



## Safety data sheet

This SDS is an English translation of COMMISSION REGULATION (EU) 2020/878, without any country-specific legislation

### F-IX Factor IX Deficient Plasma REF13309 R1 6x1mL

#### SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

- 1.1 Product identifier:** F-IX  
Factor IX Deficient Plasma  
REF13309 R1 6x1mL
- Other means of identification:**  
Non-applicable
- 1.2 Relevant identified uses of the substance or mixture and uses advised against:**  
Relevant uses: In vitro diagnostic. For professional users only.  
Uses advised against: All uses not specified in this section or in section 7.3
- 1.3 Details of the supplier of the safety data sheet:**  
BIOLABO SAS  
Les Hautes Rives  
02160 Maizy - France  
Phone: 0323251550 - Fax: 0323256256  
info@biolabo.fr  
www.biolabo.fr
- 1.4 Emergency telephone number:** BIOLABO (33) (0) 323251550 ( 08h00-18h00), ORFILA (33) (0)145 42 59 59

#### SECTION 2: HAZARDS IDENTIFICATION

- 2.1 Classification of the substance or mixture:**  
**CLP Regulation (EC) No 1272/2008:**  
The product is not classified as hazardous according to CLP Regulation (EC) No 1272/2008.
- 2.2 Label elements:**  
**CLP Regulation (EC) No 1272/2008:**  
**Hazard statements:**  
Non-applicable  
**Precautionary statements:**  
P260: Do not breathe dust/fume/gas/mist/vapours/spray.  
P280: Wear protective gloves/protective clothing/eye protection/protective footwear.  
P501: Dispose of contents/ container in accordance with local/regional/national/international regulation.  
**Additional labeling:**  
Each unit of plasma used in the preparation has been tested and found to be negative for surface antigen of hepatitis B, anti-HCV antibodies and anti-HIV 1 and 2 antibodies.  
No test can prove the absence of HIV virus, hepatitis B virus, Hepatitis C virus or any other infectious agent.
- 2.3 Other hazards:**  
Product does not meet PBT/vPvB criteria  
Endocrine-disrupting properties: The product does not meet the criteria.  
Freeze dried human plasma  
Sodium azide < 0.1%

#### SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

- 3.1 Substance:**  
Non-applicable
- 3.2 Mixture:**  
**Chemical description:** Mixture of substances  
**Components:**  
None of the substances contained in the mixture are above the limits specified in Annex II of Regulation (EC) No 1907/2006

#### SECTION 4: FIRST AID MEASURES

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#### SECTION 4: FIRST AID MEASURES (continued)

##### 4.1 Description of first aid measures:

Consult a doctor in case of discomfort showing the SDS for the product.

##### By inhalation:

In case of symptoms, move the person affected into fresh air.

##### By skin contact:

In case of contact it is recommended to clean the affected area thoroughly with water and neutral soap. In case of changes to the skin (stinging, redness, rashes, blisters,...), seek medical advice with this Safety Data Sheet

##### By eye contact:

Rinse with water until the product has been eliminated. In case of problems, consult a doctor showing the SDS for the product.

##### By ingestion/aspiration:

In case of consumption in large quantities, it is recommended to seek medical assistance.

##### 4.2 Most important symptoms and effects, both acute and delayed:

Acute and delayed effects are indicated in sections 2 and 11.

##### 4.3 Indication of any immediate medical attention and special treatment needed:

Non-applicable

#### SECTION 5: FIREFIGHTING MEASURES

##### 5.1 Extinguishing media:

###### Suitable extinguishing media:

Product is non-flammable, with a low risk of fire due to the flammability characteristics of the product in normal conditions of storage, handling and use. In the case of the existence of sustained combustion as a result of improper handling, storage or use any type of extinguishing agent can be used (ABC Powder, water,...)

###### Unsuitable extinguishing media:

Non-applicable

##### 5.2 Special hazards arising from the substance or mixture:

Due to its non-inflammable nature, the product does not present a fire risk under normal conditions of storage, handling and use.

