

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

|   |                                    |
|---|------------------------------------|
| <b>Trade name or designation of the mixture</b> | LA Phospholipid, in ACTICLOT® dPT™ |
| <b>Registration number</b>                      | -                                  |
| <b>Synonyms</b>                                 | None.                              |
| <b>Product code</b>                             | 824, LA Phospholipid               |
| <b>Issue date</b>                               | 01-December-2017                   |
| <b>Version number</b>                           | 02                                 |
| <b>Revision date</b>                            | 17-July-2017                       |
| <b>Supersedes date</b>                          | 21-April-2015                      |

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

|                             |  |
|-----------------------------|--|
| <b>Identified uses</b>      | The ACTICLOT® dPT™ is intended for the qualitative determination of Lupus Anticoagulants (LA) in human plasma. |
| <b>Uses advised against</b> | Use in accordance with supplier's recommendations.   |

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

|                               |   |
|-------------------------------|---|
| <b>Corporate Headquarters</b> | BioMedica Diagnostics Inc.<br>94 Wentworth Road, PO Box 1030<br>Windsor, Nova Scotia CANADA B0N 2T0   |
| <b>Contact person</b>         | Corporate Phone: 1-902-798-5105<br>Corporate Fax: 1-902-798-1025<br>Email: info@biomedicadiagnostics.com<br>Website: www.biomedicadiagnostics.com |

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

**Contract number** MIS9591327

**SECTION 2: Hazards identification****2.1. Classification of the substance or mixture**

The mixture 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**

**Classification** Xn;R22, R32, R52/53

The full text for all R-phrases is displayed in section 16.

**Classification according to Regulation (EC) No 1272/2008 as amended****Environmental hazards**

|  |            |   |
|--|------------|---|
| Hazardous to the aquatic environment, long-term aquatic hazard | Category 3 | H412 - Harmful to aquatic life with long lasting effects. |
|--|------------|---|

**Hazard summary**

|                              |  |
|------------------------------|--|
| <b>Physical hazards</b>      | Not classified for physical hazards.   |
| <b>Health hazards</b>        | Harmful if swallowed. Contact with acids liberates very toxic gas.   |
| <b>Environmental hazards</b> | Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.  |
| <b>Specific hazards</b>      | Avoid contact with eyes and skin. Do not ingest or inhale.   |
| <b>Main symptoms</b>         | Ingestion of sodium azide may cause nausea, diarrhea, vomiting, headache, slight lowering of blood pressure, abdominal pain, and a general feeling of apprehension and unwellness. |

**2.2. Label elements**

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

|                          |  |
|--------------------------|--|
| <b>Hazard pictograms</b> | None.  |
| <b>Signal word</b>       | None.  |
| <b>Hazard statements</b> |  |
| H412                     | Harmful to aquatic life with long lasting effects. |

**Precautionary statements**

|                   |                                   |
|-------------------|-----------------------------------|
| <b>Prevention</b> |                                   |
| P273              | Avoid release to the environment. |
| <b>Response</b>   | None.                             |
| <b>Storage</b>    | None.                             |
| <b>Disposal</b>   | None.                             |

**Supplemental label information** EUH032 - Contact with acids liberates very toxic gas.

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

**SECTION 3: Composition/information on ingredients****3.2. Mixtures****General information**

| Chemical name              | %  | CAS-No. / EC No.        | REACH Registration No. | INDEX No.    | Notes |
|----------------------------|--|-------------------------|------------------------|--------------|-------|
| Vinylpyrrolidinone polymer | 1 - 5  | 9003-39-8               | -                      | -            |       |
| <b>Classification:</b>     | <b>DSD:</b> -  |                         |                        |              |       |
|                            | <b>CLP:</b> -  |                         |                        |              |       |
| Sodium azide               | 0.1 - < 1.0  | 26628-22-8<br>247-852-1 | -                      | 011-004-00-7 | #     |
| <b>Classification:</b>     | <b>DSD:</b> T+;R28, R32, N;R50/53  |                         |                        |              |       |
|                            | <b>CLP:</b> Acute Tox. 2;H300, Acute Tox. 1;H310, Aquatic Acute 1;H400, Aquatic Chronic 1;H410 |                         |                        |              |       |

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

DSD: Directive 67/548/EEC.

CLP: Regulation No. 1272/2008.

#: This substance has been assigned Community workplace exposure limit(s).

