

SAFETY DATA SHEET

Coagulation Factor VIII Deficient Plasma



SDS no.:

mrhm0176

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

1.1 Product identifier

Product name : Coagulation Factor VIII Deficient Plasma**Product code** : OTXW17, 10446411

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

Identified uses Diagnostic agents.**Restrictions on use** For professional users only.

Supplier : Siemens Healthcare Diagnostics Limited
Park View,
Watchmoor Park,
Camberley,
Surrey,
GU15 3YL
United Kingdom

Phone: +44 (0) 345 600 1955

e-mail address of person responsible for this SDS : dx.msds.healthcare@siemens-healthineers.com

1.4 Emergency telephone number

CHEMTREC: +44 20 3807 3798

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Product definition : Mixture

Classification according to UK CLP/GHS

Not classified.

The product is not classified as hazardous according to UK CLP Regulation SI 2019/720 as amended.
See Section 11 for more detailed information on health effects and symptoms.

2.2 Label elements

Signal word : No signal word.**Hazard statements** : No known significant effects or critical hazards.

Precautionary statements

Prevention : Not applicable.**Response** : Not applicable.**Storage** : Not applicable.**Disposal** : Not applicable.

Supplemental label elements : Not applicable.

SECTION 2: Hazards identification

Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles : Not applicable.

2.3 Other hazards

Product meets the criteria for PBT or vPvB according to Regulation (EC) No. 1907/2006, Annex XIII : This mixture does not contain any substances that are assessed to be a PBT or a vPvB.

Other hazards which do not result in classification : None known.

Additional information : Potentially biohazardous material.
Not available.

SECTION 3: Composition/information on ingredients

3.2 Mixtures : Mixture

There are no ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment, are PBTs, vPvBs or Substances of equivalent concern, or have been assigned a workplace exposure limit and hence require reporting in this section.

SECTION 4: First aid measures**4.1 Description of first aid measures**

Eye contact : Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Get medical attention if irritation occurs.

Inhalation : Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if symptoms occur. In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.

Skin contact : Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.

Ingestion : Wash out mouth with water. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.

Protection of first-aiders : No action shall be taken involving any personal risk or without suitable training.

4.2 Most important symptoms and effects, both acute and delayed**Over-exposure signs/symptoms**

Eye contact : No specific data.

Inhalation : No specific data.

Skin contact : No specific data.

Ingestion : No specific data.

4.3 Indication of any immediate medical attention and special treatment needed

Notes to physician : In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.

Specific treatments : No specific treatment.

SECTION 5: Firefighting measures**5.1 Extinguishing media**

Suitable extinguishing media : Use an extinguishing agent suitable for the surrounding fire.

Unsuitable extinguishing media : None known.

5.2 Special hazards arising from the substance or mixture

Hazards from the substance or mixture : No specific fire or explosion hazard.

Hazardous combustion products : Decomposition products may include the following materials:
carbon dioxide
carbon monoxide
nitrogen oxides
sulfur oxides
metal oxide/oxides

5.3 Advice for firefighters

Special protective actions for fire-fighters : Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.

Special protective equipment for fire-fighters : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

SECTION 6: Accidental release measures**6.1 Personal precautions, protective equipment and emergency procedures**

For non-emergency personnel : No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilt material. Put on appropriate personal protective equipment.

For emergency responders : If specialised clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

6.2 Environmental precautions : Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

6.3 Methods and material for containment and cleaning up

Small spill : Move containers from spill area. Vacuum or sweep up material and place in a designated, labelled waste container. Dispose of via a licensed waste disposal contractor.

Large spill : Move containers from spill area. Prevent entry into sewers, water courses, basements or confined areas. Vacuum or sweep up material and place in a designated, labelled waste container. Dispose of via a licensed waste disposal contractor. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.

6.4 Reference to other sections : See Section 1 for emergency contact information.
See Section 8 for information on appropriate personal protective equipment.
See Section 13 for additional waste treatment information.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

- Protective measures** : Put on appropriate personal protective equipment (see Section 8).
- Advice on general occupational hygiene** : Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

7.2 Conditions for safe storage, including any incompatibilities

Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabelled containers. Use appropriate containment to avoid environmental contamination. See Section 10 for incompatible materials before handling or use.

7.3 Specific end use(s)

- Recommendations** : Not available.
- Industrial sector specific solutions** : Not available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational exposure limits

No exposure limit value known.