##### 5.3 Advice for firefighters:

Depending on the magnitude of the fire it may be necessary to use full protective clothing and self-contained breathing apparatus (SCBA). Minimum emergency facilities and equipment should be available (fire blankets, portable first aid kit,...) in accordance with Directive 89/654/EC.

###### Additional provisions:

Act in accordance with the Internal Emergency Plan and the Information Sheets on actions to take after an accident or other emergencies. Eliminate all sources of ignition. In case of fire, cool the storage containers and tanks for products susceptible to combustion, explosion or BLEVE as a result of high temperatures. Avoid spillage of the products used to extinguish the fire into an aqueous medium.

#### SECTION 6: ACCIDENTAL RELEASE MEASURES

##### 6.1 Personal precautions, protective equipment and emergency procedures:

###### For non-emergency personnel:

Isolate leaks provided that there is no additional risk for the people performing this task.

###### For emergency responders:

Wear protective equipment. Keep unprotected persons away. See section 8.

##### 6.2 Environmental precautions:

This product is not classified as hazardous to the environment. Keep product away from drains, surface and ground water.

##### 6.3 Methods and material for containment and cleaning up:

It is recommended:

Sweep up and shovel product or collect by other means and place in container for reuse (preferred) or disposal

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**SECTION 6: ACCIDENTAL RELEASE MEASURES (continued)**

**6.4 Reference to other sections:**

See sections 8 and 13.

**SECTION 7: HANDLING AND STORAGE**

**7.1 Precautions for safe handling:**

A.- General precautions for safe use

Comply with the current legislation concerning the prevention of industrial risks with regards manually handling weights. Maintain order, cleanliness and dispose of using safe methods (section 6).

B.- Technical recommendations for the prevention of fires and explosions

It is recommended to transfer at a slow speed to avoid the creation of electrostatic charges that could affect flammable products. Consult section 10 for conditions and materials that should be avoided.

C.- Technical recommendations on general occupational hygiene

Do not eat or drink during the process, washing hands afterwards with suitable cleaning products.

D.- Technical recommendations to prevent environmental risks

It is not necessary to take special measures to prevent environmental risks. For more information see subsection 6.2

**7.2 Conditions for safe storage, including any incompatibilities:**

A.- Technical measures for storage

Store in a cool, dry, well-ventilated location

B.- General conditions for storage

Avoid sources of heat, radiation, static electricity and contact with food. For additional information see subsection 10.5

**Other information:**

Store at 2-8°C

**7.3 Specific end use(s):**

Handle as if it is capable of transmitting infectious agents

**SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

**8.1 Control parameters:**

Substances whose occupational exposure limits have to be monitored in the workplace (European OEL, not country-specific legislation):

Nuisance dust: Inhalable dust 10 mg/m<sup>3</sup> // Respirable dust 4 mg/m<sup>3</sup>

**8.2 Exposure controls:**

A.- Individual protection measures, such as personal protective equipment

As a preventative measure it is recommended to use basic Personal Protective Equipment, with the corresponding <<CE marking>> in accordance with Regulation (EU) 2016/425. For more information on Personal Protective Equipment (storage, use, cleaning, maintenance, class of protection,...) consult the information leaflet provided by the manufacturer. For more information see subsection 7.1. All information contained herein is a recommendation which needs some specification from the labour risk prevention services as it is not known whether the company has additional measures at its disposal.

B.- Respiratory protection

The use of protection equipment will be necessary if a mist forms or if the occupational exposure limits are exceeded.

C.- Specific protection for the hands

Pictogram	PPE	Labelling	CEN Standard	Remarks
 Mandatory hand protection	Protective gloves against minor risks			Replace gloves in case of any sign of damage. For prolonged periods of exposure to the product for professional users/industrials, we recommend using CE III gloves in line with standards EN ISO 21420:2020 and EN ISO 374-1:2016+A1:2018

As the product is a mixture of several substances, the resistance of the glove material can not be calculated in advance with total reliability and has therefore to be checked prior to the application.

