

## Section 1 – Product and Company Identification

**Manufacturer Information**

Quidel Corporation 10165 McKellar Court San Diego, CA 92121	Phone: 1.800.874.1517 Fax: 1.858.453.4338 Emergency # (24-Hour): 1.866.519.4752	Web: <a href="http://quidel.com">quidel.com</a> E-mail: <a href="mailto:gehs@quidel.com">gehs@quidel.com</a>
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**Product Information**

**Product Name:** hCG Control Set (Catalog #: 00272)

**Intended Use:** The hCG Control Set is intended for use with the QuickVue hCG Urine or Combo, QuickVue+ hCG Combo and the RapidVue hCG tests. These controls provide an aid in the interpretation of positive and negative test results and verify test performance. Not for use by the general public.


**Components:** Kit is composed of one single use 4.5 mL vial of the hCG Positive Control and one single use 4.5 mL vial of the Negative hCG Control.

## Section 2 – Hazards Identification

**Emergency Overview**

Component	OSHA Hazards	Target Organs	GHS Classification
<b>Positive Control</b> (Microcide III, 0.68%, Sodium Azide 0.1%)	Irritant, Sensitizer	Skin, eyes	Skin Corrosion (Category 1B) Eye Irritation (Category 2A) Skin Sensitizer (Category 1) Chronic Aquatic, Toxicity (Category 3)
<b>Negative Control</b> (Microcide III, 0.3%, Sodium Azide, 0.1%)	Irritant, Sensitizer	Skin, eyes	Eye Irritation (Category 2A) Skin Irritation (Category 2) Skin Sensitizer (Category 1) Chronic Aquatic, Toxicity (Category 3)

**GHS Classification and Label Elements**

Component	Pictogram	Hazard Statements	Precautionary Statements
Positive Control and Negative Control	 <b>Warning</b>	H303 May be harmful if swallowed. H313 May be harmful in contact with skin. H315 Causes skin irritation. H317 May cause an allergic skin reaction. H319 Causes serious eye irritation. H412 Harmful to aquatic life with long lasting effects	P261 Avoid breathing mist or spray. P264 Wash hands thoroughly after handling. P273 Avoid release to the environment. P280 Wear protective gloves and eye protection. P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
<b>Supplemental Hazard Statements</b>		1. Follow Universal Precautions when working with the components within this kit. 2. Avoid disposal of the controls within this kit down sanitary or industrial drains. 3. Avoid release to the environment.	

### Section 3 – Composition / Information on Ingredients

Component	Chemical Name	CAS #	EINECS #	Concentration (%)	Component Volume
Positive Control, Negative Control	Glycerol	56-81-5	200-289-5	<3.0	4.5 mL
	Microcide III	55965-84-9	--	<0.7	
	Sodium Azide	26628-22-8	247-852-1	0.1	

### Section 4 – First Aid Measures

**General Advice**

Move out of the exposure area. Consult a physician. Show this safety data sheet to the doctor in attendance, as necessary.

- 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. Seek medical advice if irritation develops.

Note to Physicians: Treat symptomatically.

### Section 5 – Fire Fighting Measures

**General Advice**

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

- Suitable Extinguishing Media:* For small fires, use dry chemical, carbon dioxide or alcohol-resistant foam.
- General Fire Hazards:* The components within this kit will not significantly contribute to the intensity of a fire.
- Hazardous Combustion Products:* No data available.
- Fire Fighting Equipment:* Firefighters should wear full protective gear when responding to fires.

### Section 6 – Accidental Release Measures

**General Advice**

Only individuals properly trained and issued appropriate personal protective equipment should respond and attempt to clean up a spill or release. Large spills of the Positive or Negative Controls contained within this kit are unlikely.

- Personal Precautions:* Use personal protective equipment, including protective gloves and safety glasses when cleaning up small spills. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Keep all unnecessary personnel away from the spill area.
- Materials and Methods for Clean-Up:* Soak up with inert absorbent material (e.g., paper towel, etc.). Thoroughly wash the area with soap and water after a spill or release clean-up.
- Recovery and Neutralization:* Collect spilled material and clean-up supplies and place in sealed container for disposal. Refer to Section 13 for disposal guidance.
- Environmental Precautions:* Contain spill to prevent migration to drains, sewers or open water sources. Discharge to the environment must be avoided.

## Section 7 – Handling and Storage

**Specific Use:** For *in vitro* diagnostic use only – Not for use by the general public.

### Precautions for Safe Handling

As with all chemical and biological substances, avoid getting the 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 handling and working with this kit. Keep out of reach of the general public.

**Conditions for Safe Storage:** To maintain efficacy, store according to the instructions in the kit specific Package Insert.

**Incompatibilities:** None.

## Section 8 – Exposure Controls and Personal Protection

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

### Exposure Controls:

**Engineering Measures** Use with adequate ventilation.

#### Personal Protective Equipment

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

*Hand Protection:* Handle with appropriately rated chemical resistant gloves (nitrile or equivalent). 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.

*Eye Protection:* Wear safety glasses with side shields or goggles to prevent eye contact.

*Skin and Body Protection:* Use body protection appropriate for the task. A laboratory coat is recommended.

*Hygiene Measures:* Wash hands before and after use and at the end of the workday.

#### Environmental Exposure Controls

No special environmental controls are required.

