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

1.1 Product identifier
Brand name: Defibrinated Human Plasma
Product no.: PLSxxx(x)A; PLSxxx(x)G; PLSxxx(x)M; PLSxxx(x)AN; PLSxxx(x)GN; PLSxxx(x)MN

1.2 Relevant identified uses of the substance or mixture and uses advised against
Identified use: In vitro diagnostic agent or component of an in vitro diagnostic agent
Discouraged uses: No other relevant information available.

1.3 Details of the supplier of the safety data sheet
Institut Virion\Serion GmbH
Friedrich-Bergius-Ring 19
97076 Würzburg
Germany
Tel. 0049 (0) 931 – 30 45 0
Fax 0049 (0) 931 – 30 45 100
Email dialog@virion-serion.de

1.4 Emergency telephone number
Manufacturer: 0049 (0) 931 – 30 45 0 (Monday to Friday, 8:30 a.m. to 4:00 p.m.)

Section 2: Possible hazards

2.1 Classification of the substance or mixture
Classification per Regulation (EC) No. 1272/2008
Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

2.2 Label elements
The product does not need to be labelled in accordance with EC directives or respective national laws.

2.3 Other hazards
This product contains chemically and/or physically inactivated biological agents and should be considered potentially infectious. The mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1 % or higher.

Section 3: Composition/information on ingredients

3.1 Substance
Not applicable

3.2 Mixture
No components need to be disclosed according to the Regulation (EC) No. 1272/2008.

Section 4: First aid measures

4.1 Description of first aid measures
After inhalation: Fresh air. See a doctor if feeling unwell.
After skin contact: Wash off with plenty of water. Remove contaminated clothing immediately. Use skin disinfectant at the affected areas. See a doctor if there are any symptoms.
After eye contact: Flush eyes with plenty of water and intermittently lift the upper and lower eyelids. Check for contact lenses and remove if present. See a doctor if irritation appears.

After swallowing: Rinse out mouth and drink plenty of water. Consult a doctor if feeling unwell.

4.2 Most important symptoms and effects, both acute and delayed
No information available.

4.3 Indication of any immediate medical attention or special treatment needed
No information available.

Section 5: Firefighting measures

5.1 Extinguishing media
Suitable extinguishing media:
Use extinguishing measures appropriate to the environment.

Unsuitable extinguishing media:
For this substance/mixture there are no limitations on extinguishing agents.

5.2 Special hazards related to this substance or mixture
Non-combustible. In case of fire may be liberated: May produce toxic fumes.

5.3 Advice for firefighters
Special protective equipment for firefighters:
Self-contained breathing apparatus required when in the hazard area. Prevent skin contact by keeping a safe distance or by wearing suitable protective clothing.

Section 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

6.1.1 Advice for non-emergency personnel
Do not inhale vapors/aerosols. Avoid contact with substance. Ensure adequate ventilation. Evacuate the danger zone, follow the emergency plan, consult specialists.

6.1.2 Information for emergency responders
Protective equipment: see section 8.

6.2 Environmental precautions
No specific procedures required.

6.3 Methods and materials for containment and cleaning up
Remove containers from the discharge area. Avoid discharging in sewer system, bodies of water, basements or closed areas. Take up material and put in appropriately labeled waste containers. Dispose of using an accredited waste disposal company. Clean.

6.4 Reference to other sections
Instructions for disposal see section 13.
Section 7: Handling and storage

7.1 Precautions for safe handling

7.1.1 Advice on safe handling
Avoid exposure. Follow the instructions on the label.

7.1.2 Hygiene measures
Change contaminated clothing immediately. Apply preventive skin protection. Wash hands after working with substance.

7.2 Conditions for safe storage, including any incompatibilities
Requirements for storage areas and containers:
Store only in original container. Prevent leakage into soil.

7.3 Specific end uses
Apart from the intended use as per section 1.2 no other specific uses are stipulated.

Section 8: Limiting and monitoring exposure / personal protective equipment

8.1 Parameters to be monitored
No components with workplace control parameters.

8.2 Limiting and monitoring exposure

8.2.1 Engineering safety measures
Provide adequate ventilation.

8.2.2 Individual protection
Do not eat, drink or smoke when working. Wash hands before breaks and after working. Use ointment for preventive skin protection.