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

**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. Call a physician if symptoms develop or persist.  |
| <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>    | If material is ingested, immediately contact a physician or poison control centre.   |

**4.2. Most important symptoms and effects, both acute and delayed** Ingestion of sodium azide may cause nausea, diarrhea, vomiting, headache, slight lowering of blood pressure, abdominal pain, and a general feeling of apprehension and unwellness.

**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** The product is not flammable.

**5.1. Extinguishing media**

**Suitable extinguishing media** Extinguish with water spray, carbon dioxide, dry chemical or material appropriate for the surrounding fire.

|   |   |
|---|---|
| <b>Unsuitable extinguishing media</b>                             | None known.   |
| <b>5.2. Special hazards arising from the substance or mixture</b> | When heated to decomposition, may produce hydrazoic acid fumes.                               |
| <b>5.3. Advice for firefighters</b>                               |   |
| <b>Special protective equipment for firefighters</b>              | 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

|   |   |
|---|---|
| <b>6.1. Personal precautions, protective equipment and emergency procedures</b> |   |
| <b>For non-emergency personnel</b>  | Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.  |
| <b>For emergency responders</b>   | Use personal protection as recommended in section 8 of the SDS.   |
| <b>6.2. Environmental precautions</b>   | Do not allow to enter drains, sewers or watercourses. This mixture contains a small amount of sodium azide which can react with copper, lead, brass or solder in plumbing systems and form potentially explosive metal azides. Follow proper disposal procedures. |
| <b>6.3. Methods and material for containment and cleaning up</b>                | Absorb spill with vermiculite or other inert material. Dispose of waste in accordance with all applicable federal, state, local and provincial environmental regulations, per Section 13.   |
| <b>6.4. Reference to other sections</b>   | For personal protection, see section 8 of the SDS. For waste disposal, see section 13 of the SDS.   |

## SECTION 7: Handling and storage

|  |  |
|--|--|
| <b>7.1. Precautions for safe handling</b>                                | Avoid contact with skin and eyes. Wash thoroughly after handling. In case of insufficient ventilation, wear suitable respiratory equipment. Handle and open container with care. |
| <b>7.2. Conditions for safe storage, including any incompatibilities</b> | Store at 2-8°C (35-46°F). Store in a closed container away from incompatible materials.  |
| <b>7.3. Specific end use(s)</b>  | The ACTICLOT® dPT™ is intended for the qualitative determination of Lupus Anticoagulants (LA) in human plasma.   |

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

#### Occupational exposure limits

##### UK. EH40 Workplace Exposure Limits (WELs)

| Components                    | Type | Value                 |
|-------------------------------|------|-----------------------|
| Sodium azide (CAS 26628-22-8) | STEL | 0.3 mg/m <sup>3</sup> |
|                               | TWA  | 0.1 mg/m <sup>3</sup> |

##### EU. Indicative Exposure Limit Values in Directives 91/322/EEC, 2000/39/EC, 2006/15/EC, 2009/161/EU

| Components                    | Type | Value                 |
|-------------------------------|------|-----------------------|
| Sodium azide (CAS 26628-22-8) | STEL | 0.3 mg/m <sup>3</sup> |
|                               | TWA  | 0.1 mg/m <sup>3</sup> |

**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.

**Exposure guidelines** Follow standard monitoring procedures.

##### UK EH40 WEL: Skin designation

Sodium azide (CAS 26628-22-8)

Can be absorbed through the skin.

### 8.2. Exposure controls

**Appropriate engineering controls** Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.

## 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>Eye/face protection</b>             | Wear approved safety glasses or goggles.  |
| <b>Skin protection</b>                 |   |
| - <b>Hand protection</b>               | Wear appropriate chemical resistant gloves.   |
| - <b>Other</b>                         | Wear lab coat or other protective garments. Remove contaminated clothing promptly.  |
| <b>Respiratory protection</b>          | Under normal conditions, respirator is not normally required.   |
| <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>                                   | White powder.     |
| <b>Physical state</b>                               | Solid.            |
| <b>Form</b>   | Powder.           |
| <b>Colour</b>                                       | White.            |
| <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>Explosive limit - lower (%)</b>                  | Not explosive.    |
| <b>Explosive limit – upper (%)</b>                  | Not explosive.    |
| <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.    |
| <b>9.2. Other information</b>                       |                   |
| <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> | Contact with acids liberates very toxic gas.  |
| <b>10.4. Conditions to avoid</b>                | Protect against direct sunlight.              |
| <b>10.5. Incompatible materials</b>             | Strong oxidising agents. Acids. Heavy metals. |

**10.6. Hazardous decomposition products**

Carbon oxides. Nitrogen oxides.  
Sodium Azide may form explosive compounds, copper azide or lead azide, when in contact with laboratory plumbing.

