

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1. Product identifier**

Trade name or designation of the mixture	Factor IXa Human, 500 ug
Registration number	-
Synonyms	None.
Product code	449B, Human Factor IXa
Issue date	01-December-2017
Version number	02
Revision date	12-July-2017
Supersedes date	11-June-2015

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

Identified uses	Assorted.
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

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

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

Hazard summary Not classified for health hazards. However, occupational exposure to the mixture or substance(s) may cause adverse health effects.

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

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

Precautionary statements

Prevention	Observe good laboratory hygiene practices.
Response	Wash with plenty of water.
Storage	Store away from incompatible materials.
Disposal	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
Glycerol	30-60	56-81-5 200-289-5	-	-	
Classification:	-				

List of abbreviations and symbols that may be used above

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.

4.1. Description of first aid measures

Inhalation	Move to fresh air. Call a physician if symptoms develop or persist.
Skin contact	For skin contact flush with large amounts of water while removing contaminated clothing. Get medical attention if irritation develops and persists.
Eye contact	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.
Ingestion	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

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 None known.

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. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.
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

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. 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)

Assorted.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits

UK. EH40 Workplace Exposure Limits (WELs)

Components	Type	Value	Form
Glycerol (CAS 56-81-5)	TWA	10 mg/m3	Mist.

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

Provide adequate ventilation. Observe Occupational Exposure Limits and minimise the risk of inhalation of vapours.

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

Under normal conditions, respirator is not normally required.

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

Slightly viscous, colorless solution.

Physical state

Liquid.

Form

Slightly viscous liquid.

Colour

Colourless.

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 The product is stable and non reactive under normal conditions of storage and transport.

10.2. Chemical stability Stable under normal storage and handling conditions.

10.3. Possibility of hazardous reactions Hazardous polymerisation does not occur.

10.4. Conditions to avoid None under normal conditions.

10.5. Incompatible materials Strong acids. Strong oxidising agents. Strong reducing agents.

10.6. Hazardous decomposition products 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

Inhalation Vapours may irritate throat and respiratory system and cause coughing.

Skin contact Prolonged skin contact may cause redness, irritation and dry skin.

Eye contact Splashes in the eyes may cause redness and irritation.

Ingestion May cause discomfort if swallowed.

Symptoms Ingestion may cause irritation and malaise.

11.1. Information on toxicological effects

Acute toxicity May cause discomfort if swallowed.

Skin corrosion/irritation Prolonged skin contact may cause redness, irritation and dry skin.

Serious eye damage/eye irritation May cause eye irritation.

Respiratory sensitisation Not classified.

Skin sensitisation Not a skin sensitiser.

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	No ecotoxicity data noted for the ingredient(s).
12.2. Persistence and degradability	No data is available on the degradability of this product.
12.3. Bioaccumulative potential	
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. 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 product does not meet the criteria for classification according to Regulation (EC) 1272/2008 (CLP Regulation) and Directive 67/548/EEC and their amendments respectively. 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

DSD: Directive 67/548/EEC.
CLP: Regulation No. 1272/2008.
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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