

SAFETY INFORMATION

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

Revision date: 10 Jul 2023

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Version: 1

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Defibrinated human plasma - PLSxxx

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

1.1. Product identifier

Trade name/designation:

Defibrinated human plasma - PLSxxx

Article No.:

PLSxxx

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

1.4. Emergency telephone number

No data available

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

Hazardous ingredients / Hazardous impurities / Stabilisers:

Product identifiers	Substance name Classification according to Regulation (EC) No 1272/2008 [CLP]	Concentration
CAS No.: 26628-22-8 EC No.: 247-852-1 Index No.: 011-004-00-7	sodium azide Acute Tox. 2 (H300), Aquatic Acute 1 (H400), Aquatic Chronic 1 (H410)  Danger EUH032	0 - ≤ 0.09 weight-%

Full text of H- and EUH-phrases: see section 16.

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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

8.1.1. Occupational exposure limit values

Limit value type (country of origin)	Substance name	① Long-term occupational exposure limit value ② Short-term occupational exposure limit value ③ Instantaneous value ④ Monitoring and observation processes ⑤ Remark
WEL (GB)	sodium azide CAS No.: 26628-22-8 EC No.: 247-852-1	① 0.1 mg/m ³ ② 0.3 mg/m ³ ⑤ (may be absorbed through the skin)
IOELV (EU)	sodium azide CAS No.: 26628-22-8 EC No.: 247-852-1	① 0.1 mg/m ³ ② 0.3 mg/m ³ ⑤ (may be absorbed through the skin)

8.1.2. Biological limit values

No data available

8.1.3. DNEL-/PNEC-values

Substance name	DNEL value	① DNEL type ② Exposure route
sodium azide CAS No.: 26628-22-8 EC No.: 247-852-1	0.0164	① DNEL worker ② Long-term - inhalation, systemic effects
sodium azide CAS No.: 26628-22-8 EC No.: 247-852-1	0.0467	① DNEL worker ② Long-term - dermal, systemic effects

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Substance name	DNEL value	① DNEL type ② Exposure route
sodium azide CAS No.: 26628-22-8 EC No.: 247-852-1	0.0167	① DNEL worker ② Long-term - oral, systemic effects
Substance name	PNEC Value	① PNEC type
sodium azide CAS No.: 26628-22-8 EC No.: 247-852-1	0.00035 mg/L	① PNEC aquatic, freshwater
sodium azide CAS No.: 26628-22-8 EC No.: 247-852-1	0.000015 mg/L	① PNEC aquatic, marine water
sodium azide CAS No.: 26628-22-8 EC No.: 247-852-1	0.0167 mg/kg	① PNEC sediment, freshwater
sodium azide CAS No.: 26628-22-8 EC No.: 247-852-1	0.00072 mg/kg	① PNEC sediment, marine water

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: Breakthrough time: 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

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

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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

sodium azide CAS No.: 26628-22-8 EC No.: 247-852-1
LD₅₀ oral: 27 mg/kg (Rat)
LD₅₀ dermal: 18 mg/kg (Rabbit)
LC₅₀ Acute inhalation toxicity (dust/mist): 5.4 mg/L 4 h (Rat)

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.

Additional information:

No data available

11.2. Information on other hazards

No data available

SECTION 12: Ecological information

12.1. Toxicity

sodium azide CAS No.: 26628-22-8 EC No.: 247-852-1
EC₅₀: 0.348 mg/L 4 d (Algae/water plant)

12.2. Persistence and degradability

No data available

12.3. Bioaccumulative potential

No data available

12.4. Mobility in soil

No data available

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12.5. Results of PBT and vPvB assessment

sodium azide CAS No.: 26628-22-8 EC No.: 247-852-1

Results of PBT and vPvB assessment: —

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

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):

Directive 2012/18/EU on the control of major-accident hazards involving dangerous substances [Seveso-III-Directive]: 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

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SECTION 16: Other information

16.1. Indication of changes

No data available

16.2. Abbreviations and acronyms

No data available

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. Relevant R-, H- and EUH-phrases (Number and full text)

Hazard statements	
H300	Fatal if swallowed.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

Supplemental hazard information	
EUH032	Contact with acids liberates very toxic gas.

16.6. Training advice

No data available

16.7. Additional information

No data available