

Safety Data Sheet

TECO

In accordance with 1907/2006/EG annex II, 1272/2008 and 2020/878

(All references to EU Regulations and directives are abbreviated into only the numeric term)

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

1.1. Product identifier

Trade name	Factor IX Deficient Plasma
Article number	P5401-010

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

Identified uses	For professional users only
Uses Advised Against	Not known

1.3. Details of the supplier of the safety data sheet

Company	TECO Medical Instruments Production + Trading GmbH Dieselstr. 1, 84088 Neufahrn i.NB, Germany
Telephone	+49 8773 707 80-0
E-mail	info@teco-gmbh.com

1.4. Emergency telephone number

Poisoning emergency number Munich: 089 19240 or 112.

2. SECTION: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No. 1272/2008 (CLP) Not classified as dangerous for supply/use.

2.2. Label elements

	According to Regulation (EC) No. 1272/2008 (CLP)
Product Name	Factor IX Deficient Plasma
Hazard Pictogram(s)	None.

2.3. Other hazards

None known.

2.4 Additional Information

Contains human derived material-potentially biohazardous

3. SECTION: Composition/information on ingredients

3.1. Substance

Not applicable.

3.2. Mixtures

Product does not contain any hazardous ingredients.

4. SECTION: First aid measures

4.1. Description of first aid measures

Inhalation	If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.
Skin Contact	Wash skin with water
Eye Contact	Flush eyes with water for at least 15 minutes.
Ingestion	Wash out mouth with water.

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4.2. Most important symptoms and effects, both acute and delayed

None anticipated. Treat symptomatically.

4.3. Indication of any immediate medical attention and special treatment needed

Unlikely to be required but if necessary treat symptomatically.

5. SECTION: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media: As appropriate for surrounding fire.

Unsuitable extinguishing media: None.

5.2. Special hazards arising from the substance or mixture

None anticipated. Heating may cause decomposition.

5.3. Advice for firefighters

As appropriate for surrounding fire.

6. SECTION: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Provide adequate ventilation. Wear suitable gloves if prolonged skin contact is likely.

6.2. Environmental precautions

Do not release large quantities into the surface water or into drains.

6.3. Methods and material for containment and cleaning up

Sweep spilled substances into containers if appropriate moisten first to prevent dusting.

6.4. References to other sections

See also Section 8, 13.

7. SECTION: Handling and storage

7.1. Precautions for safe handling

Not known.

7.2. Conditions for safe storage, including any incompatibilities

Storage temperature: +2 to +8°C

Storage life: Stable under normal conditions.

Incompatible materials: None known.

7.3. Specific end use(s)

In vitro diagnostic use.

8. SECTION: Exposure controls/personal protection

8.1. Control parameters

8.1.1 Occupational Exposure Limits

No Occupational Exposure Limit assigned.

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Ensure adequate ventilation.

8.2.2. Individual protective measures, such as personal protective equipment (PPE)

Eye protection

Wear eye protection with side protection (EN166).

Skin protection

Gloves recommended

Respiratory protection

Normally no personal respiratory protection is necessary.

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Thermal hazards

None known.

8.2.3. Environmental exposure controls

Do not release large quantities into the surface water or into drains.

9. SECTION: Physical and chemical properties

9.1. Information on basic physical and chemical properties

(a) Physical state	solid Form: lyophilised powder
(b) Colour	White-yellowish
(c) Odour	Odourless
(d) Melting point/freezing point	Not known
(e) Boiling point or initial boiling point and boiling range	Not applicable
(f) Flammability	Not known
(g) Lower and upper explosion limit	Not known
(h) Flash point	Not applicable
(i) Auto-ignition temperature	Not known
(j) Decomposition temperature	Not known
(k) pH	Not known
(l) Kinematic viscosity	Not known
(m) Solubility	Solubility (water): readily miscible Solubility (Other): Not known
(n) Partition coefficient: n-octanol/water (log value)	Not known
(o) Vapour pressure	Not known
(p) Density and/or relative density	Not known
(q) Relative vapour density	Not known
(r) Particle characteristics	Not known

9.2. Other information

None.

