

# SAFETY DATA SHEET

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

1.1. Product identifier

Trade name or designation

Plasminogen Activator Reagent

of the mixture

Registration number

**Synonyms** None. **Product code** 101201

01-December-2017 Issue date

02 Version number

26-July-2017 **Revision date** Supersedes date 14-July-2015

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

Identified uses Not available

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

Corporate Phone: 1-902-798-5105 Contact person

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

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

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

**Hazard summary** Avoid contact with eyes and skin. Do not ingest or inhale.

2.2. Label elements

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

None. **Hazard pictograms** Signal word None. **Hazard statements** None.

**Precautionary statements** 

Plasminogen Activator Reagent

Prevention Observe good laboratory hygiene practices.

Response Wash with plenty of water.

Store away from incompatible materials. Storage

Disposal Dispose of waste and residues in accordance with local authority requirements.

**Supplemental label information** 

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

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# **SECTION 3: Composition/information on ingredients**

### 3.2. Mixtures

**General information** 

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
Sodium chloride	30 - 50	7647-14-5 231-598-3	01-2119485491-33-XXXX	-	
Classification: -					
Disodium hydrogen orthophospl	nate 3 - < 7	7558-79-4 231-448-7	-	-	
Classification: Eye Ir	rit. 2;H319				
H-D-norleucyl-cyclohexylalanyl- para-nitroanilide diacetate salt	lysine- 1 - < 3	None -	-	-	
Classification: Skin I	rrit. 2;H315, Eye I	rrit. 2;H319, STOT	SE 3;H335		

**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 H-statements 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.

In case of contact, immediately flush eyes with fresh water for at least 15 minutes while holding the Eye contact

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

Dust may cause eye, skin and respiratory tract irritation.

delaved 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

surrounding fire. media

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.

Extinguish with water spray, carbon dioxide, dry chemical or material appropriate for the

#### **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.

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926481 Version #: 02 Revision date: 26-July-2017 Issue date: 01-December-2017 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 eves. 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) Not available.

# SECTION 8: Exposure controls/personal protection

8.1. Control parameters

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

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

Recommended monitoring

procedures

Follow standard monitoring procedures.

Derived no-effect level (DNEL) Not available. Predicted no effect Not available.

concentrations (PNECs)

8.2. Exposure controls Appropriate engineering

controls

No special ventilation requirements.

Individual protection measures, such as personal protective equipment

Personal protective equipment should be chosen according to the CEN standards and in **General information** 

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.

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

with particle filter.

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

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

**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** White powder.

Physical state Solid. **Form** Powder. White. Colour Odour None.

**Odour threshold** Not applicable. Not available. pН Not available. Melting point/freezing point Initial boiling point and boiling Not relevant.

range

Not relevant. Flash point Not available. **Evaporation rate** Non flammable. Flammability (solid, gas)

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### Upper/lower flammability or explosive limits

Flammability limit - lower

(%)

Not available.

Flammability limit - upper

Not available.

Not relevant. Vapour pressure Not relevant. Vapour density Relative density Not available. Soluble in water. Solubility(ies) **Partition coefficient** Not available.

(n-octanol/water)

**Auto-ignition temperature** Not available. **Decomposition temperature** Not available. **Viscosity** Not relevant. **Explosive properties** Not relevant. **Oxidizing properties** Not oxidising.

9.2. Other information

Percent volatile Not relevant.

# **SECTION 10: Stability and reactivity**

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 Carbon oxides. Nitrogen oxides.

decomposition products

# **SECTION 11: Toxicological information**

#### Information on likely routes of exposure

Inhalation Dust may irritate respiratory system.

Skin contact Dust may irritate skin.

Dust in the eyes will cause irritation. Eye contact May cause discomfort if swallowed. Ingestion

Mechanical irritation of skin, eyes and respiratory system. **Symptoms** 

### 11.1. Information on toxicological effects

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

Skin corrosion/irritation Dust may irritate skin. Dust may irritate the eyes. Serious eye damage/eye

irritation

Respiratory sensitisation Not classified. Skin sensitisation Not classified. Not classified. Germ cell mutagenicity Not classified. Carcinogenicity Not classified. Reproductive toxicity Specific target organ toxicity -Not classified. single exposure

Specific target organ toxicity -

repeated exposure

Not classified.

Not classified. **Aspiration hazard** Not available.

Mixture versus substance

information

Other information Not available.

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# **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 Not available.

n-octanol/water (log Kow)

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

Not a PBT or vPvB substance or mixture.

and vPvB assessment

nent

# **SECTION 13: Disposal considerations**

#### 13.1. Waste treatment methods

12.6. Other adverse effects

**Residual waste** Dispose in accordance with all applicable regulations.

No data available.

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

#### **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 applicable.

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.

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#### 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

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

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 mixture does not meet the criteria for classification according to Regulation (EC) 1272/2008

as amended. This Safety Data Sheet complies with the requirements of Regulation (EC) No

1907/2006 as amended.

**National regulations** 15.2. Chemical safety

Follow national regulation for work with chemical agents. No Chemical Safety Assessment has been carried out.

assessment

### **SECTION 16: Other information**

List of abbreviations

DNEL: Derived No-Effect Level.

Not available.

PNEC: Predicted No-Effect Concentration.

References

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

H315 Causes skin irritation. H319 Causes serious eye irritation. H335 May cause respiratory irritation.

**Training information** 

Follow training instructions when handling this material.

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