



Safety Data Sheet

Section 1: Identification

Product Name: Status iFOBT Positive & Negative Controls

Synonyms: 1000

CAS Number: 26628-22-8

Manufacturer:

Clarity Diagnostics, LLC
1060 Holland Dr. Suite A
Boca Raton, FL 33487
1(877)-722-6339

Supplier/Distributor:

LifeSign, LLC
85 Orchard Road
Skillman, NJ 08558
1-800-526-2125, 732-246-3366
www.lifesigmed.com

Intended Use:

Status iFOBT Positive and Negative controls are for use with the Status iFOBT test. The Status iFOBT test is a rapid qualitative test for the immunochemical detection of fecal occult blood/human hemoglobin (hHb) in human fecal specimens as an aid in the diagnosis of gastrointestinal disorders such as: diverticulitis, colitis, polyps, and colorectal cancer. The device is suitable for use in laboratories and physician's offices. The test is recommended for use in routine physical examination, new patient screening at admission and screening and monitoring any suspected colorectal cancer and/or gastrointestinal bleeding from any source.

Restrictions on Use: Use in accordance with manufacturer's recommendations.

Section 2: Hazard(s) Identification

GHS Classification:

Health	Environmental	Physical
N/A	N/A	Yellow Liquid

GHS Label:

Symbols	Hazard Statements	Precautionary Statements
	Non Flammable Not Fatal if inhaled Causes irritant skin	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	.05
See Section 8 For Exposure Limits		

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: May be harmful if swallowed in large quantities. Wash out mouth with water provided person is conscious. Call a physician.

Eye Contact: Rinse with copious amounts of water for 15 Minutes.

Section 5: Fire-Fighting Measures

Suitable Extinguishing Media: Suitable type for surrounding 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. Absorb spill. Wash spill site after material pick up is complete with detergent and water.

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: Fully Miscible.

Pour Point: Not Available

Molecular Formula: N.A.

Odor/Appearance: Slight

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: N/A

Molecular Weight: N/A

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 a small amount of Sodium Azide (0.05%) as a preservative. If disposed by sink, flush with generous amounts of water to prevent accumulation of potentially explosive compounds. 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 provides 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 or LifeSign, LLC shall not be held liable for any damage resulting from handling or use.

- **WARNING: URINE DONORS HAVE TESTED FOR HbsAG AND HIV. HOWEVER, HANDLE AS IF CAPABLE OF BEING INFECTIOUS.**
- **DIAGNOSTIC USE ONLY NOT FOR INTERNAL USE BY HUMANS OR ANIMALS.**
- **IN VITRO DIAGNOSTIC USE ONLY**

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