

## 1. Product and Company Identification

|            |                                                         |                                                                                                                       |
|------------|---------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------|
| <b>1.1</b> | <b>Product name</b>                                     | <b>Microalbumin Calibrator</b>                                                                                        |
|            | <b>Substance/mixture</b>                                | Mixture                                                                                                               |
|            | <b>CAS #</b>                                            | Mixture                                                                                                               |
|            | <b>Kit number</b>                                       | MD-101211                                                                                                             |
| <b>1.2</b> | <b>Recommended product use</b>                          |                                                                                                                       |
|            | <b>Mixture's intended use</b>                           | Diagnostic reagent for IN VITRO quantitative measurement of microalbumin in urine.                                    |
|            | <b>Product restrictions</b>                             | None known                                                                                                            |
| <b>1.3</b> | <b>Details of the supplier of the safety data sheet</b> |                                                                                                                       |
|            | <b>Manufacturer information</b>                         |                                                                                                                       |
|            | <b>Corporate Headquarters</b>                           | Diamond Diagnostics Inc.<br>333 Fiske St., Holliston, MA 01746 United States of America<br>www.diamonddiagnostics.com |
|            | <b>Telephone</b>                                        | +1 (508) 429-0450                                                                                                     |
|            | <b>Email</b>                                            | support@diamonddiagnostics.com                                                                                        |
|            | <b>Distributor information</b>                          |                                                                                                                       |
|            | <b>Distributor Headquarters</b>                         | Mission Diagnostics LLC<br>1 Burton Dr., Meredith, NH 03246<br>United States of America                               |
|            | <b>Telephone</b>                                        | +1 (508) 429-0450                                                                                                     |
|            | <b>Email</b>                                            | support@diamonddiagnostics.com                                                                                        |
| <b>1.4</b> | <b>Emergency Telephone</b>                              |                                                                                                                       |
|            | <b>Emergency Phone #</b>                                | +1 (508) 429-0450                                                                                                     |

## 2. Hazards Identification

### GHS- Classification

|            |                                            |                                                                                                                                     |
|------------|--------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|
| <b>2.1</b> | <b>Substance or mixture classification</b> |                                                                                                                                     |
|            | <b>Physical state</b>                      | Lyophilized – Liquid after reconstitution                                                                                           |
|            | <b>Appearance</b>                          | light yellow; clear                                                                                                                 |
|            | <b>Emergency overview</b>                  | Health injuries are not known or expected under normal use.                                                                         |
| <b>2.2</b> | <b>Label Elements</b>                      |                                                                                                                                     |
|            | <b>Signal word</b>                         | None                                                                                                                                |
|            | <b>Hazardous substances</b>                | This product contains material of human origin and should be considered as potentially capable of transmitting infectious diseases. |
|            | <b>OSHA regulatory status</b>              | This product is not hazardous according to OSHA 29CFR 1910.1200.                                                                    |

## 3. Composition/Information on ingredients

|                              |                                       |
|------------------------------|---------------------------------------|
| <b>GHS Classification</b>    | Not a hazardous substance or mixture. |
| <b>Hazardous ingredients</b> | No hazardous ingredients              |

## 4. First Aid Measures

### 4.1 Description of First Aid Measures

|                       |                                                                                                                                                                                                                                        |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Eye Contact</b>    | In case of eye contact, immediately flush eyes with fresh water for at least 15 minutes while holding eyelids open. Remove contact lenses immediately if worn by the affected person. Pursue medical treatment if irritation persists. |
| <b>Skin Contact</b>   | In case of skin contact, remove any or all of contaminated clothing, while rinsing the affected skin with large amounts of water. Pursue medical attention if irritation develops and persists.                                        |
| <b>Inhalation</b>     | If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration by trained personnel and obtain medical attention immediately.                                               |
| <b>Ingestion</b>      | If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.                                                                                                              |
| <b>General Advice</b> | If you feel unwell, seek medical advice.                                                                                                                                                                                               |

