

1. Identification

Product identifier	FACTOR VIII Def PLASMA, 10 x 1.0 mL		
Other means of identification			
Product code	268		
Recommended use	Not available.		
Recommended restrictions	Use in accordance with supplier's recommendations.		
Manufacturer/Importer/Supplier/Distributor information			
Corporate Headquarters	BioMedica Diagnostics Inc. 94 Wentworth Road, PO Box 1030 Windsor, Nova Scotia CANADA B0N 2T0		
7 cbfUWidYfgcb	Corporate Phone: 1-902-798-5105 Corporate Fax: 1-902-798-1025 Email: info@biomedicadiagnostics.com Website: www.biomedicadiagnostics.com		
9a Yf[YbWriHY Yd\ cbY Bi a VYfg	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		
7 cbfUWibi a VYf	MIS9591327		

2. Hazard(s) identification

Physical hazards	Not classified.
Health hazards	Not classified.
OSHA defined hazards	Not classified.
Label elements	
Hazard symbol	None.
Signal word	None.
Hazard statement	None.
Precautionary statement	
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.
Hazard(s) not otherwise classified (HNOC)	None known.

3. Composition/information on ingredients**Substances**

Chemical name	Common name and synonyms	CAS number	%
Human plasma		N/A	100

Composition comments All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

4. 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.

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	Rinse mouth thoroughly if dust is ingested. Get medical advice/attention if you feel unwell.
Most important symptoms/effects, acute and delayed	Dust may cause eye, skin and respiratory tract irritation.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically.
General information	Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire-fighting measures

Suitable extinguishing media	Extinguish with water spray, carbon dioxide, dry chemical or material appropriate for the surrounding fire.
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	Fire will generate toxic and irritating gases.
Special protective equipment and precautions 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.
Fire fighting equipment/instructions	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	Will burn if involved in a fire.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	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.
Methods and materials for containment and cleaning up	Avoid dust formation. Sweep or scoop up and remove.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling	Avoid prolonged exposure. Avoid contact with skin and eyes. 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.
Conditions for safe storage, including any incompatibilities	Store at 2 - 8°C. Store in a closed container away from incompatible materials.

8. Exposure controls/personal protection

Occupational exposure limits	No exposure limits noted for ingredient(s).
Biological limit values	No biological exposure limits noted for the ingredient(s).
Exposure guidelines	Follow standard monitoring procedures.
Appropriate engineering controls	No special ventilation requirements.
Individual protection measures, such as personal protective equipment	
Eye/face protection	Wear dust-resistant safety goggles.
Skin protection	
Hand protection	It is a good industrial hygiene practice to minimize skin contact. Chemical resistant gloves are recommended.
Other	It is a good industrial hygiene practice to minimize skin contact.
Respiratory protection	In case of inadequate ventilation or risk of inhalation of dust, use suitable respiratory equipment with particle filter.

Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Appearance	Straw colored powder.
Physical state	Solid.
Form	Powder.
Color	Straw colored.
Odor	None.
Odor threshold	Not applicable.
pH	Not available.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not relevant.
Flash point	Not relevant.
Evaporation rate	Not available.
Flammability (solid, gas)	Non flammable.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	Not relevant.
Vapor density	Not relevant.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Soluble in water.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not relevant.
Other information	
Explosive properties	Not relevant.
Oxidizing properties	Not oxidizing.
Percent volatile	Not relevant.

10. Stability and reactivity

Reactivity	The product is stable and non reactive under normal conditions of storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	Polymerization will not occur.
Conditions to avoid	Keep away from heat.
Incompatible materials	Strong oxidizing agents. Strong reducing agents. Strong acids.
Hazardous decomposition products	Carbon oxides. Nitrogen oxides.

11. Toxicological information

Information on likely routes of exposure

Inhalation	Dust may irritate respiratory system.
-------------------	---------------------------------------

Skin contact	Dust may irritate skin.
Eye contact	Dust in the eyes will cause irritation.
Ingestion	May cause discomfort if swallowed.
Symptoms related to the physical, chemical and toxicological characteristics	Mechanical irritation of skin, eyes and respiratory system.

Information on toxicological effects

Acute toxicity	May cause discomfort if swallowed.
Skin corrosion/irritation	Dust may irritate skin.
Serious eye damage/eye irritation	Dust may irritate the eyes.
Respiratory or skin sensitization	
Respiratory sensitization	Not classified.
Skin sensitization	Not classified.
Germ cell mutagenicity	Not classified.
Carcinogenicity	Not classified.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Reproductive toxicity	Not classified.
Specific target organ toxicity - single exposure	Not classified.
Specific target organ toxicity - repeated exposure	Not classified.
Aspiration hazard	Not classified.
Further information	No other specific acute or chronic health impact noted.

12. Ecological information

Ecotoxicity	No ecotoxicity data noted for the ingredient(s).
Persistence and degradability	No data available.
Bioaccumulative potential	No data available.
Mobility in soil	Not available.
Mobility in general	The product is soluble in water.
Other adverse effects	No data available.

13. Disposal considerations

Disposal instructions	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.
Hazardous waste code	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Waste from residues / unused products	Dispose in accordance with all applicable regulations.
Contaminated packaging	Empty containers should be taken to an approved waste handling site for recycling or disposal.

14. Transport information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not applicable.

15. Regulatory information

US federal regulations This product is not known to be a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - No
Delayed Hazard - No
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical No

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.

US state regulations This product does not contain a chemical known to the State of California to cause cancer, birth defects or other reproductive harm.

US. Massachusetts RTK - Substance List

Not regulated.

US. New Jersey Worker and Community Right-to-Know Act

Not listed.

US. Pennsylvania Worker and Community Right-to-Know Law

Not listed.

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

Not Listed.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	Yes
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	Yes
Korea	Existing Chemicals List (ECL)	Yes
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	Yes

Country(s) or region	Inventory name	On inventory (yes/no)*
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	Yes

*A "Yes" indicates this product complies with the inventory requirements administered by the governing country(s).

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date 01-December-2017

Revision date 01-August-2017

Version # 02

NFPA ratings



Disclaimer

The information above is provided in good faith. It is believed to be accurate and represents the best information currently available to us. HOWEVER, WE MAKE NO WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR OF ANY OTHER TYPE, EXPRESSED OR IMPLIED, WITH RESPECT TO PRODUCTS DESCRIBED OR DATA OR INFORMATION PROVIDED, AND WE ASSUME NO LIABILITY RESULTING FROM THE USE OF SUCH PRODUCTS, DATA OR INFORMATION. Users should make their own investigations to determine the suitability of the information for their particular purposes, and the user assumes all risk arising from their use of the material. The user is required to comply with all laws and regulations relating to the purchase, use, storage and disposal of the material, and must be familiar with and follow generally accepted safe handling procedures. In no event shall BioMedica Diagnostics be liable for any claims, losses, or damages of any individual or for lost profits or any special, indirect, incidental, consequential or exemplary damages, howsoever arising, even if BioMedica Diagnostics has been advised of the possibility of such damages.