

# STATEMENT OF REGULATORY COMPLIANCE

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TRADE NAME (AS LABELED): Envoy® 500 Rinse Solution Bulk Kit  
PRODUCT NUMBER (AS LABELED): 55100

SUPPLIER/MANUFACTURER'S NAME: Vital Diagnostics, Inc.  
ADDRESS: 27 Wellington Road  
Lincoln, RI 02865 USA

INFORMATION PHONE: 1-401-642-8400; 1-800-345-2822

This product does not present a physical or health hazard under reasonably anticipated circumstances of use or under emergency situations involving a release of only this product. Therefore, this material is not defined as a "Hazardous Chemical" by the Federal Occupational Safety and Health Administration in the Hazard Communication Standard (29 CFR 1910.1200) or the equivalent standards generated by State agencies. Accordingly, no Material Safety Data Sheet is required for this product.

Additionally, even though this product is an untested mixture of chemicals, no Material Safety Data Sheet is required because ALL of the following conditions are met::

- ◇ There are no established exposure limits for the components of this product present in greater than 1 percent concentration. Established exposure limits referenced are as follows: Threshold Limit Values, American Conference of Governmental Industrial Hygienists; Permissible Exposure Limits; Occupational Safety and Health Administration; Recommended Exposure Limits; National Institute of Occupational Safety and Health; Maximum Exposure Level, National Republic of Germany.
- ◇ No component of this product is listed by the following agencies to be carcinogenic or potentially carcinogenic to humans: National Toxicology Program, International Agency for Research on Cancer, the Occupational Safety and Health Administration, the National Institute for Occupational Safety and Health, or the California Occupational Safety and Health Administration.
- ◇ No component of this product is known to be a human reproductive toxin.
- ◇ No component of this product is on the California Proposition 65 List.
- ◇ No component of this product present in greater than 0.1% concentration has reporting requirements under the Environmental Protection Agency's Superfund Amendment and Reauthorization Act (Title III Sections 302, 304, or 313) or Clean Air Act (Section 112 (r)).
- ◇ No chemical component of this product is present in concentrations greater than 1 percent.