: Not applicable.

CALIFORNIA SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT (PROPOSITION 65):
This material is not found on either the Proposition 65 Carcinogen List or the Adverse Reproductive Effects List.

15.2 Label Information

ANSI 129.1 **CAUTION**: Harmful if swallowed, eye and skin irritant. Do not swallow or take internally. Do not get into eyes, on skin, or on clothing.

ENVIRONMENTAL HAZARDS:
Do not discharge effluent containing this product into streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

15.3 Canadian Regulations:

CANADIAN DSL/NDSL INVENTORY STATUS:
The components of this product are listed on the DSL Inventory.

CANADIAN WHMIS SYMBOLS: **None Required**

15.4 HMIS Ratings (see 'Definition of Terms' for explanation of numerical ratings):

hCG Controls
Sodium Azide 0.1%

Health	**1***
Flammability	**0**
Physical Hazard	**0**
Protective Equipment	**B**

B: Safety glasses and gloves

15.5 EU Labeling Classification:

Classification:	**Risk Phrases**:
hCG Controls **0.1% Sodium Azide** Xn Harmful	R32: Contact with acids liberates very toxic gas **Safety Phrases:** S24/25: Avoid contact with skin and eyes. S29/35: Do not empty into drains; dispose of this material and its container in a safe way.

SECTION 16 – Other Information

This MSDS has been prepared in accordance with ANSI Z400.1 format. 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.

PREPARED BY: Quidel Corporation
10165 McKellar Court
San Diego, CA 92121
(858)-552-1100

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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

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. **O**ccupational **S**afety and **H**ealth **A**dministration (**OSHA**). NIOSH issues exposure guidelines called **R**ecommended **E**xposure **L**evels (**REL**s). 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. Autoignition 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: **LD_{50}** - Lethal Dose (solids & liquids) which kills 50% of the exposed animals; **LC_{50}** - 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/m^3** 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/NDSL)**; 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.

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