

**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> | Stop Reagent     |
| <b>Registration number</b>                      | -                |
| <b>Synonyms</b>                                 | None.            |
| <b>Product code</b>                             | 101201           |
| <b>Issue date</b>                               | 01-December-2017 |
| <b>Version number</b>                           | 02               |
| <b>Revision date</b>                            | 27-July-2017     |
| <b>Supersedes date</b>                          | 07-June-2015     |

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

|                             |   |
|-----------------------------|---|
| <b>Identified uses</b>      | SPECTROLYSE® PAI-1 is intended for the quantitative determination of Plasminogen Activator Inhibitor Type-1 (PAI-1) activity in human plasma. For In Vitro Diagnostic use only. |
| <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 mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

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

|                                   |            |                                       |
|-----------------------------------|------------|---------------------------------------|
| Acute toxicity, oral              | Category 4 | H302 - Harmful if swallowed.          |
| Skin corrosion/irritation         | Category 2 | H315 - Causes skin irritation.        |
| Serious eye damage/eye irritation | Category 2 | H319 - Causes serious eye irritation. |

**Hazard summary** Harmful if swallowed. Causes skin irritation. Causes serious eye irritation.

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

**Contains:** Guanidinium chloride

**Hazard pictograms**

**Signal word** Warning

## Hazard statements

|      |                                |
|------|--------------------------------|
| H302 | Harmful if swallowed.          |
| H315 | Causes skin irritation.        |
| H319 | Causes serious eye irritation. |

## Precautionary statements

### Prevention

|      |   |
|------|---|
| P264 | Wash thoroughly after handling.                     |
| P270 | Do not eat, drink or smoke when using this product. |
| P280 | Wear protective gloves and eye/face protection.     |

### Response

|                    |  |
|--------------------|--|
| P301 + P312        | IF SWALLOWED: Call a POISON CENTRE or doctor/physician if you feel unwell.   |
| P330               | Rinse mouth.   |
| P302 + P352        | IF ON SKIN: Wash with plenty of water.   |
| P332 + P313        | If skin irritation occurs: Get medical advice/attention.   |
| P362               | Take off contaminated clothing and wash before reuse.  |
| P305 + P351 + P338 | IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. |
| P337 + P313        | If eye irritation persists: Get medical advice/attention.  |

### Storage

Store away from incompatible materials.

### Disposal

|      |   |
|------|---|
| P501 | Dispose of contents/container in accordance with local/regional/national/international regulations. |
|------|---|

**Supplemental label information** None.

**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 |
|------------------------|--|----------------------|------------------------|--------------|-------|
| Guanidinium chloride   | 60 - 80  | 50-01-1<br>200-002-3 | -                      | 607-148-00-0 |       |
| <b>Classification:</b> | Acute Tox. 4;H302, Skin Irrit. 2;H315, Eye Irrit. 2;H319 |                      |                        |              |       |
| Acetic acid            | 10 - 20  | 64-19-7<br>200-580-7 | -                      | 607-002-00-6 | #     |
| <b>Classification:</b> | Flam. Liq. 3;H226, Skin Corr. 1A;H314                    |                      |                        |              |       |

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

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

Note B: Some substances (acids, bases, etc.) are placed on the market in aqueous solutions at various concentrations and, therefore, these solutions require different classification and labelling since the hazards vary at different concentrations. In Part 3 entries with Note B have a general designation of the following type: "nitric acid ...%". In this case the supplier must state the percentage concentration of the solution on the label. Unless otherwise stated, it is assumed that the percentage concentration is calculated on a weight/weight basis.

**Composition comments** 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. 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 with water. Get medical advice/attention if you feel unwell.  |

#### 4.2. Most important symptoms and effects, both acute and delayed

Causes redness and pain. Symptoms of overexposure may be headache, dizziness, tiredness, nausea and vomiting.

**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.

**Unsuitable extinguishing media** None known.

**5.2. Special hazards arising from the substance or mixture** When heated to decomposition, may produce hydrazoic acid fumes.

**5.3. Advice for firefighters**

**Special protective equipment for firefighters** 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** Keep unnecessary personnel away. Wear appropriate protective equipment and clothing during clean-up.

**For emergency responders** Use personal protection as recommended in section 8 of the SDS.

**6.2. Environmental precautions** Do not allow to enter drains, sewers or watercourses.

**6.3. Methods and material for containment and cleaning up** 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.

**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 contact with skin and eyes. Wash thoroughly after handling. In case of insufficient ventilation, wear suitable respiratory equipment. Handle and open container with care.

**7.2. Conditions for safe storage, including any incompatibilities** Store at 2-8°C (35-46°F). Store in a closed container away from incompatible materials.

**7.3. Specific end use(s)** SPECTROLYSE® PAI-1 is intended for the quantitative determination of Plasminogen Activator Inhibitor Type-1 (PAI-1) activity in human plasma. For In Vitro Diagnostic use only.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

#### Occupational exposure limits

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

| Components                | Type | Value                          |
|---------------------------|------|--------------------------------|
| Acetic acid (CAS 64-19-7) | TWA  | 25 mg/m <sup>3</sup><br>10 ppm |