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**SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION (continued)**

D.- Eye and face protection

Pictogram	PPE	Labelling	CEN Standard	Remarks
 Mandatory face protection	Panoramic glasses against splash/projections.		EN 166:2002 EN ISO 4007:2018	Clean daily and disinfect periodically according to the manufacturer's instructions. Use if there is a risk of splashing.

E.- Body protection

Pictogram	PPE	Labelling	CEN Standard	Remarks
	Work clothing			Replace before any evidence of deterioration. For periods of prolonged exposure to the product for professional/industrial users CE III is recommended, in accordance with the regulations in EN ISO 6529:2013, EN ISO 6530:2005, EN ISO 13688:2013, EN 464:1994.
	Anti-slip work shoes		EN ISO 20347:2012	Replace before any evidence of deterioration. For periods of prolonged exposure to the product for professional/industrial users CE III is recommended, in accordance with the regulations in EN ISO 20345:2012 y EN 13832-1:2007

F.- Additional emergency measures

It is not necessary to take additional emergency measures.

**Environmental exposure controls:**

In accordance with the community legislation for the protection of the environment it is recommended to avoid environmental spillage of both the product and its container. For additional information see subsection 7.1.D

**SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**

**9.1 Information on basic physical and chemical properties:**

For complete information see the product datasheet.

**Appearance:**

Physical state at 20 °C:	Solid
Appearance:	Compact
Colour:	Yellowish
Odour:	Not available
Odour threshold:	Non-applicable *

**Volatility:**

Boiling point at atmospheric pressure:	Non-applicable *
Vapour pressure at 20 °C:	Non-applicable *
Vapour pressure at 50 °C:	Non-applicable *
Evaporation rate at 20 °C:	Non-applicable *

**Product description:**

Density at 20 °C:	Non-applicable *
Relative density at 20 °C:	Non-applicable *
Dynamic viscosity at 20 °C:	Non-applicable *
Kinematic viscosity at 20 °C:	Non-applicable *
Kinematic viscosity at 40 °C:	>20,5 mm <sup>2</sup> /s
Concentration:	Non-applicable *
pH:	7,4
Vapour density at 20 °C:	Non-applicable *

\*Not relevant due to the nature of the product, not providing information property of its hazards.

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**SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES (continued)**

Partition coefficient n-octanol/water 20 °C:	Non-applicable *
Solubility in water at 20 °C:	Non-applicable *
Solubility properties:	Non-applicable *
Decomposition temperature:	Non-applicable *
Melting point/freezing point:	Non-applicable *
<b>Flammability:</b>	
Flash Point:	Non-applicable
Flammability (solid, gas):	Non-applicable *
Autoignition temperature:	Non-applicable *
Lower flammability limit:	Non-applicable *
Upper flammability limit:	Non-applicable *
<b>Explosive (Solid):</b>	
Lower explosive limit:	Non-applicable *
Upper explosive limit:	Non-applicable *
<b>Particle characteristics:</b>	
Median equivalent diameter:	Non-applicable *

**9.2 Other information:**

**Information with regard to physical hazard classes:**

Explosive properties:	Non-applicable *
Oxidising properties:	Non-applicable *
Corrosive to metals:	Non-applicable *
Heat of combustion:	Non-applicable *
Aerosols-total percentage (by mass) of flammable components:	Non-applicable *

**Other safety characteristics:**

Surface tension at 20 °C:	Non-applicable *
Refraction index:	Non-applicable *

\*Not relevant due to the nature of the product, not providing information property of its hazards.

**SECTION 10: STABILITY AND REACTIVITY**

**10.1 Reactivity:**

No hazardous reactions are expected because the product is stable under recommended storage conditions. See section 7 from Safety Data Sheet.

**10.2 Chemical stability:**

Chemically stable under the indicated conditions of storage, handling and use.

**10.3 Possibility of hazardous reactions:**

Under the specified conditions, hazardous reactions that lead to excessive temperatures or pressure are not expected.

