

MATERIAL SAFETY DATA SHEET
 According to 1907/2006/EG

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

- 1.1 Product name / Code: Protein C Deficient plasma, immunads. (2 x 1 mL) REF 5346806
 Factor II Deficient plasma, immunads. (5 x 1 mL) REF 5114008
 Factor V Deficient plasma, immunads. (5 x 1 mL) REF 5134004
 Factor VII Deficient plasma, immunads. (5 x 1 mL) REF 5144015
 Factor VIII Deficient plasma, immunads. (5 x 1 mL) REF 5154002
 Factor VIII Deficient plasma, immunads. (50 x 1 mL) REF 5154004
 Factor IX Deficient plasma, immunads. (5 x 1 mL) REF 5164003
 Factor X Deficient plasma, native (5 x 1 mL) REF 5174004
 Factor XI Deficient plasma, native (5 x 1 mL) REF 5184004
 Factor XII Deficient plasma, native (5 x 1 mL) REF 5194008
 Faktor XIII Deficient plasma, immunads. (5 x 1 mL) REF 5194104
 Fletcher Trait Plasma, native (2 x 1 mL) REF 5205006
 Fitzgerald Trait Plasma, immunads. (2 x 1 mL) REF 5204006
 Lupus Inhibitor Plasma (2 x 1 mL) REF 5343010
 Lupus Inhibitor Plasma (2 x 1 mL) REF 5343010
- 1.2. Recommended use: In-vitro diagnostic
- 1.3. Manufacturer: Technoclone GmbH
 Brunner Str. 59/5
 1230 Vienna
 AUSTRIA
 Tel. + 43 1 86373 - 0
 Fax + 43 1 86373 - 44
- 1.4 Emergency Email: sales@technoclone.com
- 1.5 Emergency Phone: +43 1 86373 -10 (08:00 – 16:00 h)

2. HAZARDS IDENTIFICATION

- 2.1 Emergency overview: General rules for handling biological material have to be followed
- 2.2 Health hazard: Health hazard upon ingestion
 Presents little hazard if spilled or in fire

3. COMPOSITION, INFORMATION ON INGREDIENTS

Each package contains different amounts of vial 1 (see 1. product identification)

All vials contain human plasma.

Hazard classification: None

CAS No: None

MATERIAL SAFETY DATA SHEET
 According to 1907/2006/EG

4. FIRST AID MEASURES

- | | | |
|-----|---------------|---|
| 4.1 | General: | Miscible with water |
| 4.2 | Eyes: | Flush eyes with water, if persistent irritation occurs, seek medical advice |
| 4.3 | Skin contact: | Wash with water, and wipe with skin disinfectant |
| 4.4 | Ingestion: | Drink water, seek medical advice |

5. FIRE-FIGHTING MEASURES

- | | | |
|-----|-----------------------|-----------------|
| 5.1 | Extinguishing media: | No limitation |
| 5.2 | Flammable properties: | Not combustible |

6. ACCIDENTAL RELEASE MEASURES

- | | | |
|-----|-----------------------|--|
| 6.1 | Personal precautions: | Wear gloves, avoid substance contact |
| 6.2 | Cleanup procedures: | Take up dry and discard according to the rules for biological material |

7. HANDLING AND STORAGE

- | | | |
|-----|-----------------------|------------------------|
| 7.1 | Handling precautions: | No special precautions |
| 7.2 | Storage: | Store at +2 – 8 °C |

8. EXPOSURE CONTROLS, PERSONAL PROTECTION

- | | | |
|-----|---|---|
| 8.1 | General protective and hygienic measures: | The usual precautionary measures are to be adhered to when handling biological material. |
| 8.2 | Eye protection: | Eye protection is recommended. |
| 8.3 | Protection of hands: | The glove material has to be impermeable and resistant to the product/the substance/the preparation. |
| | Material of gloves: | Due to missing tests no recommendation to the glove material can be given for the product/the preparation/the chemical mixture |
| | Penetration time of glove material: | The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application |
| | | The exact break trough time has to be found out by the manufacturer of the protective gloves and has to be observed. |
| 8.4 | Ventilation: | No particular ventilation requirements. |
| 8.5 | Protective clothing: | Protective clothing is not necessary. |

MATERIAL SAFETY DATA SHEET
According to 1907/2006/EG

9. PHYSICAL AND CHEMICAL PROPERTIES

| | | |
|-----|-------------|---------------------|
| 9.1 | Appearance: | Solid |
| 9.2 | Colour: | Colourless |
| 9.3 | Odour: | Odourless |
| 9.4 | Solubility: | Miscible with water |
| 9.5 | Viscosity: | No data available |
| 9.6 | pH-value: | No data available |

10. STABILITY AND REACTIVITY

| | | |
|------|-----------------------------------|---------------------------------|
| 10.1 | Hazardous reactions: | None known if handled correctly |
| 10.2 | Hazardous decomposition products: | None |

11. TOXICOLOGICAL INFORMATION

| | | |
|------|------------------------------------|--|
| 11.1 | Acute toxicity: | Not known |
| 11.2 | Skin effects: | Not known |
| 11.3 | Eye effects: | Not known |
| 11.4 | Further toxicological information: | No cases of intoxication known so far. |

Human Plasma used for production of control plasma is derived exclusively from donors who have been tested negative for antibodies against HIV, HCV and HBs antigen using approved test procedures. Nevertheless human plasma should be considered as potentially infectious and handled with care.

12. ECOLOGICAL INFORMATION

| | | |
|------|----------|--|
| 12.1 | Summary: | This product is readily miscible with water, rapidly degraded and biodegradable. |
|------|----------|--|

13. DISPOSAL CONSIDERATIONS

| | | |
|------|----------------------|---|
| 13.1 | General information: | Disposal should be made in accordance with existing local disposal practices for biological material. |
|------|----------------------|---|

14. TRANSPORT INFORMATION

| | | |
|------|----------------------|--|
| 14.1 | General information: | Not subject to transport regulations Fragile containers, handle with care |
|------|----------------------|--|

MATERIAL SAFETY DATA SHEET
According to 1907/2006/EG

15. REGULATORY INFORMATION

- 15.1 Safety rules: This product is not in accordance with danger material regulation and the appropriate European Union guidelines marking requiring. Keep Containers closed. Keep away from food and beverages. Avoid contact with the skin.

16. OTHER INFORMATION

This Safety Data Sheet complies with the European Community Directive 1907/2006/EG.

All information and instructions provided in this Safety Data Sheet are based on the current state of scientific and technical knowledge a the date indicated on this Safety Data Sheet. Technoclone GmbH shall not be held responsible for any defect in the product covered by this Safety Data Sheet, should the existence of such a defect not be detectable considering the current state of scientific and technical knowledge.

It characterizes the product with regard to the appropriate safety precautions. It does not represent a guarantee of the properties of the product.