

**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>	Factor VIIa Inhibitor
<b>Registration number</b>	-
<b>Synonyms</b>	None.
<b>Product code</b>	Inhibitor, in 827 IMUBIND® Factor VIIa ELISA
<b>Issue date</b>	01-December-2017
<b>Version number</b>	02
<b>Revision date</b>	17-July-2017
<b>Supersedes date</b>	21-July-2015

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

<b>Identified uses</b>	Research 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 product 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**

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

**Hazard summary** Health injuries are not known or expected under normal use. Occupational exposure to the substance or mixture may cause adverse health effects.

**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>	None.

**Precautionary statements**

<b>Prevention</b>	Observe good laboratory hygiene practices.
<b>Response</b>	Wash with plenty of water.
<b>Storage</b>	Store away from incompatible materials.
<b>Disposal</b>	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

### 3.2. Mixtures

#### General information

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
Glycine	90 - 100	56-40-6 200-272-2	-	-	
<b>Classification:</b>	-				
Hydrochloric acid	1 - < 3	7647-01-0 231-595-7	01-2119484862-27-XXXX	017-002-01-X	#
<b>Classification:</b>	Met. Corr. 1;H290, Skin Corr. 1B;H314, STOT SE 3;H335				B

**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. If you feel unwell, seek medical advice (show the label where possible).

### 4.1. Description of first aid measures

<b>Inhalation</b>	Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTRE or doctor/physician if you feel unwell.
<b>Skin contact</b>	Remove contaminated clothing. Wash with plenty of soap and water. If skin irritation occurs: Get medical advice/attention. Wash contaminated clothing before reuse.
<b>Eye contact</b>	Do not rub eyes. Immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.
<b>Ingestion</b>	Rinse mouth. Get medical attention if symptoms occur.

**4.2. Most important symptoms and effects, both acute and delayed** Symptoms may include stinging, tearing, redness, swelling, and blurred vision.

**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** No unusual fire or explosion hazards noted. Will burn if involved in a fire.

### 5.1. Extinguishing media

<b>Suitable extinguishing media</b>	Water spray. Foam. Dry chemical powder. Carbon dioxide (CO <sub>2</sub> ).
<b>Unsuitable extinguishing media</b>	Do not use water jet as an extinguisher, as this will spread the fire.

**5.2. Special hazards arising from the substance or mixture** During fire, gases hazardous to health may be formed.

### 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

<b>For non-emergency personnel</b>	Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Wear appropriate protective equipment and clothing during clean-up. Avoid inhalation of dust. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained.
<b>For emergency responders</b>	Keep unnecessary personnel away. 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 dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Collect dust using a vacuum cleaner equipped with HEPA filter. Stop the flow of material, if this is without risk.

Large Spills: Wet down with water and dike for later disposal. Shovel the material into waste container. Following product recovery, flush area with water.

Small Spills: Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination.

### 6.4. Reference to other sections

For personal protection, see section 8. 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.

### 7.2. Conditions for safe storage, including any incompatibilities

Store at 2 - 8°C. Store in a cool, dry, well-ventilated place. Store in a closed container away from incompatible materials.

### 7.3. Specific end use(s)

Research use only.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

#### Occupational exposure limits

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

Components	Type	Value	Form
Hydrochloric acid (CAS 7647-01-0)	STEL	8 mg/m <sup>3</sup>	Gas and aerosol mists.
	TWA	5 ppm	Gas and aerosol mists.
		2 mg/m <sup>3</sup>	Gas and aerosol mists.
		1 ppm	Gas and aerosol mists.

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

Components	Type	Value
Hydrochloric acid (CAS 7647-01-0)	STEL	15 mg/m <sup>3</sup>
	TWA	10 ppm
		8 mg/m <sup>3</sup>
		5 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)

Components	Type	Route	Value	Form
Hydrochloric acid (CAS 7647-01-0)	Workers	Inhalation	8 mg/m <sup>3</sup>	Long term Local effects
		Inhalation	15 mg/m <sup>3</sup>	Short term exposure - local effects

### Predicted no effect concentrations (PNECs)

Components	Type	Route	Value	Form
Hydrochloric acid (CAS 7647-01-0)	Aqua (freshwater)	Water	36 µg/l	
	Aqua (intermittent releases)	Water	46 µg/l	
	Aqua (marine water)	Water	36 µg/l	
	Sewage Treatment Plant	Not applicable	36 µg/l	

### Exposure guidelines

No exposure standards allocated.