**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** 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

**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 approved safety glasses or goggles.

**Skin protection**

|                                 |   |
|---------------------------------|---|
| - Hand protection               | Wear appropriate chemical resistant gloves.   |
| - Other                         | Wear lab coat or other protective garments. Remove contaminated clothing promptly.                      |
| Respiratory protection          | In case of inadequate ventilation or risk of inhalation of vapours, use suitable respiratory equipment. |
| 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                                   | Colourless liquid.                            |
| Physical state                               | Liquid.                                       |
| Form   | Liquid.                                       |
| Colour                                       | Colourless, clear.                            |
| Odour  | Slightly pungent.                             |
| Odour threshold                              | Not available.                                |
| pH   | 3.7   |
| Melting point/freezing point                 | Not available.                                |
| Initial boiling point and boiling range      | Not available.                                |
| Flash point                                  | Not available.                                |
| Evaporation rate                             | Not available.                                |
| Flammability (solid, gas)                    | Not applicable.                               |
| Upper/lower flammability or explosive limits |   |
| Flammability limit - lower (%)               | Not available.                                |
| Flammability limit - upper (%)               | Not available.                                |
| Vapour pressure                              | Not available.                                |
| Vapour density                               | Not available.                                |
| 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 available.                                |
| Explosive properties                         | Not available.                                |
| Oxidizing properties                         | Not available.                                |
| 9.2. Other information                       | No relevant additional information available. |

## SECTION 10: Stability and reactivity

|  |   |
|--|---|
| 10.1. Reactivity                         | The product is stable and non reactive under normal conditions of use, storage and transport. |
| 10.2. Chemical stability                 | Material is stable under normal conditions.   |
| 10.3. Possibility of hazardous reactions | Hazardous polymerisation does not occur.  |
| 10.4. Conditions to avoid                | Protect against direct sunlight.  |
| 10.5. Incompatible materials             | Strong oxidising agents.  |
| 10.6. Hazardous decomposition products   | Hydrogen chloride gas.  |

## 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                             | Causes skin irritation.  |

|                    |  |
|--------------------|--|
| <b>Eye contact</b> | Causes serious eye irritation.   |
| <b>Ingestion</b>   | Harmful if swallowed.  |
| <b>Symptoms</b>    | May cause redness and pain. Symptoms of overexposure may be headache, dizziness, tiredness, nausea and vomiting. |

#### 11.1. Information on toxicological effects

**Acute toxicity** Harmful if swallowed.

| Components | Species | Test results |
|------------|---------|--------------|
|------------|---------|--------------|

Acetic acid (CAS 64-19-7)

**Acute**

*Dermal*

|      |        |            |
|------|--------|------------|
| LD50 | Rabbit | 1060 mg/kg |
|------|--------|------------|

*Inhalation*

|      |     |                    |
|------|-----|--------------------|
| LC50 | Rat | 11.4 mg/l, 4 Hours |
|------|-----|--------------------|

*Oral*

|      |     |            |
|------|-----|------------|
| LD50 | Rat | 3310 mg/kg |
|------|-----|------------|

Guanidinium chloride (CAS 50-01-1)

**Acute**

*Oral*

|      |     |           |
|------|-----|-----------|
| LD50 | Rat | 475 mg/kg |
|------|-----|-----------|

**Skin corrosion/irritation** Causes skin irritation.

**Serious eye damage/eye irritation** Causes serious eye irritation.

**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

| Components | Species | Test results |
|------------|---------|--------------|
|------------|---------|--------------|

Acetic acid (CAS 64-19-7)

**Aquatic**

|           |      |                                     |                   |
|-----------|------|-------------------------------------|-------------------|
| Crustacea | EC50 | Water flea ( <i>Daphnia magna</i> ) | 65 mg/l, 48 hours |
|-----------|------|-------------------------------------|-------------------|

|      |      |   |                   |
|------|------|---|-------------------|
| Fish | LC50 | Bluegill ( <i>Lepomis macrochirus</i> ) | 75 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)**

|                           |       |
|---------------------------|-------|
| Acetic acid (CAS 64-19-7) | -0.17 |
|---------------------------|-------|

**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** The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

**Residual waste** 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).

**Contaminated packaging** Empty containers should be taken to an approved waste handling site for recycling or disposal.

**EU waste code** Waste codes should be assigned by the user based on the application for which the product was used.

**Disposal methods/information** Dispose in accordance with all applicable regulations.

## 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

Acetic acid (CAS 64-19-7)

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

Acetic acid (CAS 64-19-7)

Guanidinium chloride (CAS 50-01-1)

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

Acetic acid (CAS 64-19-7)

## 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. In the European Union this product is regulated under the In Vitro Diagnostic Medical Devices Directive (98/79/EC).

## 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

DNEL: Derived No-Effect Level.  
PNEC: Predicted No-Effect Concentration.

### References

HSDB

### 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 H-statements not written out in full under Sections 2 to 15

H226 Flammable liquid and vapour.  
H302 Harmful if swallowed.  
H314 Causes severe skin burns and eye damage.  
H315 Causes skin irritation.  
H319 Causes serious eye irritation.

### Training information

Follow training instructions when handling this material.

### Disclaimer

The information above is provided in good faith. It is believed to be accurate and represents the best information currently available to us. HOWEVER, WE MAKE NO WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR OF ANY OTHER TYPE, EXPRESSED OR IMPLIED, WITH RESPECT TO PRODUCTS DESCRIBED OR DATA OR INFORMATION PROVIDED, AND WE ASSUME NO LIABILITY RESULTING FROM THE USE OF SUCH PRODUCTS, DATA OR INFORMATION. Users should make their own investigations to determine the suitability of the information for their particular purposes, and the user assumes all risk arising from their use of the material. The user is required to comply with all laws and regulations relating to the purchase, use, storage and disposal of the material, and must be familiar with and follow generally accepted safe handling procedures. In no event shall BioMedica Diagnostics be liable for any claims, losses, or damages of any individual or for lost profits or any special, indirect, incidental, consequential or exemplary damages, howsoever arising, even if BioMedica Diagnostics has been advised of the possibility of such damages.