

**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 XIIa Human, 0.5 mg
<b>Registration number</b>	-
<b>Synonyms</b>	None.
<b>Product code</b>	412HA
<b>Issue date</b>	01-December-2017
<b>Version number</b>	02
<b>Revision date</b>	12-July-2017
<b>Supersedes date</b>	22-June-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

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Corporate Fax: 1-902-798-1025  
Email: info@biomedicadiagnostics.com  
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**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**

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**

<b>Hazard pictograms</b>	None.
<b>Signal word</b>	None.
<b>Hazard statements</b>	The mixture does not meet the criteria for classification.

**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

The components are not hazardous or are below required disclosure limits.

## SECTION 4: First aid measures

**General information** Ensure that medical personnel are aware of the material(s) involved.

### 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 may cause irritation and malaise.

**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

<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.

**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 inhalation of mists or aerosols. Avoid contact with skin and eyes. Avoid prolonged and repeated contact. Provide adequate ventilation. 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.

**7.2. Conditions for safe storage, including any incompatibilities** Store in closed original container at temperature -70°C . 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

<b>Occupational exposure limits</b>	No exposure limits noted for ingredient(s).
<b>Biological limit values</b>	No biological exposure limits noted for the ingredient(s).
<b>Recommended monitoring procedures</b>	Follow standard monitoring procedures.
<b>Derived no-effect level (DNEL)</b>	Not available.
<b>Predicted no effect concentrations (PNECs)</b>	Not available.
<b>8.2. Exposure controls</b>	
<b>Appropriate engineering controls</b>	Provide adequate ventilation. Observe Occupational Exposure Limits and minimise the risk of inhalation of vapours.
<b>Individual protection measures, such as personal protective equipment</b>	
<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>	Clear, colorless solution.
<b>Physical state</b>	Liquid.
<b>Form</b>	Liquid.
<b>Colour</b>	Not available.
<b>Odour</b>	None.
<b>Odour threshold</b>	Not available.
<b>pH</b>	5.3
<b>Melting point/freezing point</b>	Not available.
<b>Initial boiling point and boiling range</b>	Not available.
<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>	Water 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>	The product is stable and non reactive under normal conditions of storage and transport.
<b>10.2. Chemical stability</b>	Stable under normal storage and handling conditions.
<b>10.3. Possibility of hazardous reactions</b>	Hazardous polymerisation does not occur.
<b>10.4. Conditions to avoid</b>	None under normal conditions.
<b>10.5. Incompatible materials</b>	Strong oxidizers, strong acids, and strong bases.
<b>10.6. Hazardous decomposition products</b>	None expected under normal conditions of use.

## 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>	Prolonged skin contact may cause redness, irritation and dry skin.
<b>Eye contact</b>	Splashes in the eyes may cause redness and irritation.
<b>Ingestion</b>	May cause discomfort if swallowed.

**Symptoms** Ingestion may cause irritation and malaise.

### 11.1. Information on toxicological effects

<b>Acute toxicity</b>	May cause discomfort if swallowed.
<b>Skin corrosion/irritation</b>	Prolonged skin contact may cause redness, irritation and dry skin.
<b>Serious eye damage/eye irritation</b>	May cause eye irritation.
<b>Respiratory sensitisation</b>	Not classified.
<b>Skin sensitisation</b>	No data available.
<b>Germ cell mutagenicity</b>	Not classified.
<b>Carcinogenicity</b>	Not classified.
<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>	No other specific acute or chronic health impact noted.

## SECTION 12: Ecological information

<b>12.1. Toxicity</b>	No ecotoxicity data noted for the ingredient(s).
<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>	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>	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

<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. Contract with a licensed chemical disposal agency.

## 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**

Not listed.

**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

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

None.

### Training information

Follow training instructions when handling this material.

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