

Section 1 – Product and Company Identification

Manufacturer Information

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Product Information

Product Name: Serum hCG Control Set (Catalog #: 00281)

Intended Use: The Serum hCG Control Set is intended for use with the QuickVue hCG Combo or QuickVue+ hCG Combo 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 5 mL vial of the Serum hCG Low Positive Control, one single use 5 mL vial of the Serum hCG High Positive Control and one single use 5 mL vial of the Serum hCG Negative Control. All of the controls are in a lyophilized form.


Section 2 – Hazards Identification

Emergency Overview

Significant health effects are not anticipated from routine use of this kit when following the precautions listed within this SDS and the kit specific Package Insert. The Low and High Positive and Negative Controls (0.1% Sodium Azide) within this kit are considered hazardous as defined by the Occupational Safety and Health Administration (OSHA), the Canadian Workplace Materials Information System (WHMIS), or the European Union (EU) Directives 1999/45/EC, 67/548/EEC and/or 1272/2008.

OSHA Hazards	Target Organs	GHS Classification
None	No data available	Acute Toxicity, Oral (Category 4) Acute Toxicity, Dermal (Category 5) Chronic Aquatic, Toxicity (Category 3)

GHS Classification and Label Elements

Component	Pictogram	Signal Word	Hazard Statements	Precautionary Statements
Low and High Positive Controls and Negative Control		Warning	H303 May be harmful if swallowed. H313 May be harmful in contact with skin. H412 Harmful to aquatic life with long lasting effects	P264 Wash hands thoroughly after handling P273 Avoid release to the environment. P281 Use personal protective equipment, as required
Supplemental Hazard Statements			Avoid release to the environment.	

Section 3 – Composition / Information on Ingredients

Component	Chemical Name	CAS #	EINECS #	Concentration (%)	Volume
Low / High Positive Controls and Negative Control	Human Serum	--	--	>95.0	5 mL
	Sodium Azide	26628-22-8	247-852-1	0.1	

Section 4 – First Aid Measures

General Advice

Move out of the exposure area. 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.

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.

Indication of any immediate medical attention and special treatment needed

No data available.

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 Low / High 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 spill area.
- Materials and Methods for Clean-Up:* Wipe up with appropriate absorbent. Thoroughly wash the area with soap and water.
- 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 public industrial / sanitary sewers or open water sources.

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: Contains no components with occupational exposure limit values.

Exposure Controls:

Engineering Measures Use with adequate ventilation to maintain worker exposure below limits listed above.

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: Handle in accordance with good industrial hygiene and safety practice. 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	Low / High Positive and Negative Controls
Boiling Point (°C)	No data available
Melting Point (°C)	No data available
Specific Gravity (H ₂ 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	Low / High 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
Additional Information:	
Sodium azide is present in the Low / High 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		
Sodium Azide	26628-22-8	VY8050000	Oral LD ₅₀	Rabbit	10 mg/kg
			Inhalation LC ₅₀	Rat	37 mg/m ³
			Dermal LD ₅₀	Rabbit	20 mg/kg

Potential Health Effects

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

Carcinogenicity

The chemicals in the Low / High Positive and Negative Controls are not listed as carcinogens by any of the following: 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 Low / High Positive and Negative Controls contained within this kit.

Synergistic Effects

No data available

Additional Information

No data available

Section 12 – Ecological Information

Ecotoxicity

No data available

Mobility in Soil

No data available

Persistence / Degradability

No data available

PBT and vPvB Assessment

No data available

Bioaccumulation

No data available

Other Adverse Effects

An environmental hazard cannot be excluded in the event of unprofessional handling or disposal. The sodium azide (0.1%) within the Low / High Positive and Negative Controls may be harmful to aquatic life with long lasting effects.

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 Low / High Positive or Negative Controls 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

U.S. Department of Transportation (DOT)	Not regulated as a hazardous material.
International Air Transportation (IATA)	Not regulated as a dangerous good.
International Maritime Dangerous Goods (IMDG)	Not regulated as a dangerous good.

Section 15 – Regulatory Information

Regulatory Information

U.S. Federal Regulations

OSHA Hazards	No known OSHA hazards.
SARA 302	No chemicals in this kit are subject to the reporting requirements of SARA Title III, Section 302.
SARA 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.
SARA 311/312	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
Sodium Azide	26628-22-8	Yes	Yes	Yes	Yes	Yes

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

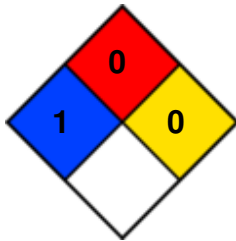
Chemical Name	CAS #	Minimum Concentration
Sodium Azide	26628-22-8	Not WHMIS Controlled below 1%

Section 15 – Regulatory Information (cont'd)

Additional Regulatory Information

Safety, Health and Environmental regulations/legislation specific for the mixture No data available
Chemical Safety Assessment No data available
European Directive 67/548/EEC as amended

Danger Symbol	Risk Phrases	Safety Phrases
 Xn Harmful	R25: Toxic if swallowed. R32: Contact with acids liberates very toxic gas. R52: Harmful to aquatic organisms.	S23: Do not breathe vapor. 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.

NFPA 704 Rating

HMIS Classification


Section 16 – Other Information

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SUPERCEDES: November 7, 2011

REVISIONS: Updated to GHS format and new branding

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