10. SECTION: Stability and reactivity

10.1. Reactivity

None anticipated.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No hazardous reactions known if used for its intended purpose.

10.4. Conditions to avoid

None anticipated.

10.5. Incompatible materials

Not known.

10.6. Hazardous decomposition products

No hazardous decomposition products known.

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11. SECTION: Toxicological information

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

Acute toxicity- Ingestion	Low acute toxicity
Acute toxicity- Skin contact	Low acute toxicity
Acute toxicity- Inhalation	Low acute toxicity
Skin corrosion/irritation	Non-irritant
Serious eye damage/irritation	Non-irritant
Skin sensitization data	Not classified
Respiratory sensitization data	Not classified
Germ cell mutagenicity	There is no evidence of mutagenic potential
Carcinogenicity	No evidence of carcinogenicity
Reproductive toxicity	Not classified
Lactation	Not classified
STOT-single exposure	Not classified
STOT-repeated exposure	Not classified
Aspiration hazard	Not classified

11.2. Information on other hazard

Not known

12. SECTION: Ecological information

12.1. Toxicity

Toxicity-Aquatic invertebrates	Low toxicity to invertebrates.
Toxicity-Fish	Low toxicity to fish
Toxicity-Algae	Low toxicity to algae
Toxicity - Sediment Compartment	Not classified
Toxicity - Terrestrial Compartment	Not classified

12.2. Persistence and degradability

Not known.

12.3. Bioaccumulative potential

Not known.

12.4. Mobility in soil

Not known.

12.5. Results of PBT and vPvB assessment

Not known.

12.6. Endocrine disrupting properties

None known.

12.7. Other adverse effects

Not known.

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13. SECTION: Disposal considerations

13.1. Waste treatment methods

Dispose at suitable refuse site.

13.2. Additional Information

No special precautions are required for this product.

14. SECTION: Transport information

Not classified as hazardous for transport.

14.1. UN number or ID number

Not applicable

14.2 UN proper shipping name

Not applicable

14.3 Transport hazard class(es)

Not applicable

14.4 Packing group

Not applicable

14.5 Environmental hazards

Not classified as a Marine Pollutant.

14.6 Special precautions for user

Not known

14.7 Maritime transport in bulk according to IMO instruments

Not known.

15. SECTION: Regulatory information

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

European Regulations - Authorisations and/or Restrictions on Use

Candidate List of Substances of Very High Concern for Authorisation	Not listed
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REACH: ANNEX XIV list of substances subject to authorisation	Not listed
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REACH: Annex XVII Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles	Not listed
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Community Rolling Action Plan (CoRAP)	Not listed
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Regulation (EC) N° 850/2004 of the European Parliament and of the Council on persistent organic pollutants	Not listed
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Regulation (EC) N° 1005/2009 on substances that deplete the ozone layer	Not listed
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Regulation (EU) N° 649/2012 of the European Parliament and of the Council concerning the export and import of hazardous chemicals	Not listed
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National regulations

Other	Not known
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15.2. Chemical safety assessment

A REACH chemical safety assessment has not been carried out.

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16. SECTION: Other information

16a. Indication of where changes have been made to the previous version of the safety data sheet

Revisions of this document

This is Revision 3 of this document.

Changes in all sections.

16b. Legend to abbreviations and acronyms used in the safety data sheet

Explanations of the abbreviations and Acronyms:

Hazard Pictograms	None
Precautionary Statement(s)	None
ATE	Acute Toxicity Estimate
CAS	Chemical Abstracts Service
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
DNEL	Derived No Effect Level
EC	European Community
EINECS	European Inventory of Existing Commercial Chemical Substances
LTEL	Long term exposure limit
PBT	Persistent, Bioaccumulative and Toxic
PNEC	Predicted No Effect Concentration
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
STEL	Short term exposure limit
STOT	Specific target organ toxicity
vPvB	Very persistent and very bioaccumulative

16c. Key literature references and sources for data

Sources for data

Primary data for the calculation of the hazards has preferentially been taken from the official European classification list, 1272/2008 Annex I, as updated to 2025-09-08.

Full texts for Regulations mentioned in this Safety Data Sheet

1272/2008	REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006
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