

# MATERIAL SAFETY DATA SHEET

## Section 1: Chemical Product and Company Identification

BioStar® Acceava® *H. pylori* diagnostic test kit, manufactured for Inverness Medical – BioStar Inc.

Inverness Medical – BioStar Inc.  
331 South 104<sup>th</sup> Street, Louisville, CO 80027  
For information in North America, call 800-637-3717

## Section 2: Composition, Information or Ingredients

- Nitrocellulose membrane (<0.5gm) test strips contain the following dried chemical materials: Sodium azide, sodium phosphate (dibasic and monobasic), sodium chloride, potassium chloride, potassium phosphate (monobasic), EDTA, bovine serum albumin, and colloidal gold.
- Developer solution contains 0.1% sodium azide.

## Section 3: Hazard Identification

There are no hazards associated with this kit. See composition information in Section 2.

## Section 4: First Aid Measures

Medical condition Aggravated by Exposure: None.  
First Aid: Flush with excess water and call a physician or poison control center  
Poison Control Center: 1-800-876-4766

## Section 5: Fire-Fighting Measures

Flash point (method used): N/A  
Flammable limits: N/A  
LEL: N/A  
UEL: N/A  
Extinguishing Media: Water, dry chemical or carbon dioxide type extinguishers. Water is most effective fire-extinguishing medium.  
Special fire fighting procedure: None  
Unusual fire and explosion hazards: None

## Section 6: Accidental Release Measures

Spill Response Procedures: Wear appropriate personal protective equipment, including but not limited to protective eyewear, clothing and gloves.  
Waste Disposal Method: Follow standard laboratory safety guidelines in disposal of controls, patient specimens and all items exposed to patient specimens.

## Section 7: Handling and Storage

Handle and store materials as described in the product package insert. Keep away from heat, sparks or open flame.

## Section 8: Exposure Controls and Personal Protection

Eye Protection: Wear safety glasses or full face shield.  
Skin Protection: Wear protective clothing and gloves.

## Section 9: Physical and Chemical Properties

Boiling point: N/A  
Vapor pressure (mm Hg): N/A  
Vapor density (air = 1): N/A  
Solubility in water: Test strip may release minute amounts of the chemicals listed above in Section II upon reconstitution in water. Nitrocellulose membrane is not soluble in water.  
Appearance and odor: Test strip in a sealed pouch. Odorless.

Specific gravity (H<sub>2</sub>O = 1): Not available  
Melting point: N/A  
Evaporation rate (Butyl Acetate = 1): N/A

## Section 10: Stability and Reactivity

This product is stable under normal storage/handling procedures.

## Section 11: Toxicological Information

- Developer solution: Sodium azide, 0.1%

## Section 12: Ecological Information

There is no identified environmental impact from accidental release of this product.

### **Section 13: Disposal Considerations**

Because used devices contain processed human samples, they should be disposed of as if biohazardous. As always, dispose of reagent in compliance with your laboratories practices and in compliance with all applicable local and state requirements.

### **Section 14: Transportation Information**

No special transportation conditions are required. Consult the product Package Insert for proper handling and storage conditions.

### **Section 15: Regulatory Information**

This product is regulated under the Federal Food Drug and Cosmetic Act as an *In Vitro* Diagnostic Device.

### **Section 16: Other Information**

The information above is believed to be accurate and represents the best information currently available to us. However, we make no warranty of merchantability or any other warranty, express or implied, with respect to such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of this information for their particular purposes. In no way shall Inverness Medical – BioStar Inc. be liable for any claims, losses, or damages of any third party or for lost profits or any special, indirect, incidental, consequential or exemplary damages, howsoever arising, even if Inverness Medical – BioStar Inc. has been advised of the possibility of such damages.