

**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>	PAI-1 Enzyme Conjugate
<b>Registration number</b>	-
<b>Synonyms</b>	None.
<b>Product code</b>	899, 821
<b>Issue date</b>	01-December-2017
<b>Version number</b>	02
<b>Revision date</b>	31-July-2017
<b>Supersedes date</b>	24-July-2015

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

<b>Identified uses</b>	Assorted.
<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**

<b>Health hazards</b>		
Skin sensitisation	Category 1	H317 - May cause an allergic skin reaction.

**Hazard summary** May cause an allergic skin reaction.

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

**Contains:** 2-Methyl-4-isothiazol-3-one

**Hazard pictograms**

**Signal word** Warning

**Hazard statements**

H317 May cause an allergic skin reaction.

## Precautionary statements

### Prevention

P261	Avoid breathing mist or vapour.
P272	Contaminated work clothing must not be allowed out of the workplace.
P280	Wear protective gloves.

### Response

P302 + P352	IF ON SKIN: Wash with plenty of water.
P333 + P313	If skin irritation or rash occurs: Get medical advice/attention.
P362	Take off contaminated clothing and wash before reuse.

### Storage

Store away from incompatible materials.

### Disposal

P501	Dispose of contents/container in accordance with local/regional/national/international regulations.
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**Supplemental label information** Not applicable.

**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
2-Methyl-4-isothiazol-3-one	0.01 - 0.03	2682-20-4 220-239-6	-	613-167-00-5	
<b>Classification:</b>	Acute Tox. 3;H301, Acute Tox. 3;H311, Skin Corr. 1B;H314, Skin Sens. 1;H317, Acute Tox. 3;H331, Aquatic Acute 1;H400, Aquatic Chronic 1;H410				

**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

<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. If skin rash or an allergic skin reaction develops, get medical attention.
<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** Headaches, nausea and vomiting. Dermatitis.

**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

<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** None known.

### 5.3. Advice for firefighters

<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

### 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. Persons susceptible for allergic reactions should not handle this product. 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 in a closed container away from incompatible materials.

**7.3. Specific end use(s)** Assorted.

## 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.

**Exposure guidelines** Follow standard monitoring procedures.

### 8.2. Exposure controls

**Appropriate engineering controls** Provide adequate ventilation. Provide easy access to water supply and eye wash facilities.

### 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** Clear, pale yellow liquid.

**Physical state** Liquid.

**Form** Liquid.

**Colour** Clear, pale yellow.

**Odour** None.

**Odour threshold** Not available.

**pH** 6.5 - 7.5

**Melting point/freezing point** Not available.

<b>Initial boiling point and boiling range</b>	100 °C (212 °F)
<b>Flash point</b>	Not available.
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not applicable.
<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 available.
<b>Vapour density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	Completely soluble.
<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 available.
<b>Explosive properties</b>	Not explosive.
<b>Oxidizing properties</b>	Not oxidising.
<b>9.2. Other information</b>	No relevant additional information available.

## 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.
<b>10.6. Hazardous decomposition products</b>	Carbon oxides. Nitrogen oxides.

## SECTION 11: Toxicological information

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

### Information on likely routes of exposure

<b>Inhalation</b>	Vapours may irritate throat and respiratory system and cause coughing.
<b>Skin contact</b>	May cause skin irritation. May cause eczema-like skin disorders (dermatitis).
<b>Eye contact</b>	May cause eye irritation.
<b>Ingestion</b>	May cause discomfort if swallowed.

**Symptoms** Headaches, nausea and vomiting. Dermatitis.

### 11.1. Information on toxicological effects

<b>Acute toxicity</b>	May cause discomfort if swallowed.
<b>Skin corrosion/irritation</b>	May cause skin irritation.
<b>Serious eye damage/eye irritation</b>	May cause eye irritation.
<b>Respiratory sensitisation</b>	No data available.
<b>Skin sensitisation</b>	May cause an allergic skin reaction.
<b>Germ cell mutagenicity</b>	No data available.
<b>Carcinogenicity</b>	No data available.
<b>Reproductive toxicity</b>	No data available.
<b>Specific target organ toxicity - single exposure</b>	No data available.
<b>Specific target organ toxicity - repeated exposure</b>	No data available.
<b>Aspiration hazard</b>	No data available.

<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>	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.
<b>12.2. Persistence and degradability</b>	No data is available on the degradability of this product.
<b>12.3. Bioaccumulative potential</b>	Not available.
<b>Partition coefficient n-octanol/water (log Kow)</b>	Not available.
<b>Bioconcentration factor (BCF)</b>	Not available.
<b>12.4. Mobility in soil</b>	Not available.
<b>Mobility in general</b>	No data available.
<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>	The Waste code should be assigned in discussion between the user, the producer and the waste disposal company.
<b>Disposal methods/information</b>	Dispose waste and residues in accordance with applicable federal, state, and local regulations. 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.

<b>14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code</b>	Not applicable.
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## 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**

2-Methyl-4-isothiazol-3-one (CAS 2682-20-4)

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

2-Methyl-4-isothiazol-3-one (CAS 2682-20-4)

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

2-Methyl-4-isothiazol-3-one (CAS 2682-20-4)

#### **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. Young people under 18 years old are not allowed to work with this product according to the EU Directive 94/33/EC on the protection of young people at work. 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**

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

H301 Toxic if swallowed.  
H311 Toxic in contact with skin.  
H314 Causes severe skin burns and eye damage.  
H317 May cause an allergic skin reaction.  
H331 Toxic if inhaled.  
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.

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