**10.4 Conditions to avoid:**

Applicable for handling and storage at room temperature:

Shock and friction	Contact with air	Increase in temperature	Sunlight	Humidity
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable

**10.5 Incompatible materials:**

Acids	Water	Oxidising materials	Combustible materials	Others
Avoid strong acids	Not applicable	Not applicable	Not applicable	Avoid alkalis or strong bases

**10.6 Hazardous decomposition products:**

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#### SECTION 10: STABILITY AND REACTIVITY (continued)

See subsection 10.3, 10.4 and 10.5 to find out the specific decomposition products. Depending on the decomposition conditions, complex mixtures of chemical substances can be released: carbon dioxide (CO<sub>2</sub>), carbon monoxide and other organic compounds.

#### SECTION 11: TOXICOLOGICAL INFORMATION

##### 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008:

LD50 oral > 2000 mg/kg (rat)

##### Dangerous health implications:

In case of exposure that is repetitive, prolonged or at concentrations higher than the recommended occupational exposure limits, adverse effects on health may result, depending on the means of exposure:

A- Ingestion (acute effect):

- Acute toxicity: Based on available data, the classification criteria are not met
- Corrosivity/Irritability: Based on available data, the classification criteria are not met

B- Inhalation (acute effect):

- Acute toxicity : Based on available data, the classification criteria are not met
- Corrosivity/Irritability: Based on available data, the classification criteria are not met

C- Contact with the skin and the eyes (acute effect):

- Contact with the skin: Based on available data, the classification criteria are not met
- Contact with the eyes: Based on available data, the classification criteria are not met

D- CMR effects (carcinogenicity, mutagenicity and toxicity to reproduction):

- Carcinogenicity: Based on available data, the classification criteria are not met  
IARC: Non-applicable
- Mutagenicity: Based on available data, the classification criteria are not met
- Reproductive toxicity: Based on available data, the classification criteria are not met

E- Sensitizing effects:

- Respiratory: Based on available data, the classification criteria are not met
- Skin: Based on available data, the classification criteria are not met

F- Specific target organ toxicity (STOT) - single exposure:

Based on available data, the classification criteria are not met

G- Specific target organ toxicity (STOT)-repeated exposure:

- Specific target organ toxicity (STOT)-repeated exposure: Based on available data, the classification criteria are not met
- Skin: Based on available data, the classification criteria are not met

H- Aspiration hazard:

Based on available data, the classification criteria are not met

##### Other information:

Non-applicable

##### Specific toxicology information on the substances:

Not available

##### 11.2 Information on other hazards:

##### Endocrine disrupting properties

Endocrine-disrupting properties: The product does not meet the criteria.

##### Other information

Non-applicable

#### SECTION 12: ECOLOGICAL INFORMATION

The experimental information related to the eco-toxicological properties of the product itself is not available

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#### SECTION 12: ECOLOGICAL INFORMATION (continued)

Based on available data, the classification criteria are not met

**12.1 Toxicity:**

Not available

**12.2 Persistence and degradability:**

Not available

**12.3 Bioaccumulative potential:**

Not available

**12.4 Mobility in soil:**

Not available

**12.5 Results of PBT and vPvB assessment:**

Product does not meet PBT/vPvB criteria

**12.6 Endocrine disrupting properties:**

Endocrine-disrupting properties: The product does not meet the criteria.

**12.7 Other adverse effects:**

Not described

#### SECTION 13: DISPOSAL CONSIDERATIONS

**13.1 Waste treatment methods:**

Code	Description	Waste class (Regulation (EU) No 1357/2014)
16 05 09	discarded chemicals other than those mentioned in 16 05 06, 16 05 07 or 16 05 08	Non dangerous

**Type of waste (Regulation (EU) No 1357/2014):**

Non-applicable

**Waste management (disposal and evaluation):**

Consult the authorized waste service manager on the assessment and disposal operations in accordance with Annex 1 and Annex 2 (Directive 2008/98/EC). As under 15 01 (2014/955/EC) of the code and in case the container has been in direct contact with the product, it will be processed the same way as the actual product. Otherwise, it will be processed as non-dangerous residue. Waste should not be disposed of to drains. See paragraph 6.2.