### 8.2. Exposure controls

**Appropriate engineering controls** Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. If engineering measures are not sufficient to maintain concentrations of dust particulates below the OEL (occupational exposure limit), suitable respiratory protection must be worn. If material is ground, cut, or used in any operation which may generate dusts, use appropriate local exhaust ventilation to keep exposures below the recommended exposure limits. Eye wash facilities and emergency shower must be available when handling this product.

**Individual protection measures, such as personal protective equipment**

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

**Eye/face protection** Wear safety goggles and a face shield.

**Skin protection**

**- Hand protection** Wear appropriate chemical resistant gloves. Suitable gloves can be recommended by the glove supplier.

**- Other** Wear appropriate chemical resistant clothing.

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

**Thermal hazards** Wear appropriate thermal protective clothing, when necessary.

**Hygiene measures** Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

**Environmental exposure controls** Environmental manager must be informed of all major releases.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

#### Appearance

**Physical state** Solid.

**Form** White powder.

**Colour** White.

**Odour** Not available.

**Odour threshold** Not available.

**pH** Not available.

**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 available.

#### 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)** Water soluble.

**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	Strong oxidizers, strong acids, and strong bases.
10.2. Chemical stability	Material is stable under normal conditions.
10.3. Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
10.4. Conditions to avoid	Dust generation. Heat, flames and sparks.
10.5. Incompatible materials	Strong oxidising agents. Strong acids.
10.6. Hazardous decomposition products	Nitrogen oxides, carbon monoxide and carbon dioxide.

## 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>	Dust may irritate respiratory system.
<b>Skin contact</b>	May cause skin irritation.
<b>Eye contact</b>	May cause eye irritation.
<b>Ingestion</b>	May cause discomfort if swallowed.

**Symptoms** Symptoms may include stinging, tearing, redness, swelling, and blurred vision.

### 11.1. Information on toxicological effects

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

Components	Species	Test results
Hydrochloric acid (CAS 7647-01-0)		
<b>Acute</b>		
<i>Inhalation</i>		
LC50	Rat	3124 ppm, 1 Hours
<i>Oral</i>		
LD50	Rabbit	900 mg/kg
<b>Skin corrosion/irritation</b>	May cause skin irritation.	
<b>Serious eye damage/eye irritation</b>	May cause eye irritation.	
<b>Respiratory sensitisation</b>	Not classified.	
<b>Skin sensitisation</b>	Not a skin sensitiser.	
<b>Germ cell mutagenicity</b>	Not classified.	
<b>Carcinogenicity</b>	Not classified.	
<b>IARC Monographs. Overall Evaluation of Carcinogenicity</b>		
Hydrochloric acid (CAS 7647-01-0)		3 Not classifiable as to carcinogenicity to humans.
<b>Reproductive toxicity</b>	No data available.	
<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** 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.

Components	Species	Test results
Hydrochloric acid (CAS 7647-01-0)		
<b>Aquatic</b>		
Fish	LC50	Western mosquitofish ( <i>Gambusia affinis</i> ) 282 mg/l, 24 hours
<b>12.2. Persistence and degradability</b>	No data is available on the degradability of this product.	

<b>12.3. Bioaccumulative potential</b>	No data 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>	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>	No data available.

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

<b>Residual waste</b>	Dispose in accordance with all applicable regulations.
<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>	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**

Hydrochloric acid (CAS 7647-01-0)

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

Hydrochloric acid (CAS 7647-01-0)

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

Hydrochloric acid (CAS 7647-01-0)

#### **Other regulations**

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.  
LD50: Lethal Dose, 50%.

#### **References**

HSDB® - Hazardous Substances Data Bank  
IARC Monographs. Overall Evaluation of Carcinogenicity  
EPA: AQUIRE database

#### **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**

H290 May be corrosive to metals.  
H314 Causes severe skin burns and eye damage.  
H335 May cause respiratory irritation.

#### **Training information**

Follow training instructions when handling this material.

#### **Disclaimer**

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