

### Section 1: Identification

**Product Name: Status First hCG Control Kit**

**Manufactured for: LifeSign LLC**

**Address: 85 Orchard Road Skillman, NJ 08558**

**Contact: Toll Free: (800) 526-2125**

**Main Number: (732) 246-3366**

**Fax Number: (732) 246-0570**

**Status First hCG Control Kit- Positive and Negative Urine Controls are intended for use as unassayed control materials for in vitro tests that detect hCG in urine.**

### Section 2: Hazard(s) Identification

**GHS Classification:**

Health	Environmental	Physical
N/A	N/A	Pale Liquid

**GHS Label:**

Symbols	
<b>Hazard Statements</b> Non Flammable Not Fatal if inhaled Causes irritant skin	<b>Precautionary Statements</b> Very Toxic if Swallowed Contact with acid liberates very toxic gases Do not breathe vapors Wear protective eye and face protection Wear gloves. Store at room temperature

### Section 3: Composition/Information on Ingredients

Component	CAS Number	Weight
Sodium Azide	26628-22-8	.1
<b>See Section 8 For Exposure Limits</b>		

### Section 4: First-Aid Measures

**Skin:** In case of contact, flush with copious amounts of water for at least 15 minutes. Remove contaminated clothing and shoes. Call a physician.

**Inhalation:** Remove to Fresh Air. If breathing becomes difficult, refer to a physician

**Ingestion:** Wash out mouth with water provided person is conscious. Call a physician.

### Section 5: Fire-Fighting Measures

**Suitable Extinguishing Media:** Use Media appropriate for surrounded materials

**Fire Fighting Procedures:** Small fire: Use DRY chemical powder. Large Fire: Use Water Spray, Fog, or Foam. Do Not use water jet.

**Unusual Fire and Explosion Hazards:** None Known

**Combustion Products:** None known

### Section 6: Accidental Release Measures

**Accidental release measures:** Wear respirator, chemical safety goggles, rubber boots and heavy rubber gloves. Ventilate area and wash spill site after material pick up is complete.

### Section 7: Handling and Storage

**Handling:** NIOSH/MSHA approved respirator. Mechanical exhaust required. Compatible chemical-resistant gloves. Chemical safety goggles. Potentially biohazards material.

**Storage:** Keep container dry. Keep in a cool place. Ground all equipment containing material. Keep container tightly closed. Keep in cool, well-ventilated place. Highly toxic or infectious materials should be stored in a separate locked safety storage cabinet or room.

### Section 8: Exposure Controls/Personal Protection

**Exposure Limits:** Consult local authorities for acceptable exposure limits.

**Engineering Controls:** Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

**Personal Protective Equipment (PPE):** Splash goggles. Lab coat. Dust respirator. Be sure to use an approved/certified respirator or equivalent. Gloves.

### Section 9: Physical and Chemical Properties

**Flashpoint:** N.A

**Auto ignition Temperature:** N.A.

**Boiling Point:** N.A

**Melting Point:** <0.1

**Vapor Pressure:**<0.1

**Vapor Density (Air=1):**

**% Solubility in Water:**N.A.

**Pour Point:** Not Available

**Molecular Formula:**N.A.

**Odor/Appearance:**None Known

**Lower Flammability Limit:**N.A.

**Upper Flammability Limit:**N.A

**Specific Gravity:**1.846 (Water=1)

**% Volatile:** N.A.

**Evaporation Rate (Water=1):** N.A.

**Viscosity:**Not Available.

**Octanol/Water Partition Coefficient:**Not Available

**pH:**Not Available

**Molecular Weight:** 65.02 g/mole

### Section 10: Stability and Reactivity

**Stability and reactivity:**This product is stable up to the expiration date printed on the label if kept at 35.6-46.4°F (2-8°C) Non- reactive within this kit.

**Hazardous Reactions/Decomposition Products:** Will not occur/None known

### Section 11: Toxicological Information

**Signs and Symptoms of Overexposure:** No effects of overexposure

**Acute Effects:**

**Eye Contact:** May cause conjunctival irritation.

**Skin Contact:** May cause reddening. May cause irritant skin reaction.

**Inhalation:** Not Considered Health Risk

**Ingestion:** May cause irritant conditions if swallowed.

**Target Organ Effects:** None

**Chronic Effects:** None

**Medical Conditions Aggravated by Exposure:** N/A

Acute Toxicity Values: N/A

**Section 12: Ecological Information\* (non-mandatory)**

- No ecological information available

**Section 13: Disposal Considerations\* (non-mandatory)**

Appropriate Methods of Disposal	The above product contains 0.10% Sodium Azide as preservative. Best disposal method for biological material containing sodium Azide is to wash it down the sewer with large excess of water. Disposal should be made in accordance with existing disposal practices. Observe all Federal, State and Local law.
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**Section 14: Transport Information\* (non-mandatory)**

Transport Precautions	Consult applicable regulation when transporting this product
Additional Information	Follow the instructed guidelines listed in package for proper transportation.

**Section 15: Regulatory Information\* (non-mandatory)**

Federal and State Regulations	The FDA and CDC emphasize the importance of practicing good microbiological laboratory techniques when handling products manufactured from human source materials. The FDA recommends the use of Biosafety Level 2 techniques prescribed in the CDC/NIH manual of "Biosafety in Microbiological and Biochemical Laboratories, 1984." It is known that some materials negative for HbsAg by radioimmunoassay is potentially infectious and should be treated as if capable of infecting the handlers. The possibility of contracting Human Immunodeficiency Virus (HIV - 1) infection from human material should be taken seriously. Hepatitis virus or other infectious agents are absent from the materials used in the production of in vitro diagnostic products. However, it must be noted, "there has been no known reported cases of HIV - 1 transmission by contact with in vitro diagnostic products "(FDA letter of December 6, 1985).
Other Regulations	OSHA; Hazardous by definition of Hazard Communication Standard (29 CFR 1910.1200)
Risk Phrases	None
Additional Information	Consult country codes for specific requirements

**Section 16: Other Information**

**Other Precautions:** No other precautions needed. Clarity Diagnostics and LifeSign, LLC provide the information contained herein in good faith but makes no representation as to its comprehensiveness or

accuracy. This document is intended only as a guide to the appropriate precautionary handling of the materials contained in this kit by a properly trained person using this product. Clarity Diagnostics and LifeSign, LLCdiagno shall not be held liable for any damage resulting from handling or use.

**WARNING: HANDLE AS IF CAPABLE OF TRANSMITTING HEPATITIS FOR IN VITRO DIAGNOSTIC USE ONLY NOT FOR INTERNAL USE BY HUMANS OR ANIMALS**

\*Note: Since other Agencies regulate this information, OSHA will not be enforcing Sections 12 through 15(29 CFR 1910.1200(g)(2)).