

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1. Product identifier**

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

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

| | |
|-----------------------------|--|
| Identified uses | For use in quality control in Lupus Anticoagulant testing. |
| Uses advised against | 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
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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

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

2.2. Label elements**Label according to Regulation (EC) No. 1272/2008 as amended**

| | |
|--------------------------|--------------|
| Contains: | Human plasma |
| Hazard pictograms | None. |
| Signal word | None. |
| Hazard statements | None. |

Precautionary statements

| | |
|-------------------|--|
| Prevention | Observe good laboratory hygiene practices. |
| Response | Wash with plenty of water. |
| Storage | Store away from incompatible materials. |
| Disposal | 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 | - | - | |
| Classification: | DSD: - | | | | |
| | CLP: - | | | | |

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

| | |
|---------------------|--|
| Inhalation | Move to fresh air. If breathing is difficult, give oxygen. Get medical attention if any discomfort continues. |
| Skin contact | For skin contact flush with large amounts of water while removing contaminated clothing. Get medical attention if irritation develops and persists. |
| Eye contact | 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. |
| Ingestion | 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

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

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

5.3. Advice for firefighters

| | |
|--|---|
| Special protective equipment for firefighters | 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. |
| Special fire fighting procedures | 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

- For non-emergency personnel** 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.
- For emergency responders** 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

Occupational exposure limits No exposure limits noted for ingredient(s).

Biological limit values No biological exposure limits noted for the ingredient(s).

Recommended monitoring procedures Follow standard monitoring procedures.

Derived no-effect level (DNEL) Not available.

Predicted no effect concentrations (PNECs) Not available.

8.2. Exposure controls

Appropriate engineering controls No special ventilation requirements.

Individual protection measures, such as personal protective equipment

General information Personal protective equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment.

Eye/face protection Wear dust-resistant safety goggles.

Skin protection

- Hand protection It is a good industrial hygiene practice to minimise skin contact. Chemical resistant gloves are recommended.

- Other It is a good industrial hygiene practice to minimise skin contact.

Respiratory protection In case of inadequate ventilation or risk of inhalation of dust, use suitable respiratory equipment with particle filter.

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

Hygiene measures Handle in accordance with good industrial hygiene and safety practices.

Environmental exposure controls 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

Appearance Straw colored powder.

Physical state Solid.

Form Powder.

Colour Straw colored.

Odour None.

Odour threshold Not applicable.

| | |
|---|-------------------|
| pH | Not available. |
| Melting point/freezing point | Not available. |
| Initial boiling point and boiling range | Not relevant. |
| Flash point | Not relevant. |
| Evaporation rate | Not available. |
| Flammability (solid, gas) | Non flammable. |
| Upper/lower flammability or explosive limits | |
| Flammability limit - lower (%) | Not available. |
| Flammability limit - upper (%) | Not available. |
| Vapour pressure | Not relevant. |
| Vapour density | Not relevant. |
| Relative density | Not available. |
| Solubility(ies) | Soluble in water. |
| Partition coefficient (n-octanol/water) | Not available. |
| Auto-ignition temperature | Not available. |
| Decomposition temperature | Not available. |
| Viscosity | Not relevant. |
| Explosive properties | Not relevant. |
| Oxidizing properties | Not oxidizing. |
| 9.2. Other information | |
| Percent volatile | Not relevant. |

SECTION 10: Stability and reactivity

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

SECTION 11: Toxicological information

Information on likely routes of exposure

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

Symptoms Mechanical irritation of skin, eyes and respiratory system.

11.1. Information on toxicological effects

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

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

SECTION 12: Ecological information

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

SECTION 13: Disposal considerations

| | |
|--------------------------------------|---|
| 13.1. Waste treatment methods | |
| Residual waste | Dispose in accordance with all applicable regulations. |
| Contaminated packaging | Empty containers should be taken to an approved waste handling site for recycling or disposal. |
| EU waste code | The Waste code should be assigned in discussion between the user, the producer and the waste disposal company. |
| Disposal methods/information | 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

ADR

Not regulated as dangerous goods.

RID

Not regulated as dangerous goods.

ADN

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code 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.

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