## Section 9 – Physical and Chemical

Characteristic	Positive and Negative Controls
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	6.5
Solubility in Water	Soluble
Appearance and Odor	Clear to slightly yellow; odorless

## Section 10 – Stability and Reactivity

Characteristic	Positive and Negative Controls
Component Stability	Stable
Hazard Reaction Potential	Will not occur
Conditions to Avoid	None
Materials to Avoid	None
Hazardous Decomposition Products	No data available
<b>Additional Information:</b>	
Sodium azide is present in the Positive and Negative Controls (as a preservative). Contact with acidic solutions or metal compounds over time may form potentially explosive metal azides. Avoid disposal into a sanitary sewer system.	

## Section 11 – Toxicological Information

### Acute Toxicity

#### Component Analysis – LD50 / LC50

Chemical Name	CAS #	RTECS #	Information
Microcide III	55965-84-9	--	Oral LD <sub>50</sub> Rat >5000 mg/kg Inhalation LC <sub>50</sub> Rat (4-hr) 0.33 mg/L (dust/mist) Dermal LD <sub>50</sub> Rabbit >5000 mg/kg
Sodium Azide	26628-22-8	VY8050000	Oral LD <sub>50</sub> Rabbit 10 mg/kg Inhalation LC <sub>50</sub> Rat 37 mg/m <sup>3</sup> Dermal LD <sub>50</sub> Rabbit 20 mg/kg
Glycerol	56-81-5	MA8050000	Oral LD <sub>50</sub> Rat 12,600 mg/kg Inhalation LC <sub>50</sub> -- No data Dermal LD <sub>50</sub> Rabbit >10,000 mg/kg

#### Potential Health Effects

<i>Skin Corrosion/Irritation:</i>	May cause transient irritation.	<i>Inhalation:</i>	May be harmful if inhaled. May cause respiratory tract irritation.
<i>Serious Eye Damage / Irritation:</i>	No data available	<i>Skin:</i>	May be harmful if absorbed through the skin. May cause skin irritation upon contact.
<i>Respiratory or Skin Sensitization:</i>	May cause sensitization by skin contact.	<i>Eyes:</i>	May cause eye irritation.
<i>Generative Cell Mutagenicity:</i>	No data available	<i>Ingestion:</i>	May cause irritation if swallowed.

### 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 ACGIH, IARC, NTP or OSHA.

**Reproductive Toxicity** No data available

**Teratogenicity** No data available

### Specified Target Organ General Toxicity

*Single Exposure (GHS):* No data available

*Repeated Exposure (GHS):* No data available

### Aspiration Respiratory Organs Hazard

None anticipated under product use conditions.

### 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 contained within this kit.

### Synergistic Effects

No data available

### Additional Information

No data available

## Section 12 – Ecological Information

<b>Ecotoxicity</b>	No data available	<b>Mobility in Soil</b>	No data available
<b>Persistence / Degradability</b>	No data available	<b>PBT and vPvB Assessment</b>	No data available
<b>Bioaccumulation</b>	No data available		
<b>Other Adverse Effects</b>	<p>An environmental hazard cannot be excluded in the event of unprofessional handling or disposal. Avoid release to the environment.</p> <p><i>Microcide III (&lt;0.7%) and Sodium Azide (0.1%) may be harmful to aquatic life with long lasting effects.</i></p>		

## Section 13 – Disposal Considerations

### Waste Disposal Instructions

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

### Disposal of Product and Contaminated Packaging

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

## Section 14 – Transportation Information

<b>U.S. Department of Transportation (DOT)</b>	This kit is not regulated for transport.
<b>International Air Transportation (IATA)</b>	This kit is not regulated for transport.
<b>International Maritime Dangerous Goods (IMDG)</b>	This kit is not regulated for transport.

## Section 15 – Regulatory Information

### Regulatory Information

#### U.S. Federal Regulations

<b>OSHA Hazards</b>	Positive Control and Negative Control: Irritant, Sensitizer
<b>SARA 302</b>	No chemicals in this kit are subject to the reporting requirements of SARA Title III, Section 302.
<b>SARA 313</b>	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.
<b>SARA 311/312</b>	No SARA Hazards.

#### State Regulations

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

Chemical Name	CAS #	CA	MA	MN	NJ	PA	RI
Microcide III	55965-84-9	No	No	No	No	No	No
Sodium Azide	26628-22-8	Yes	Yes	Yes	Yes	Yes	Yes

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

**California Proposition 65**

This product does not contain any chemicals known to the State of California to cause cancer, birth, or any other reproductive defects.

**Canadian - WHMIS IDL**

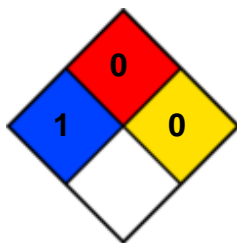
Chemical Name	CAS #	Minimum Concentration
Microcide III	55965-84-9	No data available
Sodium Azide	26628-22-8	No data available

**Additional Regulatory Information**
**Safety, Health and Environmental regulations/legislation specific for the mixture**

No data available

**Chemical Safety Assessment**

No data available

**NFPA 704 Kit Rating**

**HMIS Kit Classification**


### Section 16 – Other Information

**PREPARED BY:** Quidel Corporation  
 EHS Department  
 12544 High Bluff Drive, Suite 200, San Diego, CA 92130

**SUPERCEDES:** December 10, 2013

**REVISIONS:** Added Microcide III to composition for the Positive Control and Negative Control.

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.

SD0027200EN00 (03/16)