8.2.2.1 Eye/face protection
Safety goggles

8.2.2.2 Skin protection
Hand protection
Glove material, e.g. nitrile rubber or butyl rubber

Other safety precautions
Protective clothing

8.2.3 Respiratory protection
Not necessary.

8.2.3 Limiting and monitoring environmental exposure
No specific procedures required.
Section 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance shape</td>
<td>liquid</td>
</tr>
<tr>
<td>Appearance color</td>
<td>colourless</td>
</tr>
<tr>
<td>Odor</td>
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</tr>
<tr>
<td>Odor threshold</td>
<td>No information available</td>
</tr>
<tr>
<td>pH</td>
<td>No information available</td>
</tr>
<tr>
<td>Melting point</td>
<td>0 °C</td>
</tr>
<tr>
<td>Boiling point</td>
<td>100 °C</td>
</tr>
<tr>
<td>Flash point</td>
<td>No information available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No information available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>No information available</td>
</tr>
<tr>
<td>Lower explosion limit</td>
<td>No information available</td>
</tr>
<tr>
<td>Upper explosion limit</td>
<td>No information available</td>
</tr>
<tr>
<td>Vapor pressure</td>
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</tr>
<tr>
<td>Vapor density</td>
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</tr>
<tr>
<td>Relative density</td>
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</tr>
<tr>
<td>Water solubility at 20 °C</td>
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</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
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</tr>
<tr>
<td>Auto-ignition temperature</td>
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</tr>
<tr>
<td>Decomposition temperature</td>
<td>No information available</td>
</tr>
<tr>
<td>Viscosity, dynamic</td>
<td>No information available</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>No information available</td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>No information available</td>
</tr>
</tbody>
</table>

9.2 Other information
No other relevant information available.

Section 10: Stability and reactivity

10.1 Reactivity
No information available.

10.2 Chemical stability
The product is chemically stable under the specified storage conditions.

10.3 Possibility of hazardous reactions
No information available.

10.4 Conditions to avoid
No information available.

10.5 Incompatible materials
No information available.

10.6 Hazardous decomposition products
Under fire conditions, formation of Sulphur oxides (SOx) possible.
Section 11: Toxicological information

11.1 Information on toxicological effects

Mixture

Acute oral toxicity
No information available.

Acute inhalation toxicity
No information available.

Acute dermal toxicity
No information available.

Skin irritation
No information available.

Eye irritation
No information available.

Sensitization
No information available.

Germ cell mutagenicity
No information available.

Carcinogenicity
No information available.

Reproductive toxicity
No information available.

Teratogenicity
No information available.

Specific target organ toxicity - single exposure
No information available.

Specific target organ toxicity - repeated exposure
No information available.

Aspiration hazard
No information available.

11.2 Further information

Quantitative data on the toxicity of this product are not available.

This product contains chemically inactivated biological agents and should be considered potentially infectious.

Section 12: Ecological information

Mixture

12.1 Toxicity
No information available.

12.2 Persistence and degradability
No information available.
12.3 Bioaccumulation potential
No information available.

12.4 Mobility in soil
No information available.

12.5 Results of PBT and vPvB assessment
There is no PBT/vPvB assessment available because no chemical safety assessment is required/was conducted.

12.6 Other adverse effects
No information available.

Additional ecological information
Discharge into the environment must be avoided.

Section 13: Disposal considerations

Waste treatment methods
Dispose of leftover product in accordance with Directive 2008/98/EC on Waste and national and regional regulations. Do not mix with other waste. Treat uncleaned containers depending on the product.

Section 14: Transport information

14.1 ADR, IMDG, IATA not classified as dangerous in the meaning of transport regulations
14.2 Proper UN shipping name not subject to transport regulations (ADR/RID, IATA, IMDG)
14.3 Transport hazard class not applicable
14.4 Packing group not applicable
14.5 Environmentally hazardous No
14.6 Special precautions for user No
14.7 Transport in bulk according to Annex II of the MARPOL Convention 73/78 and the IBC Code Not relevant

Section 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
EU legislation none known
National laws none known
15.2 Chemical safety assessment
A chemical safety assessment has not been conducted for this product.

Section 16: Other information

The information describes the product with reference to the applicable safety precautions. It is not an assurance of the properties of the product.