## 5. Fire-Fighting Measures

|                                                              |                                                                                                                                                             |
|--------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>5.1 Flammable properties</b>                              | This product is not flammable.                                                                                                                              |
| <b>5.2 Extinguishing media</b>                               |                                                                                                                                                             |
| <b>Suitable extinguishing media</b>                          | Extinguish with water spray, carbon dioxide (CO <sub>2</sub> ), dry chemical or material appropriate for the surrounding fire.                              |
| <b>Unsuitable extinguishing media</b>                        | No limitations are given.                                                                                                                                   |
| <b>5.3 Protection of firefighters</b>                        |                                                                                                                                                             |
| <b>Specific hazards arising from the chemical</b>            | No data available                                                                                                                                           |
| <b>Protective equipment and precautions for firefighters</b> | Self-contained breathing apparatus and full protective clothing must be worn in case of fire.                                                               |
| <b>Firefighting equipment/instructions</b>                   | Use standard firefighting procedures and consider the hazards of other involved materials. Avoid contaminating surface water with fire extinguishing water. |
| <b>Hazardous combustion Products</b>                         | No data available                                                                                                                                           |

## 6. Accidental Release Measures

|                                                    |                                                                                                                                                                                                          |
|----------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>6.1 Personal precautions</b>                    | This product contains material of human origin and should be handled as though capable of transmitting infectious diseases. Observe general safety guidelines for protection during clean up procedures. |
| <b>6.2 Environmental precautions</b>               | Contain spill to prevent migration. Do not allow the undiluted product to enter sewers/surface or ground water                                                                                           |
| <b>6.3 Methods for containment and cleaning up</b> | A For small spills, soak up material with absorbent material. For large spills, cordon off the area to prevent the spreading of the spill. Soak up the spill with absorbent. Wash spill area with water. |
| <b>Other information</b>                           | Clean up in accordance with all applicable regulations.                                                                                                                                                  |

## 7. Handling and Storage

|                          |                                                                                                                                                         |
|--------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>7.1 Safe Handling</b> | This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product. |
| <b>Hygiene Measures</b>  | Wash exposed skin thoroughly after handling                                                                                                             |
| <b>7.2 Storage</b>       | Store at 2-8°C. Store in a closed container away from incompatible materials.                                                                           |
| <b>7.3 Specific use</b>  | See section 1 – Recommended Use                                                                                                                         |

## 8. Exposure Controls / Personnel

|                                          |                                                                                                                                                                                         |
|------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>8.1 Occupational exposure limits</b>  | No exposure limits noted for ingredient(s).                                                                                                                                             |
| <b>Exposure guidelines</b>               | Follow standard monitoring procedures.                                                                                                                                                  |
| <b>Engineering controls</b>              | No specific controls or precautions are required. Selection and use of containment devices and personal protective equipment should be based on a risk assessment of exposure potential |
| <b>8.2 Personal protective equipment</b> |                                                                                                                                                                                         |
| <b>Eye / face protection</b>             | Wear appropriate safety glasses, goggles or face shields.                                                                                                                               |
| <b>Skin protection</b>                   | Wear lab coat or other protective garments. Wear protective gloves.                                                                                                                     |
| <b>Respiratory protection</b>            | Under normal conditions, respirator is not required.                                                                                                                                    |
| <b>General hygiene considerations</b>    | Handle in accordance with good industrial hygiene and safety practice.                                                                                                                  |
| <b>Other information</b>                 | Do NOT eat, drink or smoke during use.                                                                                                                                                  |
| <b>Environment Exposure</b>              | No data available                                                                                                                                                                       |

## 9. Physical and Chemical Properties

### 9.1 Information on basic physical and chemical properties

|                                                       |                   |
|-------------------------------------------------------|-------------------|
| <b>Appearance</b>                                     | Liquid            |
| <b>Form</b>                                           | Liquid            |
| <b>Color</b>                                          | Clear/colorless   |
| <b>Odor</b>                                           | Odorless          |
| <b>Odor threshold</b>                                 | No data available |
| <b>pH</b>                                             | No data available |
| <b>Vapor pressure</b>                                 | No data available |
| <b>Vapor density</b>                                  | No data available |
| <b>Boiling point</b>                                  | No data available |
| <b>Viscosity (mm<sup>2</sup>/s)</b>                   | No data available |
| <b>Melting/Freezing point</b>                         | No data available |
| <b>Solubility (water)</b>                             | Miscible          |
| <b>Specific gravity</b>                               | No data available |
| <b>Flash point</b>                                    | No data available |
| <b>Flammability limits in air, upper, % by volume</b> | No data available |

