

## SECTION 1: Identification of the substance/mixture and of the company/undertaking

### 1.1. Product identifier

|                              |                                                           |
|------------------------------|-----------------------------------------------------------|
| <b>Name of the substance</b> | LAtrol™ Abnormal Control Plasma                           |
| <b>Identification number</b> | -                                                         |
| <b>Registration number</b>   | -                                                         |
| <b>Synonyms</b>              | None.                                                     |
| <b>Product code</b>          | 816A, LAtrol™ Lupus Anticoagulant Abnormal Control Plasma |
| <b>Issue date</b>            | 01-December-2017                                          |
| <b>Version number</b>        | 02                                                        |
| <b>Revision date</b>         | 14-July-2017                                              |
| <b>Supersedes date</b>       | 28-May-2015                                               |

### 1.2. Relevant identified uses of the substance or mixture and uses advised against

|                             |                                                            |
|-----------------------------|------------------------------------------------------------|
| <b>Identified uses</b>      | For use in quality control in Lupus Anticoagulant testing. |
| <b>Uses advised against</b> | Use in accordance with supplier's recommendations.         |

### 1.3. Details of the supplier of the safety data sheet

**Corporate Headquarters** BioMedica Diagnostics Inc.  
 94 Wentworth Road, PO Box 1030  
 Windsor, Nova Scotia CANADA B0N 2T0

**Contact person** Corporate Phone: 1-902-798-5105  
 Corporate Fax: 1-902-798-1025  
 Email: info@biomedicadiagnostics.com  
 Website: www.biomedicadiagnostics.com

**1.4. Emergency telephone number** US, Canada, Puerto Rico & Virgin Islands 1-800-255-3924  
 International +1-813-248-0585  
 Australia 1-300-954-583  
 Brazil 0-800-591-6042  
 China 400-120-0751  
 India 000-800-100-4086  
 Mexico 01-800-099-0731

**Contract number** MIS9591327

## SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture

The substance has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

#### Classification according to Directive 67/548/EEC or 1999/45/EC as amended

This substance does not meet the criteria for classification according to Directive 67/548/EEC as amended.

#### Classification according to Regulation (EC) No 1272/2008 as amended

This substance does not meet the criteria for classification according to Regulation (EC) 1272/2008 as amended.

#### Hazard summary

|                              |                                                             |
|------------------------------|-------------------------------------------------------------|
| <b>Physical hazards</b>      | Not classified for physical hazards.                        |
| <b>Health hazards</b>        | Not classified for health hazards.                          |
| <b>Environmental hazards</b> | Not classified for hazards to the environment.              |
| <b>Specific hazards</b>      | Dust may cause eye, skin and respiratory tract irritation.  |
| <b>Main symptoms</b>         | Mechanical irritation of skin, eyes and respiratory system. |

### 2.2. Label elements

#### Label according to Regulation (EC) No. 1272/2008 as amended

|                          |              |
|--------------------------|--------------|
| <b>Contains:</b>         | Human plasma |
| <b>Hazard pictograms</b> | None.        |
| <b>Signal word</b>       | None.        |
| <b>Hazard statements</b> | None.        |

## Precautionary statements

|                   |                                                                                |
|-------------------|--------------------------------------------------------------------------------|
| <b>Prevention</b> | Observe good laboratory hygiene practices.                                     |
| <b>Response</b>   | Wash with plenty of water.                                                     |
| <b>Storage</b>    | Store away from incompatible materials.                                        |
| <b>Disposal</b>   | Dispose of waste and residues in accordance with local authority requirements. |

**Supplemental label information** None.

**2.3. Other hazards** Not a PBT or vPvB substance or mixture.

## SECTION 3: Composition/information on ingredients

### 3.1. Substances

#### General information

| Chemical name          | %             | CAS-No. / EC No. | REACH Registration No. | INDEX No. | Notes |
|------------------------|---------------|------------------|------------------------|-----------|-------|
| Human plasma           | 100           | N/A              | -                      | -         |       |
| <b>Classification:</b> | <b>DSD:</b> - |                  |                        |           |       |
|                        | <b>CLP:</b> - |                  |                        |           |       |

#### List of abbreviations and symbols that may be used above

CLP: Regulation No. 1272/2008.

DSD: Directive 67/548/EEC.

**Composition comments** All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume. The full text for all R- and H-phrases is displayed in section 16.