**SECTION 11: Toxicological information**

**General information** Occupational exposure to the substance or mixture may cause adverse effects.

**Information on likely routes of exposure**

- Inhalation** Vapours may irritate throat and respiratory system and cause coughing.
- Skin contact** Prolonged skin contact may cause redness, irritation and dry skin. Sodium azide may be absorbed through the skin and result in systemic effects.
- Eye contact** Splashes in the eyes may cause redness and irritation.
- Ingestion** May be harmful if swallowed.

**Symptoms** Ingestion of sodium azide may cause nausea, diarrhea, vomiting, headache, slight lowering of blood pressure, abdominal pain, and a general feeling of apprehension and unwellness.

**11.1. Information on toxicological effects**

**Acute toxicity** May cause discomfort if swallowed.

| Components  | Species  | Test results  |
|---|--|---|
| Sodium azide (CAS 26628-22-8)                                 |  |   |
| <b>Acute</b>  |  |   |
| <i>Dermal</i>   |  |   |
| LD50  | Rabbit   | 20 mg/kg  |
| <i>Oral</i>   |  |   |
| LD50  | Rat  | 27 mg/kg  |
| <b>Skin corrosion/irritation</b>                              | Prolonged skin contact may cause redness, irritation and dry skin. |   |
| <b>Serious eye damage/eye irritation</b>                      | Not classified.  |   |
| <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>IARC Monographs. Overall Evaluation of Carcinogenicity</b> |  |   |
| Vinylpyrrolidinone polymer (CAS 9003-39-8)                    |  | 3 Not classifiable as to carcinogenicity to humans. |
| <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>                                      | Not available.   |   |

**SECTION 12: Ecological information**

**12.1. Toxicity** Harmful to aquatic life with long lasting effects.

| Components                    | Species                             | Test results        |
|-------------------------------|-------------------------------------|---------------------|
| Sodium azide (CAS 26628-22-8) |                                     |                     |
| <b>Aquatic</b>                |                                     |                     |
| Algae                         | EC50 Pseudokirchnerella subcapitata | 0.35 mg/l, 96 hours |
| Fish                          | LC50 Fish                           | 5.7 mg/l, 96 hours  |

**12.2. Persistence and degradability** No data is available on the degradability of this product.

**12.3. Bioaccumulative potential** Not available.

**Partition coefficient n-octanol/water (log Kow)** Not available.

**Bioconcentration factor (BCF)** Not available.

**12.4. Mobility in soil** 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>              | Not available.                          |

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

|                                     |  |
|-------------------------------------|--|
| <b>Residual waste</b>               | Dispose in accordance with all applicable regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).   |
| <b>Contaminated packaging</b>       | Empty containers should be taken to an approved waste handling site for recycling or disposal.   |
| <b>EU waste code</b>                | Waste codes should be assigned by the user based on the application for which the product was used.  |
| <b>Disposal methods/information</b> | Dispose in accordance with all applicable regulations. This preparation contains a small amount of sodium azide which can react with copper, lead, brass or solder in plumbing systems and form potentially explosive metal azides. If preparation enters drain, flush with a large volume of water to prevent azide build-up. |

## 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**

Sodium azide (CAS 26628-22-8)

**Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work**

Sodium azide (CAS 26628-22-8)

**Directive 94/33/EC on the protection of young people at work**

Sodium azide (CAS 26628-22-8)

#### Other regulations

The product is classified and labelled in accordance with Regulation (EC) 1272/2008 (CLP Regulation) as amended and respective national laws implementing EC directives. This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006 as amended.

#### National regulations

The product has not been classified as dangerous according to the legislation in force.

#### 15.2. Chemical safety assessment

No Chemical Safety Assessment has been carried out.

### SECTION 16: Other information

#### List of abbreviations

DNEL: Derived No-Effect Level.  
PNEC: Predicted No-Effect Concentration.  
PBT: Persistent, bioaccumulative and toxic.  
vPvB: Very Persistent and very Bioaccumulative.

#### 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

R22 Harmful if swallowed.  
R28 Very toxic if swallowed.  
R32 Contact with acids liberates very toxic gas.  
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.  
R52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.  
H300 Fatal if swallowed.  
H310 Fatal in contact with skin.  
H400 Very toxic to aquatic life.  
H410 Very toxic to aquatic life with long lasting effects.

#### Training information

Follow training instructions when handling this material.

#### Disclaimer

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