



Material Safety Data Sheet

1. Product Identification

1.1. Identification of the product:

Product Name: Factor IX Deficient Plasma
Product Nos.: ADG269
Configuration: 1 x 1 ml, lyophilized
Use of Substance: For Research use only

1.2. Manufacturer:

American Diagnostica GmbH
Kaplaneigasse 35
D-64319 Pfungstadt
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1.3 Date of last revision: 17.02.2014

1.4 Changed information

2. Possible Hazards

The single components do not contain hazardous substances above the limit as per REACH – Regulation 1907/2006/EC and do thus not need special labelling.

The product is of human blood/plasma origin. The source material was screened for CJD and has been found to be non-reactive for Hepatitis B Surface Antigen (HBsAg), Hepatitis C Virus (HCV), RPR (syphilis) 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 blood 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.

3. Composition and Information on Ingredients

Chemical name:	Human Source plasma
Hazards identification:	Products derived from human plasma are potentially biohazardous material. Handle with caution as if capable of transmitting infectious agents.
CAS no.:	not applicable
LD50 (species and route):	not applicable
LC50 (species and route):	not applicable

4. First-aid Measures

Eye and Skin contact:

In case of contact, please wash them under flowing water for at least 15 minutes and possibly consult a doctor. Change contaminated clothing and shoes.

After inhalation:

Not available.

After swallowing:

After swallowing, rinse the mouth with adequate amount of water, and notify medical personal.

5. Fire-fighting Measures

Flammability:

Solutions are non-flammable. Boxing, instruction papers and powdered reagents are flammable.

Extinguishing Media:

Use extinguishing media appropriate to the surrounding fire conditions.

Fire Fighting Instructions:

Wear self-contained breathing apparatus and protective clothing

6. Accidental Release Measures

Personal Precautions:

Wear protective equipment.

Procedure to be followed in case of leak or spill:

Wear protective equipment. Collect or absorb onto an inert material. Place in suitable container for prompt disposal. Label the container as to the potential hazard (viral). Spill areas can be decontaminated with 0.5% sodium hypochlorite, e.g. a 1:10 dilution of common household bleach, i.e., Chlorox, which is prepared fresh each month.

7. Handling and Storage

Handling:

Wear gloves. Avoid inhalation. Avoid contact with eyes, skin and clothing. Keep container closed when not in use.

Storage:

The product is stable until the expiration date stated on its labeling when stored at 2°-8°C (lyophilized product) or -20 °C or lower (frozen product).

Hygienic Practice:

Wash hands with soap and water following use.

8. Exposure Controls and Personal Protection

Exposure Limits:

The product does not contain dangerous substances.

Breathing mask:

It is not necessary to wear a mask for respiratory protection.

Gloves:

To prevent skin contact, disposable gloves in accordance with DIN EN 455 shall be worn. (Use powder free gloves to avoid allergic reactions.)

Safety glasses:

Wear safety glasses (or full face-shield) depending on risk of splashes.

Lab clothing:

To prevent skin and body contact, wear laboratory clothing.

General Hygiene Practices:

Wash promptly if skin comes into contact with product. Wash thoroughly after handling. Remove any clothing that comes into contact with the product. Do not smoke or eat in the work environment.

9. Physical and Chemical Properties**Physical state:**

Frozen: Should be in frozen state until use. Thaw to liquid prior to use.

Lyophilized: Solid. Should be reconstituted prior to use.

Odour & appearance:

Frozen: Yellowish, translucent.

Lyophilized: Pale yellow

10. Stability and Reactivity**Conditions under which the product is chemically unstable:**

Product is stable

Incompatibilities:

None known

Conditions of reactivity:

None known

Hazardous decomposition products:

None known

11. Toxicological Information**Route of entry:**

Include skin absorption, inhalation and ingestion

Effects of acute exposure to product:

May cause irritation. Potential viral infection. Although this material was prepared with plasma collected from donors screened for CJD and which was tested at source and found negative for HBsAg, RPR (syphilis) and antibodies to HIV and HCV and non-reactive for HIV-1 RNA and HCV RNA by registered tests, it should be handled by personnel trained in the proper procedures for handling potential viral contaminants.

Effects of chronic exposure to product:

The chemical, physical and toxicological properties have not been thoroughly investigated

Irritancy of product:

see above

12. Ecological Information

No data available.

13. Disposal Considerations**Waste disposal:**

Autoclave at 121 °C or higher for 40 minutes or longer. Label the container with the hazard that was present. Dispose of by means that comply with all local, regional and national regulations.

14. Transportation Information

Special shipping information:

Frozen: Ship frozen on dry ice.

Lyophilized: Ship at ambient or 2-8°C.

15. Regulatory Information

This product has been classified in accordance with the hazard criteria of the *Controlled Products Regulations* and the MSDS contains all the information required by the *Controlled Products Regulations*.

16. Other information

For Research use only.

The information compiled and given above is to the best of our knowledge correct, but does not purport to be all inclusive and should only be understood by the user as a set of guidelines. These data do not represent a guarantee of product properties and do not constitute a legal contract. The products should be handled by qualified and experienced professionals only.

American Diagnostica GmbH rejects all liability for consequential, special or indirect damage resulting from the handling, storage or use of this product We refer to our general terms of trade.

This Material Safety Data Sheet corresponds to the REACH regulation EC No. 1907/2006.