**Regulations related to waste management:**

In accordance with Annex II of Regulation (EC) No 1907/2006 (REACH) the community or state provisions related to waste management are stated

Community legislation: Directive 2008/98/EC, 2014/955/EU, Regulation (EU) No 1357/2014

#### SECTION 14: TRANSPORT INFORMATION

This product is not regulated for transport (ADR/RID,IMDG,IATA)

#### SECTION 15: REGULATORY INFORMATION

**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture:**

Candidate substances for authorisation under the Regulation (EC) No 1907/2006 (REACH): Non-applicable

Substances included in Annex XIV of REACH ("Authorisation List") and sunset date: Non-applicable

Regulation (EC) No 1005/2009, about substances that deplete the ozone layer: Non-applicable

Article 95, REGULATION (EU) No 528/2012: Non-applicable

REGULATION (EU) No 649/2012, in relation to the import and export of hazardous chemical products: Non-applicable

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#### SECTION 15: REGULATORY INFORMATION (continued)

Non-applicable

**Limitations to commercialisation and the use of certain dangerous substances and mixtures (Annex XVII REACH, etc ....)**

:

Non-applicable

**Specific provisions in terms of protecting people or the environment:**

It is recommended to use the information included in this safety data sheet as a basis for conducting workplace-specific risk assessments in order to establish the necessary risk prevention measures for the handling, use, storage and disposal of this product.

**Other legislation:**

The product could be affected by sectorial legislation

**Other information:**

18 01 03, wastes whose collection and disposal is subject to special requirements in order to prevent infection.  
Dispose of product and containers in accordance with national or regional regulations

#### 15.2 Chemical safety assessment:

The supplier has not carried out evaluation of chemical safety.

#### SECTION 16: OTHER INFORMATION

**Legislation related to safety data sheets:**

The SDS shall be supplied in an official language of the country where the product is placed on the market. This safety data sheet has been designed in accordance with ANNEX II-Guide to the compilation of safety data sheets of Regulation (EC) No 1907/2006 (COMMISSION REGULATION (EU) 2020/878).

**Modifications related to the previous Safety Data Sheet which concerns the ways of managing risks.:**

Non-applicable

**Texts of the legislative phrases mentioned in section 3:**

The phrases indicated do not refer to the product itself; they are present merely for informative purposes and refer to the individual components which appear in section 3

**CLP Regulation (EC) No 1272/2008:**

Non-applicable

**Classification procedure:**

Non-applicable

**Advice related to training:**

Training is recommended in order to prevent industrial risks for staff using this product and to facilitate their comprehension and interpretation of this safety data sheet, as well as the label on the product.

**Principal bibliographical sources:**

<http://echa.europa.eu>

<http://eur-lex.europa.eu>

**Abbreviations and acronyms:**

ADR: European agreement concerning the international carriage of dangerous goods by road

IMDG: International maritime dangerous goods code

IATA: International Air Transport Association

ICAO: International Civil Aviation Organisation

COD: Chemical Oxygen Demand

BOD5: 5day biochemical oxygen demand

BCF: Bioconcentration factor

LD50: Lethal Dose 50

LC50: Lethal Concentration 50

EC50: Effective concentration 50

LogPOW: Octanolwater partition coefficient

Koc: Partition coefficient of organic carbon

UFI: unique formula identifier

IARC: International Agency for Research on Cancer

The information contained in this safety data sheet is based on sources, technical knowledge and current legislation at European and state level, without being able to guarantee its accuracy. This information cannot be considered a guarantee of the properties of the product, it is simply a description of the security requirements. The occupational methodology and conditions for users of this product are not within our awareness or control, and it is ultimately the responsibility of the user to take the necessary measures to obtain the legal requirements concerning the manipulation, storage, use and disposal of chemical products. The information on this safety data sheet only refers to this product, which should not be used for needs other than those specified.

- END OF SAFETY DATA SHEET -