hCG Control Set

Safety Data Sheet

Catalog No.: 00272 **Revision Date**: May 29, 2012

1. Product 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 Urine or Combo, QuickVue+ One-Step hCG Combo and the RapidVue hCG tests. 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 @ 1-800-222-1222 (USA only)

2. Hazards Identification

2.1 **Emergency Overview**

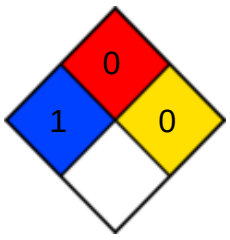
OSHA Hazards: No known OSHA hazards

GHS Classification: Not a dangerous substance or mixture

EU Classification:

HMIS Classification:

NFPA Classification:



2.2 **Risk and Safety Phrases (EU):**

R22: Harmful if swallowed
S24/25: Avoid contact with skin and eyes
S29: Do not empty into drains

2.3 **Potential Health Effects**

Inhalation: May be harmful if inhaled. May cause respiratory tract irritation.
Skin: May be harmful if absorbed through skin. May cause skin irritation.
Eyes: May cause eye irritation.
Ingestion: May be harmful if swallowed

2.4 **Potential Effects of Chronic Exposure:** Irritation to exposed areas

2.5 **Universal Precautions:** The positive control should be handled as potentially infectious. Wear personal protective equipment and wash hands after working with controls.

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

3. Composition / Information on Components

3.1 Description of Components: hCG Negative Control in buffered solution and hCG Positive Control in buffered solution. Both controls are in vials.

3.2 Hazardous Ingredients:

CAS#	EC Number	Chemical Name	Kit Component	% Weight	Volume (mL)
26628-22-8	247-852-1	Sodium Azide	**Negative and Positive Controls**	0.1%	4.5

4. First Aid Measures

4.1 If inhaled: Inhalation of the controls contained within this kit is unlikely, however care should be taken when opening each vial.

4.2 In case of skin contact: If any control contacts the skin and causes discomfort, remove any contaminated clothing and wash affected area with plenty of soap and water. If pain or irritation occurs, obtain medical attention.

4.3 In case of eye contact: If any control makes contact with 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.

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

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 spilled / released controls.

6.2 Environmental Precautions: No environmental risks are anticipated from the controls within this kit.

6.3 Spill and Leak Procedures: For both the negative and positive control, wipe up with paper towel or other inert absorbent material. Place clean-up materials into biohazardous waste container for disposal.

7. Handling and Storage

7.1 Precautions for Safe Handling:

As with all chemicals and biological substances, avoid getting components within this controls 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 these controls.

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 for the components of this kit

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.

8.2.2 Personal Protective Equipment (PPE): Safety glasses and impervious gloves are recommended.

8.2.3 Hygiene Measures: Wash hands and work surfaces after handling the controls within this kit.

8.2.4 Environmental Controls: No special environmental controls are required.

9. Physical and Chemical Properties

Characteristic	Negative and Positive Controls
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)	Not available
Lower Explosion Limit (LEL) / Upper Explosion Limit (UEL)	Not available
pH:	Neutral
Solubility in Water:	Soluble
Appearance and Odor:	Clear to slightly yellow; odorless

10. Stability and Reactivity

Characteristic	Negative and Positive Controls
Stability	Stable
Conditions to Avoid	Incompatible materials
Materials to avoid (Incompatibilities)	Acids
Hazardous Decomposition or Byproducts	Nature of decomposition of the controls are unknown
Hazardous Polymerization	Will not occur

11. Toxicological Information

11.1 Toxicity Data for Hazardous Ingredients: No toxicity data available for the controls within this kit.

Acute Toxicity Values: Sodium Azide LD50 Oral Rat: 27 mg/kg LD50 Dermal Rat: 20 mg/kg

11.2 Primary Routes of Exposure: Common routes of exposure may include ingestion, inhalation and eye/skin contact. Specific paths of concern for potentially infectious and irritating materials are skin puncture, contact with broken skin, contact with eyes, contact with mucous membranes and inhalation of aerosolized material.

11.3 Potential Health Effects (Chronic / Acute): General irritation to skin, eyes, respiratory and GI tracts may be experienced with repeated exposure to these controls.

11.4 Symptoms of Overexposure: Overexposures to the controls within this kit are not expected. However, 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.

11.5 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 over exposure to the controls within this kit.

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:

12.1.1 No data available with regards to the controls within this kit.

12.2.2 Sodium Azide is considered to be toxic to aquatic life. Avoid placing unused controls down the drain.

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:

15.1.1 OSHA Hazards: No known OSHA hazards

15.1.2 SARA 302 Components: Sodium Azide 26628-22-8

15.1.3 SARA 313 Components: 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

15.1.4 SARA 311/312 Hazards: No SARA hazards

15.1.5 Right to Know Components: Sodium Azide 26628-22-8

15.2 Label Information – ANSI Z129.1: CAUTION: Harmful if swallowed, eye and skin irritant. Do not swallow or take internally. Do not get into eyes, on skin, or on clothing.

15.3 Canadian Regulations: WHMIS Classification: This product has been classified in accordance with the hazard criteria of the CPR, and the MSDS contains all the information required by the CPR.

DSL: No NDSL: No

15.4 Canadian WHMIS Symbols: Not applicable

15.5 Japan – Existing and New Chemical Substances (ENCS): Sodium azide 26628-22-8 1-482

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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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. **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.

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: **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.