

# Safety data sheet

classification per Article 31 of Regulation (EC) No. 1907/2006

Valid from: 20180401

Version: 201804\_EN\_1

replaces version dated: 20130506

Page 1 of 6

## 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](mailto: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.

## Safety data sheet

classification per Article 31 of Regulation (EC) No. 1907/2006

Valid from: 20180401

Version: 201804\_EN\_1

replaces version dated: 20130506

Page 2 of 6

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.

# Safety data sheet

classification per Article 31 of Regulation (EC) No. 1907/2006

Valid from: 20180401

Version: 201804\_EN\_1

replaces version dated: 20130506

Page 3 of 6

## 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

The protective gloves must conform to the specifications of EC Directive 89/686/EEC and the related standard EN 374.

###### Other safety precautions

Protective clothing

##### 8.2.2.3 Respiratory protection

Not necessary.

### 8.2.3 Limiting and monitoring environmental exposure

No specific procedures required.

# Safety data sheet

classification per Article 31 of Regulation (EC) No. 1907/2006

Valid from: 20180401

Version: 201804\_EN\_1

replaces version dated: 20130506

Page 4 of 6

## Section 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

Appearance	shape: liquid Color: colourless
Odor	No information available
Odor threshold	No information available
pH	No information available
Melting point	0 °C
Boiling point	100 °C
Flash point	No information available
Evaporation rate	No information available
Flammability (solid, gas)	No information available
Lower explosion limit	No information available
Upper explosion limit	No information available
Vapor pressure	No information available
Vapor density	No information available
Relative density	1.0 g/cm <sup>3</sup> (20 °C)
Water solubility at 20 °C	soluble
Partition coefficient: n-octanol/water	No information available
Auto-ignition temperature	not applicable
Decomposition temperature	No information available
Viscosity, dynamic	No information available.
Explosive properties	No information available.
Oxidizing properties	No information available

### 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 (SO<sub>x</sub>) possible.

# Safety data sheet

classification per Article 31 of Regulation (EC) No. 1907/2006

Valid from: 20180401

Version: 201804\_EN\_1

replaces version dated: 20130506

Page 5 of 6

## 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.

## Safety data sheet

classification per Article 31 of Regulation (EC) No. 1907/2006

Valid from: 20180401

Version: 201804\_EN\_1

replaces version dated: 20130506

Page 6 of 6

### 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.