SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Factor VIII Deficient plasma, native (5 x 1 mL)  REF 5154007
Factor VIII Deficient plasma, native (50 x 1 mL) REF 5154016
Factor VIII Inhibitor Plasma (5 x 1 mL)  REF 5159008
Factor X Deficient plasma, native (5 x 1 mL)  REF 5174004
Factor IX Deficient plasma, native (5 x 1 mL)  REF 5164008
Factor IX Deficient plasma, native (50 x 1 mL)  REF 5164016

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

Identified use: For in vitro diagnostic use

1.3. Details of the supplier of the safety data sheet

Technoclone Herstellung von Diagnostika und Arzneimitteln Gesellschaft mbH
Brunner Str. 67
1230 Wien
Österreich
Tel. +43 1 86373-0
Fax +43 1 86373-44
Email (competent person): products@technoclone.com

1.4 Emergency telephone number: +43 1 86373-10 (8:00 – 16:00)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

No hazardous product according to 1907/2006/EC and 1272/2008/EC

2.2. Label elements

not applicable

2.3. Other hazards

These products contain human plasma that tested non-reactive for HIV antibody and Hepatitis B Surface Antigen.

But as donors can be positive for HCV and thus HCV antibodies may be present these products have to be handled as infectious material with the corresponding laboratory safety procedures for handling infectious material.

This mixture does not contain any components in concentrations of 0.1 % or above, which are classified either as PBT or vPvB.
SECTION 3: Composition/Information on ingredients

3.2. Mixtures
There are no components to declare according to the applicable regulations.

SECTION 4: First aid measures

4.1. Description of first aid measures

General
Remove contaminated clothes

Contact with eyes
Wash immediately with plenty of water or normal saline for at least 15 minutes. Keep eye lid open with the finger.

Contact with skin
Wash immediately affected area with soap or mild detergent and plenty of water until removal of the mixture (15 to 20 minutes).

Ingestion
If swallowed rinse mouth with plenty of water provided person is conscious. Do not induce vomiting. Get medical advice if adverse symptoms appear.

4.2. Most important symptoms and effects, both acute and delayed
Toxic symptoms and effects are not known.

4.3. Indication of any immediate medical attention and special treatment needed
Seek medical advice if HCV positive plasma enters the blood stream in case of injury.

SECTION 5: Firefighting measures

5.1. Extinguishing media
suitable extinguishing media: water spray or regular foam, CO₂, dry powder
unsuitable extinguishing media: not known

5.2 Special hazards arising from the substance or mixture
Thermal decomposition or combustion may generate toxic and hazardous fumes of COx, NOx.

5.3. Advice for fire fighters
Protective actions:
Water jets can be used successfully to cool containers exposed to the fire and disperse fumes.

Equipment for self-protection:
Breathing apparatus (SCBA), flame and chemical resistant clothing (boots, gloves, overalls, eye and face protection). Equipment must be conformed to the national/international standards and used in highest condition of protection on the basis of the information reported in the previous sub-sections.
SECTION 6: Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Wear gloves and avoid contact with the substance or mixture.

6.2. Environmental precautions

Do not let the product enter drainage system.

6.3. Methods and material for containment and cleaning up

Collect spilled powder or dissolved product with inert absorbent material and clean with plenty of water.

Discard spilled material according to standard regulations.

6.4. Reference to other sections

Use personal protection equipment as described in Section 8 and dispose waste according to instructions given in Section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Handle in a well ventilated place, and away from sparkles and flames. Keep the mixture away from drains, surface or ground waters. Wear suitable Personal Protection Equipment (see section 8). Do not eat, drink and smoke in the working areas. Wash hands with soap and water after handling the mixture. Remove contaminated clothing and protective equipment before entering eating areas.

7.2 Conditions for safe storage, including any incompatibilities

Recommended temperature: store at 2 to 8°C

Avoid light exposure and keep away from heat sources. Work in a well ventilated workplace. Keep containers tightly closed and labelled with the name of the product. Avoid environmental release. Keep away from food and drinks.

7.3. Specific end use(s)

The product is intended for in-vitro diagnostic use. Read and understand safety notes as given in the package insert. Use the product in accordance with the Good Laboratory Practice (GLP).

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Workplace exposure limit values are not established.

8.2. Exposure Control

8.2.1. Appropriate engineering controls

Appropriate risk management measures, that must be adopted at the workplace, have to be selected and applied, following the risks assessment carried out by the employer, in connection with his working activity. If the results of this evaluation show that the general and collective prevention measures are not sufficient to reduce the risk, and if you cannot prevent exposure to the mixture by other measures, adequate personal protective equipments must be adopted, complying with relevant technical national/international standards.

8.2.2. Individual protection measures, such as Personal Protective Equipment (PPE)

a) General protective and hygienic measures:
The usual precautionary measures are to be adhered to when handling chemicals or biological material.
b) Eye/face protection: Use of safety glasses is recommended.
c) Skin protection:
   i) protection of hands
   The glove material has to be impermeable and resistant to the product/the substance/the mixture. Due to missing tests no recommendation on the glove material can be given for the product/the substance/the mixture. Choose glove material with respect to penetration time, permeation rates and degradation. The selection of the suitable gloves does not only depend on the material, but also on further quality features and varies between manufacturers. 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. Information about the exact penetration time should be received from the manufacturer of the protective gloves and has to be observed.
   ii) other protective measures: not required

d) Respiratory protection: Respiratory protection not required.
e) Thermal hazards: No information available.
f) Environmental exposure controls: Avoid release into the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties
   Appearance: white- yellowish powder
   Odor: odourless
   pH: pH 6-8
   Density: not applicable
   Solubility: readily soluble in water

9.2. Other information
   No further information available.

SECTION 10: Stability and Reactivity

10.1. Reactivity
   The product is considered not reactive under normal conditions of usage.

10.2. Chemical Stability
   The product is stable until the expiry date shown on the package or the label when stored at the temperature indicated.