## SECTION 4: First aid measures

**General information** Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

### 4.1. Description of first aid measures

|                     |                                                                                                                                                                                                  |
|---------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Inhalation</b>   | Move to fresh air. If breathing is difficult, give oxygen. Get medical attention if any discomfort continues.                                                                                    |
| <b>Skin contact</b> | For skin contact flush with large amounts of water while removing contaminated clothing. Get medical attention if irritation develops and persists.                                              |
| <b>Eye contact</b>  | In case of contact, immediately flush eyes with fresh water for at least 15 minutes while holding the eyelids open. Remove contact lenses if worn. Get medical attention if irritation persists. |
| <b>Ingestion</b>    | Rinse mouth thoroughly if dust is ingested. Get medical advice/attention if you feel unwell.                                                                                                     |

**4.2. Most important symptoms and effects, both acute and delayed** Dust may cause eye, skin and respiratory tract irritation.

**4.3. Indication of any immediate medical attention and special treatment needed** Provide general supportive measures and treat symptomatically.

## SECTION 5: Firefighting measures

**General fire hazards** Will burn if involved in a fire.

### 5.1. Extinguishing media

|                                       |                                                                                                             |
|---------------------------------------|-------------------------------------------------------------------------------------------------------------|
| <b>Suitable extinguishing media</b>   | Extinguish with water spray, carbon dioxide, dry chemical or material appropriate for the surrounding fire. |
| <b>Unsuitable extinguishing media</b> | None known.                                                                                                 |

**5.2. Special hazards arising from the substance or mixture** Fire will generate toxic and irritating gases.

### 5.3. Advice for firefighters

|                                                      |                                                                                                                                                                                                                     |
|------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Special protective equipment for firefighters</b> | Selection of respiratory protection for firefighting: follow the general fire precautions indicated in the workplace. Self-contained breathing apparatus and full protective clothing must be worn in case of fire. |
| <b>Special fire fighting procedures</b>              | Use standard firefighting procedures and consider the hazards of other involved materials.                                                                                                                          |

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

|                                    |                                                                                                                                                                           |
|------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>For non-emergency personnel</b> | No special precautions are necessary beyond normal good hygiene practices. See Section 8 of the SDS for additional personal protection advice when handling this product. |
| <b>For emergency responders</b>    | Use personal protection recommended in Section 8 of the SDS.                                                                                                              |

**6.2. Environmental precautions** Avoid discharge into drains, water courses or onto the ground.

**6.3. Methods and material for containment and cleaning up** Avoid dust formation. Sweep or scoop up and remove.

**6.4. Reference to other sections** For personal protection, see Section 8 of the SDS. For waste disposal, see Section 13 of the SDS.

## SECTION 7: Handling and storage

**7.1. Precautions for safe handling** Avoid prolonged exposure. Avoid contact with skin and eyes. The source material for this product is of human origin and has been found to be non-reactive for Hepatitis B Surface Antigen (HBsAg), Hepatitis C Virus (HCV) and Human Immunodeficiency Virus Type 1 and Type 2 (HIV-1, HIV-2) using registered methods. As no known test method can provide complete assurance that products derived from human specimens will not transmit HBsAg, HCV, HIV-1, HIV-2 or other blood-borne pathogens, this reagent should be handled as recommended for any potentially infectious human specimen. Observe good laboratory hygiene practices.

**7.2. Conditions for safe storage, including any incompatibilities** Store at 2 - 8°C. Store in a closed container away from incompatible materials.

**7.3. Specific end use(s)** For use in quality control in Lupus Anticoagulant testing.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

|                                                   |                                                            |
|---------------------------------------------------|------------------------------------------------------------|
| <b>Occupational exposure limits</b>               | No exposure limits noted for ingredient(s).                |
| <b>Biological limit values</b>                    | No biological exposure limits noted for the ingredient(s). |
| <b>Recommended monitoring procedures</b>          | Follow standard monitoring procedures.                     |
| <b>Derived no-effect level (DNEL)</b>             | Not available.                                             |
| <b>Predicted no effect concentrations (PNECs)</b> | Not available.                                             |

### 8.2. Exposure controls

**Appropriate engineering controls** No special ventilation requirements.

#### Individual protection measures, such as personal protective equipment

|                                        |                                                                                                                                                         |
|----------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>General information</b>             | Personal protective equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment. |
| <b>Eyeface protection</b>              | Wear dust-resistant safety goggles.                                                                                                                     |
| <b>Skin protection</b>                 |                                                                                                                                                         |
| - <b>Hand protection</b>               | It is a good industrial hygiene practice to minimise skin contact. Chemical resistant gloves are recommended.                                           |
| - <b>Other</b>                         | It is a good industrial hygiene practice to minimise skin contact.                                                                                      |
| <b>Respiratory protection</b>          | In case of inadequate ventilation or risk of inhalation of dust, use suitable respiratory equipment with particle filter.                               |
| <b>Thermal hazards</b>                 | Wear appropriate thermal protective clothing, when necessary.                                                                                           |
| <b>Hygiene measures</b>                | Handle in accordance with good industrial hygiene and safety practices.                                                                                 |
| <b>Environmental exposure controls</b> | Inform appropriate managerial or supervisory personnel of all environmental releases.                                                                   |