- Recommended monitoring procedures** : If this product contains ingredients with exposure limits, personal, workplace atmosphere or biological monitoring may be required to determine the effectiveness of the ventilation or other control measures and/or the necessity to use respiratory protective equipment. Reference should be made to appropriate monitoring standards. Reference to national guidance documents for methods for the determination of hazardous substances will also be required.

DNELs/DMELs

No DNELs/DMELs available.

PNECs

No PNECs available

8.2 Exposure controls

- Appropriate engineering controls** : Good general ventilation should be sufficient to control worker exposure to airborne contaminants.

Individual protection measures

- Hygiene measures** : Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.
- Eye/face protection** : Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields.

Skin protection

- Hand protection** : Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary.

SECTION 8: Exposure controls/personal protection

Body protection	: Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
Other skin protection	: Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
Respiratory protection	: Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.
Environmental exposure controls	: Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

SECTION 9: Physical and chemical properties

The conditions of measurement of all properties are at standard temperature and pressure unless otherwise indicated.

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

Physical state	: Solid.
Colour	: White to light yellow.
Odour	: Odourless.
Odour threshold	: Not relevant/applicable due to nature of the product.
Melting point/freezing point	: Not relevant/applicable due to nature of the product.
Softening point	: Not relevant/applicable due to nature of the product.
Sublimation temperature	: Not relevant/applicable due to nature of the product.
Initial boiling point and boiling range	: Not available.
Flammability (solid, gas)	: Not relevant/applicable due to nature of the product.
Upper/lower flammability or explosive limits	: Not applicable.
Flash point	: [Product does not sustain combustion.]
Decomposition temperature	: Not relevant/applicable due to nature of the product.
pH	: Not applicable.
Viscosity	: Not applicable.
Solubility(ies)	: Not available.
Solubility in water	: Not relevant/applicable due to nature of the product.
Miscible with water	: Not relevant/applicable due to nature of the product.
Partition coefficient: n-octanol/ water	: Not relevant/applicable due to nature of the product.
Vapour pressure	: Not available.
Evaporation rate	: Not relevant/applicable due to nature of the product.
Relative density	: Not available.
Vapour density	: Not applicable.
Explosive properties	: Non-explosive in the presence of the following materials or conditions: open flames, sparks and static discharge and oxidising materials.
Oxidising properties	: Not available.
<u>Particle characteristics</u>	
Median particle size	: Not available.

SECTION 9: Physical and chemical properties

Fire point	: Not available.
Burning time	: Not relevant/applicable due to nature of the product.
Fundamental burning velocity	: Not relevant/applicable due to nature of the product.
Burning rate	: Not relevant/applicable due to nature of the product.
SADT	: Not relevant/applicable due to nature of the product.
SAPT	: Not relevant/applicable due to nature of the product.
Heat of reaction	: Not relevant/applicable due to nature of the product.
Heat of combustion	: Not relevant/applicable due to nature of the product.
Flow time (ISO 2431)	: Not relevant/applicable due to nature of the product.
Molecular weight	: Not relevant/applicable due to nature of the product.

SECTION 10: Stability and reactivity

10.1 Reactivity	: No specific test data related to reactivity available for this product or its ingredients.
10.2 Chemical stability	: The product is stable.
10.3 Possibility of hazardous reactions	: Under normal conditions of storage and use, hazardous reactions will not occur.
10.4 Conditions to avoid	: No specific data.
10.5 Incompatible materials	: No specific data.
10.6 Hazardous decomposition products	: Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information**11.1 Information on toxicological effects****Acute toxicity**

Conclusion/Summary : Not available.

Acute toxicity estimates

N/A

Irritation/Corrosion

Conclusion/Summary : Not available.

Sensitisation

Conclusion/Summary : Not available.

Mutagenicity

Conclusion/Summary : Not available.

Carcinogenicity

Conclusion/Summary : Not available.

Reproductive toxicity

Conclusion/Summary : Not available.

Teratogenicity

Conclusion/Summary : Not available.

Specific target organ toxicity (single exposure)

Not available.

Specific target organ toxicity (repeated exposure)

Not available.

Aspiration hazard

SECTION 11: Toxicological information

Not available.

Information on likely routes of exposure : Not available.**Potential acute health effects**

Eye contact : No known significant effects or critical hazards.
Inhalation : No known significant effects or critical hazards.
Skin contact : No known significant effects or critical hazards.
Ingestion : No known significant effects or critical hazards.

Symptoms related to the physical, chemical and toxicological characteristics

Eye contact : No specific data.
Inhalation : No specific data.
Skin contact : No specific data.
Ingestion : No specific data.