10.3. Possibility of hazardous reactions
   No hazardous reactions foreseen under normal conditions of storage and use.

10.4. Conditions to avoid
   Keep out from heat, water, humidity or light.

10.5. Incompatible materials
   Oxidizing agents, strong acid agents and strong alkaline agents.

10.6. Hazardous decomposition products
   Thermal decomposition or combustion may include toxic and hazardous fumes of (COx, NOx).
SECTION 11: Toxicological information

11.1 Information on toxicological effects

<table>
<thead>
<tr>
<th>Effect</th>
<th>Data Availability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute toxicity</td>
<td>No data available</td>
</tr>
<tr>
<td>Skin corrosion/irritation</td>
<td>Prolonged and repeated contact may cause skin irritations.</td>
</tr>
<tr>
<td>Serious eye damage/irritation</td>
<td>May cause eye irritation</td>
</tr>
<tr>
<td>Skin and respiratory sensitization</td>
<td></td>
</tr>
<tr>
<td>Germ cell mutagenicity</td>
<td>No data available</td>
</tr>
<tr>
<td>Carcinogenesis</td>
<td>No data available</td>
</tr>
<tr>
<td>Reproductive toxicity</td>
<td>No data available</td>
</tr>
<tr>
<td>Specific target organ toxicity (STOT)-single exposure</td>
<td>No data available.</td>
</tr>
<tr>
<td>Specific target organ toxicity (STOT)-repeated exposure</td>
<td>No data available.</td>
</tr>
<tr>
<td>Aspiration hazards</td>
<td>No data available</td>
</tr>
</tbody>
</table>

Reasons for the lack of classification:
Where the mixture resulted in a non-classification, this may be due to the availability of data which does not impose a classification for that specific end-point, or due to lack of data or due to availability of inconclusive data or data which are not sufficient to get a classification as for the criteria adopted in regulations mentioned in this data sheet.

SECTION 12: Ecological information

12.1. Toxicity                               No data available
12.2. Persistency and degradability         No data available.
12.3. Bioaccumulation potential             No data available
12.4. Mobility in soil                      No data available
12.5. Results of PBT and vPvB assessment    not applicable
12.6. Other toxic effects                   No data available

SECTION 13: Disposal considerations

National laws on disposal must be considered, local and EU requirements for waste recycling must be respected.

13.1 Waste treatment methods

Used waste product, surplus product or spillage products shall be disposed of in accordance with national state and local laws.

SECTION 14: Transport information

The product is not subject to transport regulations according to ADR/RID, IMDG, IATA and DOT.

SECTION 15: Regulatory Information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture
The contained information in this MSDS is in accordance with Annex II of regulation no. 1907/2006 (REACH) and in accordance with ANSI “Standard for Hazardous Industrial Chemicals – Material Safety Sheets – Preparation” (ANSI Z400.1-2004) as recommended by US OSHA.

The product/components are not subject to regulation 93/21/EEC about transport and labeling dangerous substances.

15.2. Chemical safety assessment

Chemical safety assessment for this product/mixture is not necessary according to EC 1907/2006 article 14 paragraph 2.

SECTION 16: Other information

Revisions:
General revision according to regulation (EC) 2015/830

Abbreviations and Acronyms:

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>SDS</td>
<td>Safety Data Sheet</td>
</tr>
<tr>
<td>PBT</td>
<td>Persistence, Bioaccumulation, Toxicity</td>
</tr>
<tr>
<td>vPvB</td>
<td>Very persistent and very bioaccumulative</td>
</tr>
<tr>
<td>STOT</td>
<td>Specific target organ toxicity</td>
</tr>
<tr>
<td>SCBA</td>
<td>Self-contained breathing apparatus</td>
</tr>
<tr>
<td>ADR</td>
<td>Agreement concerning the carriage of dangerous goods by road</td>
</tr>
<tr>
<td>RID</td>
<td>Regulation concerning the international carriage of dangerous goods by rail</td>
</tr>
<tr>
<td>IMDG</td>
<td>International Maritime Dangerous Goods code</td>
</tr>
<tr>
<td>IATA</td>
<td>International air transport organization</td>
</tr>
<tr>
<td>DOT</td>
<td>US Department of Transportation</td>
</tr>
<tr>
<td>ANSI</td>
<td>American National Standards Institute</td>
</tr>
<tr>
<td>OSHA</td>
<td>Occupational Safety &amp; Health Administration (US)</td>
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<tr>
<td>HBsAG</td>
<td>Hepatitis Virus B surface antigen</td>
</tr>
<tr>
<td>HCV</td>
<td>Hepatitis C Virus</td>
</tr>
<tr>
<td>HIV</td>
<td>Human Immunodeficiency Virus</td>
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</tbody>
</table>

All information and instructions provided in this Safety Data Sheet are based on the current state of scientific and technical knowledge at the date indicated on this Safety Data Sheet. Technoclon 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.