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

|                        |                       |
|------------------------|-----------------------|
| <b>Appearance</b>      | Straw colored powder. |
| <b>Physical state</b>  | Solid.                |
| <b>Form</b>            | Powder.               |
| <b>Colour</b>          | Straw colored.        |
| <b>Odour</b>           | None.                 |
| <b>Odour threshold</b> | Not applicable.       |

|                                                     |                   |
|-----------------------------------------------------|-------------------|
| <b>pH</b>                                           | Not available.    |
| <b>Melting point/freezing point</b>                 | Not available.    |
| <b>Initial boiling point and boiling range</b>      | Not relevant.     |
| <b>Flash point</b>                                  | Not relevant.     |
| <b>Evaporation rate</b>                             | Not available.    |
| <b>Flammability (solid, gas)</b>                    | Non flammable.    |
| <b>Upper/lower flammability or explosive limits</b> |                   |
| <b>Flammability limit - lower (%)</b>               | Not available.    |
| <b>Flammability limit - upper (%)</b>               | Not available.    |
| <b>Vapour pressure</b>                              | Not relevant.     |
| <b>Vapour density</b>                               | Not relevant.     |
| <b>Relative density</b>                             | Not available.    |
| <b>Solubility(ies)</b>                              | Soluble in water. |
| <b>Partition coefficient (n-octanol/water)</b>      | Not available.    |
| <b>Auto-ignition temperature</b>                    | Not available.    |
| <b>Decomposition temperature</b>                    | Not available.    |
| <b>Viscosity</b>                                    | Not relevant.     |
| <b>Explosive properties</b>                         | Not relevant.     |
| <b>Oxidizing properties</b>                         | Not oxidizing.    |

## 9.2. Other information

|                         |               |
|-------------------------|---------------|
| <b>Percent volatile</b> | Not relevant. |
|-------------------------|---------------|

## SECTION 10: Stability and reactivity

|                                                 |                                                                |
|-------------------------------------------------|----------------------------------------------------------------|
| <b>10.1. Reactivity</b>                         | Stable at normal conditions.                                   |
| <b>10.2. Chemical stability</b>                 | Material is stable under normal conditions.                    |
| <b>10.3. Possibility of hazardous reactions</b> | Polymerization will not occur.                                 |
| <b>10.4. Conditions to avoid</b>                | Keep away from heat.                                           |
| <b>10.5. Incompatible materials</b>             | Strong oxidising agents. Strong reducing agents. Strong acids. |
| <b>10.6. Hazardous decomposition products</b>   | Carbon oxides. Nitrogen oxides.                                |

## SECTION 11: Toxicological information

### Information on likely routes of exposure

|                     |                                         |
|---------------------|-----------------------------------------|
| <b>Inhalation</b>   | Dust may irritate respiratory system.   |
| <b>Skin contact</b> | Dust may irritate skin.                 |
| <b>Eye contact</b>  | Dust in the eyes will cause irritation. |
| <b>Ingestion</b>    | May cause discomfort if swallowed.      |

|                 |                                                             |
|-----------------|-------------------------------------------------------------|
| <b>Symptoms</b> | Mechanical irritation of skin, eyes and respiratory system. |
|-----------------|-------------------------------------------------------------|

### 11.1. Information on toxicological effects

|                                                         |                                    |
|---------------------------------------------------------|------------------------------------|
| <b>Acute toxicity</b>                                   | May cause discomfort if swallowed. |
| <b>Skin corrosion/irritation</b>                        | Dust may irritate skin.            |
| <b>Serious eye damage/eye irritation</b>                | Dust may irritate the eyes.        |
| <b>Respiratory sensitisation</b>                        | Not classified.                    |
| <b>Skin sensitisation</b>                               | Not classified.                    |
| <b>Germ cell mutagenicity</b>                           | Not classified.                    |
| <b>Carcinogenicity</b>                                  | Not classified.                    |
| <b>Reproductive toxicity</b>                            | Not classified.                    |
| <b>Specific target organ toxicity - single exposure</b> | Not classified.                    |

|                                                           |                                                         |
|-----------------------------------------------------------|---------------------------------------------------------|
| <b>Specific target organ toxicity - repeated exposure</b> | Not classified.                                         |
| <b>Aspiration hazard</b>                                  | Not classified.                                         |
| <b>Mixture versus substance information</b>               | Not available.                                          |
| <b>Other information</b>                                  | No other specific acute or chronic health impact noted. |

