

MATERIAL SAFETY DATA SHEET**Wampole Laboratories**

Princeton, NJ 08540

H. Pylori IgG ELISA

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SECTION I – IDENTITY**Product Type:** Diagnostic test kit.**Description:** Enzyme-linked immunosorbent assay for the qualitative detection of IgG antibodies to *Helicobacter pylori* in human sera.**Product Code:** 446400.

Ingredients Potentially Hazardous: 1. *human source material*. (in calibrator, negative and positive controls). 2. *sodium azide* (as a preservative in the calibrator, negative and positive controls); CAS #: 26628-22-8; Content: 0.1% (each unit); ACGIH TLV (ceiling) - 0.29 ppm as sodium azide and 0.11 ppm as hydrazoic acid vapor; NIOSH REL (ceiling) - 0.3 mg/m³ as sodium azide and 0.1 ppm as hydrazoic acid vapor. 3. *sulfuric acid 1N* (stop solution); CAS#: 7664-93-9; Content: 80 - 98%; OSHA PEL: 1mg/m³; ACGIH TLV: 1 mg/m³ with a STEL of 3 mg/m³.

SECTION II – PHYSICAL/CHEMICAL CHARACTERISTICS

Appearance: Test kit consisting of assay plates, reagents, controls, buffer and stop solution. This kit contains biological material. The stop solution has the following characteristics:

Boiling Point: 327°F.**Specific Gravity:** 1.84.**Solubility:** complete.**pH:** 1.0.**Vapor Pressure:** <0.3.**SECTION III – FIRE AND EXPLOSION HAZARD DATA**

Condition: No fire or explosion hazards. Packaging material will burn in a fire.

Extinguishing Media: Use standard fire fighting procedures depending on the source of the surrounding fire.

SECTION IV – REACTIVITY DATA

Incompatibilities: If disposed down a drain, the sodium azide in this kit may react with lead and copper plumbing to form highly explosive metal azides. The stop solution is incompatible with water, common metals, organic materials, strong oxidizing agents, strong reducing agents, combustible materials, sulfides, cyanides, and carbides.

Hazardous Polymerization: Will not occur.**Conditions to Avoid:** None known.

Hazardous Decomposition or Byproducts: This product is stable. If involved in a fire, the packaging materials may produce poisonous gas. The stop solution will produce oxides of sulfur and hydrogen.

SECTION V – TOXICOLOGY/HEALTH EFFECTS

Occupational exposure to this product is not expected to produce adverse human health effects following prudent workplace practices. The human serum components used in the preparation of this kit have been tested by a FDA approved method for the presence of the antibody to HIV and hepatitis B surface antigen and found to be

negative. Because no test method can offer complete assurance that HIV, hepatitis B virus or other infectious agents are absent, specimens and human-based reagents should be handled as if capable of transmitting infectious agents. Note: The Center for Disease Control and Center for Devices and Radiological Health recommend that potentially infectious agents be handled at the Biosafety Level 2. The stop solution is a poison and causes severe burns. The oral LD₅₀ (rat) for sulfuric acid is 2140 mg/kg.

SECTION VI – FIRST AID

Route of Entry: Accidental ingestion is possible. Skin and eye contact with the stop solution will cause burns.

Medical Conditions Generally Aggravated by Exposure: No specific information known.

Emergency and First Aid Procedures:

- For ingestion of large quantities or any test specimens, seek immediate medical attention.
- For eye contact with stop solution, flush with plenty of water for at least 15 minutes. For eye contact with test specimens, flush with plenty of water and seek medical attention.
- For skin contact with reagent or test specimens, wash with soap and water.

SECTION VII – PRECAUTIONS FOR SAFE HANDLING

General: Read the package insert. Always follow good laboratory practices when using this product. Handle all test specimens as if capable of transmitting disease. Employee exposure to human source material is regulated under the Code of Federal Regulations 29 CFR 1910.1030. Refer to the Centers for Disease Control/National Institutes of Health manual "Biosafety in Microbiological and Biomedical Laboratories".

Steps to Be Taken in Case Material is Spilled: Decontaminate spill with a bleach solution or appropriate germicide prior to pick up. If material is spilled down drain, flush with a large volume of water to prevent azide buildup in copper or lead plumbing. Decontamination procedures are available on request. If stop solution spills, neutralize with soda ash, lime, or a commercially available acid neutralizer.

Waste Disposal Method: Place material in a sealed container and dispose of as medical/infectious waste (for human source material) in accordance with applicable environmental regulations.

SECTION VIII – CONTROL MEASURES

Personal Protective Equipment: Barrier gloves (rubber), eye protection, and laboratory coat may be required as laboratory conditions indicate.

Ventilation: No special ventilation is necessary, however, a biosafety cabinet, as recommended in the CDC/NIH manual, may be necessary if there is a possibility of aerosolization of test specimens or controls.