**Flammability limits in air, lower, % by volume**

No data available

**Decomposition temperature**

No data available

**Auto-ignition temperature**

No data available

**Evaporation rate**

No data available

**Relative Density**

No data available

**Partition coefficient:**

No data available

(n-octanol/water)

**Explosive properties**

No data available

**Oxidizing properties**

No data available

## 10. Stability and Reactivity

**10.1 Reactivity**

No data available

**10.2 Chemical stability**

No data available

**10.3 Possibility of hazardous Reactions**

Not expected to occur

**10.4 Conditions to avoid**

Excessive heat or freezing conditions

**10.5 Incompatible materials**

No data available

**10.6 Hazardous polymerization**

No data available

**10.7 Hazardous decomposition Products**

No data available

## 11. Toxicological Information

**11.1 Information on toxicological effects**
**Sensitization**

Not classified

**Acute effects**

Non-hazardous reagent.

**Local effects**

No data available

**Chronic effects**

No data available

**Target Organ Effects**

No data available

**Carcinogenicity**

No data on product formulation. None of the components of the product present at levels greater than or equal to 0.1% are listed by NTP, IARC, ACGIH or OSHA as a carcinogen.

**Epidemiology**

No epidemiological data is available for this product.

**Mutagenicity**

Not classified

**Reproductive effects**

Not classified

**Symptoms and target organs**

No data available

**Additional information**

This product contains material of human origin and should be considered as potentially capable of transmitting infectious diseases.

## 12. Ecological Information

### 12.1 Toxicity

**Ecotoxicity** No data available

**Environmental effects** No data available

### 12.2 Persistence and degradability

No data is available

### 12.3 Bioaccumulation/Accumulation

No data available

### 12.4 Mobility in environmental media

No data available

## 13. Disposal Considerations

### 13.1 Disposal methods

**Disposal instructions** Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

#### Waste from residues / unused products

Dispose in accordance with all applicable local and national regulations. Avoid releasing unused products into drainage systems and/or into the environment.

## 14. Transport Information

**DOT** Not regulated as a hazardous material by DOT.

**DOR** Not regulated as dangerous goods.

**IATA** Not regulated as dangerous goods.

**IMDG** Not regulated as dangerous goods.

**TDG** Not regulated as dangerous goods.

## 15. Regulatory Information

**US federal regulations** This product is not hazardous according to OSHA 29CFR 1910.1200. This mixture is a component of an in vitro diagnostic device regulated by the U.S. Food and Drug Administration.

#### TSCA Section 12(b) Export Notification (40 CFR 707, Subpart. D)

Not regulated.

#### Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

**CERCLA (Superfund) reportable quantity (lb.) (40 CFR 302.4)**

None

**Superfund Amendments and Reauthorization Act of 1986 (SARA)**

**Hazard categories** Immediate Hazard - No  
 Delayed Hazard - No  
 Fire Hazard - No  
 Pressure Hazard - No  
 Reactivity Hazard - No

**Section 302 extremely  
 Hazardous substance  
 (40 CFR 355, Appendix  
 A) Section 311/312 (40  
 CFR370)**

No

No

**Drug Enforcement Administration (DEA) (21 CFR 1308.11-15)**

Not controlled

**Canadian regulations**

This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all the information required by the CPR.

**WHMIS status**

Non-controlled

**State regulations**

This product does not contain a chemical known to the State of California to cause cancer, birth defects or other reproductive harm.

**US - California Proposition 65 - Carcinogens & Reproductive Toxicity (CRT): Listed substance**

Not listed.

**US. Massachusetts RTK - Substance List**

Not regulated.

**US. New Jersey Worker and Community Right-to-Know Act**

Not regulated.

**US. Pennsylvania RTK - Hazardous Substances**

Not regulated.

**Mexico regulations**

This safety data sheet was prepared in accordance with the Official Mexican Standard (NOM-018-STPS-2000).

## 16. Other Information

|                                 |                                                           |
|---------------------------------|-----------------------------------------------------------|
| <b>Recommended restrictions</b> | Use in accordance with supplier's recommendations.        |
| <b>Further information</b>      | HMIS® is a registered trade and service mark of the NPCA. |
| <b>HMIS® ratings</b>            | Health: 0<br>Flammability: 0<br>Physical hazard: 0        |
| <b>NFPA ratings</b>             | Health: 0<br>Flammability: 0<br>Instability: 0            |

### Disclaimer

The information provided on this SDS is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in text.