## SECTION 12: Ecological information

|                                                                   |                                               |
|-------------------------------------------------------------------|-----------------------------------------------|
| <b>12.1. Toxicity</b>                                             | No toxicity data noted for the ingredient(s). |
| <b>12.2. Persistence and degradability</b>                        | No data available.                            |
| <b>12.3. Bioaccumulative potential</b>                            | No data available.                            |
| <b>Partition coefficient n-octanol/water (log K<sub>ow</sub>)</b> | Not available.                                |
| <b>Bioconcentration factor (BCF)</b>                              | Not available.                                |
| <b>12.4. Mobility in soil</b>                                     | Not available.                                |
| <b>Mobility in general</b>                                        | The product is soluble in water.              |
| <b>12.5. Results of PBT and vPvB assessment</b>                   | Not a PBT or vPvB substance or mixture.       |
| <b>12.6. Other adverse effects</b>                                | No data available.                            |

## SECTION 13: Disposal considerations

|                                      |                                                                                                                                                                                                                                           |
|--------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>13.1. Waste treatment methods</b> |                                                                                                                                                                                                                                           |
| <b>Residual waste</b>                | Dispose in accordance with all applicable regulations.                                                                                                                                                                                    |
| <b>Contaminated packaging</b>        | Empty containers should be taken to an approved waste handling site for recycling or disposal.                                                                                                                                            |
| <b>EU waste code</b>                 | The Waste code should be assigned in discussion between the user, the producer and the waste disposal company.                                                                                                                            |
| <b>Disposal methods/information</b>  | Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Contaminated instruments and surfaces should be disinfected in accordance with your employer's chemical-specific and universal/standard precautions. |

## SECTION 14: Transport information

|                                                                                       |                                   |
|---------------------------------------------------------------------------------------|-----------------------------------|
| <b>ADR</b>                                                                            | Not regulated as dangerous goods. |
| <b>RID</b>                                                                            | Not regulated as dangerous goods. |
| <b>ADN</b>                                                                            | Not regulated as dangerous goods. |
| <b>IATA</b>                                                                           | Not regulated as dangerous goods. |
| <b>IMDG</b>                                                                           | Not regulated as dangerous goods. |
| <b>14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code</b> | Not applicable.                   |

## SECTION 15: Regulatory information

### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

#### EU regulations

**Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex I and II, as amended**

Not listed.

**Regulation (EC) No. 850/2004 On persistent organic pollutants, Annex I as amended**

Not listed.

**Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 1 as amended**

Not listed.

**Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 2 as amended**

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 3 as amended  
Not listed.  
Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex V as amended  
Not listed.  
Regulation (EC) No. 166/2006 Annex II Pollutant Release and Transfer Registry, as amended  
Not listed.  
Regulation (EC) No. 1907/2006, REACH Article 59(10) Candidate List as currently published by ECHA  
Not listed.

#### Authorisations

Regulation (EC) No. 1907/2006, REACH Annex XIV Substances subject to authorization, as amended  
Not listed.

#### Restrictions on use

Regulation (EC) No. 1907/2006, REACH Annex XVII Substances subject to restriction on marketing and use as amended  
Not listed.  
Directive 2004/37/EC: on the protection of workers from the risks related to exposure to carcinogens and mutagens at work, as amended  
Not listed.  
Directive 92/85/EEC: on the safety and health of pregnant workers and workers who have recently given birth or are breastfeeding, as amended  
Not listed.

#### Other EU regulations

Directive 2012/18/EU on major accident hazards involving dangerous substances  
Not listed.  
Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work  
Not listed.  
Directive 94/33/EC on the protection of young people at work  
Not listed.

#### Other regulations

This product does not meet the criteria for classification according to Regulation (EC) 1272/2008 (CLP Regulation) and Directive 67/548/EEC and their amendments respectively. This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006 as amended.

#### National regulations

Follow national regulation for work with chemical agents.

#### 15.2. Chemical safety assessment

No Chemical Safety Assessment has been carried out.

## SECTION 16: Other information

#### List of abbreviations

DSD: Directive 67/548/EEC.  
CLP: Regulation No. 1272/2008.  
DNEL: Derived No-Effect Level.  
PNEC: Predicted No-Effect Concentration.

#### References

Not available.

#### Information on evaluation method leading to the classification of mixture

The classification for health and environmental hazards is derived by a combination of calculation methods and test data, if available.

#### Full text of any statements or R-phrases and H-statements under Sections 2 to 15

None.

#### Training information

Follow training instructions when handling this material.

#### Disclaimer

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