

SAFETY INFORMATION

Voluntary safety information following the Safety Data Sheet format according to Regulation (EC) No. 1907/2006 (REACH)

Revision date: 9 Apr 2024

Print date: 10 Apr 2024

Version: 1.1

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

1.1. Product identifier

Trade name/designation:

Human plasma - PLxxx

Article No.:

PLxxx

UFI:

FTY4-6TR5-ME5F-5J47

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

Use of the substance/mixture:

The product is intended for professional use.

* 1.3. Details of the supplier of the safety data sheet

Supplier (manufacturer/importer/only representative/downstream user/distributor):

Institut Virion\Serion GmbH

Productmanagement

Friedrich-Bergius-Ring 19

97076 Würzburg

Germany

Telephone: +49 931 3045 0

Telefax: +49 931 3045 100

E-mail: product.safety@virion-serion.de

Website: www.virion-serion.de

E-mail (competent person): product.safety@virion-serion.de

* 1.4. Emergency telephone number

Institut Virion\Serion GmbH, Friedrich-Bergius-Ring 19; 97076 Würzburg, Germany, +49 931 3045 0 (Only available during office hours.)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008 [CLP]

The mixture is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

According to EC directives or the corresponding national regulations the product does not have to be labelled.

Hazard statements: none

Supplemental hazard information: none

Precautionary statements: none

2.3. Other hazards

No data available

SECTION 3: Composition/information on ingredients

3.2. Mixtures

No data available

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SECTION 4: First aid measures

4.1. Description of first aid measures

General information:

In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible). Remove victim out of the danger area. Remove contaminated, saturated clothing. If unconscious but breathing normally, place in recovery position and seek medical advice. Do not leave affected person unattended.

Following inhalation:

Provide fresh air.

After eye contact:

Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

Following ingestion:

Rinse mouth. Let 1 glass of water be drunken in little sips (dilution effect). Get medical advice/attention if you feel unwell.

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

No known symptoms to date.

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

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

No data available

5.2. Special hazards arising from the substance or mixture

Hazardous combustion products:

In case of fire: Gases/vapours, toxic

5.3. Advice for firefighters

Wear a self-contained breathing apparatus and chemical protective clothing.

5.4. Additional information

Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Personal precautions:

Avoid breathing dust/fume/gas/mist/vapours/spray. Remove persons to safety.

Protective equipment:

Wear protective gloves/protective clothing/eye protection/face protection.

6.1.2. For emergency responders

Personal protection equipment:

Personal protection equipment: see section 8

6.2. Environmental precautions

Do not allow to enter into surface water or drains.

6.3. Methods and material for containment and cleaning up

For containment:

Collect spillage. Measures to prevent aerosol and dust generation Wet clean or vacuum up solids.

For cleaning up:

Water (with cleaning agent)

6.4. Reference to other sections

Safe handling: see section 7 Personal protection equipment: see section 8 Disposal: see section 13

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6.5. Additional information

Use appropriate container to avoid environmental contamination.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Protective measures

Advices on safe handling:

Wear personal protection equipment (refer to section 8).

Measures to prevent aerosol and dust generation:

Dust should be exhausted directly at the point of origin.

Advices on general occupational hygiene

When using do not eat, drink, smoke, sniff. Avoid contact with skin, eyes and clothes.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures and storage conditions:

Keep container tightly closed in a cool, well-ventilated place.

7.3. Specific end use(s)

No data available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No data available

* 8.2. Exposure controls

8.2.1. Appropriate engineering controls

No data available

8.2.2. Personal protection equipment

Eye/face protection:

Eye glasses with side protection EN 166

Skin protection:

Tested protective gloves must be worn EN ISO 374 Suitable material:NBR (Nitrile rubber) Breakthrough time:480 min. In the case of wanting to use the gloves again, clean them before taking off and air them well.

Respiratory protection:

Particle filter device (EN 143)

8.2.3. Environmental exposure controls

No data available

SECTION 9: Physical and chemical properties

* 9.1. Information on basic physical and chemical properties

Appearance

Physical state: Liquid

Colour: not determined

Odour: not determined

Safety relevant basis data

| Parameter | Value | ① Method ② Remark |
|---|-------------------|----------------------|
| pH | No data available | |
| Melting point | No data available | |
| Freezing point | No data available | |
| Initial boiling point and boiling range | No data available | |
| Evaporation rate | No data available | |
| Vapour pressure | No data available | |

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| Parameter | Value | ① Method ② Remark |
|------------------|-------------------|----------------------|
| Density | No data available | |
| Bulk density | No data available | |
| Water solubility | No data available | |

particle characteristics:

No data available

9.2. Other information

No data available

SECTION 10: Stability and reactivity

10.1. Reactivity

No data available

10.2. Chemical stability

No data available

10.3. Possibility of hazardous reactions

No data available

10.4. Conditions to avoid

No data available

10.5. Incompatible materials

No data available

10.6. Hazardous decomposition products

No data available

SECTION 11: Toxicological information

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

Acute oral toxicity:

Based on available data, the classification criteria are not met.