Delayed and immediate effects as well as chronic effects from short and long-term exposure**Short term exposure**

Potential immediate effects : Not available.
Potential delayed effects : Not available.

Long term exposure

Potential immediate effects : Not available.
Potential delayed effects : Not available.

Potential chronic health effects

Not available.

Conclusion/Summary : Not available.
General : No known significant effects or critical hazards.
Carcinogenicity : No known significant effects or critical hazards.
Mutagenicity : No known significant effects or critical hazards.
Reproductive toxicity : No known significant effects or critical hazards.

Other information : Not available.**SECTION 12: Ecological information****12.1 Toxicity****Conclusion/Summary** : Not available.**12.2 Persistence and degradability****Conclusion/Summary** : Not available.**12.3 Bioaccumulative potential**

Not available.

12.4 Mobility in soil

Soil/water partition coefficient (K_{oc}) : Not available.
Mobility : Not available.

SECTION 12: Ecological information**12.5 Results of PBT and vPvB assessment**

This mixture does not contain any substances that are assessed to be a PBT or a vPvB.

12.6 Other adverse effects : No known significant effects or critical hazards.

SECTION 13: Disposal considerations**13.1 Waste treatment methods****Product**

Methods of disposal : The generation of waste should be avoided or minimised wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction.

Hazardous waste : Within the present knowledge of the supplier, this product is not regarded as hazardous waste, as defined by EU Directive 2008/98/EC.

Packaging

Methods of disposal : The generation of waste should be avoided or minimised wherever possible. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible.

Special precautions : This material and its container must be disposed of in a safe way. Empty containers or liners may retain some product residues. Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers.

SECTION 14: Transport information**ADR/RID**

14.1 UN number Not regulated.

14.2 UN proper shipping name -

14.3 Transport hazard class(es) -

14.4 Packing group -

14.5 Environmental hazards No.

Additional information -

ADN

14.1 UN number Not regulated.

14.2 UN proper shipping name -

14.3 Transport hazard class(es) -

SECTION 14: Transport information

14.4 Packing group -

14.5 Environmental hazards No.

Additional information -

IMDG

14.1 UN number Not regulated.

14.2 UN proper shipping name -

14.3 Transport hazard class(es) -

14.4 Packing group -

14.5 Environmental hazards No.

Additional information -

IATA

14.1 UN number Not regulated.

14.2 UN proper shipping name -

14.3 Transport hazard class(es) -

14.4 Packing group -

14.5 Environmental hazards No.

Additional information -

14.6 Special precautions for user : **Transport within user's premises:** always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

14.7 Transport in bulk according to IMO instruments : Not applicable.

SECTION 15: Regulatory information

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

UK (GB) /REACH

Annex XIV - List of substances subject to authorisation

Annex XIV

None of the components are listed.

Substances of very high concern

None of the components are listed.

Ozone depleting substances

Not listed.

Prior Informed Consent (PIC)

Not listed.

Persistent Organic Pollutants

Not listed.

Annex XVII - Restrictions : Not applicable.
**on the manufacture,
placing on the market
and use of certain
dangerous substances,
mixtures and articles**

Seveso Directive

This product is not controlled under the Seveso Directive.

National regulations

EU regulations

Industrial emissions : Not listed
**(integrated pollution
prevention and control) -
Air**

Industrial emissions : Not listed
**(integrated pollution
prevention and control) -
Water**

International regulations

Montreal Protocol

Not listed.

Stockholm Convention on Persistent Organic Pollutants

Not listed.

Rotterdam Convention on Prior Informed Consent (PIC)

Not listed.

UNECE Aarhus Protocol on POPs and Heavy Metals

Not listed.

15.2 Chemical safety : Not applicable.
assessment

SECTION 16: Other information

Indicates information that has changed from previously issued version.

Abbreviations and acronyms

- : ATE = Acute Toxicity Estimate
- GB CLP = UK CLP (EC No 1272/2008) on the Classification, Labelling and Packaging of Substances and Mixtures as amended by (EU Exit) Regulations 2019 No. 720 and amendments
- DMEL = Derived Minimal Effect Level
- DNEL = Derived No Effect Level
- EUH statement = GB CLP-specific Hazard statement
- N/A = Not available
- PBT = Persistent, Bioaccumulative and Toxic
- PNEC = Predicted No Effect Concentration
- RRN = REACH Registration Number
- SGG = Segregation Group
- vPvB = Very Persistent and Very Bioaccumulative

Procedure used to derive the classification

Not classified.

Full text of abbreviated H statements

Not applicable.

Full text of classifications

Not applicable.

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