Acute dermal toxicity:

Based on available data, the classification criteria are not met.

Acute inhalation toxicity:

Based on available data, the classification criteria are not met.

Skin corrosion/irritation:

Based on available data, the classification criteria are not met.

Serious eye damage/irritation:

Based on available data, the classification criteria are not met.

Respiratory or skin sensitisation:

Based on available data, the classification criteria are not met.

Germ cell mutagenicity:

Based on available data, the classification criteria are not met.

Carcinogenicity:

Based on available data, the classification criteria are not met.

Reproductive toxicity:

Based on available data, the classification criteria are not met.

STOT-single exposure:

Based on available data, the classification criteria are not met.

STOT-repeated exposure:

Based on available data, the classification criteria are not met.

Aspiration hazard:

Based on available data, the classification criteria are not met.

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Additional information:

No data available

11.2. Information on other hazards

No data available

SECTION 12: Ecological information

12.1. Toxicity

No data available

12.2. Persistence and degradability

No data available

12.3. Bioaccumulative potential

No data available

12.4. Mobility in soil

No data available

12.5. Results of PBT and vPvB assessment

No data available

12.6. Endocrine disrupting properties

No data available

12.7. Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment options

Appropriate disposal / Product:

Consult the appropriate local waste disposal expert about waste disposal.

SECTION 14: Transport information

| Land transport (ADR/RID) | Inland waterway craft (ADN) | Sea transport (IMDG) | Air transport (ICAO-TI / IATA-DGR) |
|--|--|--|--|
| 14.1. UN number or ID number | | | |
| No dangerous good in sense of these transport regulations. | No dangerous good in sense of these transport regulations. | No dangerous good in sense of these transport regulations. | No dangerous good in sense of these transport regulations. |
| 14.2. UN proper shipping name | | | |
| No dangerous good in sense of these transport regulations. | No dangerous good in sense of these transport regulations. | No dangerous good in sense of these transport regulations. | No dangerous good in sense of these transport regulations. |
| 14.3. Transport hazard class(es) | | | |
| not relevant | not relevant | not relevant | not relevant |
| 14.4. Packing group | | | |
| not relevant | not relevant | not relevant | not relevant |
| 14.5. Environmental hazards | | | |
| not relevant | not relevant | not relevant | not relevant |
| 14.6. Special precautions for user | | | |
| not relevant | not relevant | not relevant | not relevant |

14.7. Maritime transport in bulk according to IMO instruments

No data available

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SECTION 15: Regulatory information

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

15.1.1. EU legislation

Other regulations (EU):

This product is not assigned to a hazard category.

15.1.2. National regulations

No data available

15.2. Chemical Safety Assessment

No data available

SECTION 16: Other information

* 16.1. Indication of changes

| | |
|-------|--|
| 1.3. | Details of the supplier of the safety data sheet |
| 1.4. | Emergency telephone number |
| 8.2. | Exposure controls |
| 9.1. | Information on basic physical and chemical properties |
| 15.1. | Safety, health and environmental regulations/legislation specific for the substance or mixture |
| 16.1. | Indication of changes |
| 16.5. | List of relevant hazard statements and/or precautionary statements from sections 2 to 15 |

16.2. Abbreviations and acronyms

| | |
|-------|---|
| ADN | European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways |
| ADR | European Agreement concerning the International Carriage of Dangerous Goods by Road |
| CLP | Classification, Labelling and Packaging |
| DIN | German Institute for Standardization / German Industrial Standard |
| EN | European Standard |
| ICAO | International Civil Aviation Organization |
| IMDG | International Maritime Dangerous Goods |
| IMO | International Maritime Organization |
| ISO | International Standards Organisation |
| NFPA | National Fire Protection Association |
| PBT | persistent and bioaccumulative and toxic |
| REACH | Registration, Evaluation and Authorization of Chemicals |
| RID | Dangerous goods regulations for transport by rail |
| UN | United Nations |

16.3. Key literature references and sources for data

No data available

16.4. Classification for mixtures and used evaluation method according to regulation (EC) No 1272/2008 [CLP]

The mixture is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].

* 16.5. List of relevant hazard statements and/or precautionary statements from sections 2 to 15

No data available

16.6. Training advice

No data available

16.7. Additional information

No data available

* Data changed compared with the previous version.